

This Evidence Bulletin summarises a Cochrane systematic review.

In a systematic review the researchers aim to locate, quality appraise and synthesise all of the available evidence related to a specific research question.

Cochrane review authors adopt rigorous methods to minimise bias as a way of producing reliable findings with the ultimate goal of making the evidence more useful for practice. For more information see: <http://cccr.org.uk/about>.

The intended audience of this Evidence Bulletin is researchers and others involved in the informed consent process for people considering participating in clinical trials.

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

### **Cochrane review summary**

In this Cochrane systematic review, Anneliese Synnot and colleagues sought to answer:

*Does audio-visual presentation of information for informed consent for participation in clinical trials improve outcomes related to the informed consent process?*

### **What is audio-visual presentation of information for informed consent?**

Informed consent is an essential component of clinical research. During informed consent participants are advised about features of the clinical trial including the aims, methods, anticipated benefits and potential harms of participation in the research. Audio-visual presentation includes providing this information on the Internet or on computer DVD.

### **Key findings**

This review found there is still much uncertainty about the effect of audio-visual informed consent strategies on a range of patient-important outcomes. However, there is limited evidence from studies about real and hypothetical (made-up) clinical trials that audio-visual informed consent:

- may slightly improve knowledge or understanding of the parent trial (i.e. the clinical trial for which the audio-visual informed consent strategy is based)
- makes little or no difference to rate of participation or willingness to participate
- may improve participant satisfaction with the consent information provided.

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

### **Full citation for this Cochrane review:**

Synnot A., et al. [Audio-visual presentation of information for informed consent for participation in clinical trials](#). Cochrane Database of Systematic Reviews 2014, Issue 5. Art. No. CD003717. DOI: 10.1002/14651858.CD003717.pub.3.

## Detailed review information

### Background

Informed consent is an essential component of clinical research. 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, any anticipated discomfort and potential and actual conflicts of interest.

However, 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.

Different strategies may improve the informed consent process. One potential method is the use of audio-visual enhancements, such presenting the information on the Internet or on DVD.

### Information about this review

Synnot and colleagues conducted a detailed search of studies published up to June 2012. Using pre-determined criteria to select studies the review looked for:

#### *Types of studies*

- Randomised controlled trials (RCTs) and quasi-RCTs (i.e. 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).

#### *Participants*

- Individuals or the guardians of individuals asked to participate in a real or hypothetical clinical trial.

#### *Types of intervention*

- Audio-visual informed consent
- Audio-visual plus standard informed consent.

#### *Comparisons*

- Standard (written and/or verbal) informed consent
- Placebo informed consent.

#### *Outcomes*

Participant/guardian outcomes:

- knowledge and understanding of parent trial
- satisfaction with the information provided
- rate of participation/willingness to participate
- anxiety (or other psychological stress) associated with the informed consent process
- retention of knowledge and understanding for at least two weeks post intervention

- satisfaction with the decision-making process
- level of adherence to study protocol for participants who entered the parent study
- satisfaction with the media used to convey the information
- rate of withdrawal from the parent study following consent.

Clinical researcher outcomes:

- ease of use of informed consent process
- satisfaction with the informed consent process
- time taken to administer the consent procedure

Unintended adverse effects due to the intervention.

### Main results

This review included 16 RCTs and quasi-RCTs.

#### *About the studies*

The majority of studies were conducted in the United States, with two studies conducted in Canada and one each in the United Kingdom and Australia. The studies were predominantly conducted in hospitals or medical centres.

#### *About the participants*

In total, 2330 people participated in the 16 trials. Half the studies asked people to consider taking part in real clinical trials of cancer or psychiatric drugs. Many of these participants had cancer or schizophrenia. The participants asked to consider taking part in hypothetical studies included both 'nominally well' people and people with a health condition. Two studies included parents who were asked to imagine their child participating in a hypothetical clinical trial.

Half the studies in this review excluded participants with inadequate English comprehension. Only one study explicitly recruited participants with low literacy, and only three studies included more than 20% of participants from minority backgrounds.

#### *About the interventions*

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 included additional elements, such as written materials and/or face-to-face explanation.

For example, in one study, participants watched a 20-minute DVD at home that consisted of footage of clinical trial participants and health care providers giving unscripted perspectives on trial participation. Participants were also given a standard written information and

consent form.

In a second study, participants watched a 20-minute computer program on site. It included text that covered standard consent, hyperlinks to diagrams and video clips of procedures and online quizzes.

#### *About the comparisons*

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

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

#### *Effects of interventions*

There is low quality evidence that audio-visual informed consent interventions about real and hypothetical trials:

- may slightly improve knowledge or understanding of the parent trial
- make little or no difference to rate of participation or willingness to participate
- may improve participant satisfaction with the consent information provided.

There is insufficient evidence from trials to determine if the intervention affects:

- satisfaction with other aspects of the

process

- anxiety arising from audio-visual informed consent.

There is conflicting evidence about whether audio-visual interventions take more or less time to administer.

No study measured researcher satisfaction with the informed consent process, nor ease of use.

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

It does not appear that the included studies were funded by organisations with a vested interest in the results.

#### **What this review does not show**

From this review, it is unclear which elements of audio-visual presentation are the most important to include (e.g. interactivity, whether they can be watched alone or need supervision, whether they should be accompanied by written materials).

There was also very limited information about the perspectives of researchers in using audio-visual informed consent documents.

Finally, based on the results of this review, the ability of hypothetical clinical trials to mimic real clinical trial results is unclear. The results of both types of studies in this review were, however, broadly consistent.

### **Related Resources**

- NHMRC [National Statement on Ethical Conduct in Human Research 2007](#) (Updated May 2015 )
- Parliament of Victoria [Victorian Charter of Human Rights and Responsibilities Act 2006](#)
- Nishimura 2013 [Improving understanding in the research informed consent process: a systematic review of 54 interventions in randomised controlled trials](#)

#### *Related Cochrane systematic reviews*

- Kinnersley 2013. [Interventions to promote](#)

[informed consent for patients undergoing surgical and other invasive healthcare procedures](#)

- Gillies 2015 [Decision aids for people considering taking part in clinical trials](#)

#### *Related Evidence Bulletins*

- Interventions to promote informed consent for patients undergoing surgical and other invasive health care procedures

Evidence Bulletins are available [here](#)

## Results table

### Comparison 1: Audio-visual informed consent interventions compared with standard (written and/or verbal) informed consent interventions

	<b>Narrative summary of findings</b>	<b>No. of participants (studies)</b>	<b>Evidence quality (GRADE) #</b>
<b>Knowledge (single component interventions)</b>	There is uncertainty whether single audio-visual informed consent improves knowledge	155 (1 study)	Very low
<b>Knowledge (multi-component interventions)</b>	There is uncertainty whether multi-component audio-visual informed consent improves knowledge	126 (1 study)	Very low
<b>Satisfaction with the information provided</b>	No studies were found that measured this outcome		
<b>Rate of participation (single component intervention)</b>	No studies were found that measured this outcome		
<b>Rate of participation (multi-component intervention)</b>	There is uncertainty whether multi-component audio-visual informed consent improves rate of participation	110 (1 study)	Very low
<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 (single intervention)</b>	No studies were found that measured this outcome		
<b>Satisfaction with the decision making process (multi-component intervention)</b>	There is uncertainty whether multi-component audio-visual informed consent improves satisfaction with decision-making process	126 (1 study)	Very low

# For more information about GRADE, see [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org)

## Results table

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

	Narrative summary of findings			No. of participants (studies)	Evidence quality (GRADE) #
<b>Knowledge - continuous</b>	Knowledge in audio-visual plus standard group was 0.04 standard deviations higher (-0.03 to 0.38)			143 (2 studies)	Low
<b>Knowledge - dichotomous</b>	There is uncertainty whether audio-visual plus standard informed consent interventions affect knowledge			290 (2 studies)	Low
<b>Satisfaction with the information provided</b>	No studies were found that measured this outcome				
<b>Rate of participation (immediately or up to four weeks post-intervention)</b>	Audio-visual plus standard informed consent may make little or no difference to rate of participation			258 (2 studies)	Low
<b>Anxiety (immediately post-intervention)</b>	There is uncertainty whether audio-visual informed consent interventions affect anxiety (or other psychological stress)			142 (1 study)	Low
<b>Retention of knowledge (&gt; 80% of knowledge questions correct, measured two to four weeks post-intervention)</b>	64 per 100 participants	88 per 100 participants (68 to 113)	RR 1.38 (95% CI: 1.07 to 1.77)	85 (1 study)	Low
<b>Satisfaction with the decision making process</b>	No studies were found that measured this outcome				

# For more information about GRADE, see [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org); RR = relative risk; 95% CI = 95% confidence interval.

## What does this mean for health care in Victoria, Australia?

The broader policy and clinical context	<p>The NHMRC's <a href="#">National Statement on Ethical Conduct in Human Research 2007</a> (Updated May 2015) stipulates that potential research participants should have an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research they are being invited to participate in and that this information must be presented in ways that are suitable to each participant (i.e. in written form, verbally, or in other ways).</p> <p>Similarly, the <a href="#">Victorian Charter of Human Rights</a> stipulates that “a person must not be subjected to medical or scientific experimentation or treatment without his or her full, free and informed consent.”</p>
Relevance of settings and populations	<p>The evidence in this review is drawn exclusively from high-income countries so the results should be broadly applicable to Australia. It is less clear how applicable the results are to people with limited English comprehension as many studies excluded these participants. This is an important limitation since comprehension and satisfaction with informed consent processes tend to be lower among people with low literacy, and limited education, as well as those from culturally and linguistically diverse groups. These groups are therefore potentially at greater need of an enhanced informed consent intervention.</p>
Implications for decision-makers	<p>More RCTs of interventions presenting audio-visual informed consent material for real clinical trials (in place of hypothetical 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.</p> <p>It is unclear which elements of audio-visual presentation are the most important to include, specifically, whether presentation needs to be interactive, delivered as a stand alone, accompanied by written information, or include supervision by research staff.</p>
Implications for clinical triallists	<p>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.</p> <p>The findings of a review published in 2013 on <a href="#">consent for surgery and other invasive procedures</a> suggests that all enhanced consent intervention are generally equally effective. However, the applicability of these findings to the area of clinical trial consent remains unclear.</p>

This Evidence Bulletin draws on the format developed for SUPPORT summaries (for more information on SUPPORT summaries see [www.supportsummaries.org](http://www.supportsummaries.org)).

**Centre for Health Communication and Participation**

The Centre for Health Communication and Participation produces Evidence Bulletins. The Centre receives funding from the Consumer Partnerships and Quality Standards Unit, Department of Health and Human Services, Victoria, Australia. Evidence Bulletins summarise reviews published by the Cochrane Consumers and Communication Review Group.

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