

review title

## Audio-visual presentation of information for informed consent for participation in clinical trials (Ryan et al 2007)

### *focus of the review*

The aim of this Cochrane review was to assess the effects of audio-visual presentation of information to potential clinical trial participants during the informed consent process. Audio-visual presentation was defined as any pre-recorded audio-visual material presented via the Internet, by digital video disk (DVD), video, or by other means.

Interventions for studies included in the review:

- Any intervention using audio-visual information—audio-visual information delivered alone, or in addition to standard forms of information provision (eg. written or oral information usually supplied by the service).

Outcomes of interest to review authors included:

- Satisfaction with the information provided or media used; knowledge, understanding and recall about the study; level of anxiety and decisional conflict about whether or not to participate.

### *key results of the review*

*What this review shows* about audio-visual interventions for use in the informed consent process for clinical trials:

- Audio-visual interventions, compared with standard methods for informed consent, may be associated with increases in knowledge and with improved retention (recall) of knowledge at 2 to 4 weeks post-intervention;
- They may also be associated with increased willingness to participate in a clinical trial, when assessed immediately after the intervention delivery; and they may be associated with improved quality of the research information disclosed when an ‘improved’ audio-visual intervention is used, but not when a standard audio-visual intervention is used.

*What this review does not show* about audio-visual interventions for use in the informed consent process for clinical trials—gaps in the research:

- The effects of audio-visual interventions on a range of outcomes is not known, including effects on potential participants’ understanding of research, their perceived importance (worth) of the trial for which informed consent is sought, satisfaction with information provided, satisfaction with media used to convey information, anxiety associated with the informed consent process, or satisfaction with the decision-making process, and for those who choose to participate, either the level of adherence to the study protocol or the rate of withdrawal from the study. Potential harms and adverse effects associated with audio-visual interventions are also not known.

*This bulletin summarises a Cochrane systematic review*

*This page highlights key aspects of the review*

*Pages 2-4 summarise the review*

*The evidence table on pages 6-9 contains more detail of the review*

*This evidence bulletin is provided by The Cochrane Consumers & Communication Review Group*

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### Summary of the review

#### **Background to the review**

Informed consent is a vital part of clinical research. It has been demonstrated that research participants may hold misconceptions about key aspects of the conduct of clinical trials, such as expecting therapeutic benefits and misunderstanding the randomisation process. Innovations for improved informed consent processes have been called for by researchers.

Strategies that have been utilised, that aim to improve the informed consent process, include: written information with simpler language and additional illustrations; additional written and verbal information; and enhanced computer-based provision of information. Audio-visual presentations of information may enhance the informed consent process for clinical research by enabling a more complete and clear delivery of information about the trial; they can also be used at the consumer's own pace. Complex concepts may be easier to explain using audio-visual formats and computer, Internet or digital video (DVD) formats. In particular these formats may encourage viewer interactivity with specific information of interest, in language that is easy to understand.

Despite the possible benefits of audio-visual interventions they may also have associated harms. Some health treatment decisions during the informed consent process may be inherently distressing; in some health spheres there may be a tension between informing consumers and consequential effects on uptake of treatment/participation; and trial participation may be a benefit or a harm, depending on the trial and its particular risks and benefits to participants, their understanding of these underlying risks and benefits, and the underlying quality of the trial itself.

Authors note there may also be inherent biases associated with audio-visual presentations of trial information—gender, culture and age of those presenting the information for example. They also comment that informed consent for trial participation may be a more complex process than informed consent for treatment (ie. trials

may entail more complex concepts and terminology such as randomisation).

Other reviews that have focused on informed consent for trial participation, may have aimed at improving recruitment, however in many studies no single intervention has led to consistent improvement in relevant outcomes. For consent to be informed, potential participants must understand what they are consenting to, such as the possibility that they may be randomly assigned to a study group. The Ryan et al review is the most recent systematic review of audio-visual interventions in the informed consent process for trial participation.

#### **Consumer participation**

Literature on informed consent helped to inform this review and consumer advocates were involved in assessing the review protocol and the review to ensure consumer views had been appropriately represented.

#### **Studies included in the review**

Four studies were included in the review (two further studies await assessment); three were randomised controlled trials; one was a quasi-randomised controlled trial; and 511 participants were included from relevant arms in the included studies.

Three studies were conducted in the USA and one was undertaken in Canada. One study took place in a hospital outpatient department, one in a doctor's home or office and one in a major university or government psychiatric facility. The setting for the fourth study was unclear.

All studies included potential clinical trial participants. These varied according to the aims of the trial for which informed consent was sought, and included: potential psychiatric research study participants, pregnant women and potential participants in a range of oncology protocols and in a therapeutic trial (duodenal ulcer medication).

While two of the studies did not report ethnicity the other two studies reported: a

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minority of participants were of ethnic minority status (12% and 30% respectively). Ages of participants across studies ranged from 18 to 72 years. In one study all participants were female, in two studies around 70% were male and 30% were female.

A limited range of outcomes was assessed in the included studies; no studies used validated measures of informed consent or decisional capacity; and the timing of outcome measurement varied across studies.

### **Focus of interventions**

Review authors included any intervention using audio-visual information, including audio-visual information delivered alone, or in addition to standard forms of information provision (eg. written or oral information usually supplied by the service). Audio-visual presentation was defined as any pre-recorded audio-visual material presented on the Internet, by DVD, video, or by other means.

### **Description of interventions, outcomes**

All studies included a video-based intervention. In one study it was not clear whether the video intervention was interactive or non-interactive; all other studies used video interventions that were non-interactive. One study also included a computer-assisted instruction intervention arm with a compact disk (CD) containing the relevant informed consent information.

In more detail, interventions in included studies were:

- Audio-visual (video tape containing information on study protocol and adherence to protocol) plus standard care compared with standard care alone (Norris 1990; Weston 1997); standard care in both studies consisted of some form of written information (pamphlet or consent form) and some form of verbal information (discussion with study nurse);
- Professionally produced, non-interactive video and computer-aided instruction (compact disk—CD) for informed consent (content included a description of the purpose of research/procedures; side-effects, risks, benefits and alternatives, privacy and right to withdraw from study) compared with standard consent information (Agre 2003b); and,
- Two different non-interactive video and instructor-provided information intervention arms (standard and 'improved' videos containing a description of the study—'improved' video incorporated feedback from the research team and revision of the video) compared with a routine informed consent procedure (Benson 1988).

Included studies assessed a limited range of outcomes and focused on the following:

- Knowledge/understanding (Agre 2003b);
- Subject understanding of research, quality of research information disclosed (Benson 1988);
- Patient knowledge of information in study information sheet (Norris 1990);
- Knowledge of study protocol, knowledge of PROM (pre-labour rupture of membranes), willingness for future participation, importance of study (Weston 1997).

### **What the review shows: summary of key findings**

#### **Knowledge**

There is some evidence from trials that audio-visual interventions, compared with standard care, may increase knowledge of the trial for which consent is sought: 1 trial of 3 showed an increase in the number of correct items on a consent quiz (1 trial, 200 participants).

#### **Knowledge retention**

There is some evidence from trials that audio-visual interventions may improve retention of knowledge: 1 trial reported no significant increase in knowledge immediately after the intervention, but better retention of knowledge among those in the intervention group when measured at 2 to 4 weeks post-intervention (1 trial, 85 participants).

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### **Willingness to participate**

There is some evidence from trials that audio-visual interventions may increase willingness to participate in the trial, compared with standard care: 1 trial assessing this reported a statistically significant increase among those receiving the audio-visual intervention, when assessed immediately after the intervention delivery (1 trial, 90 participants); however, this difference was not detected when assessed at 2 to 4 week follow-up.

### **Quality of research information disclosed**

There is some evidence from trials that audio-visual interventions may increase the quality of research information disclosed to potential participants: 1 trial reported a statistically significant increase in the mean quality score of information disclosed among potential participants receiving an 'improved' audio-visual intervention, compared with standard care (1 trial, 44 participants). However, this study also reported no significant differences in quality of research information disclosed between those receiving standard care and those receiving the 'standard' audio-visual intervention.

### **What the review does not show**

#### **Understanding**

There is insufficient evidence from trials to decide between audio-visual interventions and standard care with respect to potential participants' understanding of research.

#### **Perceived importance of the trial**

There is insufficient evidence from trials to decide between audio-visual interventions and standard care with respect to potential participants' perceived importance (worth) of the trial for which informed consent is sought.

#### **Satisfaction, anxiety, decision-making process**

There is insufficient evidence to decide between audio-visual interventions and standard care in relation to the following outcomes as they were not specifically

reported by included studies: satisfaction with information provided, satisfaction with media used to convey information, anxiety associated with the informed consent process, or satisfaction with the decision-making process.

### **Adherence to, withdrawal from, study**

There is insufficient evidence to decide between audio-visual interventions and standard care in relation to the following outcomes as they were not specifically reported by included studies: level of adherence to the study protocol for those who entered the study, or rate of withdrawal from the study following consent for participation.

### **Conclusions**

Informed consent is important for people who are thinking about participating in a clinical trial. Information for informed consent could be presented audio-visually via the Internet, DVD, video cassette or by other means. Uncertainty remains about the effects of audio-visual information for informed consent compared with standard forms of information provision.

All four studies in this review assessed knowledge and/or understanding of the trials for which people's informed consent was being sought. Audio-visual interventions did not consistently increase participants' levels of knowledge/understanding, although one study showed better retention of knowledge amongst intervention recipients. One study showed that an audio-visual intervention could briefly increase people's willingness to participate in trials, but this was not sustained for two to four weeks post-intervention. The audio-visual intervention did not affect people's views of the worth of the trial they were considering joining (one study). Another study found that an 'improved' audio-visual intervention may enhance the quality of the information conveyed to participants. Many outcomes including possible harms were not measured.

### **Recommendations from authors**

Authors recommend that further well-designed and clearly reported research be conducted on the effects of audio-visual and other innovative interventions to be used in the informed consent process for participation in trials.

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Future research should assess a wide range of relevant outcomes, using validated tools, and including potential harms and adverse effects of the interventions, as well as outcomes relevant to individuals' decisional capacity, such as satisfaction (with information about the trial, with the media used to convey the information, and with the decision making process); anxiety; and for those who enter the trial, adherence with the trial protocol and withdrawal from the study.

Authors also recommend that trials of audio-visual and other innovative interventions should be designed for people of differing

levels of understanding and education; for different age and cultural groups; and in different settings and countries. A choice of formats for informed consent information offered to individuals should be evaluated; as should interventions tailored for use in the informed consent process for different participant groups.

Authors recommend that researchers systematically assess the effects of different intervention content, delivery components (eg. timing, provider and duration) and delivery characteristics. Ideally, consumers should be actively involved in intervention development.

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## Evaluation of bulletin service

We are currently seeking ethics committee approval to evaluate the bulletin service we have provided for Health Knowledge Network since June 2007. This evaluation will be underway in April and will consist of an email questionnaire to members of HKN; it will ask questions about accessibility and comprehensibility of bulletins and about the reach of the bulletin service. **The evaluation will inform future development of such information and services in the health**

**sphere and contribute to knowledge of the effectiveness of this sort of knowledge transfer service.**

## Bulletins housed on Health Knowledge Network website

Evidence bulletins (as well as Resource bulletins) that have been sent to you in this series are available on the Health Knowledge Network website at: [www.latrobe.edu.au/cochrane/HKN/HKNBulletins.html](http://www.latrobe.edu.au/cochrane/HKN/HKNBulletins.html)

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## EVIDENCE TABLE

This table is part of an overview of the review created by Dr Rebecca Ryan, at The Consumers & Communication Review Group. It contains detailed data extracted from the review, and was referred to in the creation of the summary on previous pages of this EVIDENCE bulletin. This table uses standardised wording developed by the Review Group. A key to this wording follows the table and should be used to interpret the data.

**Review title:** Audio-visual presentation of information for informed consent for participation in clinical trials

**Authors:** Ryan RE, Prictor MJ, McLaughlin KJ, Hill SJ

### Description of main features

**Aim:** To assess the effects of providing audio-visual information alone, or together with standard forms of information provision, to potential clinical trial participants who are in the process of seeking informed consent, in terms of their satisfaction, understanding and recall of information about the study, their level of anxiety and their decision about whether or not to participate.

**Study design:**

Randomised and quasi-randomised controlled trials.

**Participants:**

**Included:** Individuals, or guardians of individuals, asked to participate in a real (not hypothetical) clinical trial. This included situations in which the individuals eligible for trial participation were children; or the individuals were not competent to provide informed consent. In these cases, studies of parents and/or surrogates providing informed consent on behalf of another were eligible for inclusion.

**Excluded:** Studies in which participants were asked to participate in a hypothetical (imagined) clinical trial. This included those cases where participants were asked to imagine participating in a clinical trial (eg students asked to imagine participating in a trial); and those cases where the trial was itself hypothetical (eg HIV vaccine trial). Since potential trial participation was not a real option for the individuals involved in such studies, they were excluded from this review.

**Interventions:**

**Included:** Any intervention using audio-visual information, including audio-visual information delivered alone, or in addition to standard forms of information provision (eg written or oral information usually supplied). Audio-visual presentation was defined as any pre-recorded audio-visual material presented on the Internet, by DVD, video, or by other means.

**Comparison arms:**

Audio-visual information (alone or in combination with standard information provision) versus standard information alone

**\*Outcomes:**

**Included:** *Primary outcomes* - Participant/guardian: satisfaction with information provided about the clinical study; satisfaction with media used to convey the information about the clinical study; knowledge and understanding of the clinical study; retention of knowledge/ understanding of clinical study; anxiety associated with the informed consent process; satisfaction with the decision-making process; rate of participation or willingness to participate in the clinical study.

*Primary outcomes* - Participant/guardian: satisfaction with information provided about the clinical study; satisfaction with media used to convey the information about the clinical study; knowledge and understanding of the clinical study (including the potential harms and benefits, treatment(s) involved, the outcomes assessed and data collected, the need for and duration of follow up, the concepts of equipoise (a state of genuine uncertainty as to the potential benefits and/or harms of the intervention(s) in a clinical study) and randomisation, understanding of the use of a placebo, their right to refuse participation in the trial, and their right to withdraw from the study at any time); retention of knowledge and understanding of clinical study (measured two or more weeks after viewing the video/ receiving standard information); anxiety associated with the informed consent process; satisfaction with the decision-making process (whether they felt they made the decision themselves, whether they were satisfied with their choice to participate or decline participation in the study, whether they would choose to participate or decline participation in the study based on their past experience, whether they regretted their decision to participate or decline participation in the study, whether they would advise others to participate or decline participation the study); rate of participation or willingness to participate in the clinical study.

*Secondary outcomes* - Level of adherence to the study protocol for those who entered the study; rate of withdrawal from the study following consent for study participation.

Secondary outcomes - Level of adherence to the study protocol for those who entered the study; rate of withdrawal from the study following consent for study participation.

**Number of studies included:** 4 (2 further studies await assessment).

**Types of studies included:** 3 RCTs; 1 quasi-RCT

**Number of participants included:** 551

**Meta-analysis performed:** No; narrative synthesis. Meta-analysis not appropriate due to the variability in participants, interventions, outcome measures and the purpose of trials for which informed consent was sought.

**Review methods:** Standard Cochrane Collaboration review methods were used, including the following: *a priori* research design provided; extensive searching including searching for unpublished studies; selection criteria were specified in advance and applied; list of included and excluded studies provided; quality criteria for assessment of included studies were reported and applied; methods of analysis were reported; conflict of interest stated.

**Quality:**

**Included studies:** Rated based on studies meeting a range of criteria, including randomisation, allocation concealment, blinding (participants, provider, outcome assessor), follow-up, baseline comparability of groups, use of validated outcome measures, and other sources of bias). Overall the standard was variable: none of the studies adequately met all of the quality criteria. None of the studies adequately used blinding; nor were outcome tools formally validated. Only 1 of 4 studies adequately randomised participants and concealed the allocation. However, all studies achieved high follow-up rates; and in 3 of the 4 included studies groups appeared comparable at baseline (and rated as unclear in the fourth study).

*\*Review AMSTAR rating (out of possible 11): 10 - high quality review.*

**Comments:** The review methods adequately met all items of the AMSTAR checklist with the exception of the item evaluating assessment of publication bias: the likelihood of publication bias was not explicitly addressed by the review.

**Setting:** *Country:* USA (3 studies); also Canada (1 study).

**Intervention:** Variable: included hospital outpatient department (1 study), doctor's office or home (1 study), major university medical centre or government psychiatric facility (1 study), and was unclear in 1 study.

**Recipient:** All studies included potential clinical trial participants. These varied according to the aims of the trial for which informed consent was sought, and included: potential psychiatric research study participants, pregnant women and potential participants in a range of oncology protocols and in a therapeutic trial (duodenal ulcer medication).

**Provider:** Interventions were delivered by the principal study investigator, or by one of two trained research assistants (1 study); by a psychiatric researcher (1 study); or by a research nurse (2 studies; in one of these studies the principal investigator and others were involved in presenting information on the video).

**Format:** All studies included a video-based intervention. In one study it was not clear whether the video intervention was interactive or non-interactive; all other studies used video interventions that were non-interactive. One study also included a computer-assisted instruction intervention arm with a CD containing the relevant informed consent information.

Intervention	Results of review
<p>Audio-visual presentation versus standard care</p>	<p><u>Primary outcomes:</u></p> <p><b>Some evidence from trials:</b> that audio-visual interventions may increase knowledge of the trial for which consent is sought, compared with standard care: 1 trial of 3 measuring knowledge showed an increase in the number of correct items on a consent quiz (1 trial, 200 participants).</p> <p><b>Some evidence from trials:</b> that audio-visual interventions may improve retention of knowledge: 1 trial reported no significant increase in knowledge immediately after the intervention, but better retention of knowledge among those in the intervention group when measured at 2 to 4 weeks post-intervention (1 trial, 85 participants).</p> <p><b>Insufficient evidence from trials:</b> to decide between audio-visual interventions and standard care with respect to potential participants' understanding of research.</p> <p><b>Some evidence from trials:</b> that audio-visual interventions may increase willingness to participate in the trial, compared with standard care: 1 trial assessing this reported a statistically significant increase among those receiving the audio-visual intervention, when assessed immediately after the intervention delivery (1 trial, 90 participants); however, this difference was not detected when assessed at 2 to 4 week follow-up.</p> <p><b>Insufficient evidence in relation to measurement:</b> to decide between audio-visual interventions and standard care with respect to: satisfaction with information provided, satisfaction with media used to convey information, anxiety associated with the informed consent process, or satisfaction with the decision-making process.</p> <p><u>Other outcomes:</u></p> <p><b>Some evidence from trials:</b> that audio-visual interventions may increase the quality of research information disclosed to potential participants: 1 trial reported a statistically significant increase in the mean quality score of information disclosed among potential participants receiving an 'improved' audio-visual intervention, compared with standard care (1 trial, 44 participants). However, this study also reported no significant differences in quality of research information disclosed between those receiving standard care and those receiving the 'standard' audio-visual intervention.</p> <p><b>Insufficient evidence from trials:</b> to decide between audio-visual interventions and standard care with respect to potential participants' perceived importance (worth) of the trial for which informed consent is sought.</p> <p><b>Insufficient evidence in relation to measurement:</b> to decide between audio-visual interventions and standard care with respect to: level of adherence to the study protocol for those who entered the study, or rate of withdrawal from the study following consent for participation.</p>



## KEY TO RESULTS

The table on this page presents the standardised wording that should be used to interpret the data in the results section of the EVIDENCE table on the previous two pages.

SUMMARY STATEMENT	TRANSLATION
<i>Sufficient evidence from trials</i>	<p>Evidence to support conclusions about the effect of the intervention(s) in relation to a specific outcome(s). This includes evidence of an effect in terms of:</p> <ul style="list-style-type: none"> <li>• benefit or</li> <li>• harm.</li> </ul> <p>Statistically significant results are considered to represent sufficient evidence to support conclusions, but a judgement of ‘sufficient evidence’ is also based on the number of trials/ participants included in the analysis for a particular outcome.</p> <p>A grading of ‘sufficient evidence’ is often based on meta-analysis producing a statistically significant pooled result that is based on a large number of included trials/ participants.</p> <p>This judgement may also be made based on the number of trials and/or trial participants showing a statistically significant result - for example (in a narrative synthesis) a result where 12 studies of a total of 14 for a specific outcome showed a statistically significant effect of an intervention would be considered to represent ‘sufficient evidence.’</p>
<i>Some evidence from trials</i>	<p>Less conclusive evidence to make a decision about the effects of a particular intervention(s) in relation to a specific outcome(s).</p> <p>This may be based on narrative syntheses of review results. In this case, the result is qualified according to the findings of the review - for example, ‘some evidence (5 studies of 9) reported a positive effect of ....’</p> <p>{This would be based on a more equivocal set of results than those obtained for ‘sufficient evidence’ above. For example, while 12/14 statistically significant studies would be classed as ‘sufficient evidence’, 5/9 statistically significant studies is more equivocal and would be classes as ‘some evidence.’}</p> <p>This may also be based on a statistically significant result obtained in a small number of trials; or a statistically significant result obtained from trials with a small number of participants.</p>
<i>Insufficient evidence from trials</i>	<p>Not enough evidence to support conclusions about the effects of the intervention(s) on the basis of the included studies. This should be interpreted as ‘no evidence of effect’, rather than ‘evidence of no effect’.</p> <p>Statistically non-significant results are considered to represent insufficient evidence.</p> <p>Where the number of trials is small, and/or the number of participants included in the trials is small, ‘insufficient evidence’ might reflect underpowering of the included trials to be able to detect an effect of the intervention.</p> <p>Where the number of trials is large, and/or the number of participants included in these trials is large, ‘insufficient evidence’ may reflect underlying ineffectiveness of the intervention to affect the outcomes being examined.</p>
<i>Insufficient evidence in relation to measurement</i>	<p>Not enough evidence to support conclusions about the effects of the intervention due to a lack of reporting on the specified outcomes.</p> <p>This can be the result of :</p> <p>(i) the review electing not to report on a particular outcome, or set of outcomes, despite being reported by the included trials; or</p> <p>(ii) the review was not able to report on the outcome, as data for the outcome was not reported by the included trials. Note: used for reporting against outcomes only.</p>
<i>N/A</i>	<p>Not applicable to the outcome category of interest. Note: used for reporting against outcomes only.</p>