CRD summary
The authors reported that no single intervention strategy consistently improved participant comprehension of informed consent in clinical research. They also stated that successful consent processes should include various communication modes and one-to-one interaction. Despite some methodological limitations of the review, the authors’ cautious conclusions are likely to be reliable.

Authors' objectives
To critically analyse descriptive and intervention studies of participants’ comprehension of informed consent in clinical research. Only information that related to intervention studies were presented in this abstract.

Searching
CINAHL, PubMed, Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for papers published between January 1996 and January 2007; search terms were reported. Reference lists of relevant studies were checked. Only studies published in peer-reviewed English-language journals were included in the review.

Study selection
Clinical research intervention studies of comprehension of informed consent in non-psychiatric adult populations were eligible for inclusion.

The studies included patients in oncology/chemotherapy/cancer trials, perinatal trials, influenza or HIV vaccine trials, patients with acute myocardial infarction, diabetes, asthma, chronic conditions, anaesthesia patients and healthy volunteers. Studies compared standard informed consent with simplified written consent documents, multimedia approaches (such as educational video) and the use of a consent educator. The tools used to define and measure comprehension varied widely. Measurement tools included semi-structured or open-ended interviews, questionnaires, focus group transcripts, self-report and surveys.

The authors stated neither how the papers were selected for the review nor how many reviewers performed the selection.

Assessment of study quality
The quality of the included studies was assessed by evaluating the sampling method, use of controls or comparison group, response rate, outcome measurement tool, clear description of the intervention, comparison and methods, and appropriate statistical analysis. Scores ranged from 0 to 7 and then calculated as percentages; higher percentages indicated better methodological quality.

Two authors independently assessed validity. Any disagreements were resolved by discussion.

Data extraction
The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction.

Methods of synthesis
The studies were combined in a narrative synthesis.

Results of the review
Ten intervention studies (n=7,670) were included in the review. Sample sizes ranged from 90 to 4,892 participants. Study quality ranged from 71% to 100%.
The intervention strategies were inconsistently associated with improved comprehension of informed consent. Three studies that included consent educators (such as video training combined with a consent educator) demonstrated significant improvements in comprehension (p<0.05 for all, where reported).

Authors’ conclusions
No single intervention strategy was consistently associated with improved comprehension. The results indicated that successful consent processes should include various communication modes and one-to-one interaction with someone knowledgeable about the clinical study.

CRD commentary
The review question and inclusion criteria were clearly presented. The authors searched a number of databases, but only English-language studies published in peer-reviewed journals were sought, thus potentially introducing language and publication biases and meaning some relevant studies may have been missed. A validity assessment was conducted. Two reviewers were involved in the assessment process, thus minimising risks of reviewer error and bias. No details were provided for the study selection and data extraction processes. Details of the primary studies were presented. Some information on participant characteristics were missing, which likely reflected a lack of data presented in the original studies. Data were appropriately summarised as a narrative synthesis. It appeared that three studies that involved consent educators demonstrated positive results, including one very large trial. Despite some methodological limitations of the review, the authors’ cautious conclusions are likely to be reliable.

Implications of the review for practice and research
Practice: The authors stated that consent processes should include various communication modes and one-to-one interaction with a knowledgeable person such as a consent educator.

Research: The authors did not state any implications for research.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.