



Cochrane Eyes and Vision Group

Guidelines for translators

Introduction

Many thanks for agreeing to translate articles for the Cochrane Eyes & Vision Group.

Cochrane systematic reviews summarise the evidence for the effectiveness of health care interventions. The reviews include evidence from randomised controlled trials (RCTs) and controlled clinical trials (CCTs) from any source, including those published in languages other than English, and unpublished studies.

These notes have been prepared for you to use as a guide when looking at the papers you have been sent for translation.

What you need to do

The attached papers are potentially relevant for inclusion in systematic reviews being undertaken by members of the Cochrane Eyes and Vision Group. For each paper, we need to determine the following:

1. In the first instance we need to determine whether the article is in fact describing a randomised controlled trial (RCT) or a controlled clinical trial (CCT) as defined in the attached sheets. Unless or until it is certain that the study described in the article is neither comparative nor prospective, it is extremely important to read every word the authors provide. However, you will rarely need to read the entire article. Reading the Title, Abstract and Methods sections *may* be sufficient to tell you whether or not a study meets the criteria for RCT or CCT. You need only read each article to the point where it is possible to make a definite classification of the study design
2. If the article **is not** describing an RCT or a CCT, we will need to know what the study design is so that we can state this in the review. *We do not however, need a translation of the article.* Please complete the Translation summary sheet and return this to us.
3. If the article **is** describing an RCT or a CCT, we will need to have a translation of the relevant sections of the article into English so that it can be incorporated into a review. Usually it is sufficient to translate the Methods and Results sections, along with any data tables. Please complete the separate Translation summary sheet and return this with your translation.

Please use the notes attached to guide you when determining whether the paper is or is not a randomised controlled trial or controlled clinical trial. If you have any questions please do not hesitate to contact me or the person who gave you the articles.

Many thanks

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CRITERIA FOR CODING REPORTS AS RANDOMISED CONTROLLED TRIALS (RCTS) AND CONTROLLED CLINICAL TRIALS (CCTS)

Randomised controlled trial - RCT

A trial in which the individuals (or other units) followed in the trial were:

Definitely assigned **prospectively** to one of two or more alternative forms of health care using **random** allocation A randomised controlled trial involves at least one **test treatment** and one **control treatment, concurrent enrolment** to the groups, and follow-up of the test and control treated groups. The treatments are allocated by a random process.

Controlled clinical trial - CCT

A trial in which the individuals (or other units) followed in the trial were:

Definitely assigned **prospectively** to one of two or more alternative forms of health care using some **quasi-random** method of allocation (such as alternation, date of birth, hospital number) or

Possibly assigned **prospectively** to one of two or more alternative forms of health care using **random** or **quasi-random** method of allocation

A controlled clinical trial involves at least one test treatment and one control treatment and specified outcome measures for evaluating the studied intervention. The treatments are allocated by a quasi-random process.

DEFINITIONS

Test treatment – a drug, device, procedure or intervention studied for diagnostic, therapeutic, prophylactic effectiveness

Control treatment – placebo, active treatment, no-treatment, alternative doses and regimens

Random – computer generated random numbers table, computer generated random sequence of treatments that are in turn assigned to participants, sequentially numbered opaque envelopes or vials, telephone call to a central office.

Quasi-random – alternation, patient record number, date of admission to hospital, date of birth

Concurrent Enrolment – participants for the test and control groups are enrolled at the same time

Prospective – the participants for the trial are enrolled prior to the treatment taking place

NOTES

- The study must be prospective in nature. That is, the interventions are planned prior to the experiment taking place
- Two or more treatments or interventions must be compared to one another
- Cross-over trials, in which patients have been assigned to the first intervention using random or quasi-random allocation, should be included as an RCT or CCT respectively
- Reports of trials dealing only with animals or with cadavers or parts of the human body that will not be replaced into a living human, are not relevant to Cochrane reviews and do not therefore require translation. Trials that include both human and animal participants **are** relevant to reviews
- Units of randomisation may be individuals, groups (communities, hospitals), organs (such as eyes) or other parts of the body such as legs, teeth

EXAMPLES OF DESCRIPTIONS OF ALLOCATION METHODS

Randomised controlled trial (RCTs)

‘Patients were randomly allocated to the two treatment groups using a random numbers table’

‘When the patient entered the trial the ward sister opened a numbered sealed envelope containing the randomised allocation to the test or control group’

‘Patients were randomised into two groups’

‘The order in which the drugs were given was determined by a random code’

Controlled clinical trial (CCTs)

‘The effects of propranol and identical placebo were compared in a double blind study’ [not stated]

‘Patients admitted to the trial were allocated to the test or control group by their NHS number. This with odd numbers entered the test group’ [quasi]

‘Patients with severe burns were allocated on admission alternately to a control group and to a treatment group’ [not stated]

‘All patients were given either treatment tablets or placebo tablets of similar appearance’ [not stated]

‘In a study involving 25 volunteers on a daily dose of 1 or 2 grams of the treatment drug..’ [not stated]

‘Patients admitted to the trial were divided into two groups’ [not stated]