

## **INTRODUCTION**

Many thanks for agreeing to handsearch for the Cochrane Eyes & Vision Group. These notes have been prepared for you as a quick reference to use while handsearching. You should also have received and read a copy of the CEVG Handsearching manual for more complete guidelines.

If you have any questions about these notes or about any aspect of handsearching, please do not hesitate to contact us.

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## NOTES FOR HANDSEARCHERS

- You are searching for reports of trials in ANY area of health care, and not just those relevant to a particular review or field
- Unless or until it is certain that the study described in an 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
- Making judgements as to the quality of the methods used, or whether the authors actually did what they claim, should not be used as a criterion for including a study. As a handsearcher, you need not attempt to assess for quality the studies you identify
- The code RCT is reserved for trials where randomisation is certain and explicitly stated; the code CCT is used as a collective term for possible RCTs, quasi-RCTs and possible quasi-RCTs
- If one or more outcomes were assessed using double-masking (blinding), such that neither the participant nor the assessor was aware of the intervention received, but randomisation is not explicitly mentioned in the text, a trial should be included as a CCT
- Cross-over trials, in which patients have been assigned to the first intervention using random or quasirandom 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, should not be included
- A report of a trial should be included even when no results are presented or when results are limited to base-line variables
- 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
- Reports of trials with healthy volunteers should be included
- Do not include items which simply comment on previously reported trials
- Units of randomisation may be individuals, groups (communities, hospitals), organs (such as eyes) or other parts of the body such as legs, teeth
- Take care to distinguish random *sampling* from random *allocation*. Random sampling of a population for inclusion in a trial does not automatically mean random allocation to groups within the trial was used.

# **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]

### **CRITERIA FOR CODING RCTs AND 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

## **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)

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

### **Key Definitions**

A **randomised controlled trial** involves at least one test treatment and one control treatment, concurrent enrolment and follow-up of the test and control treated groups. The treatments are allocated by a random process.

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.

A review article is any article that summarises results of randomised or quasi-randomised trials (published or unpublished).

**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

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

## FLOW CHART FOR CODING EACH REPORT

### **ASSIGN CODE:**

Х





• Is it a systematic review or meta-analysis article of a health care intervention?



• Were the comparison groups formed prospectively?



How were the comparison groups formed?

Randomised	RCT
Quasi-randomised	ССТ
Not stated or unclear	ССТ
Using a predetermined or biased method	Х
Not sure	NS



NO

