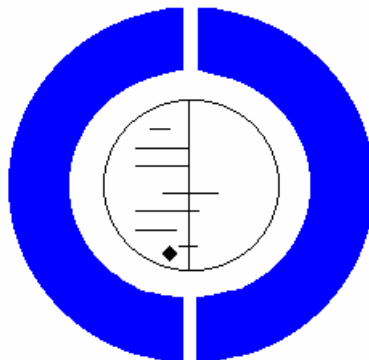


The Cochrane Collaboration



Oral Health Review Group Journal Handsearchers' Manual

Cochrane Oral Health Group

MANDEC

University Dental Hospital of Manchester

Higher Cambridge Street

MANCHESTER, M15 6FH

Tel: +44 (0)161 275 7818

Fax: +44 (0)161 275 7815

Review Group Co-ordinator / Managing Editor: Luisa Fernandez-Mauleffinch

Email: luisa.fernandez@manchester.ac.uk

Trials Search Co-ordinator / Information Manager: Anne Littlewood

Email: a.littlewood@manchester.ac.uk

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This manual has been revised from the *Oral Health Group Hand Search Training Manual* developed in 1994 by Alexia Antczak-Bouckoms, the Oral Health Group's first Co-ordinating Editor. Adapted from the Baltimore Cochrane Centre's manual, Alexia's manual was related specifically to the needs of the Oral Health Group and was ultimately adopted by the Baltimore Centre's manual as "*a fine example of how training notes can be adapted to suit the needs of an individual searching group.*"

There are many collaborators who continue to strive to find better, easier, clearer, more efficient, and more cost-effective ways to carry out the tasks involved with handsearching. The work of those who have contributed to the development of training materials and to the fore-mentioned manuals is gratefully acknowledged here.

This latest revision has been written by Sylvia Bickley, Jayne Harrison, Helen Worthington, Anne-Marie Glenny and Anne Littlewood.

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MANDEC

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INTRODUCTION

The past twenty-five years has witnessed a rapid growth in healthcare information. Every month, clinicians, policy makers, and patients face a deluge of evidence from published reports from the 20,000 journals catering to the healthcare community. These reports are now so numerous and dispersed that it is unreasonable to expect people to read and retain all the information they contain. Most healthcare providers have come to rely upon reviews of primary research and the overviews they offer.

Reviews occupy a key position in the chain that should link the results of primary research to improved outcomes in health care. Unfortunately, the quality of some reviews leaves much to be desired. While advice on some highly effective forms of health care has been delayed for years, other forms of care have continued to be recommended long after well-designed research has shown them to be either ineffective or actually harmful.

The Cochrane Collaboration seeks to improve the situation by developing a *systematic* approach to reviews that controls for bias and random error. The randomised controlled trial (RCT) has emerged as the most highly regarded tool for critical evaluation of the effects of healthcare. There is an increasing demand that clinical practice should be evidence-based. The adoption of *systematic reviews* (SR) of RCTs – using objective, reproducible methods to identify eligible studies and to abstract and analyse relevant data – should provide the most useful mechanism for assessing the value of the evidence presented by trials. Systematic reviews may include statistical pooling of the results from the individual studies. This pooling is referred to as a meta-analysis (MA) (a glossary of terms is available in appendix 1).

The first step in preparing reviews is to identify to the greatest extent possible the universe of well-controlled clinical trials. Electronic databases exist that contain the bibliographic reference and abstract of original articles reporting RCTs. Unfortunately research has shown that electronic searching for RCTs on some databases retrieves only about half the relevant available studies. Reports may either be missing from the database or have been inadequately indexed due to lack of detail in titles and abstracts. For this reason, handsearching journals to identify RCTs, controlled clinical trials (CCTs), systematic reviews (SR) and meta analyses, which may otherwise be missed, has become an important task for the Cochrane Collaboration.

Handsearching journals world-wide is a huge but most valuable operation and the Cochrane Collaboration has established a world-wide handsearching programme. To maximise resources and the efforts of those undertaking the searching, a strict protocol must be followed to register and manage searches and their results. A *Master List of Journals Being Searched* is up-dated regularly and may be accessed from the internet: <http://apps1.jhsph.edu/cochrane/masterlist.asp>.

There is also an online training course available for potential handsearchers:

https://webct.jhu.edu/public/ph_handsearching/index.html

HANDSEARCHING JOURNALS FOR THE ORAL HEALTH GROUP

The Oral Health Group contributes to the Cochrane world-wide handsearching programme through its own programme of handsearching which supports those undertaking Cochrane systematic reviews on oral health topics. Our principal objective is to identify all reports of controlled clinical trials in the biomedical literature related to the topics identified within the remit of the Oral Health Review Group. Oral health is broadly conceived to include the prevention, treatment and rehabilitation of oral and dental diseases. However, it is important to note that handsearching efforts are directed at finding reports of **all** Cochrane eligible trials and not just those relating to oral health. Trials we find on topics outside the scope of the Oral Health Group will be useful to other specialised Review Groups within the Cochrane Collaboration and a reciprocal arrangement operates throughout the Collaboration. All searching activities throughout the Collaboration must be seen as serving a dual purpose: to contribute to the comprehensive International Register of Trials and to contribute to one or more individual specialist registers. This is why it is essential that all journals and other publications are searched comprehensively for **all** eligible reports of trials, and not merely for reports relevant to a particular topic or specialised register.

Criteria for searching

Classification of Eligible Trials

The term "trial" is used in its broadest sense: it includes any prospective study that compared two or more interventions concurrently and was performed in humans. When searching journals for clinical trials, four aspects of the study design are essential:

- i. the study compares *healthcare* treatment/interventions in *human beings*,
- ii. the study is *prospective* in nature, i.e., the treatments/interventions are planned prior to the experiment taking place, and exposure to each intervention is under the control of the study investigators,
- iii. **two or more** treatments/interventions are compared to one another (or one may be a no treatment control group),

- iv. the most important aspect is that assignment to a particular treatment/intervention is intended to be **random**, i.e., not deliberately selected in any way. Units of randomisation may be individuals, groups (communities, schools, or hospitals), organs or other parts of the body (such as teeth).

Examples of what should and should not be included with regard to these criteria are listed in appendix 2. Studies meeting these four criteria are further classified according to the degree of certainty that random allocation was used to form the comparison groups. There are only three possibilities for classification.

1. **RCT (Randomised Controlled Trial):** if the trial meets the four eligibility criteria and the author(s) state **explicitly** (usually by using some variant of the term “random” to describe the allocation procedure used) that the groups compared in the study were established by random allocation.
2. **CCT (Controlled Clinical Trial):** if an eligible trial has not been explicitly described by the author as “randomised” then there is less certainty that it is, in fact, an RCT. This uncertainty is reflected in a different classification: "CCT". The classification "CCT" is also applied to quasi-randomized studies where the method of allocation is known but is not considered strictly random. The classification is based solely on what the author has written, not on the reader's interpretation. Examples of quasi-random processes for assigning treatments are, odd-even numbers, patient social security numbers, days of the week, or patient record numbers.
3. **SOS (Second Opinion Sought):** if you are not sure whether the study is an RCT, CCT, or neither, but you feel it needs further consideration, ask for a second opinion. These trials will be reviewed by a second reader in the Oral Health Group to help make the determination. **IF IN ANY DOUBT SOS**

Since the classification terms are based on the author's description of the method of allocation used, they are not meant to reflect the actual quality of the allocation procedure. A trial report which states that the study participants were randomized is classified as "RCT", despite the fact that quasi-random methods may actually have been used. Conversely, although double-blind trials are nearly always randomized, many trial reports fail to mention this explicitly and such reports are classified as "CCT". It is the responsibility of those performing systematic reviews to decide which trials to include and exclude in any given review.

We would rather include more studies that are possible reports of controlled trials than risk missing trials. Those searching the literature to identify trials should give reports the benefit of

any doubts. Once a journal is handsearched, we hope it will never have to be searched again. So if a trial is missed the first time, it may be lost forever.

Systematic Reviews

As part of the Oral Health Group's handsearching programme we are also collecting reports of **Systematic Reviews (SR)**. A **systematic review** is a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Systematic reviews may include a statistical technique known as meta-analysis to pool the data from the individual studies included in the review. The term meta-analysis is often used as a synonym for systematic review. Any review paper described as a **systematic review or meta-analysis** should be coded **SR**.

Questions that may help identify a systematic review/meta-analysis are:

- a. Does one of the phrases "systematic review", meta-analysis or overview appear in the title or abstract?
- b. Does the methods section suggest a good search for papers has been carried out? (This should include a search on at least one electronic database such as MEDLINE; EMBASE; the Cochrane Library, or PubMed).
- c. Are there any other phrases in the title, abstract, or methodology that might indicate a systematic review, such as "search strategy", "quality / validity assessment", "table of primary studies" or "pooling" of data?

If you answer "Yes" to any of the questions above, then this paper should be coded as a "systematic review" (SR).

Making a rigorous assessment of the quality of an individual study's design and the success of its implementation is no part of the handsearcher's task, but rather the task of those preparing systematic reviews. Beyond classifying eligible trials or reports as either "RCT", "CCT", "SOS", or "SR", handsearchers need not attempt to assess the quality of **or even read** those studies they identify for the Register.

Common phrases that indicate an RCT or a CCT

(A glossary of terms is provided in appendix 1);

Randomised controlled trials (RCTs)

- Patients were randomly allocated to the two treatment groups **using a random number table**.
- When the patient entered the trial the ward sister opened a **numbered sealed envelope** containing the randomized allocation to the test or control group.
- Patients were **randomized** into two groups.
- The **order** in which the drugs were given was determined by a **random code**.

Important note: *"Random selection"* vs. *"random allocation"*: *"Randomly selected"* indicates that some method of random sampling was used to select participants for the study. This does **not** imply random *allocation* of those participants to treatment/intervention and comparison groups within the study.

Controlled clinical trials (CCTs)

The effects of propranolol and identical placebo were compared in a **double-blind study**.
[randomisation not stated]

Patients admitted to the trial were **allocated** to the test or control groups **by their NHS number**.
Those with odd numbers entered the test group. [quasi-randomisation]

Patients with extensive burns were **allocated** on admission **alternately** to a control group and to a treatment group. [quasi-randomisation]

All patients were given **either treatment tablets or placebo** tablets of similar appearance.
[randomisation not stated]

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

Patients admitted to the trial **were divided into two** groups. [randomisation not stated]

Note: Other terms that indicate either an RCT or CCT include; **parallel group trial, cross-over trial, split mouth (split plot) trial, multi-centre clinical trial, cluster randomised controlled trial, Latin square design**. Definitions and examples can be found in the glossary (appendix 1)

ORAL HEALTH GROUP'S HANDSEARCH TEST

Whether or not searchers have prior experience with identifying published reports of trials, all those undertaking handsearching of journals for the Oral Health Group will be asked to first complete a test-search of a specified number of journal issues. The purpose of the test (which forms the basis for on-going reliability and quality checks) is to ensure that all searchers apply standard eligibility criteria and classify reports in the same manner.

The journal used by the Oral Health Group for the test search are the *Journal of Clinical Periodontology* or the *Journal of Dentistry*. Each issue should be searched from cover to cover in order to identify the maximum number of reports of trials, systematic reviews or meta-analyses. Letters and abstracts as well as full articles should be examined and identified for key words and phrases that describe the design of the trial.

GETTING STARTED

There are two things you must do before you begin searching on behalf of the Oral Health Group for the first time:

1. **Complete the Cochrane Handsearchers Online Training Course:** A free course has been produced to train potential handsearchers in identifying clinical trials. To register for the course, visit: https://webct.jhu.edu/public/ph_handsearching/index.html
2. **Complete a test search** so that we are sure everyone is interpreting the definitions of RCT and CCT similarly, we ask all new handsearchers to complete a “test search”. Contact the Cochrane Oral Health Group’s Trials Search Co-ordinator for more information: a.littlewood@manchester.ac.uk.
3. **Officially register your search**
Once your search test has been completed and it has passed the quality assurance test discuss and agree your proposed search with the Oral Health Group’s Trials Search Co-ordinator.

THE JOURNAL-SEARCHING PROCESS

Before searches are commenced, to avoid duplication of effort and resources, the Oral Health Group's Trials Search Co-ordinator will consult the *Master List of Journals* being searched, to check which journals and issues have been or are currently being searched. The *Master List* may also be accessed via the internet: <http://apps1.jhsph.edu/cochrane/masterlist.asp>

Registering Journal Searches

The Oral Health Group's Trials Search Co-ordinator is responsible for registering those searches undertaken by searchers registered with the Oral Health Group. It is therefore with the Trials Search Co-ordinator that your searches must initially be registered and to whom the results of your searches must be sent. These results are added to the Oral Health Group's specialised register of trials and are ultimately incorporated into the Cochrane parent database – the *Cochrane Controlled Trials Register (CENTRAL/CCTR)* within the *Cochrane Library* where they can then be readily accessed by others.

Which Journals will you Search?

The Oral Health Group holds a list of journals it intends to search and these are allocated to searchers by mutual agreement between the searcher and the OHG Trials Search Co-ordinator, taking into account journal accessibility and subject preference of the searcher. Some searchers may need to search a particular journal for their own research needs and the result of this effort can be mutually shared with the Collaboration. By agreement with the Trials Search Co-ordinator, searchers initially undertake to search a block of issues of a particular journal. As these are completed and the results submitted the search is extended according to the wishes and time available to the searcher.

PROCEDURE FOR JOURNAL SEARCHING

Using the Table of Contents

For each journal issue you search, make a photocopy of the Table of Contents to refer to as you search. Check off each item on the Table of Contents as you read the article, indicating whether it is an RCT, CCT, SOS or SR. It may help to make notes on the Table of Contents page as reminders of why an article was or was not selected. (*See example Appendix 3*)

The entire journal issue must be searched from cover to cover for reports of eligible trials. This may include abstracts from papers published in other journals; correspondence relating to trials; conference proceedings; etc.

As a handsearcher, you will rarely have to read an entire article all the way through. Often, reading through the Title, Summary/Abstract and Methods sections will be sufficient to tell you whether or not a study meets the criteria for an RCT, CCT, or SR. You need only read each article to the point where it is possible to make a definite classification of the study design. Because it is often more difficult to make a determination for CCTs, these usually will need to be read further.

Photocopies

You do not need to copy every page of every article reporting an RCT, CCT, or SR except where the paper is identified from a journal which may not be easily accessed again, (for example if it was obtained through an inter-library loan). In this case a full copy of the paper should be made.

The number of pages needed depends upon (1) the type of report, (2) the degree of certainty that the report fits the criteria for collection and (3) the location within the report of the key words that led to your decision. In every case, make sure all photocopies are clear and readable, and that margins have not been cut off.

Copy the **title page** for citation information. If you identify key words in **the title, abstract, or text of the title page** indicating that the study reported is an RCT, CCT, or SR you only need that page. For articles where the key words or phrases were found first in the **Methods** section

or general text, copy those pages as well, highlighting (on the photocopy) the words or phrases that led to your decision.

Makes sure you send all copies of Tables of Contents (even those with no relevant reports) as we need to keep reference documentation on all volumes and issues that have been searched.

For articles that you have difficulty making a decision about classification of research design, what we call an SOS or “Second Opinion Sought”, copy every page of the article and send it to the Trials Search Co-ordinator for review by a second reader.

Scanned / Electronic Copies

If you would prefer to scan the documents and send them via email, send the scanned copies to the Trials Search Co-ordinator: a.littlewood@manchester.ac.uk. If the full text of the journal is available online, you may also send downloaded copies of identified studies and tables of contents electronically via email to the Trials Search Co-ordinator.

A summary of the hand searching process is included as *Appendix 4*.

Please feel free to contact the Editorial Base if you have questions regarding any aspect of the search process. Your contact person regarding journal handsearching is: **Anne Littlewood, Trials Search Co-ordinator, email: a.littlewood@manchester.ac.uk**

Glossary of methodological terms

Blinding

Blinding (also called masking), in research, refers to the process of preventing participants and/or researchers from knowing whether a particular person is receiving the experimental or control treatment. A single blind trial refers to where only one party (e.g participants or the practitioners administering the treatment) has been masked. Double blind refers to studies where both the researcher and the participant are unaware to treatment allocation.

Clinical trial

A trial that tests out a drug or other intervention to assess its effectiveness and safety. This general term encompasses randomised controlled trials and controlled clinical trials. Also known as intervention studies and therapeutic trials.

Cluster randomised controlled trial

This design occurs when the sampling unit is the school, or clinic, or health district and the patients are clustered within this. Each unit is then randomly allocated to the treatment groups, and all the patients within that unit receive the same treatment. This is sometimes the most appropriate design where there is a problem with 'contamination'.

Example:

A study designed where the intervention is a dental health education programme given in schools to improve children's oral hygiene. Forty schools were randomly allocated to either receiving the programme (test group) or not (control group). All the children in the test group schools received the programme. This was a more appropriate design than randomly allocating individual children to test and control groups as the control children would have been exposed indirectly to the intervention through talking to the other children.

Controlled

A controlled study is one that compares one or more test treatment groups to one or more comparison or control groups. While not every controlled study is a randomised trial, all randomised trials are *controlled* studies.

Cross-over trial

A trial where each of the groups will receive each of the treatments, but in a randomised order: that is, they will start off in one arm of the trial, but will deliberately ‘cross over’ to the other arm(s) in turn. There is usually a wash-out period between treatments. The wash-out period allows time for any active effects of the first treatment to wear off before the new one gets started.

Example:

Within subject comparisons of implant-supported mandibular prostheses: Psychometric evaluation. J Dent Res 1994; 73: 1096 – 1104

Half of the patients were randomly assigned to wear the fixed prosthesis for at least 2 months first, followed by the removable prosthesis. The other half wore the removable first, followed by the fixed prosthesis.

Double-blind

See blinding

Factorial design

Most trials only consider a single factor, where an intervention is compared with one or more alternatives, or a placebo. In a trial using a 2x2 factorial design, participants are allocated to one of four possible combinations. For example in a 2x2 factorial, RCT of nicotine replacement and counselling, participants would be allocated to: nicotine replacement alone, counselling alone, both, or neither. In this way it is possible to test the independent effect of each intervention on smoking cessation and the combined effect of (interaction between) the two interventions.

Intervention study

See clinical trial

Latin Square design

Historically, a Latin Square design is an extension of a split plot design, used in agricultural experiments, where a plot of land was divided into a grid and each treatment appeared once in each row and column. This expression is now used in dentistry to describe an extension of a

crossover study with more than two treatments. It is sometimes used in mouthrinse studies to control plaque.

Example 1

Four mouthrinses, A, B, C, D, are given to each subject, each is used for seven days with a wash out period of seven days between each. The patients are randomly allocated to one of the four regimes described below.

	<i>Week 1</i>	<i>Week 3</i>	<i>Week 5</i>	<i>Week 7</i>
<i>1</i>	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>
<i>2</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>A</i>
<i>3</i>	<i>C</i>	<i>D</i>	<i>A</i>	<i>B</i>
<i>4</i>	<i>D</i>	<i>A</i>	<i>B</i>	<i>C</i>

Example 2

Effectiveness of three different types of electric toothbrushes compared with a manual technique in orthodontic patients. Am J Orthod Dentofac Orthop 1996 Vol 110: 630-8

Masking

See blinding

Meta-analysis

The use of statistical techniques in a systematic review to integrate the results of included studies. Sometimes used as a synonym for systematic reviews, where the review includes meta-analysis.

Multi-centre clinical trial

A randomised controlled trial carried out at different centres/clinics/hospitals where each centre/clinic/hospital uses the same study protocol.

Example:

See Example 1. under split mouth (split-plot) design above.

Parallel group trial

A trial that compares two groups of people, one of which receives the intervention of interest and one of which is a control group. Some parallel trials have more than two comparison groups and some compare different interventions without including a non-intervention control group.

Example:

Effects of subgingival irrigation with chlorhexidine on the periodontal status of patients with HA-coated integral dental implants. Int.J Oral & Maxillofacial Implants 1994 9(2): 156 - 162
Thirty non-adjacent implants were randomly assigned to receive one-time irrigation with either 0.12% chlorhexidine or sterile saline, or no irrigation.

Placebo

An inactive substance or procedure administered to a patient, usually to compare its effects with those of a real drug or other intervention, but sometimes for the psychological benefit to the patient through a belief that s/he is receiving treatment. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.

Quasi-randomised trial

A trial using a quasi-random method of allocating participants to different forms of care. There is a greater risk of selection bias in quasi-random trials where allocation is not adequately concealed compared with randomised controlled trials with adequate allocation concealment.

Randomisation

Method used to generate a random allocation sequence, such as using tables of random numbers or computer-generated random sequences. The method of randomisation should be distinguished from concealment of allocation because of the risk of selection bias despite the use of randomisation, if there is not adequate allocation concealment. For instance, a list of random numbers may be used to randomise participants, but if the list is open to the individuals responsible for recruiting and allocating participants, those individuals can influence the allocation process, either knowingly or unknowingly.

Randomised controlled trial

An experiment in which investigators randomly allocate eligible people into intervention groups to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the treatment and control groups.

Single blind

See blinding

Split mouth (split plot) design

Each patient is his/her own control. A pair of similar teeth, or groups of teeth (quadrants) may be selected. One tooth or group is randomly selected to receive treatment A, the other treatment B.

Example 1:

3 regimens of topical metronidazole compared with subgingival scaling on periodontal pathology in adults. J Clin Periodontol 1992 Vol 19 708-14.

This report presents the findings from an open randomised multicentre clinical trial designed to compare the clinical efficacy of scaling with application of 3 different preparations/dose frequencies of topical metronidazole in the treatment of adult periodontitis. . . . A split mouth design was used. Patients were included in the study if they had a least 1 tooth in each quadrant with a pocket depth > or = 5 mm in at least 1 of 4 sites. A total of 61 patients from 4 centres were entered into the study.

Example 2:

Guided tissue regeneration in the treatment of human infrabony defects. J Clin Periodontol 1998 Vol 25: 908 – 914

Patients provided own controls. One tooth was randomly allocated to receive one procedure and a tooth in the opposite quadrant of the mouth received another procedure.

Washout period

See crossover study

Guidance on what should and should not be included

(adapted from TSCs Workshop on Handsearching, presented by Eric Manheimer (New England Cochrane Centre) at the 8th Cochrane Collouquium, Cape Town South Africa October 2000)

- **THE STUDY COMPARES INTERVENTIONS IN HUMAN BEINGS**

- The study must not be carried out exclusively *in vitro*
- The study may be carried out on human parts that will be replaced in living humans, e.g., donor organs or blood
- The study may not be carried out exclusively in animals
- The study must be carried out on actual human beings, not on a hypothetical cohort or using simulation
- The study must be carried out on living human beings, not on cadavers
- The study may be carried out on body parts or organs of living humans, such as legs, teeth or eyes
- The study may not be carried out on parts that will not be replaced in living humans, such as extracted teeth
- The study may compare interventions in groups of humans, such as communities, schools, or medical practices
- The study may compare interventions in a single person, if a randomized design is used

- **HEALTH RELATED INTERVENTIONS ARE STUDIED**

- **THE INTERVENTION MUST BE RELATED TO HEALTH STATUS, HEALTH CARE, OR HEALTH RESEARCH**

- The intervention may be a drug, surgical, or behavioral prevention instead of an intervention
- The intervention may be a screening program
- The intervention may be a diagnostic instrument, test or technique
- The intervention may be a comparison of dose amounts, dose timing, or titration regimens
- The intervention may be a comparison of the same intervention at two different durations
- The intervention may test the effects of drug, surgical, or behavioral interventions upon athletic performance
- The intervention may be the medical education of physicians or other health professionals

- The intervention may be the education of patients or other non-health professionals about health or disease
- The intervention may lead to changes in psychological or behavioral outcomes which are explicitly related to health
- The intervention may be one designed solely to elucidate a biomechanical, pathophysiological or pharmacokinetic relationship related to a disease, an intervention, or athletic performance
- The intervention may test for differences in cost-effectiveness between interventions
- The intervention may be designed to determine outcomes related to health research, such as follow-up rates or response rates to a survey
- The study may be randomized but be ineligible for inclusion in the Cochrane Library if the intervention is not health related

- **THE STUDY IS PROSPECTIVE**

- The intervention must be planned by investigators before the study begins and the investigators must control which participants are exposed to the intervention
- The study may not be a comparison of interventions which were not planned and allocated by the investigators
- The study may not compare an intervention planned and allocated by the investigators to an intervention that was not planned and allocated by the investigators. An intervention not planned and allocated by the investigators may be found in a historical cohort comparison group or a concurrent control comparison group

- **TWO OR MORE INTERVENTIONS ARE COMPARED**

- The study may compare the conventional intervention to some new intervention, one or more active interventions to placebo intervention, or two or more interventions to each other
- The study may not give all participants the same interventions in the same order
- The study may give all participants the same interventions if the order of interventions is randomized for each patient (randomized crossover design). Sometimes this type of study has a Latin square design and the subjects are randomized to lines within the square and sometimes the study merely mentions that the order of interventions was random
- Interventions may be assigned by group or individual

- **ASSIGNMENT OF PARTICIPANTS TO INTERVENTIONS IS INTENDED TO BE RANDOM**

RCTs

- The article may explicitly state that participants were assigned to interventions by means of a random number table or other randomization technique, in which case the article is an RCT
- If the article states that participants were randomized, but does not state the method of randomization, it is assumed that randomization took place and the article is an RCT

- The study may compare participants who are assigned to interventions by individual or by group (e.g., towns, schools). In the latter case the groups must be randomly assigned to the intervention.

CCTs

- The article may explicitly state that participants were assigned to interventions by a quasi-randomization technique, in which case the article is a CCT
- If the article states that participants were allocated to intervention groups using a method which we know to be quasi-randomization, such as alternation, or medical record number, the article is a CCT
- If the article states that participants were allocated to different interventions, but does not specify how the investigators allocated participants to particular interventions, the article is a CCT

N/A

- If the article states that participants were randomly selected to participate but does not specify that the participants were allocated to different interventions, the article is not eligible
- If the article states that participants were allocated to intervention groups using a method which we know to be neither randomization nor quasi-randomization, the article is not eligible
- If the article states that participants were assigned to different interventions for clinical reasons, the article is not eligible
- If the article states that participants selected their own interventions, the article is not eligible
- If the article states that the intervention and control groups consist of different types of participants, such as sick individuals compared to healthy individuals, the article is not eligible unless both groups receive two or more interventions
- If the article states that the intervention group was compared to another group matched to the intervention group, the article is not eligible unless the matched groups were constructed before randomization to intervention

• ISSUES SURROUNDING RANDOMIZED CLINICAL TRIALS

- When an article mentions that an RCT is being planned or has begun, the article is considered an RCT
- When an article presents baseline data on randomized participants from an RCT, the article is an RCT even though no results of the intervention comparison are presented
- When an article presents preliminary results of an RCT, the article is an RCT
- When an article presents new data, a new analysis, or new information about the participants, outcome criteria, or some other aspect of a previously published RCT, the article is an RCT
- When an article presents the results of a follow-up to an RCT, such as an open-label extension or a naturalistic follow-up, the article is considered an RCT

Example of annotation of Table of Contents

Journal of Clinical Periodontology

1993: Vol. 20: No. 7

Original Articles			
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Summary of the Handsearching Process

1. Undertake & successfully complete a test search
2. Register your intended search with the Trials Search Co-ordinator (see address below).
3. Select the relevant Journal Issue/s
4. Photocopy Table of Contents page for each issue searched
5. Identify and classify studies
6. Copy page/s and highlight key words or phrases
7. Send annotated *Table of Contents* and photocopies of title pages of all RCTs, CCTs, SRs & SOSs to the Trials Search Co-ordinator at the Oral Health Group's Editorial Office. They can be emailed to the Trials Search Co-ordinator if you have a scanner or the full text of the journal is online.

<u>Guidelines for identifying and coding RCTs/CCTs</u>	Code on Table of Contents
Is it prospective study that compared two or more interventions concurrently and was performed in humans?	
No _____	→ N/R (not relevant)
If Yes, how were the comparison groups formed?	
Randomisation clearly stated _____	→ RCT
Quasi-randomised or _____	→ CCT
Not stated/unclear	
Is it a systematic review/meta-analysis?	
Yes _____	→ SR
Are you not sure? _____	→ SOS

Anne Littlewood, Trials Search Co-ordinator, Cochrane Oral Health Group, MANDEC, University Dental Hospital of Manchester, Higher Cambridge Street, MANCHESTER, M15 6FH (UK) Tel:+44(0)161 275 7818 Fax: +44(0)161 275 7815 email: a.littlewood@manchester.ac.uk