Should I publish this record to CENTRAL?

Reports of the following study designs are eligible for publication in CENTRAL:

- Randomised controlled trial
- Quasi-randomised controlled trial
- Interrupted time-series
- Controlled before and after study

These four study designs are the **only** study designs that should be published.

Further information on what constitutes a randomised controlled trial or a quasi-randomised controlled trial can be found in the Handsearching Guide: (https://methods.cochrane.org/irmg/sites/methods.cochrane.org.irmg/files/public/uploads/handsearcher_training_manual.pdf) .

The following table shows a list of different report types that may relate to one of the four eligible study designs. It is designed to help you make a decision on whether or not to publish a particular report type in CENTRAL.

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Report that presents details regarding the design or protocol of a trial, but does not have any results	Yes	"When an article provides new information about the planning, design, protocol development, recruitment strategies, or conduct of an RCT or CCT, the article is considered an RCT or CCT. By itself, the statement that a clinical trial is being planned or has begun is not sufficient to make an article an RCT." "A report of a randomized trial should be included even when no results are presented or when results are limited to the analyses of baseline variables".	Record accession number: 370537038: Protocol for a prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu: The TN-STEMI programme // Record 52900935: Comparison of usual podiatric care and early physical therapy intervention for plantar heel pain: Study protocol for a parallel-group randomized clinical trial // Record: 52915044: Transversus abdominis plane block following abdominally based breast reconstruction: Study protocol for a randomized controlled trial
Report that describes a pilot for a trial that is being planned	Yes	It is essential that the report states that the pilot is randomised. "For example, a letter which describes and presents the results of a randomized pilot study conducted by the authors (and which does not cite a report published elsewhere) would be classified as an RCT."	Record accession number 617623313: Polyethylene glycol intestinal lavage in addition to usual antibiotic treatment for severe Clostridium difficile colitis: A randomised controlled pilot study
Report with a secondary or subgroup analysis	Yes	Include if it's a report of a randomised or quasi-randomised controlled trial (definitely or possibly). Irrelevant whether the secondary analysis was pre-defined or not. "...a re-analysis of data from a randomized controlled trial would be an RCT"	Record accession number: 373969806: Effects of a home visiting nurse intervention versus care as usual on individual activities of daily living: a secondary analysis of a randomized controlled trial // Record accession number: 53102414: Crenobalneotherapy (spa therapy) in patients with knee and generalized osteoarthritis: A post-hoc subgroup analysis of a large multicentre randomized trial

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Report of long-term follow-up of participants in a trial	Yes	Include if it's a report of a randomised (RCT) or quasi-randomised controlled trial (q-RCT) (definitely or possibly). The follow up must relate to a randomised comparison, not simply take data from the trial and analysis it outside of the randomisation context. "a report presenting the results of a natural history follow-up to a randomized trial would be classified as RCT"	Record accession number: 107526: Improved survival with urodeoxycholic acid prophylaxis in allogenic stem cell transplantation: long term follow-up of a zed study
Report of an observational study (other than described above) using participants or materials from a trial (2 examples)	No	These reports no longer relate to a randomised comparison. They could provide useful background information about a condition or intervention, but are not eligible for inclusion in CENTRAL.	These reports no longer relate to a randomised comparison. They could provide useful background information about a condition or intervention, but are not eligible for inclusion in CENTRAL.
Report that describes the development or implementation of an intervention for a trial that is planned, underway or completed.	Yes	Include if the report that provides detail about how the intervention was administered or operationalised in an RCT or q-RCT (definitely or possibly). Such reports can be core to understanding the conduct of the trial even if they do not relate to a randomised comparison. Must not be simply a brief mention of an RCT or q-RCT being planned or underway (see below). "When an article provides new information about the planning, design, protocol, development, recruitment strategies, or conduct of an RCT or CCT, the article is considered an RCT or CCT. By itself, the statement that a clinical trial is being planned or has begun is not sufficient to make an article an RCT."	Record accession number: 52985734: A rehabilitation intervention to promote physical recovery following intensive care: A detailed description of construct development, rationale and content together with proposed taxonomy to capture processes in a randomised controlled trial

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Report which included a statement that a trial is being planned or has begun	No	As above - the report can only be included if substantial detail about the planning or conduct of the trial is provided. "By itself, the statement that a clinical trial is being planned or has begun is not sufficient to make an article an RCT."	Record accession number: 40247978: Concomitant chemobrachyradiotherapy with ifosfamide and cisplatin followed by consolidation chemotherapy in locally advanced squamous cell carcinoma of the uterine cervix: Results of a phase II study // Record accession number: 26293105: Supportive telephone intervention for patients receiving chemotherapy: A pilot study
Systematic reviews/meta-analyses or narrative reviews	No	Not a report of any of those original studies. Only include if it's a pooled analysis and then a report of an RCT is given "Reviews (including narrative reviews, systematic reviews, and meta-analyses) often use information from several controlled trials as part of the evidence for their conclusions. Unless the review provides new information about at least one controlled trial, however, the report of the review is not generally classified as RCT or CCT. For example, a review that pools data from several published randomized controlled trials is not considered an RCT. However, a report which includes both a meta-analysis and also previously unpublished (as far as can be detected) information about the results of a controlled trial would qualify as an RCT or CCT."	Record accession number: 52810190: A systematic review of interventions for preventing adolescent intimate partner violence // Record: 370554482: Stress ulcer prophylaxis versus placebo or no prophylaxis in critically ill patients: A systematic review of randomised clinical trials with meta-analysis and trial sequential analysis // Record: 370553243: Histamine-1 receptor antagonism for treatment of insomnia

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Report of an open-label extension study of an RCT/follow-up study (estimate 500+ records on CENTRAL)	No	These are single-arm studies using participants from an RCT, using the same intervention, but where all the participants taking part receive the intervention. Because a randomised comparison is not made these studies are not eligible for inclusion, even though they involve participants who were originally randomised	Record accession number: 71683498: Efficacy of long-term adjunctive zonisamide therapy in paediatric patients with partial epilepsy: Results of an open-label extension study of a Phase III, randomised, double-blind, placebocontrolled trial
Report of a retrospective analysis	Yes	Include if it uses data from an RCT or q-RCT and the randomised comparsion preserved. It is an analysis of the randomized data just carried out retrospectively	Record accession number: 600261713: Levosimendan increases bleeding risk after heart valve surgery: A retrospective analysis of a randomized trial
A report which contains a deposit of the patient level data for a trial	Yes	Include if it uses data from an RCT or q-RCT.	Record accession number: 370398962: Responsiveness of health state utility value in knee osteoarthritis
Report that describes baseline characteristics of an RCT?	Yes	Include if it reports on a randomised comparison.	Record accession number: 370446000: Baseline characteristics in the Bardoxolone methyl EvAluation in patients with Chronic kidney disease and type 2 diabetes mellitus: the Occurrence of renal eveNts (BEACON) trial
Report of a randomised cross-over	Yes	Include if it reports on a randomised comparison.	Record accession number: 370501972: Preventing hyperthermia: a cross-over study comparing two negative pressure devices during continuous passive heat stress

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Trial-based economic evaluation	Yes	Include if it is an economic analysis that was run alongside an RCT and uses data on individual patients.	Record accession number: 620410342: Cost-Effectiveness of Tight Control of Inflammation in Early Psoriatic Arthritis: Economic Analysis of a Multicenter Randomized Controlled Trial // Record accession number: 616609195: Costs associated with Barrett's esophagus screening in the community: an economic analysis of a prospective randomized controlled trial of sedated versus hospital unsedated versus mobile community unsedated endoscopy
Economic evaluation using decision analytical models	No	An economic evaluation that synthesises data from a variety of sources using decision analytical models, may include patient data from an RCT(s), however it is not eligible for CENTRAL, as this is a type of synthesis. Note: some economic evaluations are conducted as or directly alongside RCTs and are eligible (see above).	Record accession number: 621295508: Macroeconomic costs of the unmet burden of surgical disease in Sierra Leone: A retrospective economic analysis
Erratum to an RCT	Yes	Include if the erratum reported pertains to the methods and/or results.	Record accession number: 370568246: Erratum: A blinded, randomized, controlled trial of three doses of high-dose insulin in poison-induced cardiogenic shock
Reply/comment/letter/ editorial that simply says that a trial is being planned or has begun or that mentions that a trial was conducted	No	This would not meet the definition of 'hard', i.e. information about methods or results	Record accession number 621771493: "Trends in country-Specific surgical randomized clinical trial publications" [Letter]

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Reply/comment/letter that presents new information about the conduct, methods, or results a trial	Yes	Information is defined as 'hard' information, methods or results. Must be details or facts about the trial and must relate to a randomised comparison. Traditionally USCC might have been included these reports in CENTRAL: "However, correspondence and editorials often discuss clinical trials and it can be difficult to decide how to classify these publications. One should not refer to the original report in evaluating the design of a study described in a letter, rather, the assessment of study design should be made from the correspondence itself. If the author of the correspondence has described the study in sufficient detail to classify it as an RCT or CCT, and it appears that the correspondence is not merely reiterating data already presented elsewhere, then the correspondence is eligible for inclusion in CENTRAL. For example, a letter from the investigators of a multicenter randomized trial in which they present their rationale for using specific outcome criteria might be classified as an RCT."	Record accession number 621441214: "Three-year follow-up of a trial of close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults." [Letter]
Comment on an RCT	Yes	Include, but only if the comments provides new information about the conduct, methods, results of a trial. When an article provides new information about the planning, design, protocol development, recruitment strategies, or conduct of an RCT or CCT, the article is considered an RCT or CCT."	Record accession number: 52835329: Comment on: "Clomiphene Citrate co-treatment with low dose urinary FSH versus FSH for clomiphene resistant PCOS: Randomized controlled trial." by Ghanem et al.

Type of report	Is it eligible?	Existing guidance (from US Cochrane Centre Handsearching Guide) and/or comments:	Example records from Embase:
Editorial discussing results of an RCT	Yes	Possible include if an RCT or q-RCT is described in enough detail and if it is not simply a rehash of other report(s) about the same study. Inclusion of editorials that don't meet the above criteria may be useful in a study-based register but their value in CENTRAL is debatable. If we reach a point where CENTRAL is 'studified' we may want to revisit this decision. In that example shown there is an interesting discussion about trial methods but what does it mean for the reviewer? Argument that it's possibly the only report doesn't hold in this type of publication because it's referring to something else by it's very nature. Traditionally USCC might have been included these reports in CENTRAL: "However, correspondence and editorials often discuss clinical trials and it can be difficult to decide how to classify these publications. One should not refer to the original report in evaluating the design of a study described in a letter, rather, the assessment of study design should be made from the correspondence itself. If the author of the correspondence has described the study in sufficient detail to classify it as an RCT or CCT, and it appears that the correspondence is not merely reiterating data already presented elsewhere, then the correspondence is eligible for inclusion in CENTRAL. For example, a letter from the investigators of a multicenter randomized trial in which they present their rationale for using specific outcome criteria might be classified as an RCT."	Record accession number 611157103: "To RCT or not to RCT: Evidence on effectiveness of return-to-work interventions." [Editorial]