Searching clinical trials registers: guide for systematic reviewers

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Acknowledgement of country

We would like to acknowledge the Gadigal people of the Eora Nation, the Traditional Custodians of the land on which we are presenting from today, and pay our respects to the Elders both past and present.
Disclosures

- Co/Associate Convenors Cochrane PMA Methods Group
- Research associates, ANZCTR
- Chair & Co-chair of TOPCHILD Collaboration
- Steering Group, EPOCH Collaboration
- Chair & Steering Group, iCOMP Collaboration
What is your professional background?
Have you ever searched clinical trial registers for a systematic review?
Learning objectives

- The importance of searching clinical trials registers
- Main steps and differences to searching databases
- How to harness full potential of clinical trials registries

To help you pay attention, there will be a quiz!
What are clinical trials registers?

- Clinical trials registers are publicly accessible, online databases of planned, ongoing and completed studies.
- They include both published and *unpublished* studies.
- Include information on study design, conduct, administration, results, data sharing plans.
### WHO ICTRP Registry Network

<table>
<thead>
<tr>
<th>Primary Registries</th>
<th>Other ICMJE recognised registries</th>
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<td>• Netherlands National Trial Register</td>
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<td>• Pan African Clinical Trial Registry</td>
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</table>
Searching clinical trial registers is mandated for best practice systematic reviews

C27: Searching trials registers (Mandatory)

Cochrane Handbook for Systematic Reviews of Interventions
Why do I need to search trial registries?
Searching clinical trial registers is mandated for best practice systematic reviews

C27: Searching trials registers (Mandatory)

Search trials registers and repositories of results, where relevant to the topic, through ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) portal and other sources as appropriate. Searches for studies should be as extensive as possible in order to reduce the risk of publication bias and to identify as much relevant evidence as possible. Although ClinicalTrials.gov is included as one of the registers within the WHO ICTRP portal, it is recommended that both ClinicalTrials.gov and the ICTRP portal are searched separately due to additional features in ClinicalTrials.gov.
Publication bias

Figure adapted from De Vries et al. *Psychological Medicine*, 2018;48(15):2453-2455
Publication bias

~50% studies publish results
(Schmucker et al. PLOS One 2014)

Figure adapted from De Vries et al. Psychological Medicine, 2018;48(15):2453-2455
Publication bias

Publication bias:
~50% studies publish results
(Schmucker et al. *PLOS One* 2014)

Selective outcome reporting:
~50% of outcomes completely reported per trial
(Chan et al. *JAMA* 2004)
Tend to be more positive, with larger effect sizes

Figure adapted from De Vries et al. *Psychological Medicine*, 2018;48(15):2453-2455
Searching trial registers can...

... **reduce** publication bias:
  – Results reporting in registers
  – Individual participant data
  – Contacting authors for results

... **explore impact** of publication bias:
  – How many unpublished studies are out there?

... **reduce/help understand** selective outcome reporting
  – Did authors report all pre-specified outcomes?
  – Can they supply results for unpublished ones?
Other reasons to search clinical trials registers

- Identify additional eligible studies for inclusion in systematic reviews
- Identify research gaps and inform research prioritisation
- Identify studies & potential investigators for collaborative methodologies, e.g., prospective meta-analysis
- Plan updates of traditional or living systematic reviews
How to search trial registers

Searching registers can be challenging
- Varied & relatively unsophisticated interfaces compared to bibliographic databases
- Quality and structure of registration records

Previously limited guidance was available. We have addressed this gap!
Systematic reviews should incorporate as much relevant evidence as possible to reduce bias and reap the benefits associated with increasing the reliability of results. Clinical trials registers are a key resource for identifying potentially eligible studies.
# Guidance paper: methods

<table>
<thead>
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<th>Webster</th>
<th>Page</th>
<th>Willson</th>
<th>McDonald</th>
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**Registry websites**

**Surveys of Steering Group & expert stakeholders**

**Literature review**

**Guidance on searching trial registers**

**Consensus workshop**
**Illustrative case study**

**TOPCHILD**

Transforming Obesity Prevention for CHILDren

<table>
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<tr>
<th>Identification Method</th>
<th>Trials</th>
<th>Participants</th>
</tr>
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<tr>
<td>Identified by database searches</td>
<td>56 (79%)</td>
<td>45,900 (84%)</td>
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<tr>
<td>Identified by register searches only</td>
<td>15 (21%)</td>
<td>8764 (16%)</td>
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<tr>
<td>Total</td>
<td>71</td>
<td>54,664</td>
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</tbody>
</table>

Participants

- Identified by database searches: 56 (79%) of 45,900 (84%)
- Identified by register searches only: 15 (21%) of 8764 (16%)
- Total: 71 participants totaling 54,664
Can you sort the order of steps?
1. Determining where to search
2. Formulating search strategies
3. Conducting the search, removing duplicate records, and preparing records for screening
4. Screening
5. Obtaining data then synthesising as applicable
6. Reporting register searches
7. Updating register searches

Correct answer
Step 0: Defining the research question and eligibility criteria

**TOPCHILD**

Compared with usual care, no intervention, or attentional control, what are the effects of behavioural obesity prevention interventions that are focused on the parent or caregiver and commence during pregnancy or infancy on child weight status at age 24 months?
Step 1: Determining where to search

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world. There are several other international and national databases that can be searched for clinical trials:

- EU Clinical Trials Register
- Deutsches Register Klinischer Studien
- ReBEC
- Lebanon Clinical Trials Registry
- ChiCTR
- ANZCTR
- ISRCTN registry
- Iranian Registry of Clinical Trials
- Sri Lanka Clinical Trials Registry
- World Health Organization Clinical Trials Registry Platform
- JRCT
- CRIS
- ISRCTN registry
- Pan African Clinical Trials Registry
Step 1: Determining where to search

- Recommendation: As a minimum, search ClinicalTrials.gov and WHO ICTRP
- Recommendation: For some research questions, consider searching EU-CTR (formerly EU-CTR id@trials) or regional registries (region-specific research questions)
Step 1: Determining where to search

As a minimum, search ClinicalTrials.gov and WHO ICTRP
TRAP! Searching CENTRAL only

- Since 2019, CENTRAL has included registration records from ClinicalTrials.gov & WHO ICTRP
- However, searching CENTRAL alone is insufficient to identify registered studies due to low sensitivity\(^1\) and is therefore not supported by Cochrane guidance

Step 2: Identifying key search concepts and deriving search terms
Step 3: Formulating search strategies

• Focus on 1-2 key concepts, typically population/health condition or intervention
What might be some relevant search concepts for TOPCHILD?
Step 2: Identifying key search concepts and deriving search terms

Step 3: Formulating search strategies

- Focus on 1-2 key concepts, typically population/health condition or intervention

<table>
<thead>
<tr>
<th>Concepts searched in bibliographic databases (n=9)</th>
<th>Concepts searched in trial registers (n=2)</th>
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</thead>
<tbody>
<tr>
<td>overweight/obesity</td>
<td>overweight/obesity</td>
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<tr>
<td>behavioural/lifestyle interventions</td>
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<tr>
<td>nutrition/diet/feeding</td>
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<td>physical activity</td>
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<td>sedentary behaviours</td>
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<tr>
<td>sleep</td>
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<tr>
<td>health promotion/prevention</td>
<td></td>
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<tr>
<td>child</td>
<td>child</td>
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<tr>
<td>families</td>
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TRAP! Searching for too many concepts
### Step 3: Formulating search strategies

#### Table 2: Key differences between searching Medline (via Ovid) and trial register resources (ClinicalTrials.gov and WHO ICTRP)

<table>
<thead>
<tr>
<th>Interfaces available</th>
<th>Medline (via Ovid)</th>
<th>ClinicalTrials.gov</th>
<th>WHO ICTRP</th>
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</table>

#### Indexing

- Uses structured, hierarchical ontology: MeSH tree
- “Condition or disease” field: registrants encouraged to use MeSH terms or Unified Medical Language System terms that can be mapped to MeSH; despite this, almost half of the health conditions or diseases are not denoted by MeSH terms[^25]; ontologies not used for other fields.

- Dependent on source registry; search terms mapped to synonyms via Unified Medical Language System.

#### Specific field searches

- Yes, in advanced interface can specify which fields to search using labels, eg, ti (title), ab (abstract).
- Yes, basic interface: free text searching available for data fields: condition or disease, other terms; yes, advanced interface: free text searching available for data fields: intervention/treatment, title/abstract, outcome measure, sponsor/collaborator, study ID, location terms.
- Yes, advanced interface: free text searching available for data fields: title, condition, intervention, primary sponsor, secondary ID.

#### Operators

- Boolean (AND, OR, NOT): proximity (ADJ, ADJn); frequency (FREQ).
- Boolean (AND, OR, NOT), must be in upper case.
- Boolean (NOT, AND, OR) applied in this specific order.

#### Truncation

- Unlimited ($) limited (x$n).
- Not available.
- Basic search: yes, at the end of a string using asterisk (*), but this disables synonym searching; avoid truncation in phrases; advanced search: truncation is automatic and within word, eg, the search term “clio” should find records containing words such as infection, reduction.

#### Wildcards

- Mandatory (?); optional (?).
- Not available (alternative spellings are not harmonised, eg, tumour u tumor).
- Not available (alternative spellings are not harmonised, eg, tumour u tumor).

#### Phrase searching

- Yes, use quotation marks for literal string search, eg, “breast cancer”
- Yes, use quotation marks, eg, “breast cancer” (cannot search for an exact phrase without synonyms)[^26]
- Yes, but do not use quotation marks; simply type two or more words in succession, eg, breast cancer.

#### Punctuation

- Apostrophes treated as spaces, not searchable characters, so variants should be searched, eg, Alzheimer’s OR Alzheimers, hyphens: results will be the same with and without hyphen, eg, well being will retrieve same results as well-being (although well-being without a space should also be searched).
- Apostrophes ignored and all variations automatically searched, eg, Alzheimer’s retrieves same results as Alzheimers and Alzheimer, hyphens: ignored: well being, well-being, and well being all retrieve same results.
- Apostrophes alter results retrieved, so variants should be searched, eg, Alzheimer’s OR Alzheimers, hyphens recognised as characters, so words should be searched with and without hyphens, eg, well-being OR wellbeing.

#### Case sensitive

- No.
- Yes, for Boolean operators only (must be in capitals).
- No, since July 2021, parentheses can be used when mixing Boolean operators; although, this function can be unstable and may not work with longer search strings.

#### Nested searching

- Yes, using parentheses or line-by-line search syntax.
- Yes, using parentheses.
- Yes, since July 2021, parentheses can be used when mixing Boolean operators; although, this function can be unstable and may not work with longer search strings.

#### Filters

- Validated filters available as search strings, eg, for randomised controlled trials, only or recruitment status, stroke, age group.
- Non-validated filters available by drop-down/tick box options only or recruitment status, stroke, age group.
- Non-validated filters available by drop-down/tick box options only or clinical trial in children.
Example TOPCHILD search strategy

ClinicalTrials.gov

- Condition or disease: overweight OR obesity OR obese OR adiposity OR BMI OR weight gain
- Other terms: baby OR infant OR child OR paediatric OR pediatric OR toddler OR offspring
Filters

- Apply filters (e.g. by study type, participant age) only in exceptional circumstances (e.g. extremely limited resources, only rough search required for scoping)

**TOPCHILD**

Study type filter: 3/57 records were RCTs but wrongly categorised as observational studies

- Avoid limiting searches by recruitment status

TRAP! Limiting searches to those with completed recruitment status

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**Step 0: Defining the research question and eligibility criteria**
- Recommendation: Use an appropriate framework, such as population, intervention, comparator, outcome (PICOC) framework, to define research question and eligibility criteria

**Step 1: Determining where to search**
- Recommendation: As a minimum, search ClinicalTrials.gov and WHO ICTRP
- Recommendation: For some research questions, consider searching EU-CTIS, former EU-CTR, Idgov trials, or regional registries (region-specific research questions)

**Step 2: Identifying key search concepts and deriving search terms**
- Recommendation: Identify one or two key concepts from PICOC (or other appropriate framework)

**Step 3: Formulating search strategies**
- Recommendation: Focus search strategies on one or two concepts identified in step 2 and aim to maximise sensitivity while balancing against reasonable specificity
- Recommendation: Adjust search strategies according to specific registry resource and familiarise yourself with search tools and rules of each
- Recommendation: Test whether search strategy retrieves preidentified eligible studies (if possible)
- Recommendation: Apply filters (e.g. by study type, participant age) only in exceptional circumstances (e.g. where there are extremely limited resources or only a rough search is required for scoping)
### Step 4: Conducting the search, removing duplicate records, preparing records for screening

**DETAILED RECORDS**

| ✓ Date | each search is conducted and by whom |
| ✓ Trial registers | searched |
| ✓ Interface | used (basic or advanced) |
| ✓ Full search strings, including any limits or filters applied |
| ✓ Number of records | retrieved from each |

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**TRAP!** Information can be lost when downloading registration records to Covidence
Which of these should be searched as a minimum? (select all that apply)

Start presenting to display the poll results on this slide.
Step 5: Title screening (optional)

- Only exclude obviously irrelevant records

Trap! Titles in registration records may not be very informative → potential to exclude relevant studies
Steps 6: Full record screening

- Screen full registration records at the source registry website

Trap! Missing up-to-date and complete info by relying on exported records
Step 7: Completing PRISMA flow diagram

- Complete a PRISMA flow diagram which includes records retrieved from trial register searches.
Step 7: Completing PRISMA flow diagram

• Complete a PRISMA flow diagram which includes records retrieved from trial register searches

TRAP! Double-counting registration records & matching publications.
Step 8: Finalising eligible studies

- If there are uncertainties about study eligibility, contact registrants for clarification, if feasible
Step 9: Obtaining data then synthesising as applicable

• How can we obtain unpublished results from trial registries?
  • by direct data extraction from registries
  • by contacting registrants
Step 9: Obtaining data then synthesising as applicable

- Publication bias - estimate extent of missing results
- Selective outcome reporting - compare outcomes in registration records with publications

Step 0: Defining the research question and eligibility criteria
- Recommendation: Use an appropriate framework, such as population, intervention, comparator, outcome (PICOC) framework, to define research question and eligibility criteria

Step 1: Determining where to search
- Recommendation: As a minimum, search ClinicalTrials.gov and WHO ICTRP
- Recommendation: For some research questions, consider searching EU-CTIS, formerly EU-CTR, (drug trial or regional registers like specific research question)

Step 2: Identifying key search concepts and deriving search terms
- Recommendation: Identify one or two key concepts from PICOC for other appropriate framework

Step 3: Formulating search strategies
- Recommendation: Focus search strategies on one or two concepts identified in step 2 and aim to maximise sensitivity while balancing against reasonable specificity
- Recommendation: Adjust search strategies according to specific registry resource and familiarise yourself with search tools and rules of each
- Recommendation: Test whether search strategy retrieves preidentified eligible studies (if possible)
- Recommendation: Apply filters (eg, by study type, participant age) in exceptional circumstances (eg, where there are extremely limited resources or only a rough search is required for scoping)
- Recommendation: Avoid limiting searches by recruitment status, since this field might not be up to date, and therefore eligible studies might be missed

Step 4: Conducting the search, removing duplicate records, and preparing records for screening
- Recommendation: Keep detailed records of all register searches, including date conducted, names of registers searched, interfaces used (basic, advanced), full search strings, and number of records retrieved from each
- Recommendation: Download search records into your preferred software and remove duplicates

Step 5: Title screening (optional)
- Recommendation: If preliminary title screening is to be conducted, only exclude obviously irrelevant records

Step 6: Full record screening
- Recommendation: Screen full registration records at the source registry website
- Recommendation: Screen all records in full at least once and consider an independent second reviewer if resources allow
- Recommendation: Screen records systematically using a hierarchical list of eligibility criteria, starting from the simplest (eg, study design, then population) and use the structured data fields on registers to expedite this process

Step 7: Completing PRISMA flow diagram
- Recommendation: Complete PRISMA flow diagram, which includes records retrieved from trial register searches

Step 8: Finalising eligible studies
- Recommendation: If there are uncertainties about study eligibility, contact registrants for clarification, if feasible

Step 9: Obtaining data then synthesising as applicable
- Recommendation: Attempt to obtain unpublished results data for eligible studies by checking registers and repositories and contacting study registrants if needed
- Recommendation: Explore the potential impact of publication bias, selective outcome reporting, and data availability bias if there are missing results
Step 10: Reporting search

- Report in accordance with PRISMA 2020 & PRISMA-S
Step 11: Updating register searches

- Updating frequency as per standard SR searches
- Restrict by registration date (not study start or completion dates)
Congratulations – you have made it through all the steps!
How many key concepts should a register focus on?
Register searches should routinely be filtered.
Other reasons to search clinical trials registers

• Identify studies & potential investigators for **collaborative methodologies**, e.g., prospective meta-analysis

• Plan **updates** of traditional or living systematic reviews

• Identify research gaps and inform **research prioritisation**
Untapping hidden value of clinical trial registries

Systematic reviews provide a summary of all relevant evidence on a research topic. Since around 50% of biomedical evidence is never published, researchers conducting systematic reviews will find that only searching through bibliographic databases is insufficient for their purpose. Systematic reviewers must also search for unpublished evidence to ensure the validity and reliability of their review. Clinical trial registries are a key resource for this process.

Despite this, searching clinical trial registers is often an afterthought for systematic reviewers due to both

be encouraged to use registers for a broader range of purposes.

Moving forward, I envisage registries will increasingly be used as a valuable source of unpublished data, leading to more valid systematic reviews that are not prone to publication bias. I hope that trial registries will also play a vital part in facilitating collaboration, by enabling trialists to identify similar studies with which they may coordinate their research efforts to avoid unnecessary duplication and research waste. By providing an overview of trial activity, registries
To identify studies & potential investigators for collaboration, e.g. prospective meta-analysis

**Definition** **prospective meta-analysis (PMA)**

Studies are identified as eligible for inclusion in the meta-analysis, and hypotheses and analysis strategies are specified, **before** the results of the studies or cohorts related to the PMA research question are known.


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Add value, e.g. outcome harmonisation $\rightarrow$ facilitates evidence synthesis $\rightarrow$ improves statistical power

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The University of Sydney’s NHMRC Clinical Trials Centre
Main advantages of PMA

LESS BIASED
• Reduced risk of publication/selective outcome reporting bias

HARMONIOUS
• Harmonisation of outcomes, interventions and populations possible

POWERFUL
• Core outcome sets & ability to include rare outcomes

COLLABORATIVE
• Researchers working together instead of competing

ADAPTIVE
• Newly planned trials, & new relevant intervention groups can be included along the way

RESEARCH METHODS AND REPORTING

A guide to prospective meta-analysis

Anna Lene Seidler,1 Kylie E Hunter,1 Saskia Cheyne,1 Davina Gherzi,1,2 Jesse A Berlin,2 Lisa Askie1

Seidler et al (2019). BMJ.
To plan updates of traditional or living systematic reviews

What is a living systematic review?

- A systematic review which is continually updated, incorporating relevant new evidence as it becomes available (Cochrane 2022)
- Requires continual, active monitoring of the evidence via regular searches
To identify research gaps & inform research prioritisation

• Are additional studies on this topic needed?

• Avoid duplication (if there is an abundance of emerging evidence)

• Avoid research waste (no more trials on interventions that aren’t particularly promising, e.g. hydroxychloroquine)

The landscape of COVID-19 trials in Australia

Anna Lene Seidler, Mason Aberoumand, Jonathan G Williams, Aidan Tan, Kylie E Hunter and Angela Webster
Published online: 19 July 2021
Australian Covid research trials ‘wasteful and misdirected’

Research teams worked separately to investigate similar problems when combined studies might have delivered meaningful results

July 20, 2021

John Ross (/author/john-ross)

Little gain as millions spent on virus studies

The landscape of COVID-19 trials in Australia

Anna Lene Seidler, Mason Aberoumand, Jonathan G Williams, Aidan Tan, Kylie E Hunter and Angela Webster


Published online: 19 July 2021
Take home messages

- Searching clinical trials registers is mandated for best practice systematic reviews
- Access information on unpublished studies $\rightarrow$ mitigate bias, reduce research waste
- Many differences to searching bibliographic databases
- Registries are an untapped resource with many other uses
## Acknowledgements

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<th>Name</th>
<th>Institution</th>
<th>City</th>
<th>State</th>
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<td>Angela C Webster</td>
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<td>Lisa Askie</td>
<td>Methods scientist, WHO</td>
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Thank you. Questions?

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For more information:
Hunter KE, Webster AC, ... Seidler AL. Searching clinical trials registers: guide for systematic reviewers BMJ 2022; 377:e068791
Key resources

- Hunter KE, Webster AC, ... Seidler AL. Searching clinical trials registers: guide for systematic reviewers BMJ 2022; 377:e068791
- Hunter KE. Untapping the hidden value of clinical trial registries BMJ 2022; 377:o1058