Searching clinical trials registers: guide for systematic reviewers

Cochrane Methods
Prospective Meta-analysis

Kylie Hunter, MPH BA(Hons)
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NHMRC Clinical Trials Centre
University of Sydney, Australia

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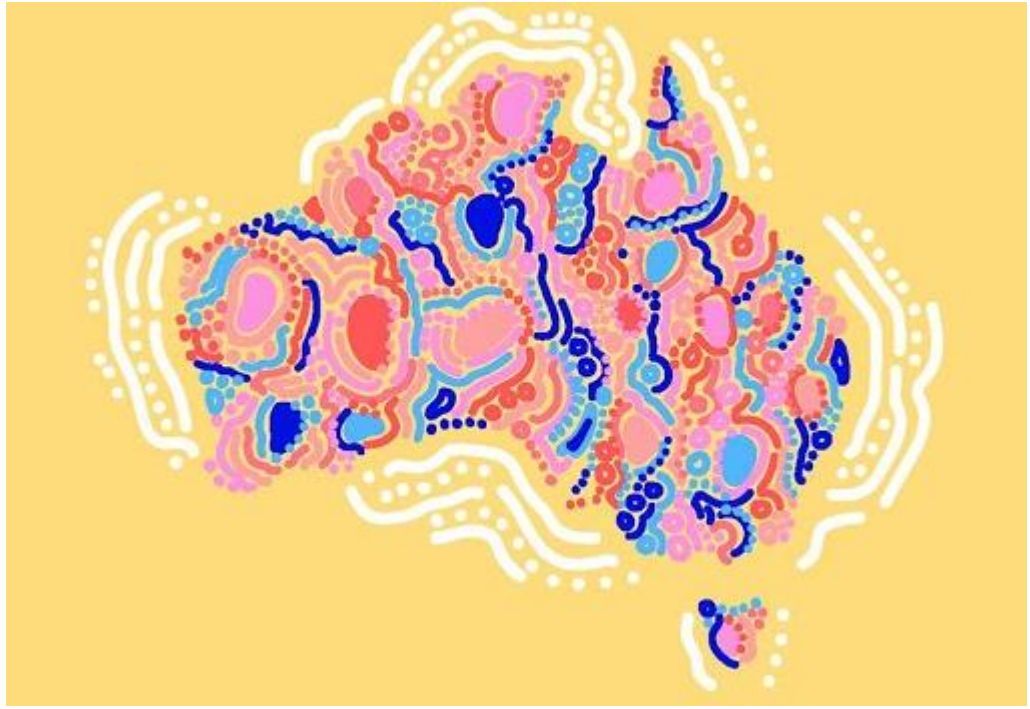
@KylieEHunter

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.



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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

Cochrane Methods
Prospective Meta-analysis

ANZCTR
Australian New Zealand Clinical Trials Registry

TOPCHILD
Transforming Obesity Prevention for CHILDren

epoch
Early Prevention Of Obesity In Childhood

iCOMP
individual participant data on Cord Management at Preterm birth

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What is your professional background?

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Have you ever searched clinical trial registers for a systematic review?

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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!

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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- They include both published and **unpublished** studies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

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WHO ICTRP Registry Network

World Health Organization

International Clinical Trials Registry Platform

Primary Registries	Other ICMJE recognised registries
ANZ • Australian New Zealand Clinical Trials Registry **Americas** • Cuban Public Registry of Clinical Trials • Brazilian Clinical Trials Registry • Peruvian Clinical Trial Registry **Asia** • Chinese Clinical Trial Register • Clinical Research Information Service - Republic of Korea • Clinical Trials Registry - India • Sri Lanka Clinical Trials Registry • Japan Primary Registries Network • Thai Clinical Trials Registry • Iranian Registry of Clinical Trials • Lebanese Clinical Trials Registry **Europe** • EU Clinical Trials Information System (replaced the European Union Clinical Trials Register on 31 January 2022) • German Clinical Trials Register • ISRCTN.org • Netherlands National Trial Register **Africa** • Pan African Clinical Trial Registry	**USA** • ClinicalTrials.gov

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Searching clinical trial registers is mandated for best practice systematic reviews

C27: Searching trials registers (**Mandatory**)

Cochrane Handbook for Systematic Reviews of Interventions

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Why do I need to search trial registries?

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Searching clinical trial registers is mandated for best practice systematic reviews

Cochrane Handbook for Systematic Reviews of Interventions

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.

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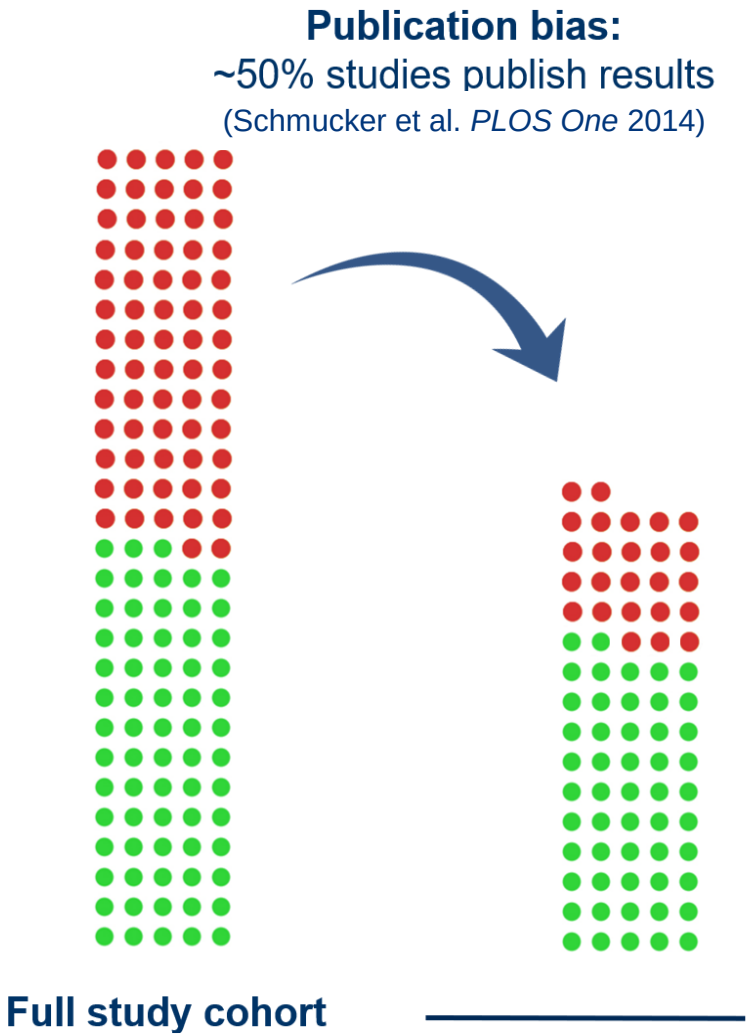
Publication bias

Full study cohort

- Negative trial
- Positive trial

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

Publication bias



- Negative trial
- Positive trial

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

Publication bias

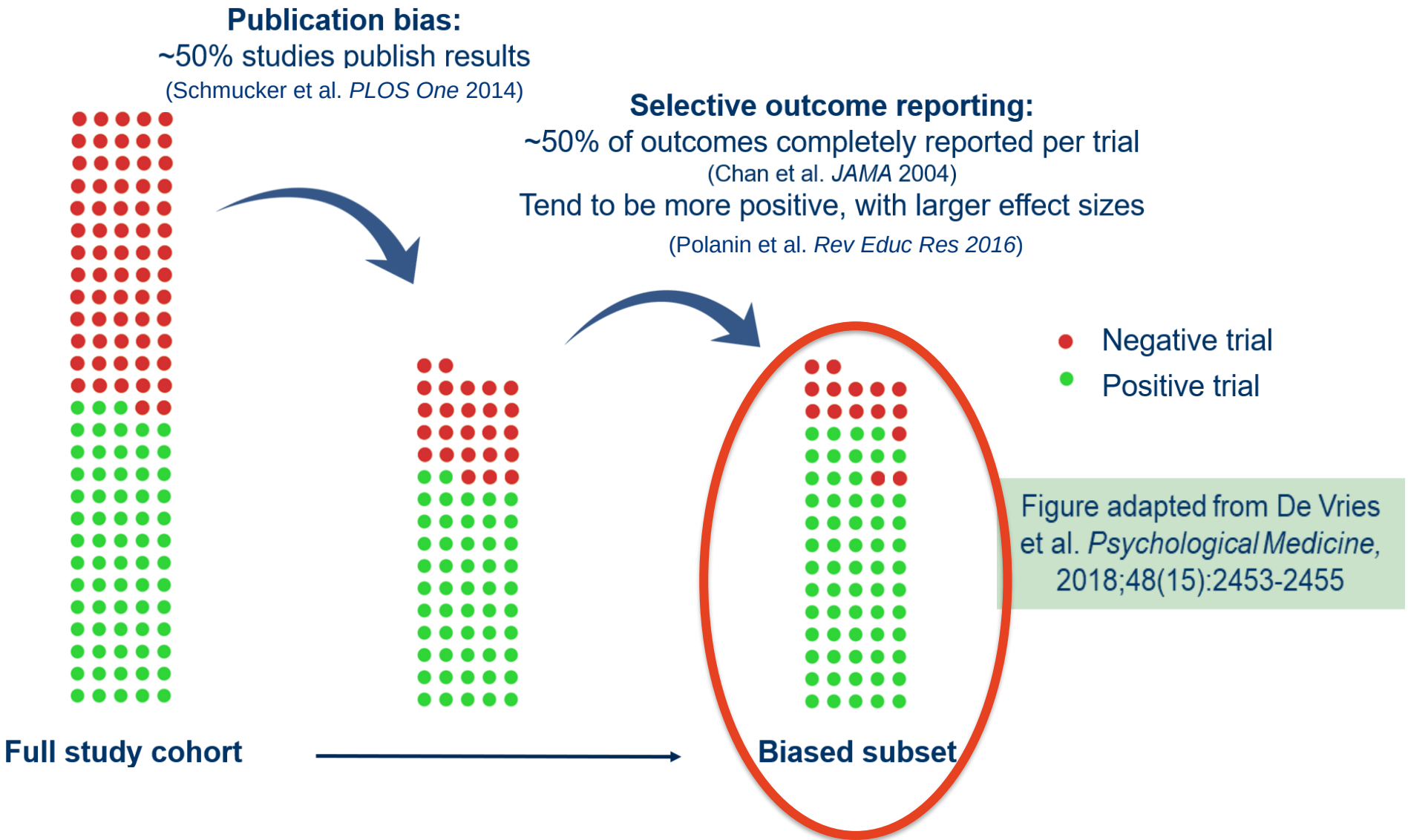


Figure adapted from De Vries et al. *Psychological Medicine*, 2018;48(15):2453-2455

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

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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!

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Guidance paper

thebmj

RESEARCH METHODS AND REPORTING

Check for updates

Searching clinical trials registers: guide for systematic reviewers

Kylie E Hunter,[1] Angela C Webster,[1,2] Matthew J Page,[3] Melina Willson,[1] Steve McDonald,[3] Slavica Berber,[4] Peta Skeers,[1] Ava G Tan-Koay,[1] Anne Parkhill,[5] Anna Lene Seidler[1]

[1]Evidence Integration, NHMRC Clinical Trials Centre, University of Sydney, Camperdown, NSW, Australia
[2]School of Public Health, University of Sydney, Camperdown, NSW, Australia
[3]Methods in Evidence Synthesis Unit, School of Public Health and Preventive Medicine

Systematic reviews should incorporate as much relevant evidence as possible to reduce bias and research waste and increase reliability of results. Clinical trials registers are a key resource for identifying potentially eligible studies, hierarchy, these reviews frequently underpin healthcare guidelines, policy, and practice.[2] Yet, their validity relies on identification and inclusion of all relevant and available evidence, both published and unpublished. Unpublished studies, however, are often difficult and time consuming to identify, resulting in suboptimal attempts at retrieval or even complete omission from systematic reviews.[3-7] This incomplete

Citation: Hunter KE, Webster AC, Page MJ, Willson M, McDonald S, Berber S, Skeers P, Tan-Koay AG, Parkhill A, Seidler AL. Searching clinical trials registers: guide for systematic reviewers *BMJ* 2022; 377 :e068791 doi:10.1136/bmj-2021-068791

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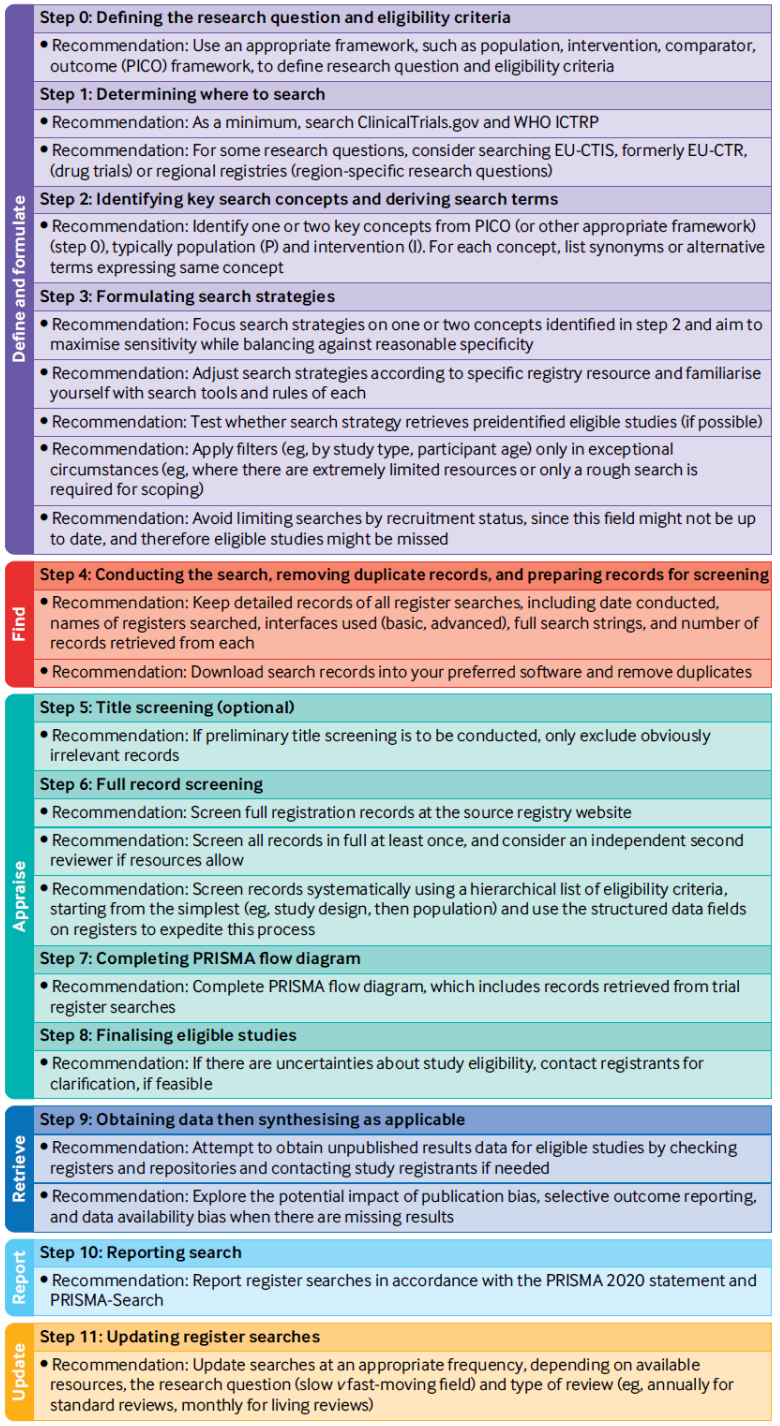

Define and formulate

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- Recommendation: Use an appropriate framework, such as population, intervention, comparator, outcome (PICO) framework, to define research question and eligibility criteria

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- Recommendation: Avoid limiting searches by recruitment status, since this field might not be up to date, and therefore eligible studies might be missed

Find

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

Appraise

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

Retrieve

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 when there are missing results

Report

Step 10: Reporting search
- Recommendation: Report register searches in accordance with the PRISMA 2020 statement and PRISMA-Search

Update

Step 11: Updating register searches
- Recommendation: Update searches at an appropriate frequency, depending on available resources, the research question (slow v fast-moving field) and type of review (eg, annually for standard reviews, monthly for living reviews)

Guidance paper: methods

@LeneSeidler
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Expertise	Hunter	Webster	Page	Willson	McDonald	Berber	Skeers	Tan-Koay	Parkhill	Seidler
Systematic reviews										
Information retrieval										
Clinical trials										
Prospective meta-analysis										
Methods/meta-research										
Guideline development/HTA										
Clinical										
Biostatistics										

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Illustrative case study

TOPCHILD

Transforming Obesity Prevention for CHILDren

	Trials	Participants
Identified by database searches	56 (79%)	45,900 (84%)
Identified by register searches only	**15 (21%)**	**8764 (16%)**
Total	71	54,664

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Can you sort the order of steps?

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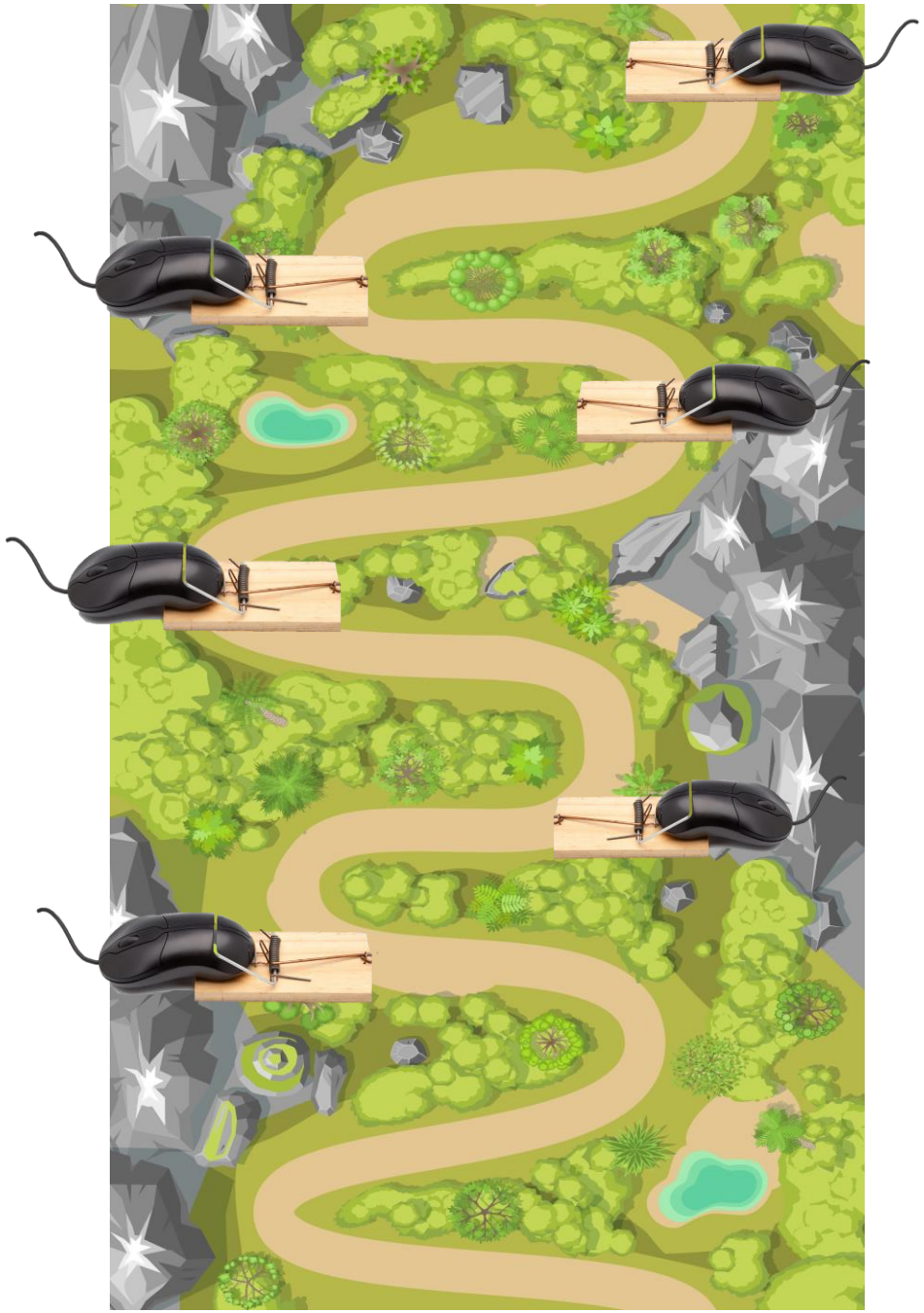
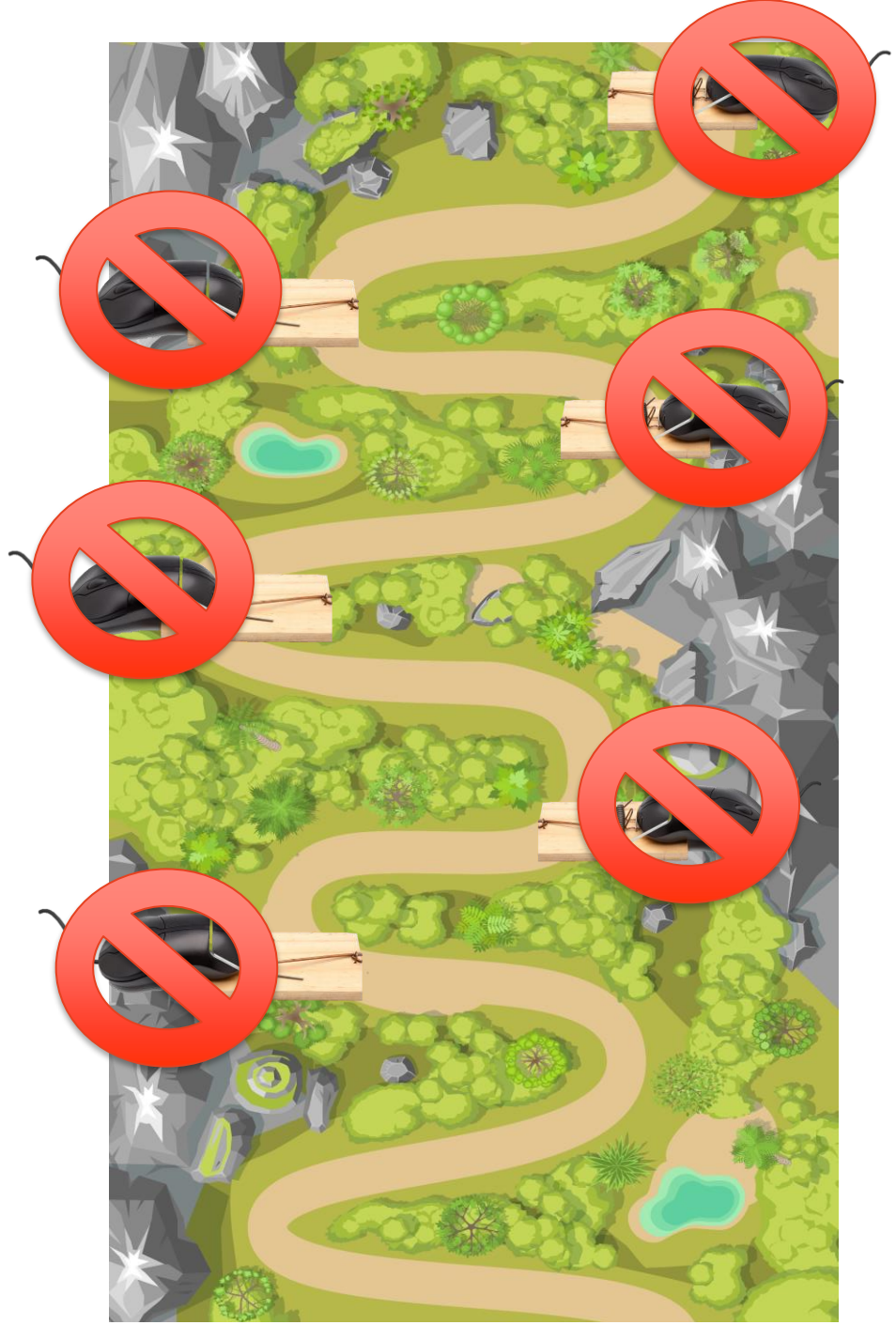
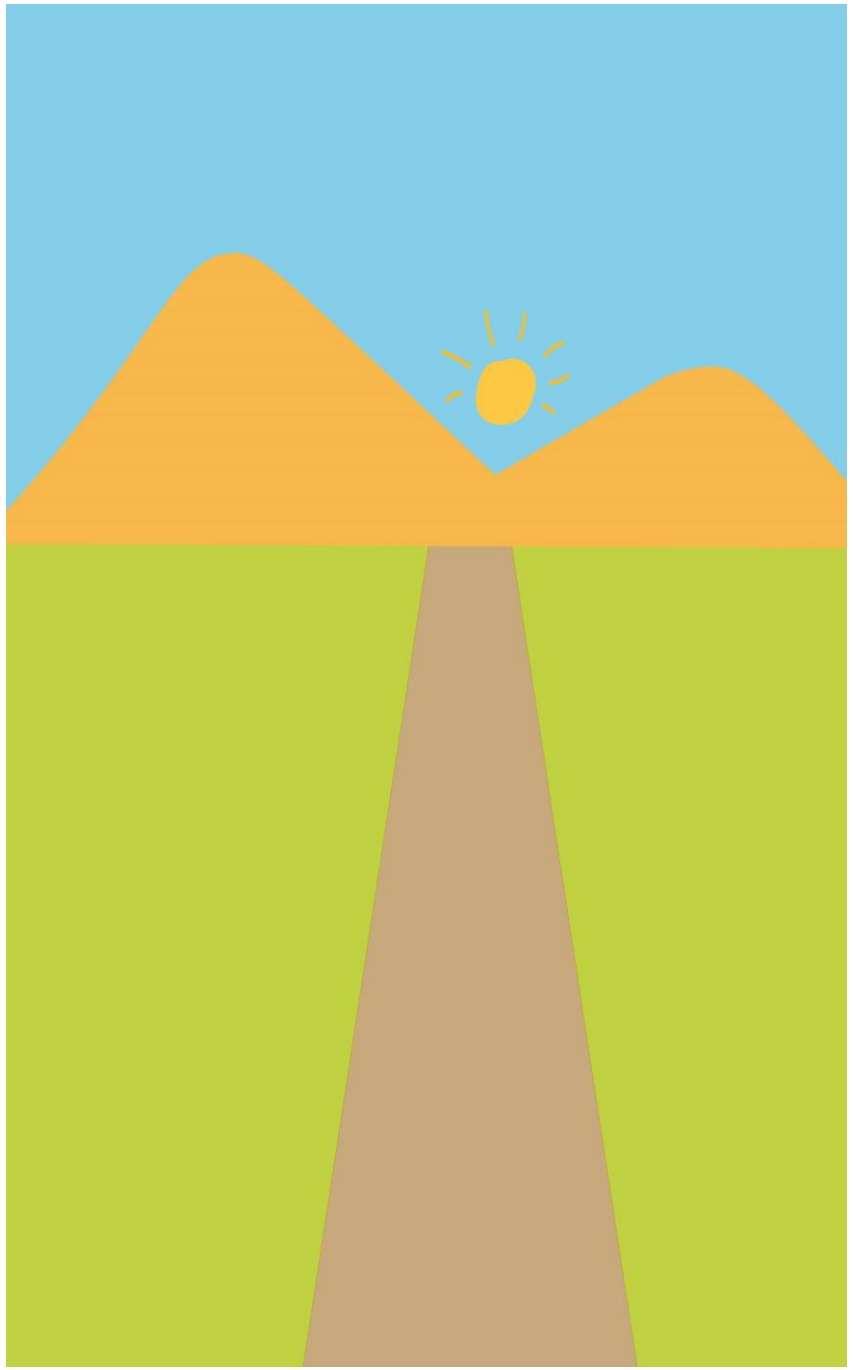
✓ Correct answer

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







Step 0: Defining the research question and eligibility criteria

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• Recommendation: Use an appropriate framework, such as population, intervention, comparator, outcome (PICO) framework, to define 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

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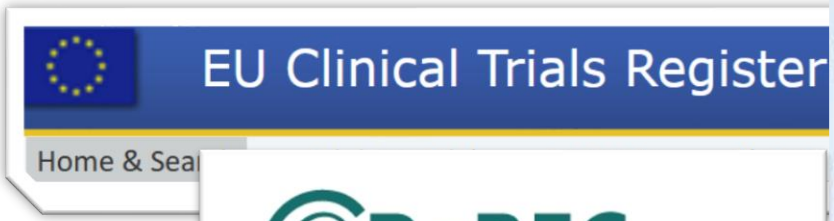

ISRCTN registry

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As a minimum, search ClinicalTrials.gov and WHO ICTRP

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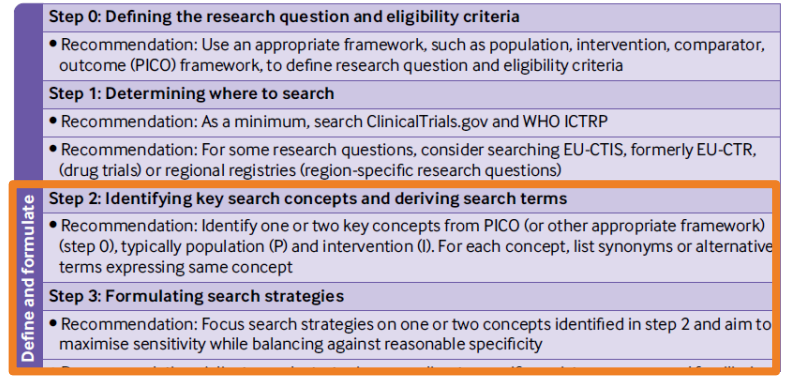
TRAP! Searching CENTRAL only

- 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

[1]Banno M, Tsujimoto Y, Kataoka Y. Using the Cochrane Central Register of Controlled Trials to identify clinical trial registration is insufficient: a cross-sectional study. *BMC Med Res Methodol* 2020;20:200.

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



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What might be some relevant search concepts for TOPCHILD

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

Define and formulate	
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TOPCHILD

Concepts searched in bibliographic databases (n=9)	Concepts searched in trial registers (n=2)
overweight/obesity	overweight/obesity
behavioural/lifestyle interventions	
nutrition/diet/feeding	
physical activity	
sedentary behaviours	
sleep	
health promotion/prevention	
child	child
families	

TRAP! Searching for too many concepts

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Step 3: Formulating search strategies

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

	Medline (via Ovid)	ClinicalTrials.gov	WHO ICTRP
Interfaces available	Basic: uses Ovid's natural language searching algorithm; advanced (default): search syntax	Basic (default): free text for limited data fields, some filters; advanced: combination free text (field specific) and categorical filters; "expert search": command line searches using expert syntax	Basic (default): free text, some filters; advanced: combination free text (field specific) and categorical filters
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[36]; 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/acronym, outcome measure, sponsor/collaborator, study IDs, 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 ($); limited ($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 "ctio" should find records containing words such as infection, reduction
Wildcards	Mandated (#); optional (?)	Not available (alternative spellings are not harmonised, eg, tumour *v* tumor)	Not available (alternative spellings are not harmonised, eg, tumour *v* 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[36])	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 wellbeing 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 wellbeing 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
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	Non-validated filters available by drop-down/tick box options only, eg, recruitment status, study type, age group	Non-validated filters available by drop-down/tick box options only, eg, clinical trials in children

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TRAP! Not adjusting search strategies for registers

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@KylieEHunter

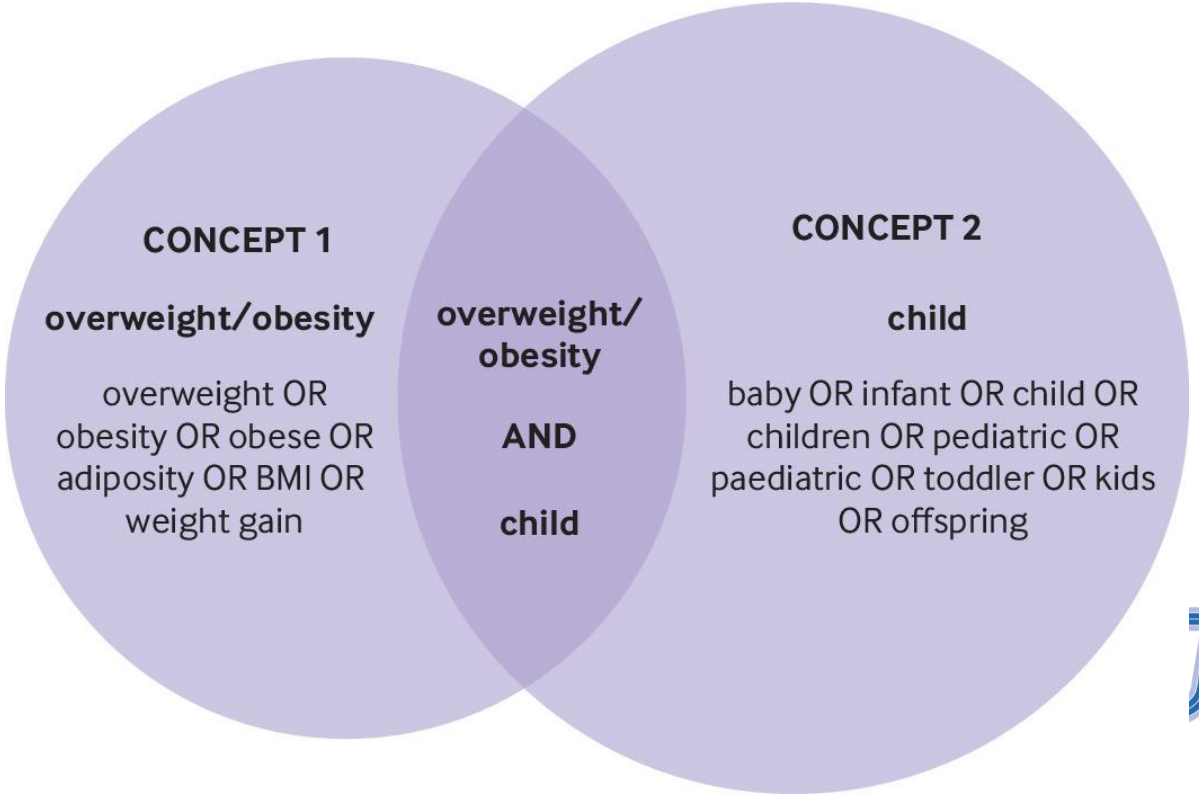
Example TOPCHILD search strategy

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

TOPCHILD



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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)

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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 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

TRAP! Information can be lost when downloading registration records to Covidence

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	• Recommendation: Download search records into your preferred software and remove duplicates

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Which of these should be searched as a

ⓘ Start presenting to display the poll results on this slide.

Step 5: Title screening (optional)

- Only exclude obviously irrelevant records

#6905 - UniversityofAlaska 2022

University of Alaska, Fairbanks; Pacific Institute for, Research; Evaluation,; University of Alaska, Anchorage; State of Alaska Department of, Health; Social, Services; Grand Valley State, University; Alaska Native Tribal Health, Consortium

Tundra Gifts: Harvesting Local And Regional Resources To Prevent Obesity Among Alaska Native Children In Remote, Underserved Communities

May 30 2022;():
2022 May 30

Hide Abstract & IDs

Trap! Titles in registration records may not be very informative → potential to exclude relevant studies

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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

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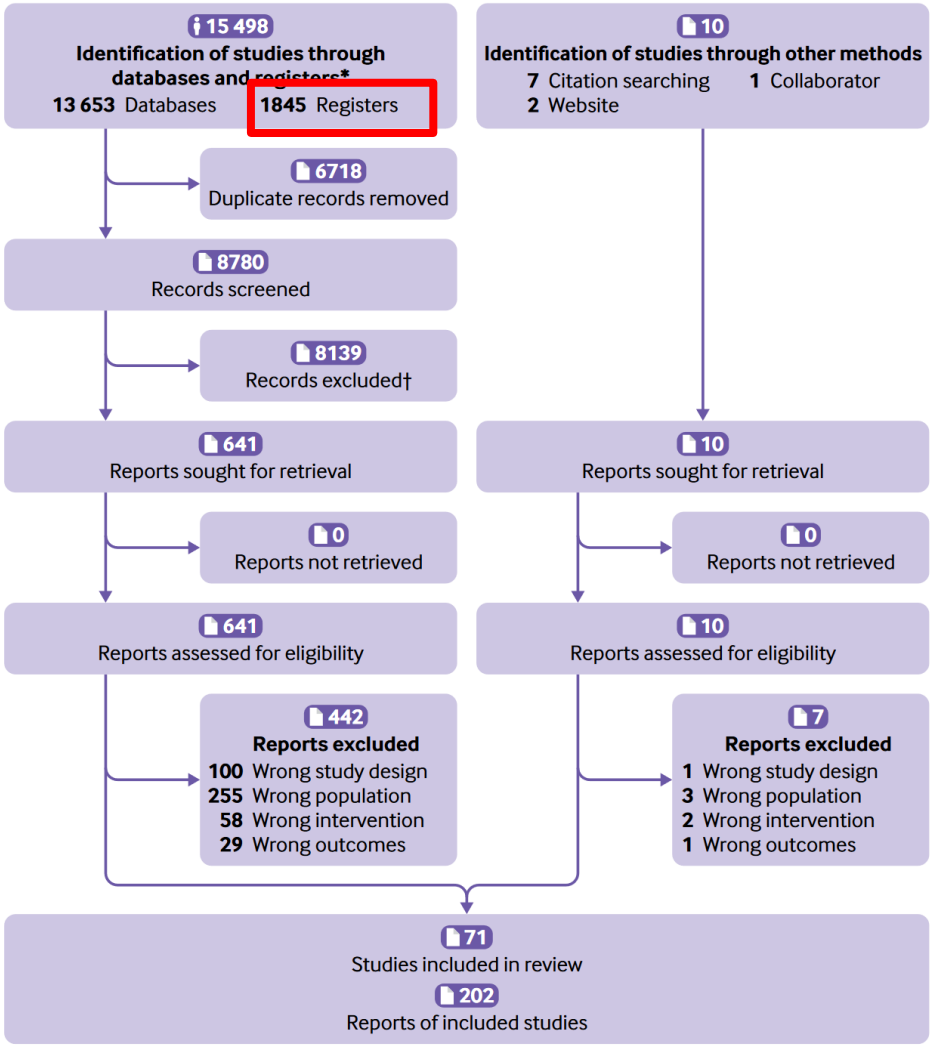
Step 7: Completing PRISMA flow diagram

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



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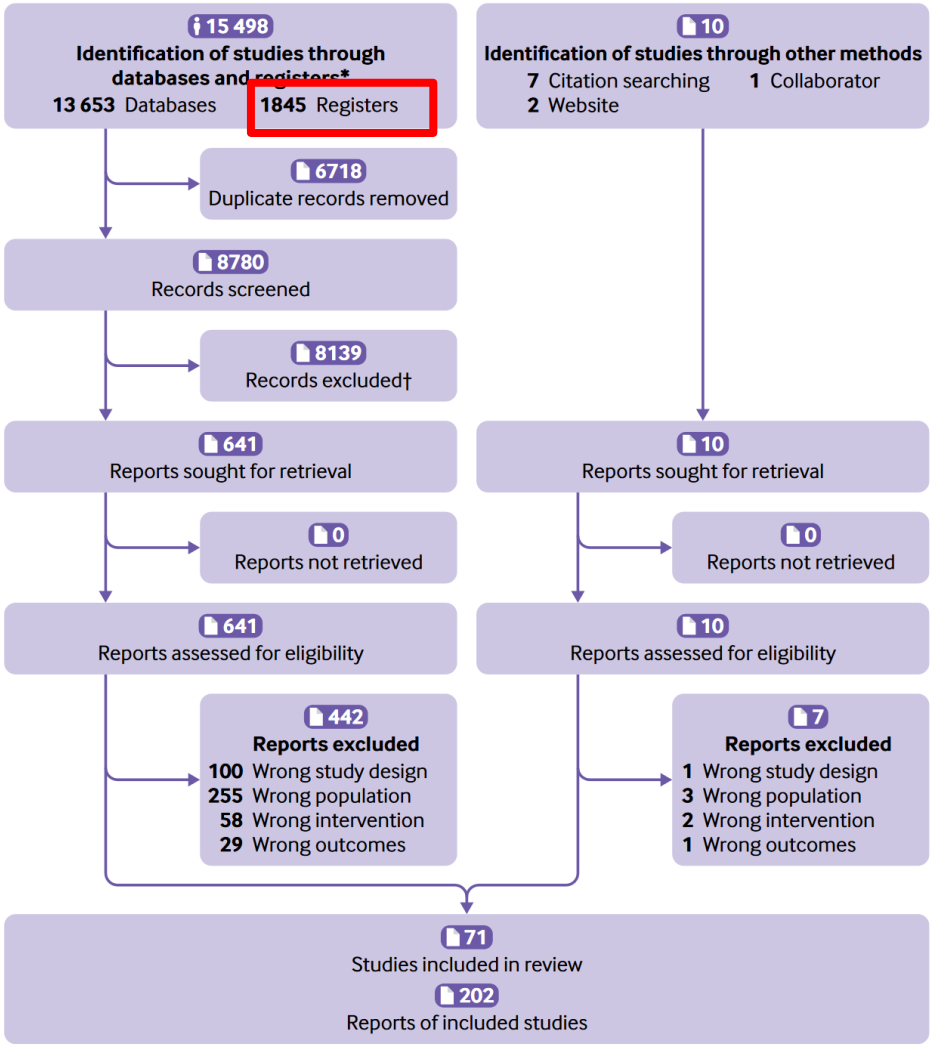

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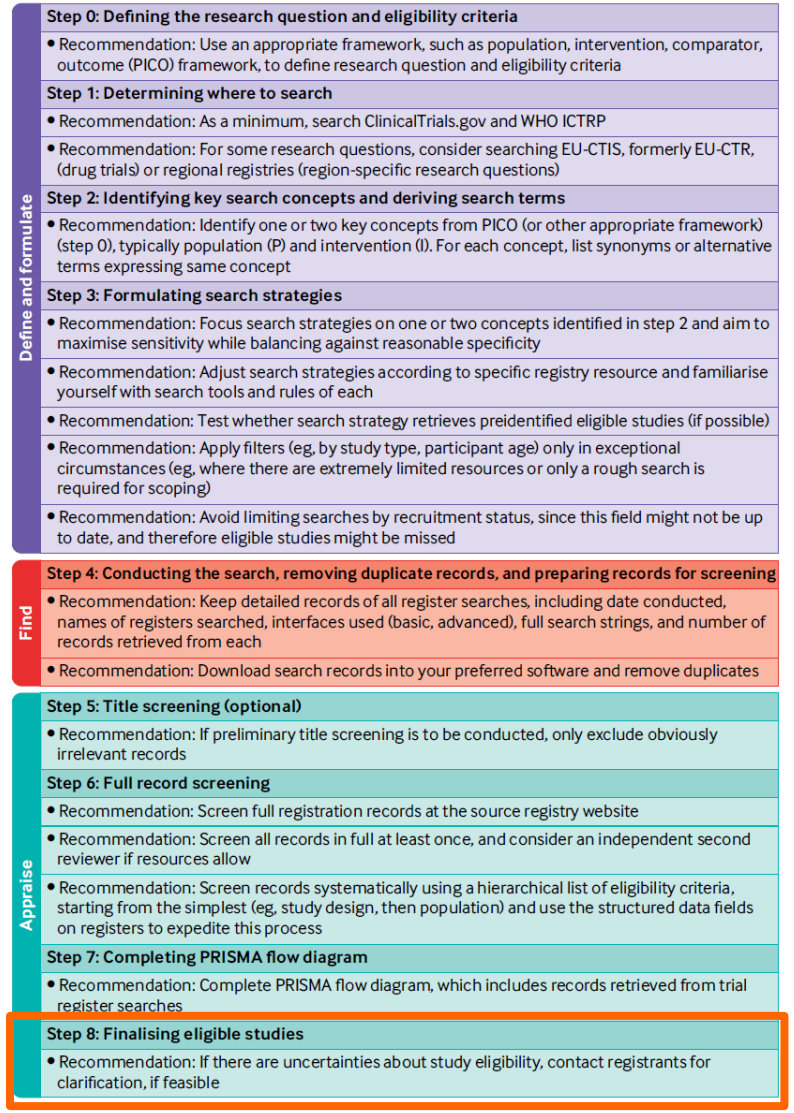

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Step 9: Obtaining data then synthesising as applicable

- How can we obtain unpublished results from trial registries?
  - by direct data extraction from registries
  - by contacting registrants

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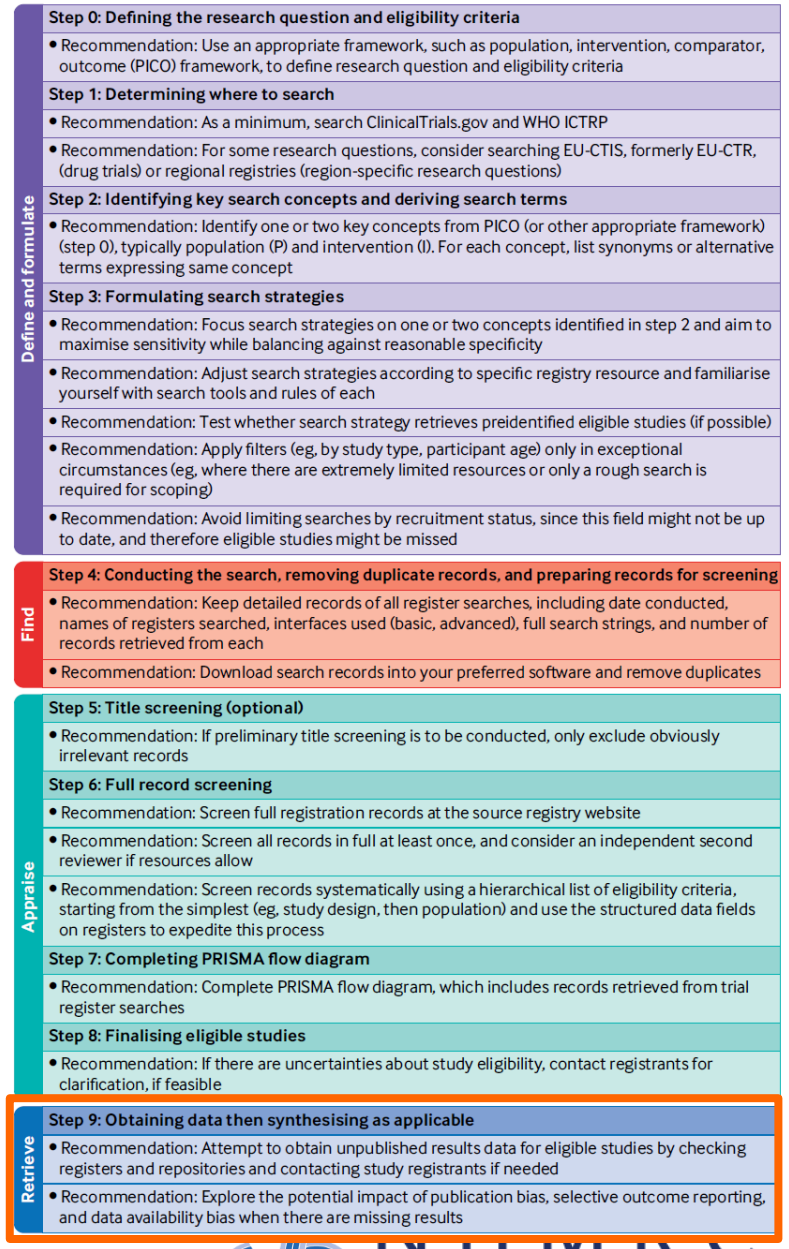
Clinical Trials Centre

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



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Step 10: Reporting search

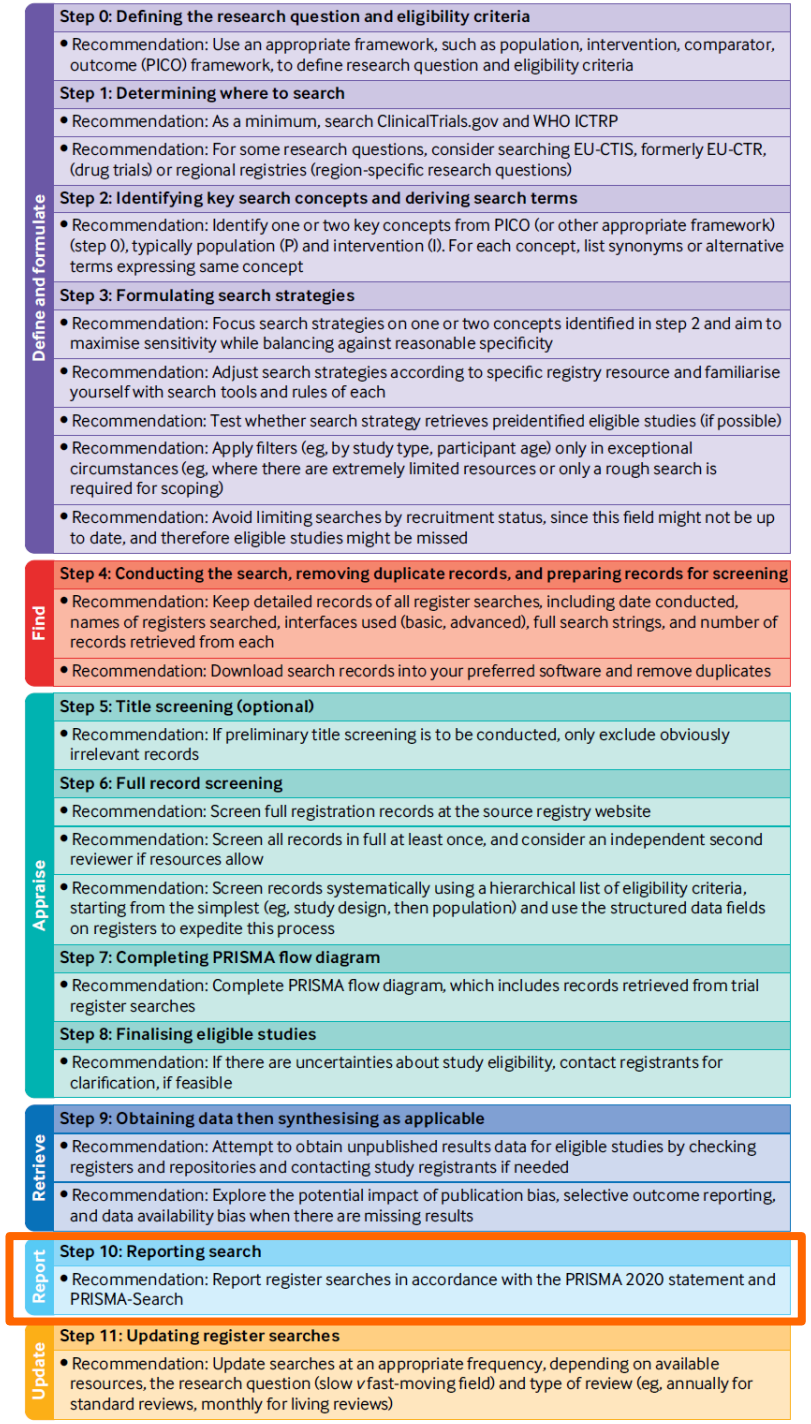
- Report in accordance with PRISMA 2020 & PRISMA-S

Table 1 | PRISMA 2020 item checklist

Section and topic	Item #	Checklist item
Title		
Title	1	Identify the report as a systematic review.
Abstract		
Abstract	2	See the PRISMA 2020 for Abstracts checklist (table 2).
Introduction		
Rationale	3	Describe the rationale for the review in the context of existing knowledge.
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.
Methods		
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers

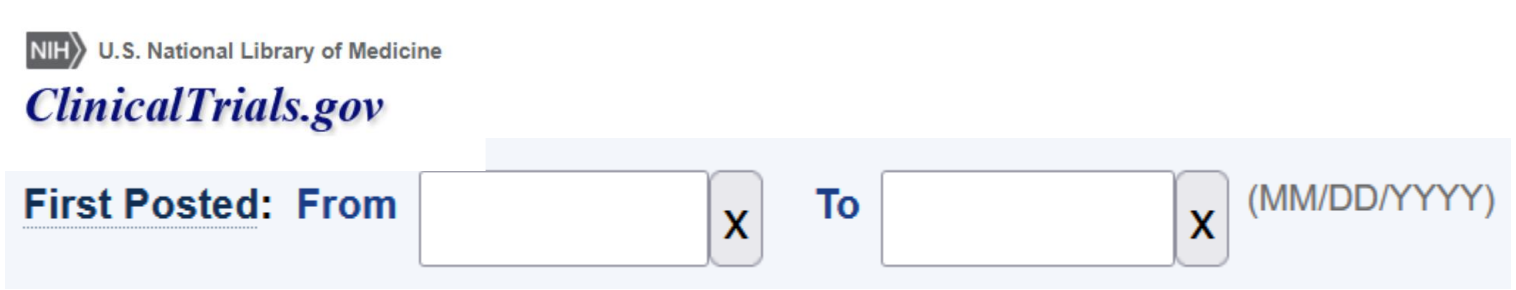
Table 1 PRISMA-S checklist. A downloadable version of the checklist is available on the PRISMA web

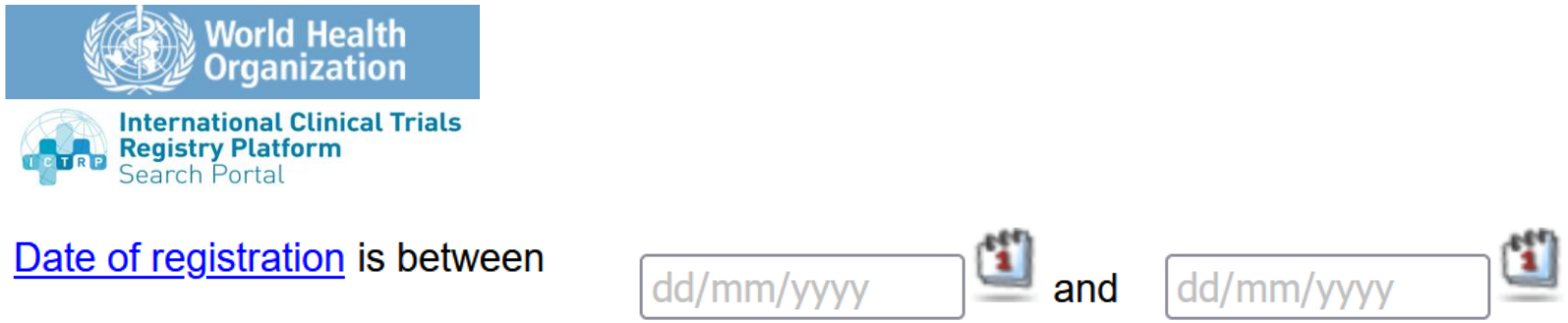
SECTION/TOPIC	ITEM #	CHECKLIST ITEM
INFORMATION SOURCES AND METHODS		
Database name	1	Name each individual database searched, stating the platform for each.
Multi-database searching	2	If databases were searched simultaneously on a single platform, state the name databases searched.
Study registries	3	List any study registries searched.
Online resources and	4	Describe any online or print source purposefully searched or browsed (e.g. table



Step 11: Updating register searches

- Updating frequency as per standard SR searches
- Restrict by registration date (not study start or completion dates)





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Report

Step 10: Reporting search

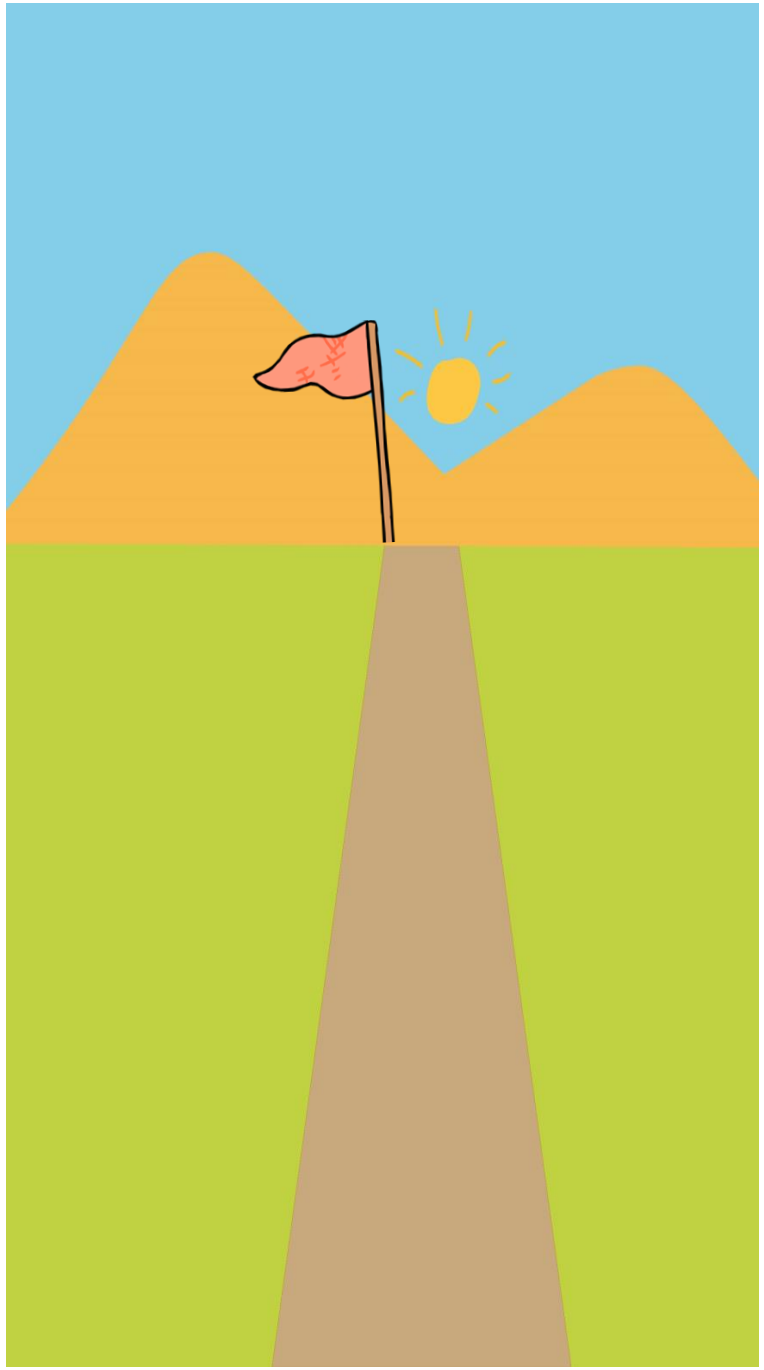
- Recommendation: Report register searches in accordance with the PRISMA 2020 statement and PRISMA-Search

Update

Step 11: Updating register searches

- Recommendation: Update searches at an appropriate frequency, depending on available resources, the research question (slow *v* fast-moving field) and type of review (eg, annually for standard reviews, monthly for living reviews)

Congratulations – you have made it through all the steps!



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slido

How many key concepts should a registe

ⓘ Start presenting to display the poll results on this slide.

slido

Register searches should routinely be filt

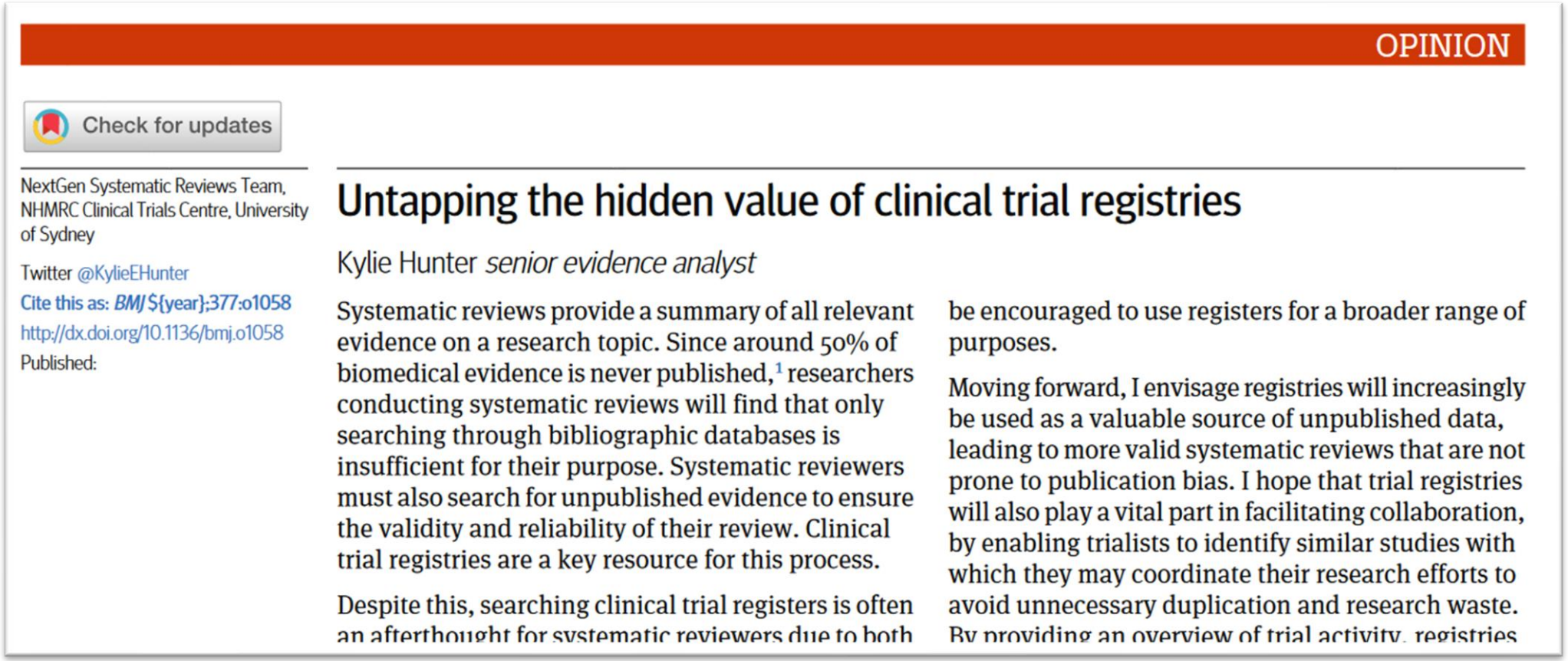
ⓘ Start presenting to display the poll results on this slide.

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**

@LeneSeidler
@KylieEHunter

Untapping hidden value of trial registries



OPINION

Check for updates

NextGen Systematic Reviews Team, NHMRC Clinical Trials Centre, University of Sydney

Twitter @KylieEHunter

Cite this as: *BMJ* ${year};377:o1058

http://dx.doi.org/10.1136/bmj.o1058

Published:

Untapping the hidden value of clinical trial registries

Kylie Hunter *senior evidence analyst*

Systematic reviews provide a summary of all relevant evidence on a research topic. Since around 50% of biomedical evidence is never published,[1] 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

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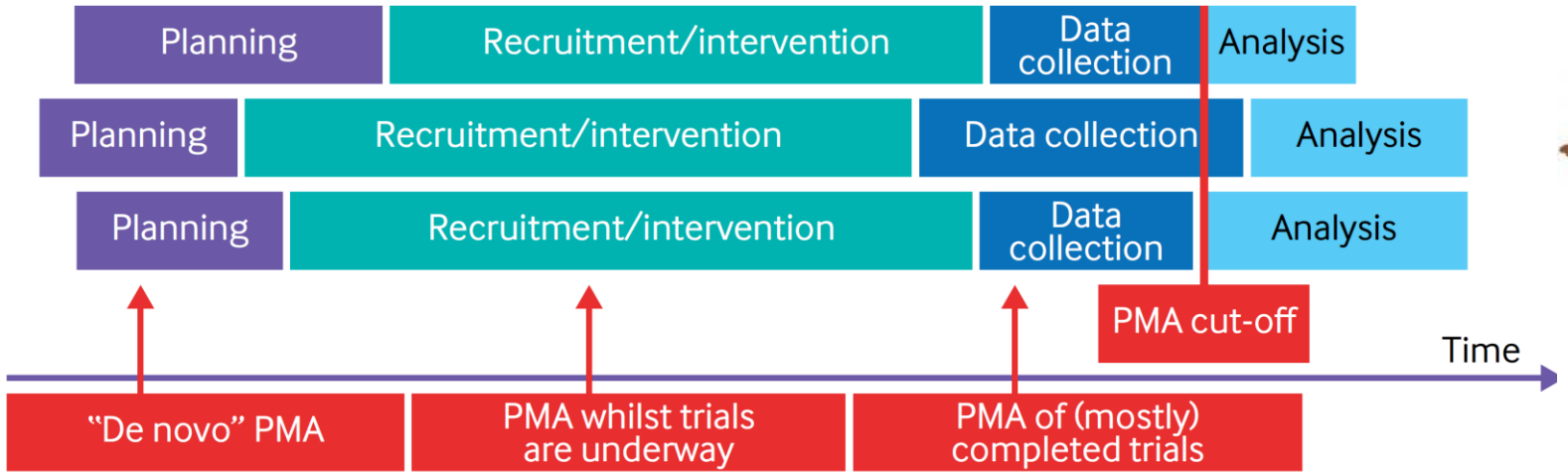
To identify studies & potential investigators for collaboration, e.g. prospective meta-analysis

Cochrane Methods 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

Source: Seidler AL, Hunter KE, Cheyne S, Ghersi D, Berlin JA, Askie L. A guide to prospective meta-analysis. BMJ. 2019;367:l5342.



Add value, e.g. outcome harmonisation → facilitates evidence synthesis → improves statistical power

@LeneSeidler
@KylieEHunter

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

Seidler et al (2019). BMJ.

@LeneSeidler
@KylieEHunter

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

@LeneSeidler
@KylieEHunter

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. hydroxycholorquine)

The landscape of COVID-19 trials in Australia

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

Med J Aust 2021; 215 (2): 58-61.e1. || doi: 10.5694/mja2.51148

Published online: 19 July 2021

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@LeneSeidler
@KylieEHunter

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

Liam Mannix
Science reporter

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@LeneSeidler
@KylieEHunter

Take home messages

Searching clinical trials registers is mandated for best practice systematic reviews

Access information on unpublished studies → mitigate bias, reduce research waste

Many differences to searching bibliographic databases

Registries are an untapped resource with many other uses

@LeneSeidler
@KylieEHunter

Acknowledgements

Angela C Webster, NHMRC Clinical Trials Centre, University of Sydney, Camperdown

Matthew J Page, School of Public Health and Preventive Medicine, Monash University, Melbourne

Melina Willson, NHMRC Clinical Trials Centre, University of Sydney, Camperdown

Steve McDonald, School of Public Health and Preventive Medicine, Monash University, Melbourne

Slavica Berber, NHMRC Clinical Trials Centre, University of Sydney, Camperdown

Peta Skeers, NHMRC Clinical Trials Centre, University of Sydney, Camperdown

Ava G Tan-Koay, NHMRC Clinical Trials Centre, University of Sydney, Camperdown

Anne Parkhill, Centre for Health Communication and Participation, La Trobe University, Melbourne

Lotty Hooft, Director of Cochrane Netherlands, member of ICTRP Advisory Group

Lisa Askie, Methods scientist, WHO

The TOPCHILD Collaboration

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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

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Key resources

- Hunter KE, Webster AC, … Seidler AL. Searching clinical trials registers: guide for systematic reviewers BMJ 2022; 377:e068791
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