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Researcher

Systematic Reviews, Episode 4: **PROTOCOL POWER!**

1. Drafting a clear SYNOPSIS
2. Writing a PRISMA-P PROTOCOL
3. Posting your protocol on PROSPERO

+ Q&A: Your questions!

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- Journal Selector
- MY protocol
- MY manuscript (formerly AuthorPath)

About Dr. Dean Meyer

BELS
Board of Editors in the Life Sciences

- Background in environmental science, with a specialist interest in toxicology and public health
- Spent eight years working at the centers for disease control and prevention (CDC) in Atlanta
- Research interests include the mechanisms of toxicity and disease causation, and the occupational sources of xenobiotics and their physiological effects
- Has an extensive background in the areas of laboratory safety and environmental health.
- Certified editor in the life sciences (ELS)
- Joined Edanz as an editor in 2015.

About Scott McCleary, M.Ed.Tech

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嘉悦大学
KAETSU UNIVERSITY

- Creator of Edanz Learning Lab
- Instructional designer with 18 years' experience in professional skill development and lifelong learning
- Lecturer at Kaetsu University, Tokyo
- Has developed and delivered training programs for more than 50 organizations worldwide in medicine, pharma, business, science, tech, government, and higher ed

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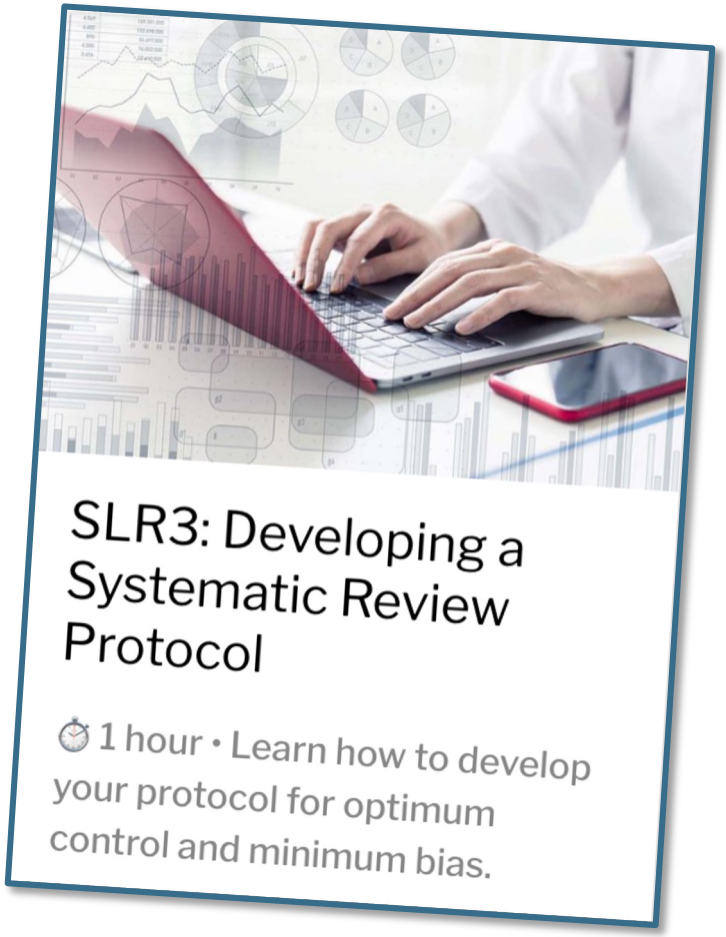

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RECAP: What is a systematic review? Why do one?

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A "**systematic literature review**", "**systematic review**", or "**SLR**" summarizes a large body of work to answer a specific research question you have shaped.

By performing a systematic review of all relevant literature, you can gauge the quality (validity and reliability) of research done so far, compare evidence of different studies, and **reach a better conclusion than with just one study**.

The goal is to improve decision-making by formulating useful guidelines for future practice and policy, as well as to develop ideas for future research.

1

Drafting Your SYNOPSIS

FAQ (Frequently-Asked Question):

Q: **What is a synopsis? Why do I need one?**

What is a **synopsis**? Why do I need one?

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Before writing a review protocol, it is a good idea to prepare a protocol **synopsis** (an overview) to help you focus your ideas. It will help your team to know what each person will do. This way, you can avoid duplicating efforts.

The synopsis is **brief**, but comprehensive -- just **bullet points** are enough.

Your synopsis can be used as **a guide for developing your protocol** into:
(1) a **registered protocol** for submission to an online registry (PROSPERO)
(2) a **protocol paper** for posting to a preprint server or submitting to a journal
(3) a protocol for journal **preregistration** as a "**registered report**".

MORE reasons why you need a **synopsis**!

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Your synopsis can be **shared between contributors** to get their feedback and comments. It can include a calendar/timeline too.

Any **gaps** (in the timeline, process, or your team's skills) **can be identified,** the missing pieces can be added, and collaboration can be discussed.

The synopsis can also be used to **guide your writing** of the first **two sections of your final manuscript**: the **Introduction** and **Methods.**

FAQ (Frequently-Asked Question):

Q: What should I include in my synopsis?

What to include in your **synopsis**

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1. Title of project
2. Draft title of systematic review
3. Type of systematic review
4. Project funding or sponsorship
5. Contributors
6. Review timeline
7. Review background
8. Review Objectives
9. Review selection criteria
10. Search and review methods
11. Appraisal of study quality & bias
12. Appraisal of review quality & bias
13. Review presentation

PRO Tips for the **synopsis**

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Synopsis Item #5: **Contributors**

a. **First reviewer/author**

b. **Other reviewers/authors**

c. **Support personnel** (for the synopsis, you can also just write, “more support needed” and then add names and contacts later)

★ for **all contributors,** give **contact details** and state any **conflicts of interest**

MY protocol

*For full tips on writing your synopsis, try edanz’s **MY protocol** online tool set – it’s FREE for all Researcher users!*

PRO Tips for the **synopsis**

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Synopsis Item #6: **Review Timeline**

a. Planning, preparing, and assembling team (+ checking that the review is novel & needed)

b. Protocol development and registration

c. Literature search

d. Literature appraisal

e. Data extraction

f. Data analysis and synthesis

g. Interpretation, and summary

h. Writing report

FREE Timeline/Checklist:
"The 12P Method of Systematic Reviews"

PRO Tips for the **synopsis**

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Synopsis Item #9: **Selection Criteria**

★ **PRO TIP**: try drafting a three-column **table**, like this:

PICO variables	Inclusion criteria	Exclusion criteria
Patient/**P**opulation **I**ntervention **C**omparison/Control **O**utcomes of Interest **t/s** (other variables)	*Specify your inclusion criteria here*	*Specify your exclusion criteria here*

PRO Tips for the **synopsis**

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Synopsis Item #10: **Search and review methods**

a. **Sources** (include a wide range to reduce publication bias and remain up-to-date): databases, journals, registries, repositories, gray literature, plus try some "chain-searching"/ "snowball searching"

b. **Search terms** (use Boolean logic, indexing tags, and keywords)

c. **Search method** (eg, check titles/abstracts first and then read full text; use two+ reviewers for study selection and a third as a "tie-breaker")

PRO Tips for the **synopsis**

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Synopsis Item #11: **Appraising study quality and bias**

Check study quality (eg, methodological/technical quality and study reporting completeness) with **a reporting guideline from the EQUATOR network**, such as CONSORT for randomized controlled trials or STROBE for observational studies

Use a **quality and bias tool for each identified study**, such as **GRADE** [Grading of Recommendations Assessment, Development and Evaluation], **Joanna Briggs** Institute Critical Appraisal Tools, or **CEBM** [Centre for Evidence-Based Medicine] Critical Appraisal Tools

FAQ (Frequently-Asked Question):

Q: What kinds of bias should I check for?

What **types of bias** should I check for?

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Possible Types of Bias:

- **sample selection bias**
- **group allocation bias**
- **assessor/detection bias**
- **data collection bias**
- **withdrawal/attrition bias**
- **confounding [interfering concomitant] factors**

Ethical considerations

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Here are some key **ethical points to consider** in your systematic review:

- **minimizing bias** (publication bias, study selection bias...)
- **funding** & sponsorship, if any (check with your institution)
- acknowledging **contributions** of additional people (i.e. reviewers)
- acknowledging true **authorship** (see ICMJE guidelines)

***Pro Tip**: Approval from an ethics board is usually not needed for SLRs*

Q&A #2

Ask us ANYTHING about drafting your SYNOPSIS!

Click the ‘raise hand’ icon, or type your question into the ‘Questions’ panel

2

Writing a PRISMA-P PROTOCOL

What is a protocol? Why do I need one?

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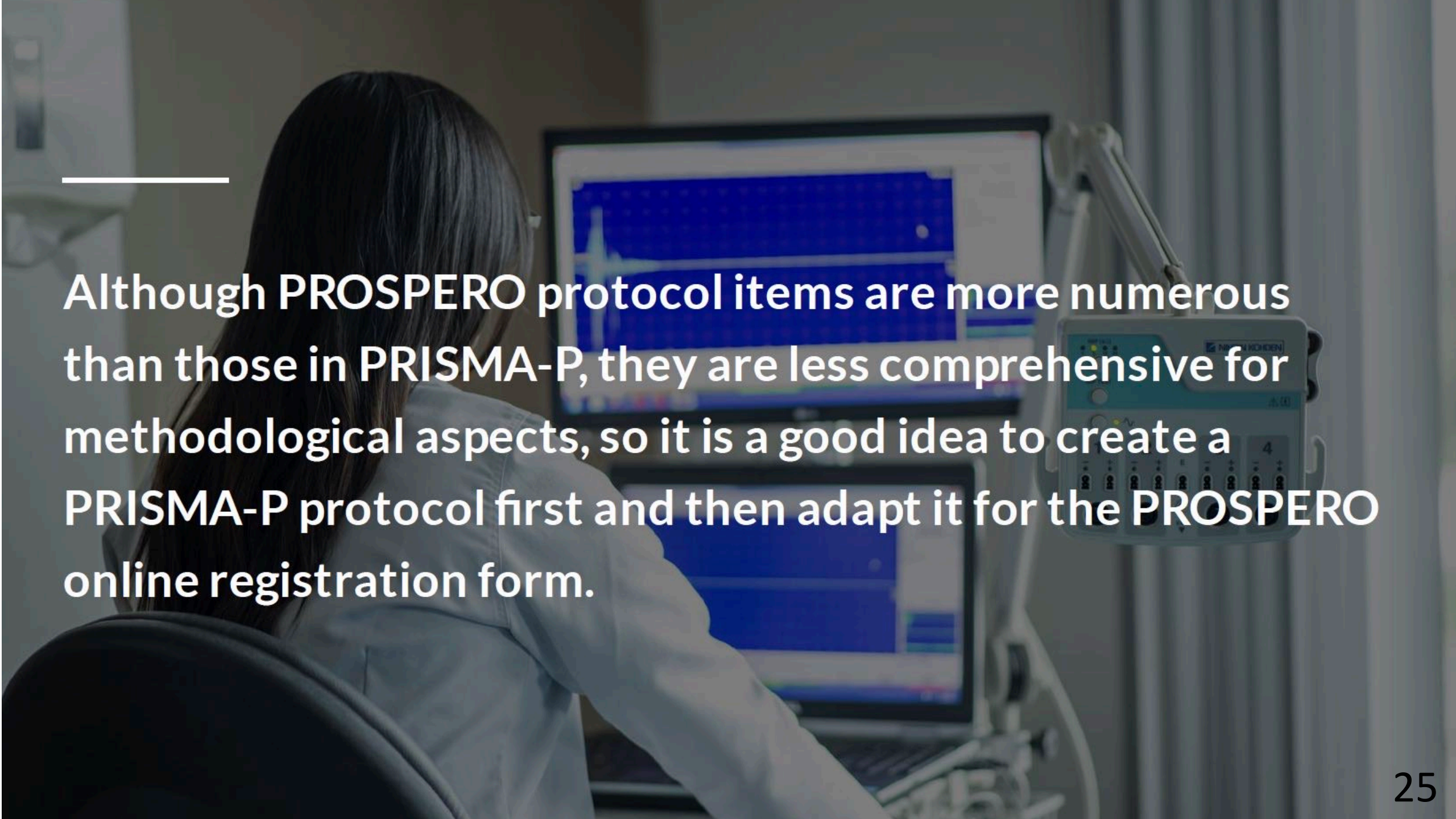
A systematic review needs to have a preplanned **protocol** that clearly explains any later changes you make. This will make your review **methods reproducible**, and your results will be more **objective** and **trustworthy**.

Ideally, the protocol (and any changes) should be **documented publicly** (such as on PROSPERO*) **before** doing your systematic review*.

This will alert other researchers that your systematic review is in progress (= establish **primacy**) so that the same review is not repeated by others (= avoid **research waste**)

FAQ (Frequently-Asked Question):

Q: Which protocol type should I create first: PRISMA-P or PROSPERO?



Although PROSPERO protocol items are more numerous than those in PRISMA-P, they are less comprehensive for methodological aspects, so it is a good idea to create a PRISMA-P protocol first and then adapt it for the PROSPERO online registration form.

What are the items of the PRISMA-P Checklist?

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A. Administration

1. Title
2. Registration
3. Authors
4. Amendments
5. Support

B. Introduction

6. Rationale
7. Objectives

C. Methods

8. Eligibility Criteria
9. Information sources
10. Search strategy
11. Study Records
12. Data Items
13. Outcomes and Prioritization
14. Risk of Bias in Individual Studies
15. Data synthesis
16. Meta-bias(es)
17. Confidence in cumulative evidence

PRO Tips for Your PRISMA-P Protocol

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#1: Title

1a. Identify your report as a **systematic review protocol**.

★ **PRO TIP**: *By labeling your document as a "systematic review protocol", you will improve its retrieval in search-engine searches.*

Finding your protocol is important to reduce waste in effort and resources, especially if other researchers are attempting to check that their planned review has not already been done.

Get step-by-step tips for all of PRISMA-P

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MY protocol

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Edanz's MY-protocol online tool is a fast, easy way to draft your protocol.

It includes pro tips for all 17 items of the PRISMA-P checklist.

PRO Tips for Your PRISMA-P Protocol

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#3: Authors

3a Contact: Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author.

3b. Contribution: Describe contributions of protocol authors and identify the guarantor of the review.

★ **Pro Tip**: *Item 3b should show transparently **who did what** (for the benefit of readers, and for journal editors to verify if each author contributed enough to qualify as authors according to the journal's definition).*

FAQ (Frequently-Asked Question):

Q: **“Author” vs “Contributor” – What’s the difference in a systematic review?**

Guidelines of Authorship

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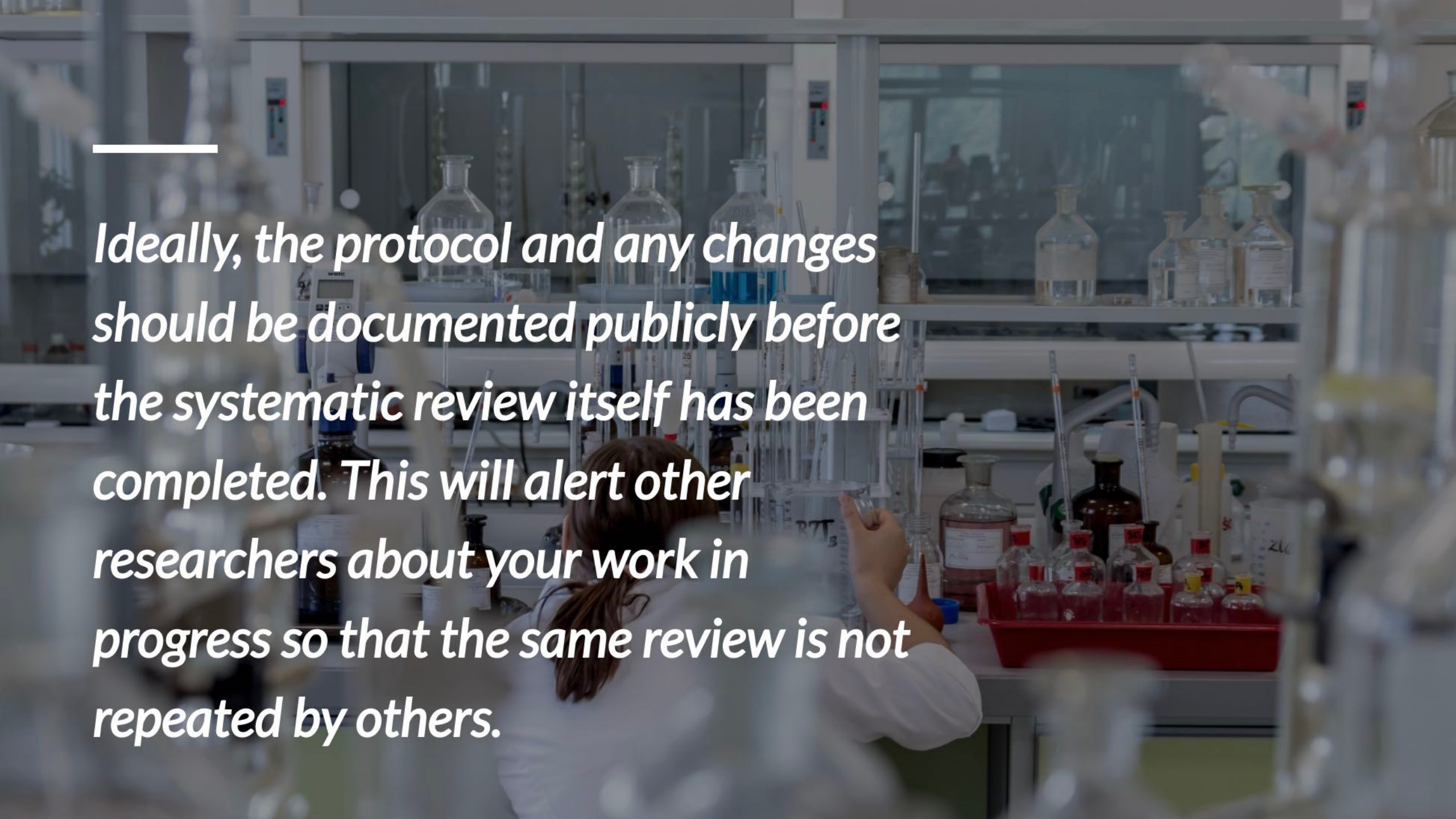
ICMJE guidelines for **authorship** require four specific roles:

1. Substantial **contributions** to the conception or **design** of the work; or the acquisition, analysis, or interpretation of **data** for the work; AND
2. **Drafting** the work or **revising it** critically for important intellectual content; AND
3. **Final approval** of the version to be published; AND
4. **Agreement to be accountable** for all aspects of the work

⚠ *DON'T do "GIFT" or "GHOST" authorship.*
DO acknowledge non-authors as contributors.



Ideally, the protocol and any changes should be documented publicly before the systematic review itself has been completed. This will alert other researchers about your work in progress so that the same review is not repeated by others.

PRO Tips for Your 17-Item PRISMA-P Protocol

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#4: Amendments (changes)

If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state your plan for documenting important protocol amendments.

★ **Pro Tip**: Because protocols and reviews should be objective, bias-free, and reproducible, **any amendments that you made to the protocol should be clearly "stated and dated", with reasons**.

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#7: Objectives

Give an explicit **statement of the research question(s)** the systematic review will address.

Example: “To synthesise the existing evidence of thoracic region dysfunction in patients with Whiplash Associated Disorder”.

https://www.crd.york.ac.uk/PROSPEROFILES/26983_PROTOCOL_20151025.pdf

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#8: Eligibility Criteria (using S.P.I.D.E.R. in this example)

(S) **Sample**: Adults patients who have experienced a whiplash associated disorder with no complications, aged >16 years.

(PI) **Phenomenon** of **Interest**: a whiplash associated disorder following motor vehicle or sporting injury

(E) **Evaluation**: Any patient reported or performance-based measure of thoracic dysfunction will be evaluated

(D) **Design**: All types of observational study; cohort, case control, single case studies

(R) **Research** type: qualitative, quantitative and mixed-methods research could be searched for.

(https://www.crd.york.ac.uk/PROSPEROFILES/26983_PROTOCOL_20151025.pdf)

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#10: Search Strategy

Example: "The search strategy will include the study population using terms and keywords derived from scoping search and expertise in the subject field. Study population terms: whiplash, whiplash associated disorder, WAD, thoracic spine, dorsal spine, trapezius, whiplash injury, motor vehicle accident, road traffic accident etc. Dysfunction location and terms: injuries, thoracic spine, symptoms. See example in Figure 1."

https://www.crd.york.ac.uk/PROSPEROFILES/26983_PROTOCOL_20151025.pdf

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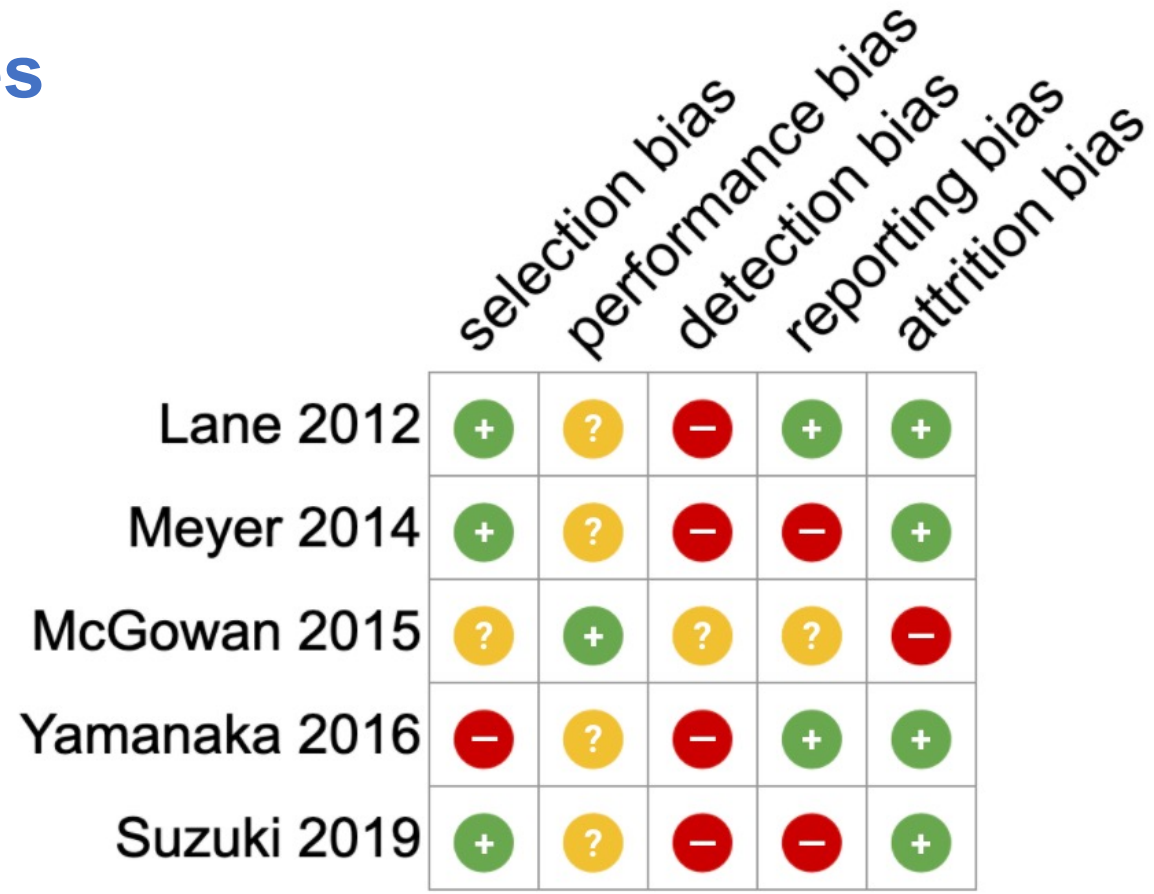
#14: Risk of bias in individual studies

Describe your anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis.



*"**Traffic light graph**" showing risk of bias*

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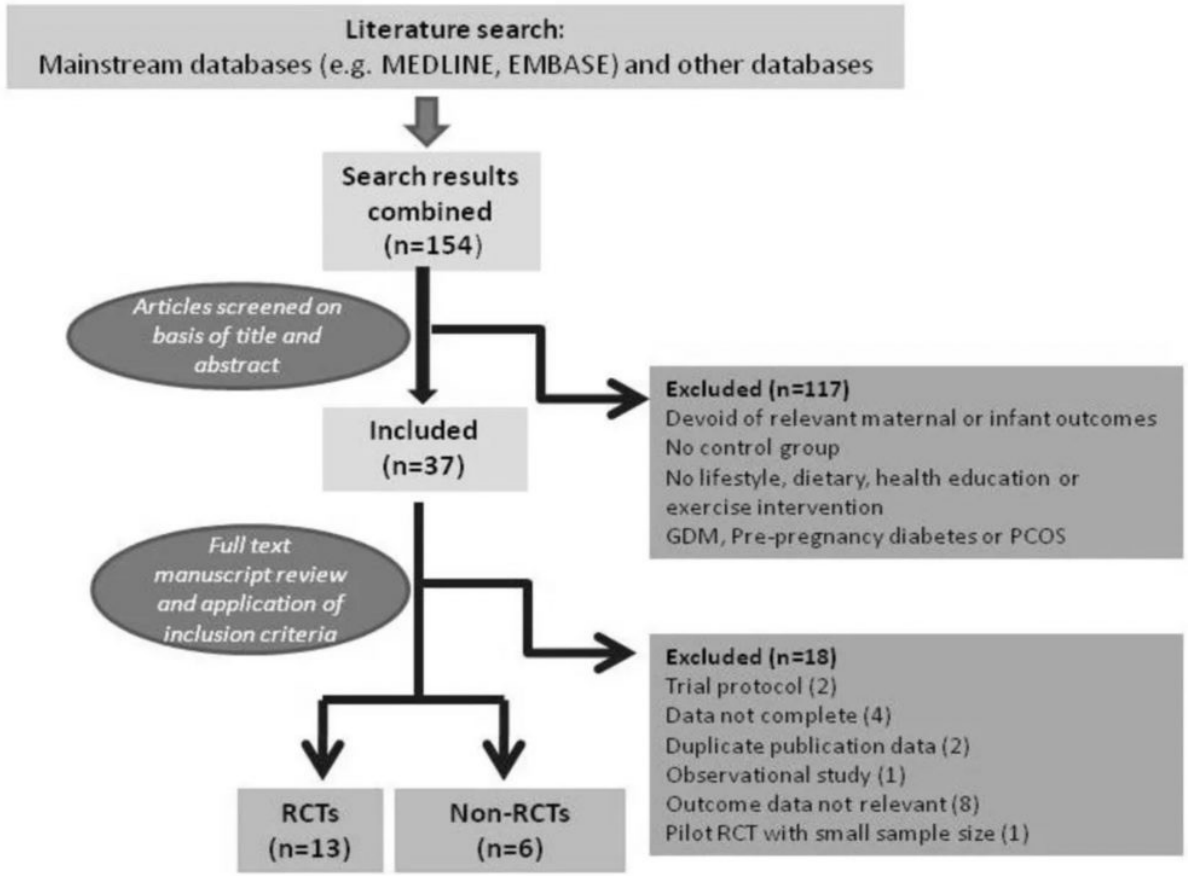
#17: Study selection flowchart



PRISMA recommends a flowchart showing how you identified and selected [get their template here].

Explain **how you selected primary studies** and **state your inclusion and exclusion criteria** based on your original PICO question.

Study selection typically takes place **in several stages,** and **two or more reviewers** are usually needed.

PRO Tips for Your PRISMA-P Protocol

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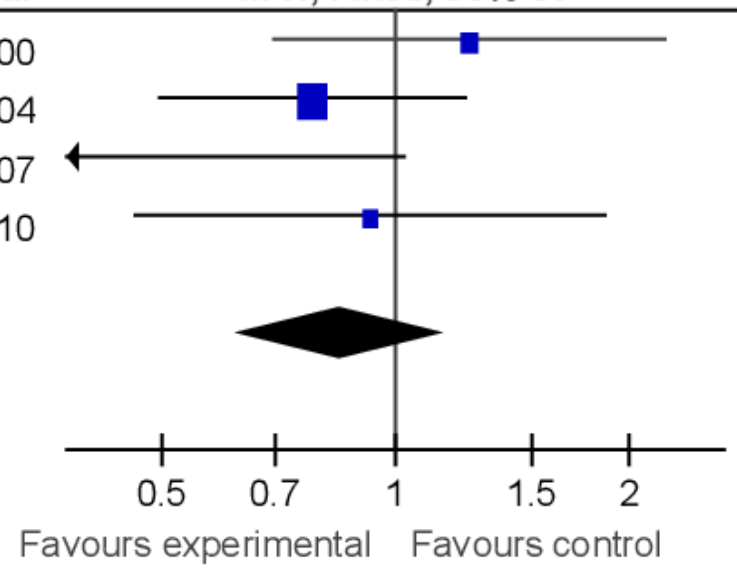
Forest Plots summarize the effects (effect sizes) and 95% confidence intervals of individual primary studies that are included in the review.

	Lifestyle advice		Standard care			Odds Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	Year
Gray-Donald 2000	37	106	31	103	23.1%	1.25 [0.70, 2.23]	2000
Olson 2004	32	179	83	381	49.2%	0.78 [0.50, 1.23]	2004
Kinnunen 2007	0	49	8	56	8.9%	0.06 [0.00, 1.03]	2007
Mottola 2010	12	65	51	260	18.8%	0.93 [0.46, 1.86]	2010
Total (95% CI)		**399**		**800**	**100.0%**	**0.85 [0.63, 1.16]**	
Total events	81		173				

Heterogeneity: $Chi^2 = 5.20$, $df = 3$ ($P = 0.16$); $I^2 = 42\%$

Test for overall effect: $Z = 1.02$ ($P = 0.31$)



Oteng-Ntim, E., Varma, R.R., Croker, H., Poston, L., & Doyle, P. (2012). Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome: systematic review and meta-analysis. BMC Medicine, 10, 47 – 47.

Q&A #2

Ask us ANYTHING about PRISMA-P protocols!

Click the ‘raise hand’ icon, or type your question into the ‘Questions’ panel

3

Posting Your Protocol on PROSPERO

Why register with PROSPERO?

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Reasons to register your protocol with PROSPERO:

1. For Honesty

- so that protocols are not altered later
- to avoid publication bias (authors and journals tend to publish only positive results)

2. For Transparency And To Reduce Research Waste

- to allow researchers and funders to know what studies are underway
- so researchers can avoid duplicating other studies

3. Some journals require PROSPERO registration

FAQ (Frequently-Asked Question):

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Q: What is the difference between a PRISMA-P protocol and a PROSPERO protocol?

FAQ (Frequently-Asked Question):

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Q: **What is the difference between a PRISMA-P protocol and a PROSPERO protocol?**

A: **PRISMA-P has 17 items, but PROSPERO has 40 items (25 mandatory + 15 optional)**

Items unique to PROSPERO

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Some extra items in PROSPERO that are not in PRISMA-P:

- **Anticipated start and end dates of the review**
- **Language of the review**
- **Search engine optimization (context, review type, keywords)**
- **Stage of review reached so far**
- **Dissemination plan**
- **Link to the published systematic review at a later date.**

Some of these additional items should be in your review **synopsis** and timeline.

PRO Tips for Your PRISMA-P Protocol

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#3: Anticipated or actual start date of the review process

The start date can be after pilot searches but before any identified studies are screened; it should be **after the protocol has been finalized** (and peer reviewed, and approved by a funder).

For more help with the PROSPERO form, try our course, "**SLR3: Developing a Systematic Review Protocol**": free for all Researcher users!

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#35: Dissemination plan

This is an optional item. State if there are plans to publicize the review to different audiences, especially after publication.

Example: "**This review will be summarized as a publicly accessible online report for the funder and will be published in a peer-reviewed journal. The review findings will also be summarized as best practice guidelines on behalf of the [professional association/society] for [name of end-user group].**"

PRO Tips for Your PRISMA-P Protocol

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#36: Keywords

(optional item): Specific keywords, i.e. MeSH (medical subject heading) keywords, will help people to find your paper on search-engines.

Examples: **Subject index terms status—Subject indexing assigned by CRD; Subject index terms—Community Health Services; Delivery of Health Care; Developed Countries; Exposure to Violence; Health Status; Health Status Disparities; Humans; Mental Health; Reproductive Health; Sexual Health; Sex Workers; Social Determinants of Health; Social Work; Socioeconomic Factors**

Q&A #3

Ask us ANYTHING about posting your protocol on PROSPERO!

Click the ‘raise hand’ icon, or type your question into the ‘Questions’ panel

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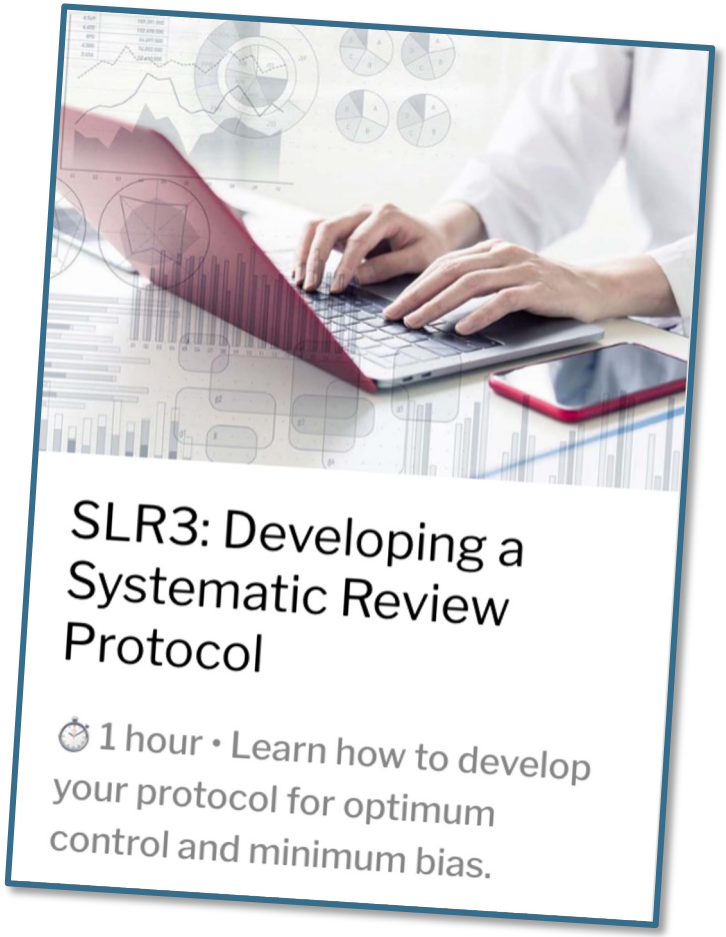

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