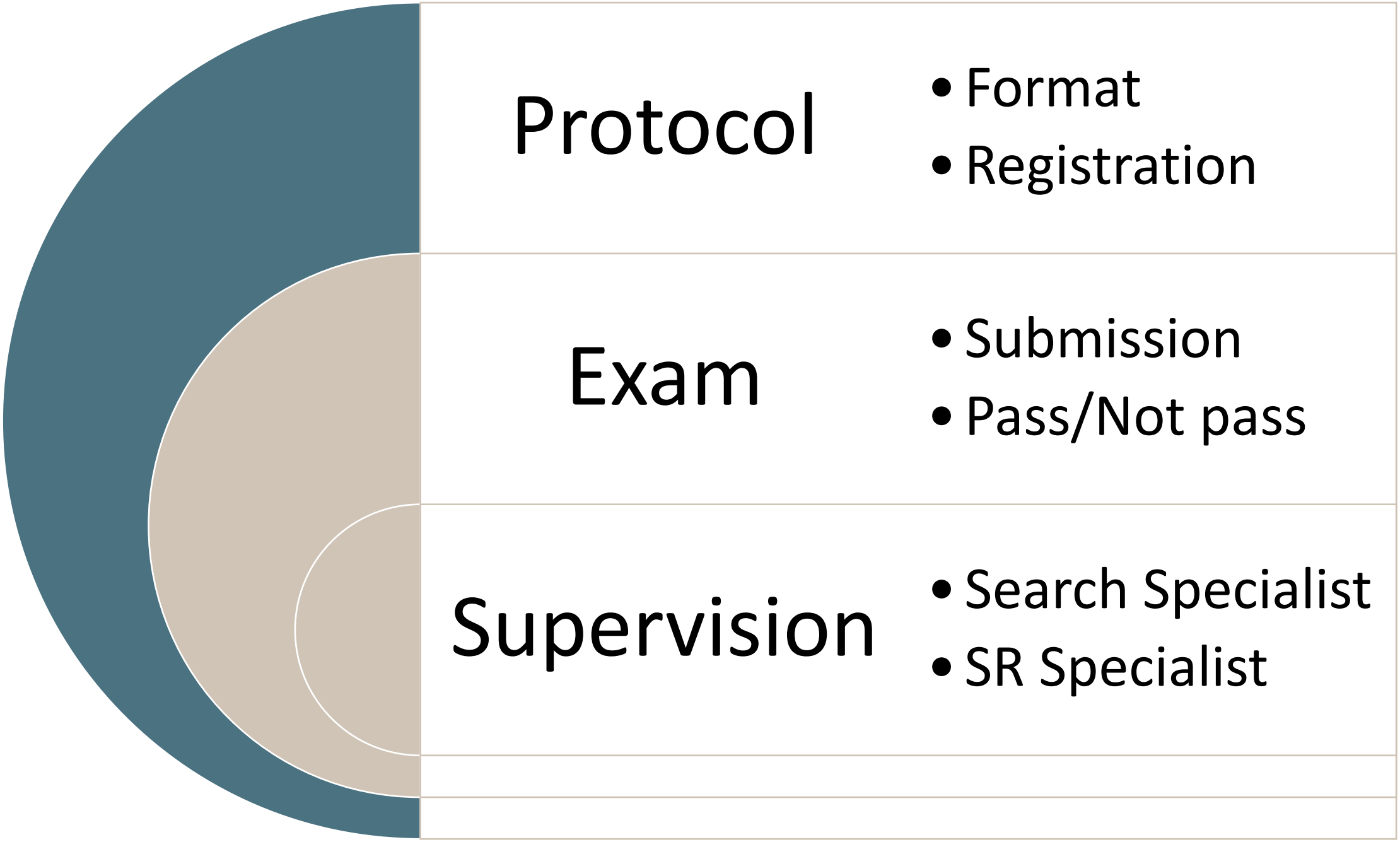
NIPH
Norwegian Institute of Public Health

Protocol development and team composition
Exam
Supervision

Lillebeth-Larun@fhi.no Thanks to Julia Bidonde for use of slides

20220928


Protocol
• Format
• Registration
Exam
• Submission
• Pass/Not pass
Supervision
• Search Specialist
• SR Specialist

What is a protocol?

- *The plan* or set of steps to be followed in a study.

- A Protocol for a **Systematic Review** should describe the rationale for the review, the objectives, and the methods that will be used to locate, select, and critically appraise studies, and to collect and analyse data from the included studies.

Writing your protocol

- Time and Commitment
  - Writing a protocol can take 2 to 6 months depending on the complexity of your topic and the time and resources available to your team
- Make sure your proposal does not duplicate any work already published or registered
  - Search for published protocols or reviews in the area
- Identify a team of authors for your review/protocol
- Use future tense “we/review authors will”

Review team

- Content knowledge
- Time and interest takes - 4-6 months
- Methodological knowledge i.e. statstics, analytical skills, experience with the primary study methods (qualitative)
- Project management
- 4-6 people (smaller is better for QES)
- Authorship sequence

Registering or Publishing

- review protocols are typically registered at conception
  - Cochrane Systematic Review
  - PROSPERO / https://www.crd.york.ac.uk/prospero/
  - OSF *Open Science Framework - https://osf.io/

OR

- Published / academic journals

  (from Systematic Review) “Protocol articles will only be considered for proposed or ongoing research that has not yet started the final data extraction stage of the review at the time of submission, and should provide a detailed account of the hypothesis, rationale and methodology of the study.”

Format of the protocol

Depends on where you will publish your protocol

- Registers:
  - PROSPERO
  - Open Science Network
  - Institutions homepage

- In Journals – individual journals standards
  - for exammle Cochrane Handbook, MECIR standards

  https://community.cochrane.org/mecir-manual

Why and when to register your protocol

- Prospective registration and before the work starts
- Registration helps avoids duplication, allows peer review and provision of other support
- Review protocols follow a highly structured format and their preparation follow a structured process

Systematic Reviews

Home About Articles Submission Guidelines

Editorial | Open Access | Published: 09 February 2012

Why prospective registration of systematic reviews makes sense

Lesley Stewart ✉ David Moher & Paul Shekelle

Systematic Reviews **1**, Article number: 7 (2012) | Cite this article

11k Accesses | **68** Citations | **19** Altmetric | Metrics

Abstract

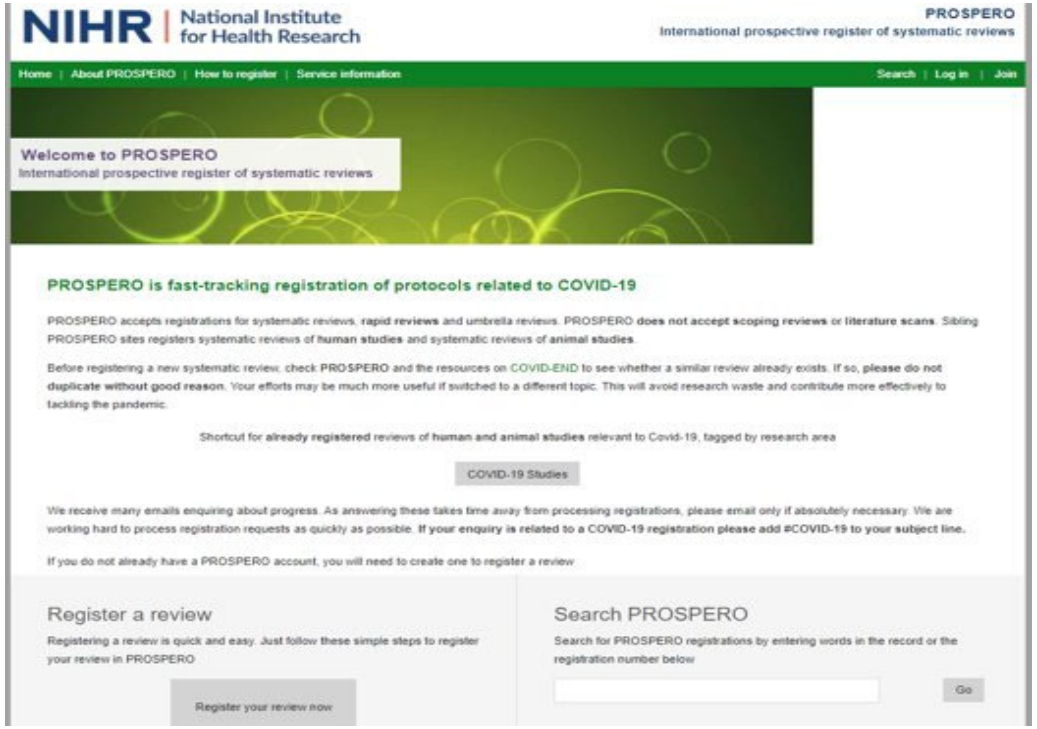
Prospective registration of systematic reviews promotes transparency, helps reduce potential for bias and serves to avoid unintended duplication of reviews. Registration offers advantages to many stakeholders in return for modest additional effort from the researchers registering their reviews.

Introduction

In this launch issue of *Systematic Reviews*, we publish a series of linked articles about prospective registration of systematic reviews. This is a topic which has received increasing attention in recent years, notably in the 2009 PRISMA guidelines for preferred reporting items for systematic reviews and meta-analyses [1] and the subsequent development [2] and

PROSPERO

Registration in PROSPERO requires provision of 22 data items, with the option to provide details of a further 18 items, and generally takes around 30 minutes to complete.



Nielsen et al. Systematic Reviews (2018) 7:232
https://doi.org/10.1186/s13643-018-0898-z

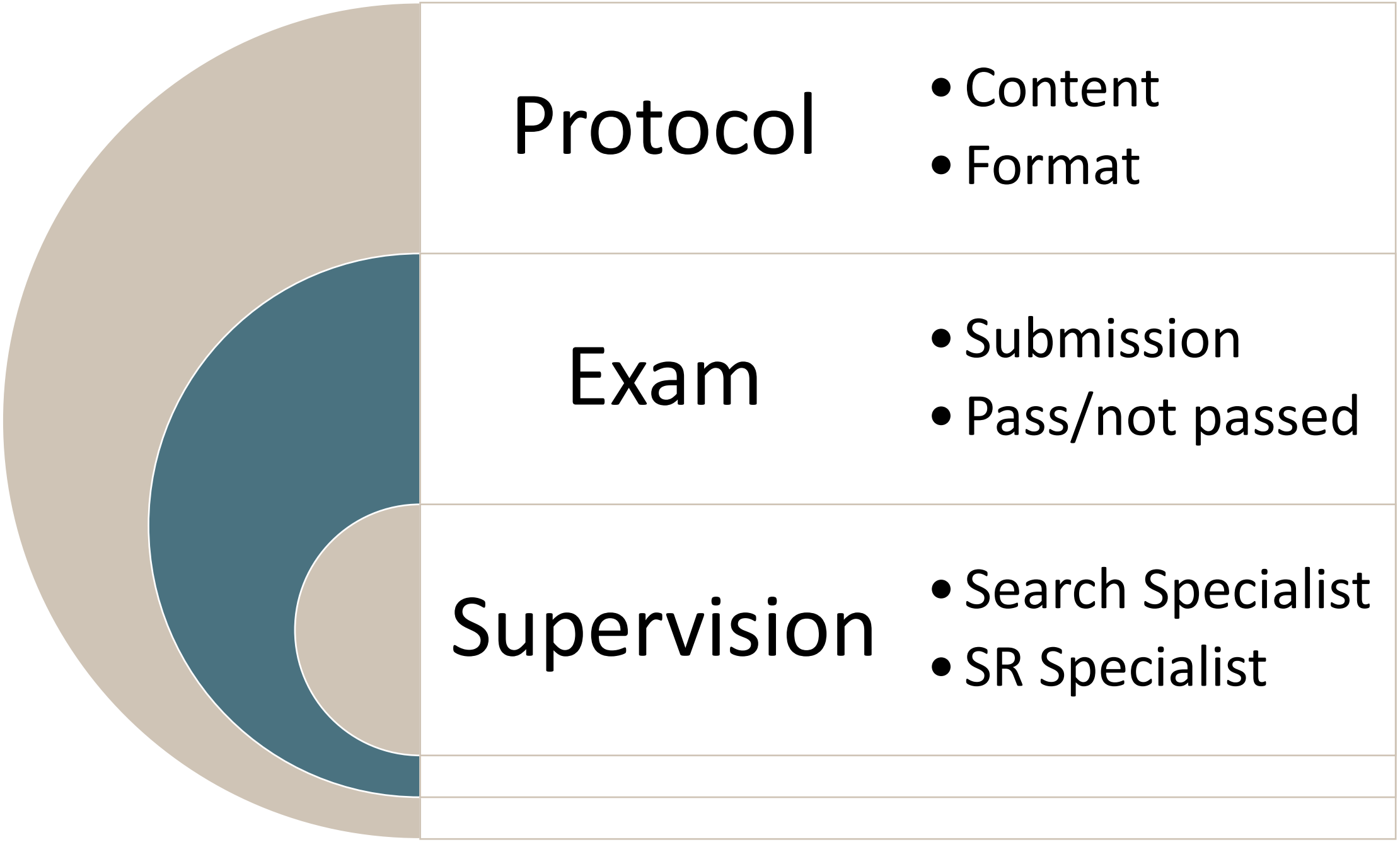
Systematic Reviews

PROTOCOL Open Access

Protocol for a systematic review and meta-analysis of research on the associations between workplace bullying and sleep

Morten Birkeland Nielsen[1,2*], Ståle Pallesen[2], Anette Harris[2] and Ståle Valvatne Einarsen[2]

Abstract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Exam

Content – max 10 pages

1. **Introduction**
    1. Background
    2. Description of the intervention
    3. Rationale
    4. Objectives
2. **Methods**
    1. Eligibility criteria
        1. Inclusion criteria
        2. Exclusion criteria
    2. Outcomes and prioritization
    3. Information sources
    4. Summary of search strategy
    5. Study records
        1. Data management
        2. Selection process
    6. Data extraction
    7. Risk of bias of included individual studies (Move to appendix if conducting a scoping review)
    8. Data synthesis (Move to appendix if conducting a scoping review)
    9. GRADE assessment (Move to appendix if conducting a scoping review)
3. **Timeline and resource use**
4. **References**
5. **Appendixes**
    1. Complete search strategy for one database
    2. Other as needed for example if conducting a scoping review

Checklist /template

- For quantitative studies
  - Equator Network - Prisma – P
  - Cochrane Handbook – Chapter 4
  - Institute of Medicine – Standards for systematic reviews (section 2.6)
- For qualitative studies
  - EPOC Qualitative Evidence Sythesis Template

PRISMA – P – quantitative

SMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended ress in a systematic review protocol*

n and topic	Item No	Checklist item
INISTRATIVE INFORMATION		
dentification	1a	Identify the report as a protocol of a systematic review
Jpdate	1b	If the protocol is for an update of a previous systematic review, identify as such
tration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
rs:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing ad corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
dments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as suc otherwise, state plan for documenting important protocol amendments
rt:		
lources	5a	Indicate sources of financial or other support for the review
sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
CODUCTION		
nale	6	Describe the rationale for the review in the context of what is already known
tives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, int comparators, and outcomes (PICO)
HODS		
ility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characterist considered, language, publication status) to be used as criteria for eligibility for the review
nation sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial grey literature sources) with planned dates of coverage
h strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, s repeated
records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

:g7647 doi: 10.1136/bmj.g7647 (Published 2 January 2015)

RESEARCH METHODS & REPORT

rred reporting items for systematic review -analysis protocols (PRISMA-P) 2015: elabor xplanation

hamseer[1], David Moher[1], Mike Clarke[2], Davina Ghersi[3], Alessandro Liberati (de icrew[5], Paul Shekelle[6], Lesley A Stewart[7], the PRISMA-P Group

tal Research Institute and University of Ottawa, Canada; [2]Queen's University Belfast, Ireland; [3]National Health and Me alia; [4]University of Modena, Italy; [5]London School of Hygiene and Tropical Medicine, UK; [6]Southern California Evidence- [7]Centre for Reviews and Dissemination, University of York, UK

PRISMA–P Administrative information

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol

PRISMA–P Introduction

INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

PRISMA–P Methods 8-12

METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications

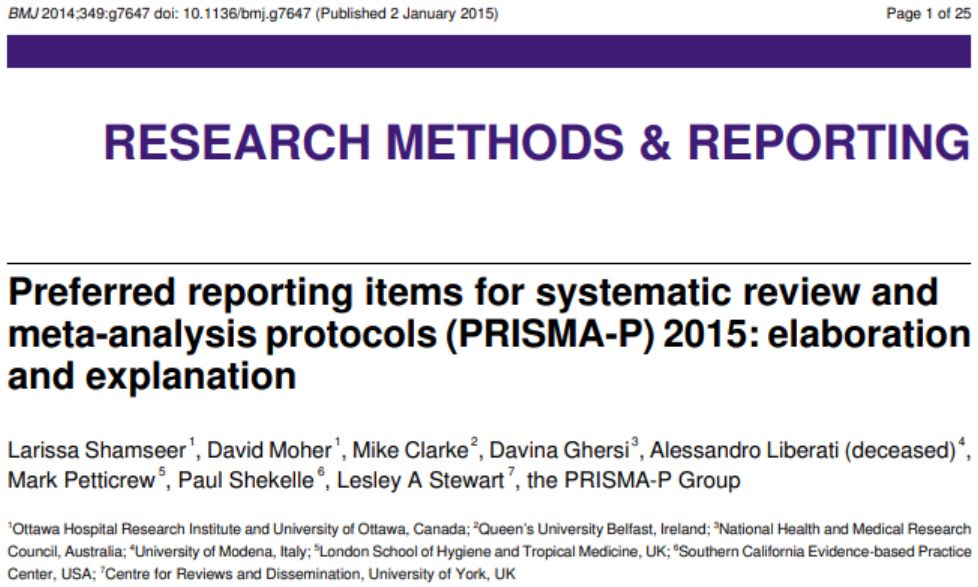
PRISMA–P Methods 13-17

Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe 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
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

Prisma- P check list and E&E

https://prisma-statement.org/Extensions/Protocols

- Checklist to see you have addressed all expected elements
- 17 items
- Do **not** fill in 2,3,4 and 5 for the exam
- Use the additional methods literature
- Remember to use references
- Check the elaboration and explanations for detailed information



BMJ 2014;349:g7647 doi: 10.1136/bmj.g7647 (Published 2 January 2015)

RESEARCH METHODS & REPORTING

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

Larissa Shamseer[1], David Moher[1], Mike Clarke[2], Davina Ghersi[3], Alessandro Liberati (deceased)[4], Mark Petticrew[5], Paul Shekelle[6], Lesley A Stewart[7], the PRISMA-P Group

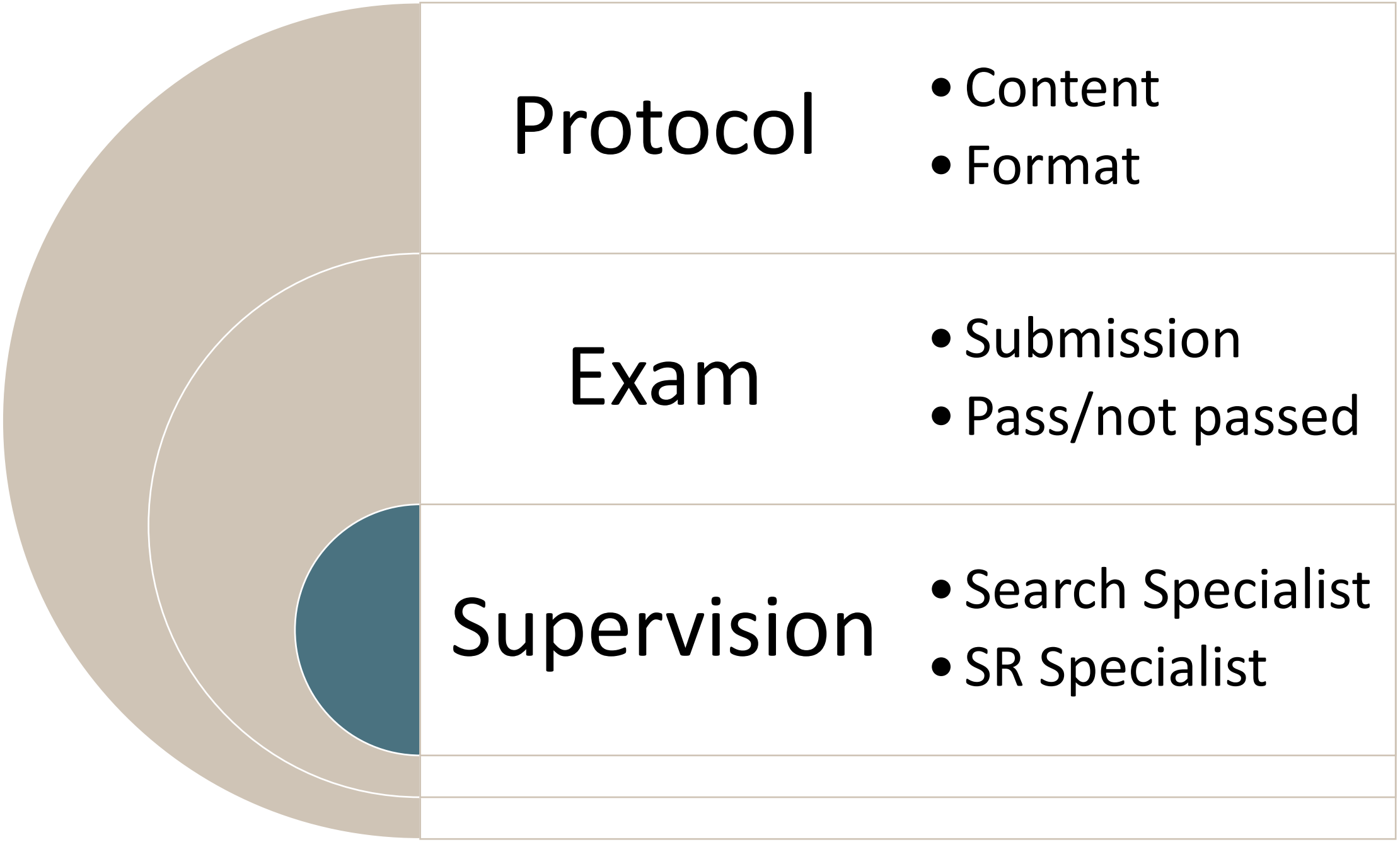
[1]Ottawa Hospital Research Institute and University of Ottawa, Canada; [2]Queen's University Belfast, Ireland; [3]National Health and Medical Research Council, Australia; [4]University of Modena, Italy; [5]London School of Hygiene and Tropical Medicine, UK; [6]Southern California Evidence-based Practice Center, USA; [7]Centre for Reviews and Dissemination, University of York, UK

Exam submission

- Lillebeth Larun will send you the exam
- To be handed in by October 31st 2022 at 1:00 pm
- We use Inspera – to **upload** your exam.
- https://ntnu.inspera.no

- Remember that you need to have **a user account and password at the NTNU system**, to log into Inspera (not your home institution)

- Questions: please contact Elin Yli Dvergsdal elin.y.dvergsdal@ntnu.no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Supervisor – Systematic Review Specialist

Your supervisor will contact you and suggest a time

Heather.Ames@fhi.no	Larsjorun.langoien@fhi.no
Christina	Israel
Lubna	Christoffer
Refilwe	Muneera
Monica	Mojtaba
Khadeja	Prabjhot

Supervisor – Systematic Review Specialist

Supervisor will contact you and suggest a time

UnniGopinathan@fhi.no	Lillebeth.Larun@fhi.no
Shimeles	Maria
Mina	Nora
Attiqa	Yamikani
Ricardo	Mojdeh
Brian	

Search supervision

Marit Johansen and Ingvild Kirkehei

- You will recieve an e-mail from Doodle where you can sign up for one supervision hour with Marit or Ingvil

After the exam

- Create your team
- Revise your protocol with your team
- Publish/register your protocol
- Write your systematic review!

https://www.youtube.com/watch?v=QUW0Q8tXVUc