

Questionable research practices in clinical trials

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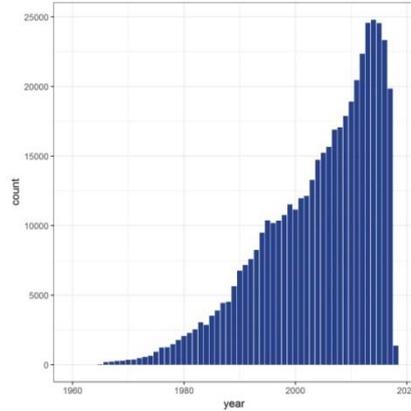
Christiaan Vinkers

Quality of trials



Figure 2.1 Evidence hierarchy: levels of evidence for different EBP questions.

Source: <https://nursekey.com/fundamentals-of-evidence-based-nursing-practice/>



Base of EBM

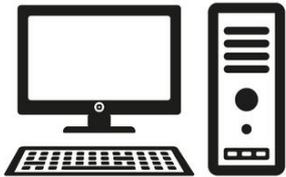
RCTs per year

quality

Methods

1

**download
RCTs**



2

extract information



Determinants

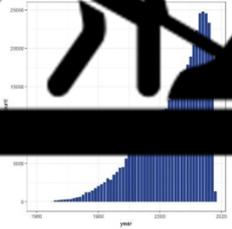
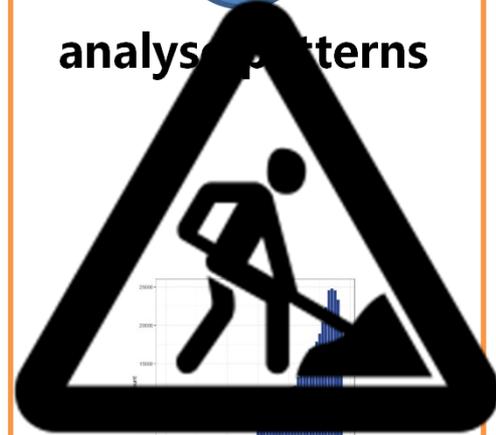
authors
journal
institute
trial

Outcomes

power
risk of bias
statistical errors
pre-registration

3

analyse patterns



Outcomes at a glance

Pre-registration ClinicalTrials.gov

Study power

- obtained sample size / planned sample size

Statistical errors

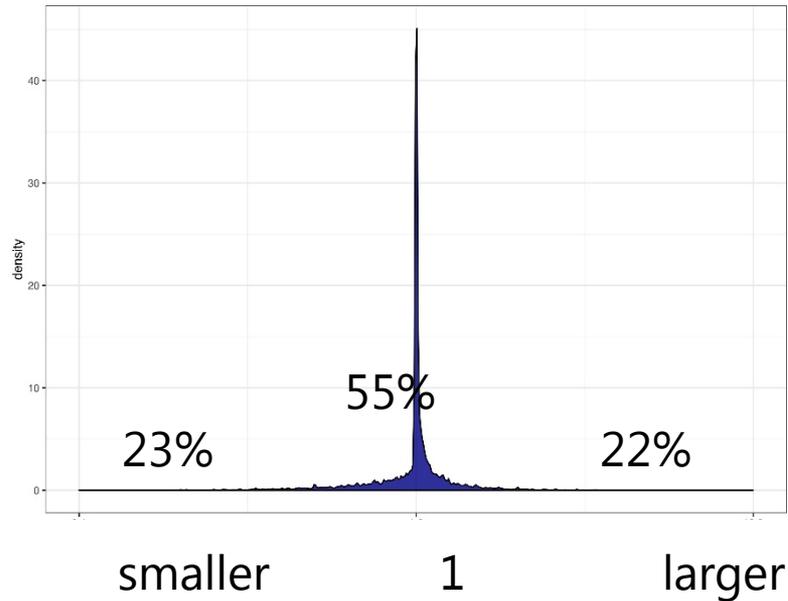
- StatCheck package in R
- Algorithm by Georgescu & Wren, 2018

Risk of bias

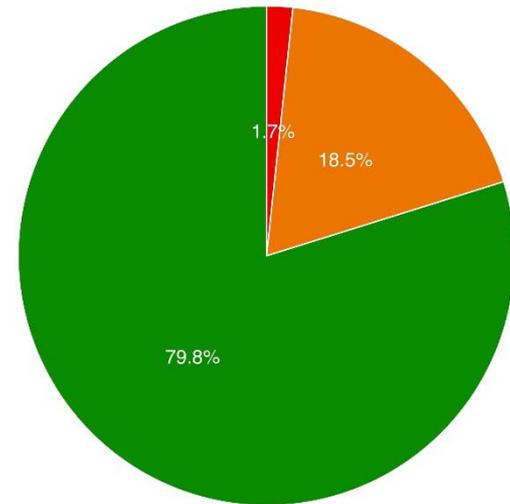
- RobotReviewer

Outcomes at a glance

sample size / planned size



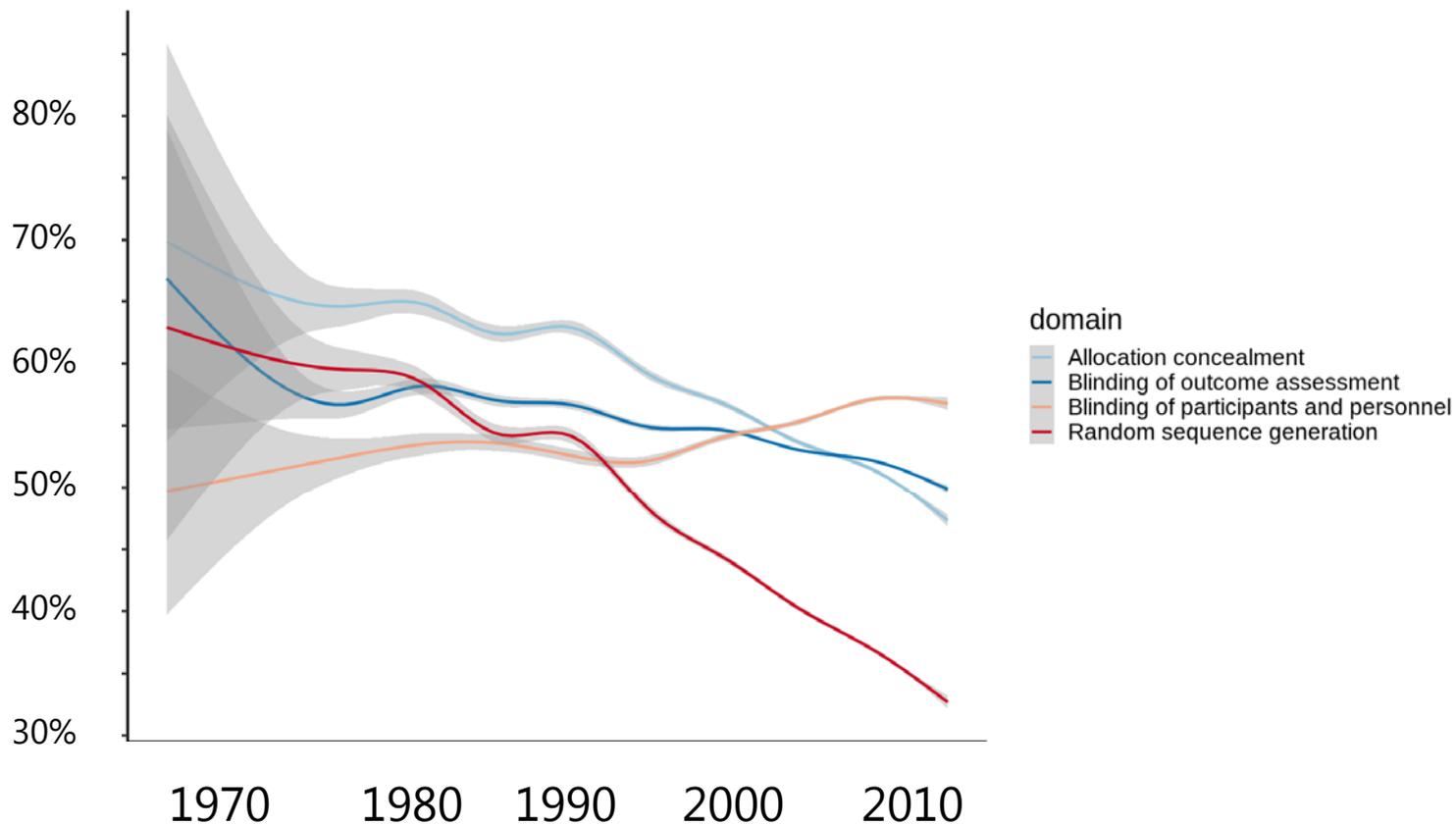
statistical errors



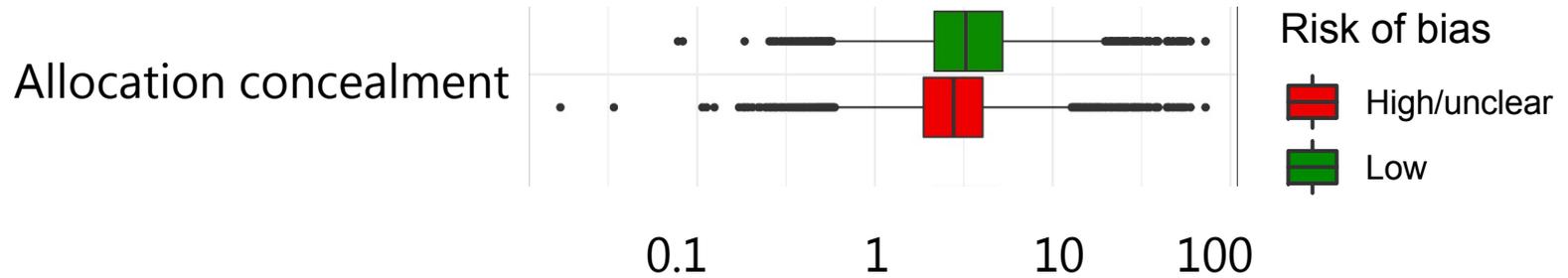
Outcomes at a glance



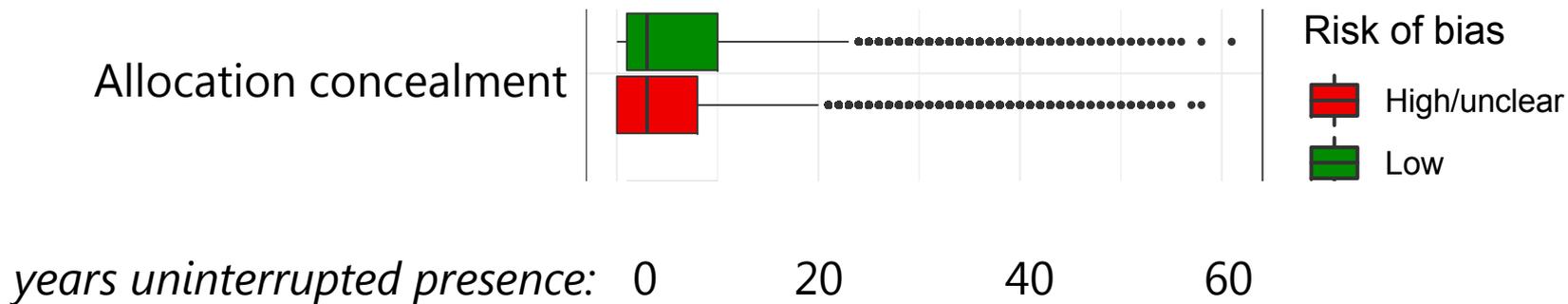
Probability
of
bias



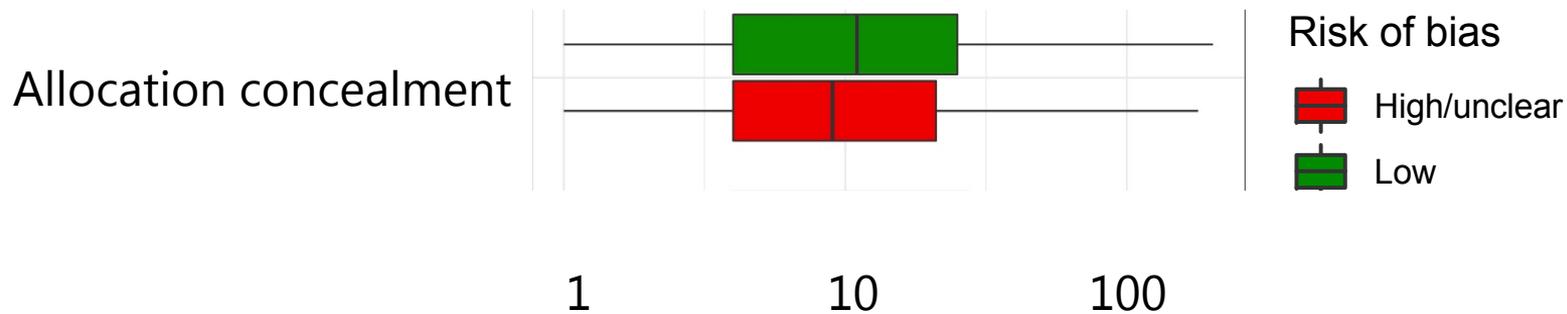
Risk of Bias & journal IF



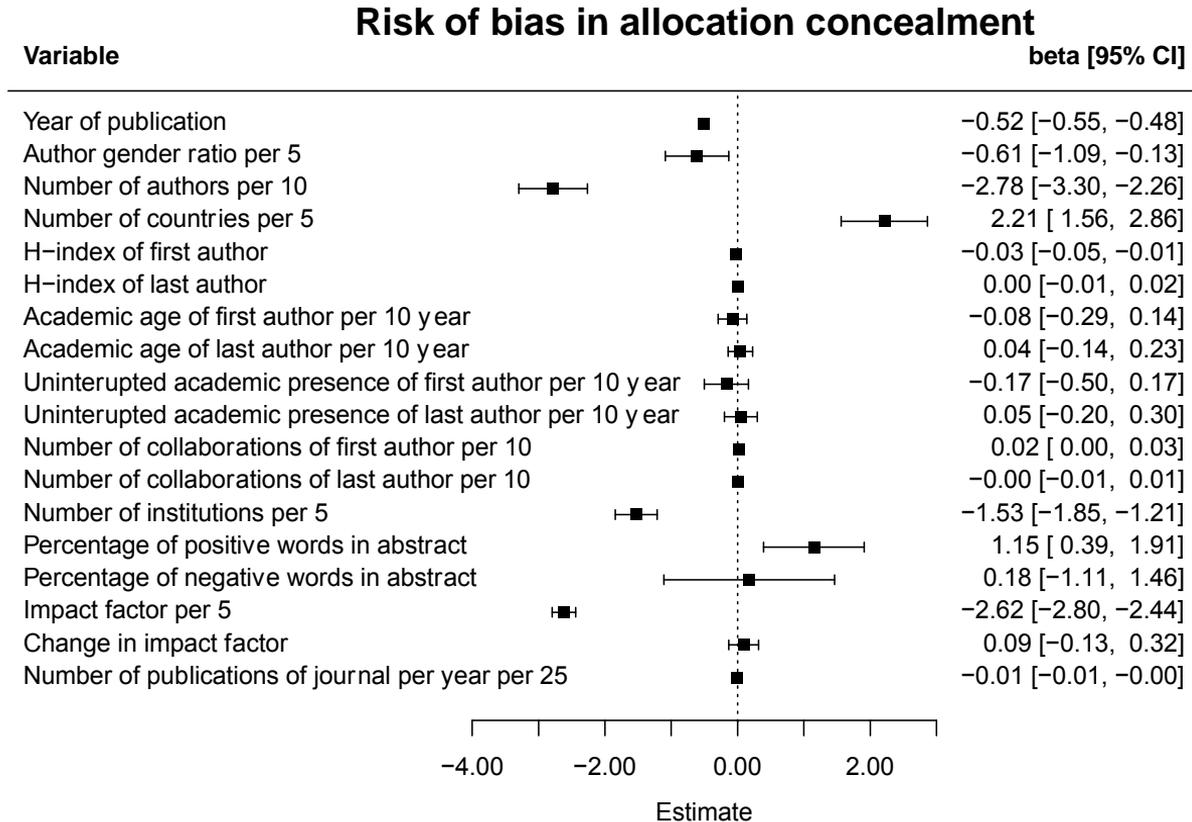
Risk of Bias & first author presence



Risk of Bias & first author H-index



Risk of allocation concealment - Multivariable model

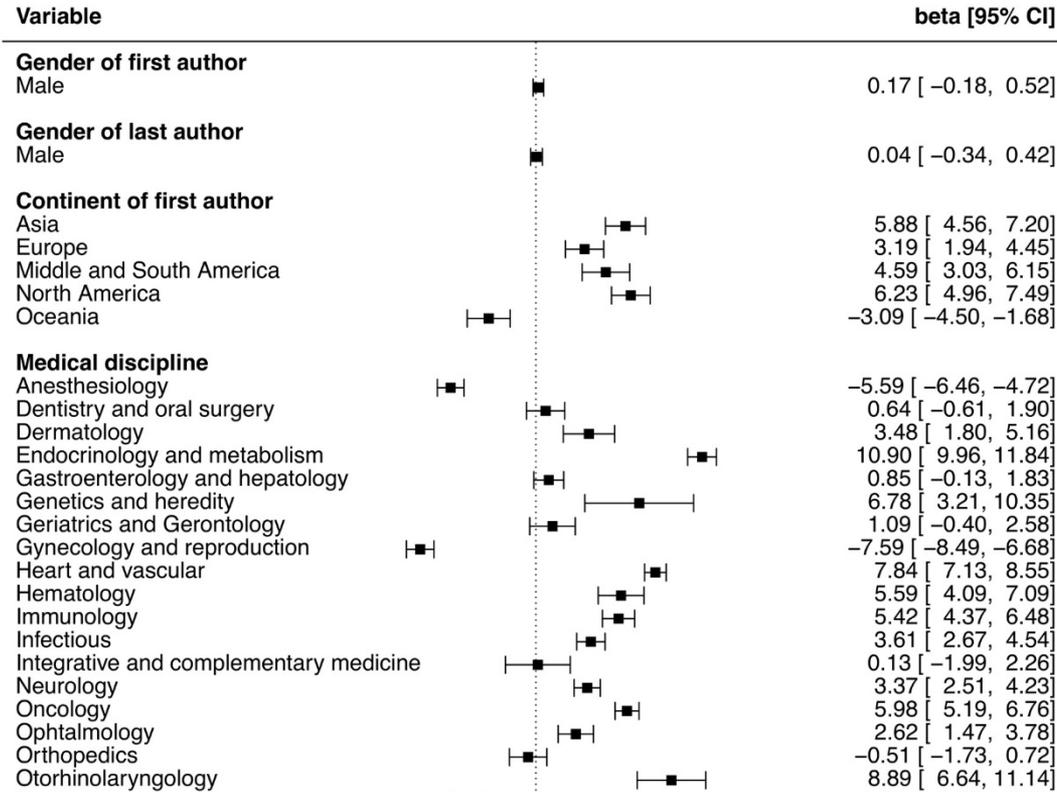


Selection RC

- Year: -0.5
- N authors: -2.8 per 10
- N instit.: -1.5 per 5
- IF -2.6 per 5

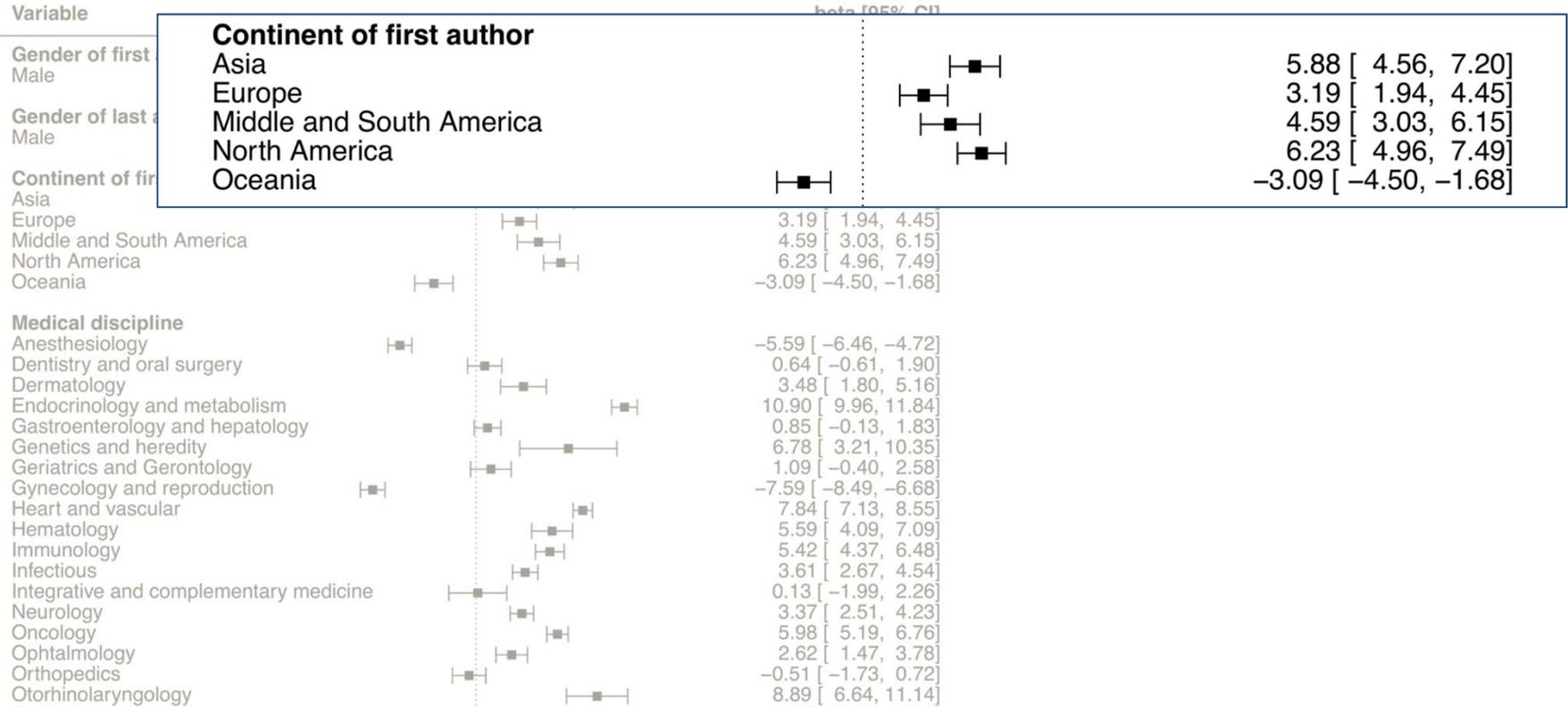
Risk of allocation concealment - Multivariable model

Risk of bias in allocation concealment

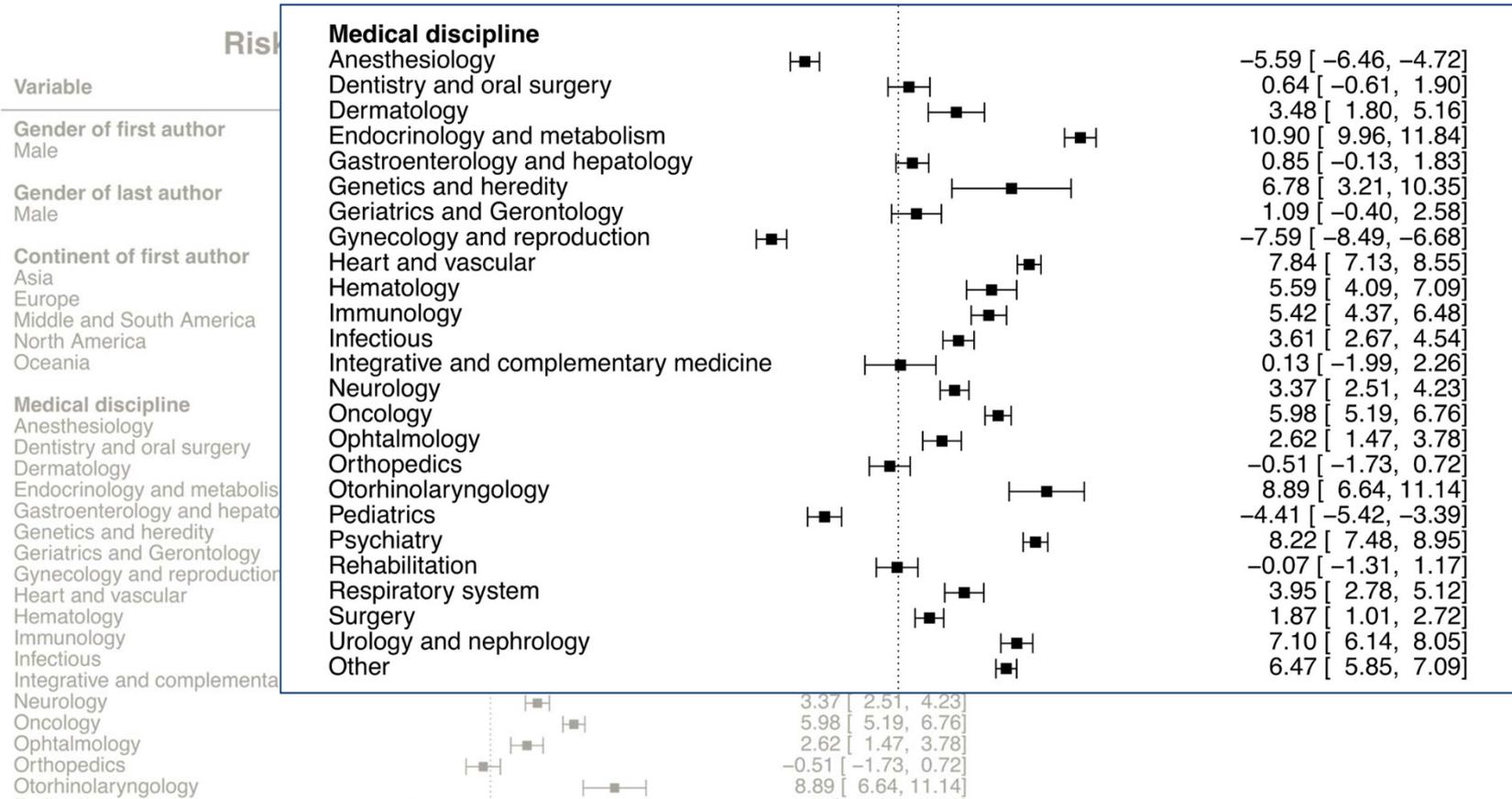


Risk of allocation concealment - Multivariable model

Risk of bias in allocation concealment



Risk of allocation concealment - Multivariable model



Summary

1. 20% does not reach planned sample size
2. 2% presents statistical significance errors
3. Risk of Bias decreased over time
4. Factors associated to lower RoB allocation concealment:
 1. year of publication
 2. number of authors
 3. number of institutions
 4. journal impact factor
 5. continent first author
 6. journal category
 7. publishing with a large publisher

Discussion

Work in progress

Decreasing RoB probability over time

? Better reporting or better trials

Number of authors & institutions

? Collaborations improve quality

Journal impact factor

? High IF journals ~ higher standards reporting

Thank you!

Core team



Collaborators

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Daniele Fanelli
David Moher
Rob Scholten
Paul Glasziou



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