



# Journal Club

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# Indicators of questionable research practices were identified in 163,129 randomized controlled trials

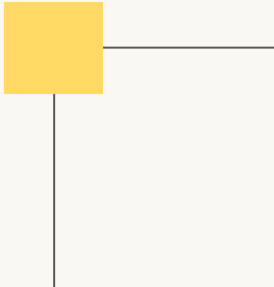
Johanna AD, Pauline H, Herm JL, et al.  
Journal of Clinical Epidemiology,  
2023, 23-32

# Introduction



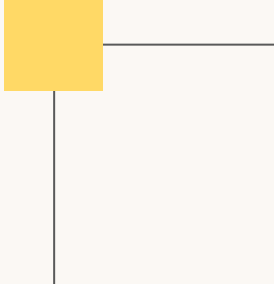
# Questionable research practices



- Questionable research practices (QRPs)
    - Design, analytic, or reporting practices that have been questioned because of the potential for the practice to be employed to present bias evidence in favor of an assertion
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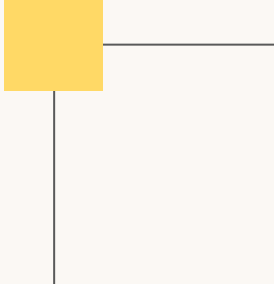
# Questionable research practices



- Example of QRPs
    - Selective reporting
    - p-hacking
    - HARKing (Hypothesizing after the results are known)
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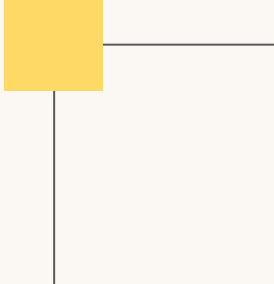
# Questionable research practices



- Evidence exists for some indicators of QRP
  - For example, associations have been reported between
    - Journal impact factor *and* risk of bias
    - Author experiences *and* effect sizes
    - Study quality *and* the continent of origin of authors
- 

# Questionable research practices



- Previous studies focus on one specific QRP and explored a limited set of indicators in small datasets
  - Furthermore, time trends in quality indicators of RCTs have been described before in large datasets, including the dataset used in the present article.
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# Objective

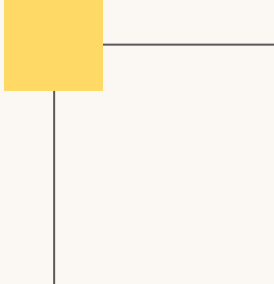
- Aim to validate existing and identify new indicators of QRPs in RCTs
- They investigated QRPs concerning
  - Risk of bias
  - Modifications in primary outcomes
  - The ratio of achieved sample size to planned sample size
  - Statistical discrepancy

- Relate to quality of the study and quality of reporting
- Essential element of responsible research



# Objective



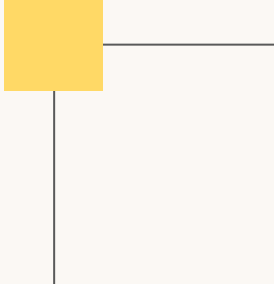
- They focused on demographic and bibliometric indicators
    - Characteristics of the author team
    - Trial/publication and journal
    - Available during different phases of a project
      - During trial registration
      - When a study is submitted for publication
      - After a study is published
- 

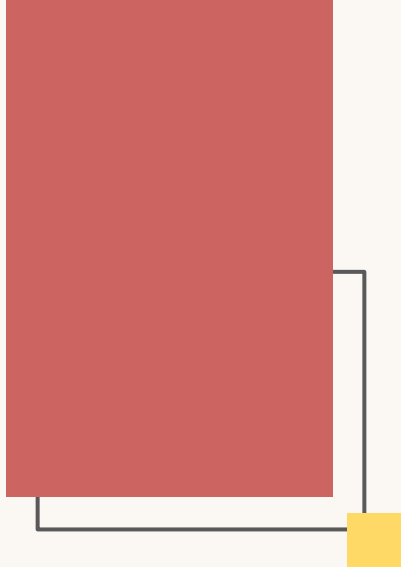
# Methods



# Methods



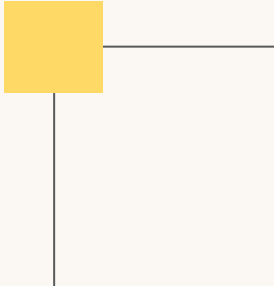
- Identification of RCTs
  - Data collection of QRPs
  - Data collection of indicators
  - Statistical analyses
- 

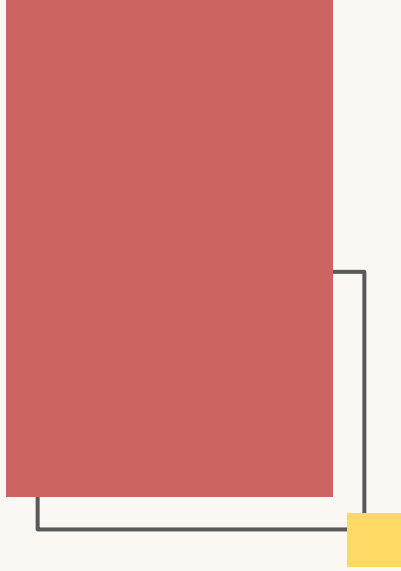


# Identification of RCTs

# Identification of RCTs



- They searched PubMed using the Entrez API on November 17, 2017 to identify studies with publication type RCT
  - Exclude
    - Non-randomized, animal, pilot and feasibility studies
    - Not English
    - Published before 1996 (CONSORT statement was published)
- 



# Data collection of QRPs

# Data collection of QRPs

- Assessed the following four QRPs
  - Risk of bias
    - The probability of bias
      - Random sequence generation
      - Allocation concealment
      - Blinding of participants and personnel
      - Blinding of outcome assessment

- Robot reviewer assess the probability that a study has bias rather than dichotomizing it into high or low risk of bias

# Data collection of QRPs

- Assessed the following four QRPs
  - Modifications in primary outcome measures
    - Based on comparing first and final versions of the public trial registration records from ClinicalTrials.gov

- Addition and deletions of complete outcome measures were extracted



# Data collection of QRPs



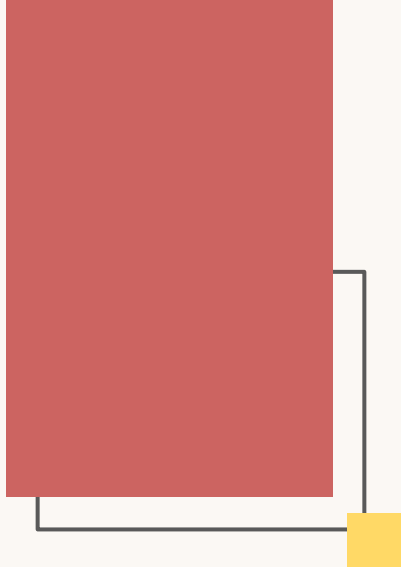
- Assessed the following four QRPs
  - The ratio of achieved sample size compared to what was planned



# Data collection of QRPs

- Assessed the following four QRPs
  - Statistical discrepancy
    - For which we compared the reported P value and actual P value of the intervention effect estimate calculated from other reported information

- **Inconsistency p value** = difference  $\geq 0.01$
- **Statistical discrepancy** = every consistency where the adjusted p value crosses the level of 0.05 compared to the original p value



# Data collection of indicators

# Data collection of indicators

## Author team

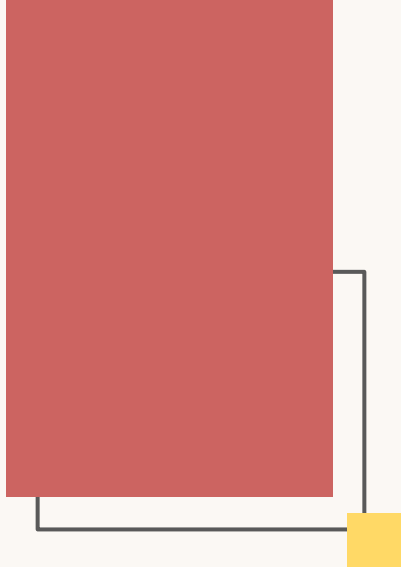
- Gender of first and last author [11,13,28,29] (<https://genderize.io/>)
- Proportion of female authors in the author team
- Total number of authors [11,30]
- Continent of first and last author [12,13,31]
- Number of countries to which the author team is affiliated
- Hirsch-index of first and last author in the year before publication [4,11,30]
- Academic age of first and last author (i.e., number of years between the trial publication and first publication by this author) [11,13,32]
- Uninterrupted presence of first and last author (i.e., the number of years the author has published at least one article in sequentially without interruption) [13]
- Number of collaborations of the first and last author (i.e., total number of co-authorships until year of publication)
- Number of institutions represented in the author team [12]
- Ranking of institution of first and last author in the Academic Ranking of World Universities ([www.shanghairanking.com](http://www.shanghairanking.com))

## Trial/publication

- Trial registration
- Financial support (industrial, other, and none) [11,12,31,33]
- Year of publication
- Conflict of interest
- Mentioning of the CONSORT Statement
- Positive and negative word frequencies in abstract [34]
- Number of words and number of names mentioned in acknowledgments

## Journal

- Medical field [12,33]
- Journal impact factor in the year before publication [33,35,36]
- Impact factor change compared to previous year
- Number of publications of the journal per year
- Journal publisher
- Continent of journal



# Statistical analyses

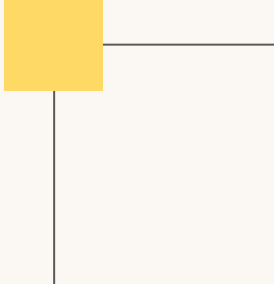
# Statistical analyses



- Associations between *indicators* and *outcomes* were assessed using univariable and multivariable regression model
- Three multivariable regression models were fitted per outcome
  - A full model including all indicators
  - A reduced model including indicators available upon journal submission of article but before publication
  - A reduced model including indicators available upon trials registration but before trial is completed

# Statistical analyses



- Beta regression model
    - Probability of bias
  - Logistic regression model
    - Modification in primary outcomes
    - Statistical discrepancy
  - Linear regression
    - Log-transformed ratio of achieved to planned sample size
- 

# Results





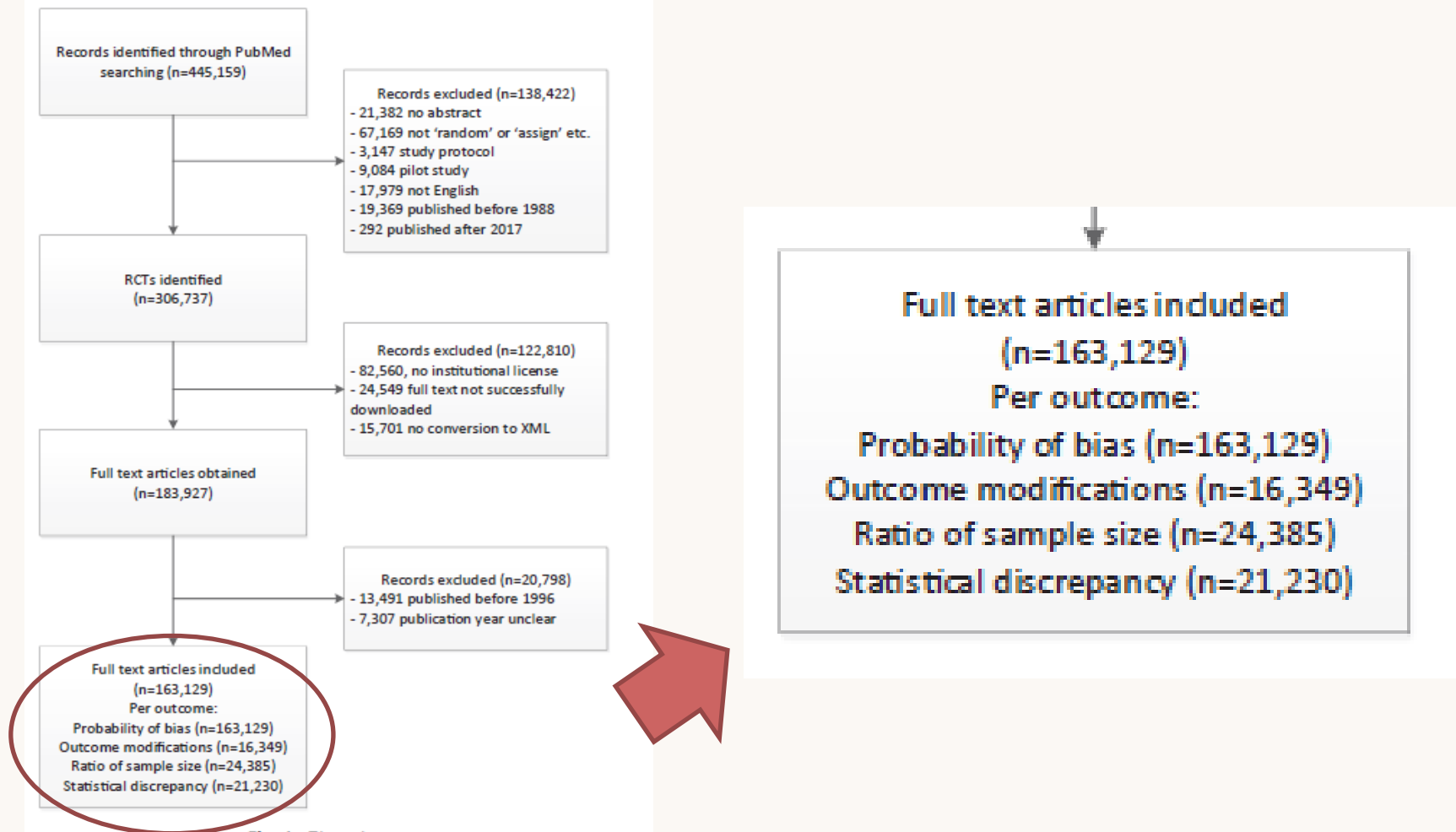


Fig. 1. Flow chart.

**Table 1.** Descriptive statistics of questionable research practices

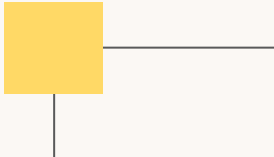
Questionable research practice	Value <sup>a</sup>	Number of references for which this outcome was available
Probability of bias (as assessed by Robot Reviewer <sup>b</sup> )		
Probability of bias in randomization	0.43 (0.18–0.59)	163,129
Probability of bias in allocation concealment	0.59 (0.40–0.71)	163,129
Probability of bias in blinding of patients and personnel	0.63 (0.40–0.75)	163,129
Probability of bias in blinding of outcome assessment	0.55 (0.44–0.64)	163,129
Modifications in primary outcome in public registration	3,615/16,349 (22.1% [95% CI 21.5–22.8])	16,349
Ratio of achieved compared to planned sample size	1 (0.98–1.04)	24,385
Statistical discrepancy	370/21,230 (1.7% [95% CI 1.6–1.9])	21,230

<sup>a</sup> Values are *N* (% [95% CI]) or median (25th–75th percentile).

<sup>b</sup> Robot Reviewer assesses the probability that a study has bias rather than dichotomizing it into high or low risk of bias. We here present the median probabilities. See methods section for definitions of questionable research practices.

# Risk of bias



- A higher proportion of female coauthors
  - Publications with the last author from Oceania
  - A more recent publication year
  - Reporting a trial registration number
  - Mentioning of CONSORT
  - Higher journal impact factor
  - Publications from a large publisher
- 
- Associated with a lower probability of bias for at least three of four domains

# Modifications in the primary outcome

- Publication with the last author from North America or Oceania
- Higher H-index of the first and last authors
- Having more institution

- Associated with a higher risk of modifications in the outcome

# Ratio of achieved compared to planned sample size



- A higher number of countries involved were associated with a higher ratio of achieved sample size
- Having more institutions involved was associated with a lower ratio



# Statistical discrepancy



- Publications reported a trials number were associated with a lower risk of statistical discrepancy

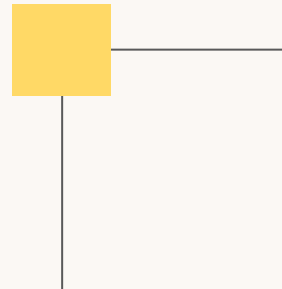
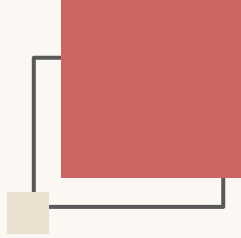


# Discussion



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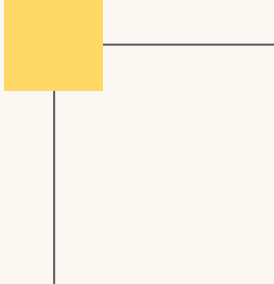
- They investigated the association between trial characteristics and QRPs and found associations with QRPs for many of the studied indicators





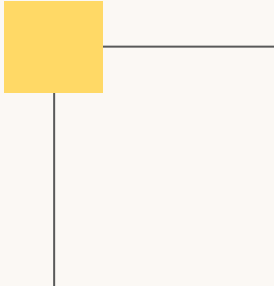
# Discussion



- The most robust indicators that were consistently associated with a lower risk of several QRPs included
    - A higher journal impact factor
    - A journal from a large publisher (such as Elsevier or Springer)
    - Having a trial registration
    - Mentioning of CONSORT reporting guideline
- 

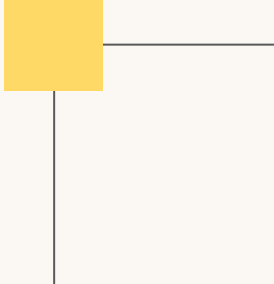
# Discussion



- Although it is not possible to draw conclusions about causal relations based on this study, the results might inform future strategies to identify those RCTs at a high risk of QRPs.
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# Limitation



- They have not manually screened all included and excluded articles
  - The automated data collection might have led to misclassification of indicators and QRPs
  - Not able to collect information on the quality of reporting, defined as adherence to the CONSORT reporting guideline
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# Thanks!

Do you have any questions?



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