

ClinicalTrials.gov

analysis of changes in primary outcome

Herm Lamberink
University Medical Center Utrecht

Research team



Anneke Damen



Lotty Hooft



Pauline Heus



**Michelle
Lancee**



Herm Lamberink



Wim Otte



Joeri Tijdink



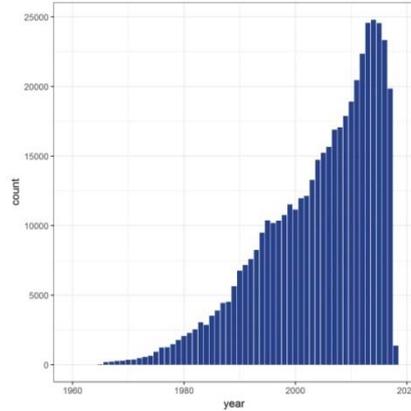
Christiaan Vinkers

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

PubMed



2

extract information
link to CT.gov



ClinicalTrials.gov

3

analyse patterns of
protocol changes



NIH U.S. National Library of Medicine
ClinicalTrials.gov archive

History of Changes for Study: NCT02988050
Conscious Sedation for Epilepsy Surgery
[Latest version \(December 8, 2016\) on ClinicalTrials.gov](#)

Study Record Versions

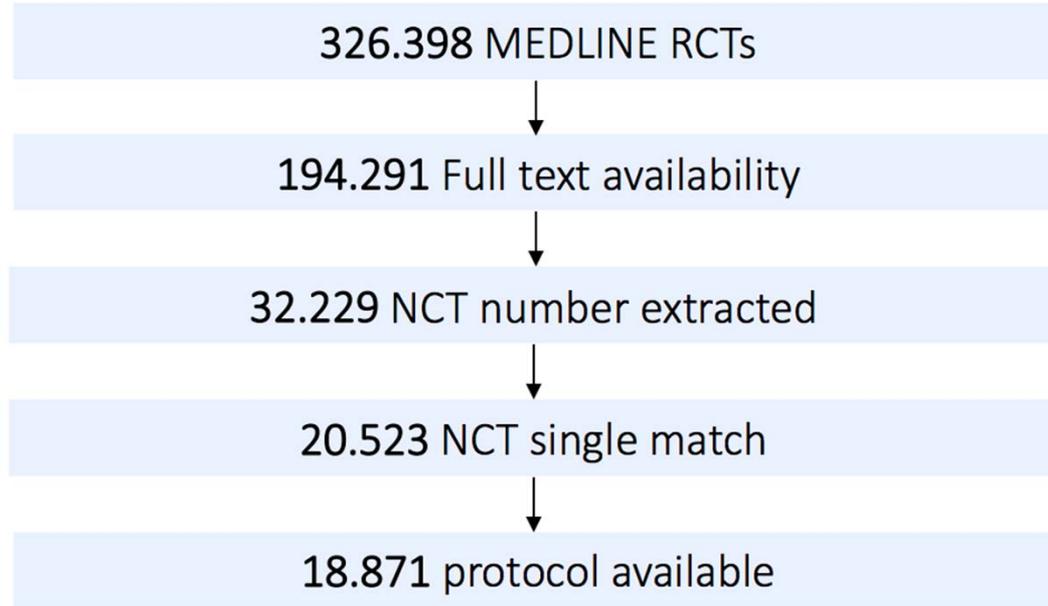
Version	A	B	Date	Changes
1	<input checked="" type="radio"/>	<input checked="" type="radio"/>	December 8, 2016	Nothing (earliest Version on record)

Compare Comparison Format: Merged Side-by-Side

- A study version
- Select two versions
- Choose either
- how the text
- only applies
- "Comp
- a version
- a version
- The
- con
- Have
- status of

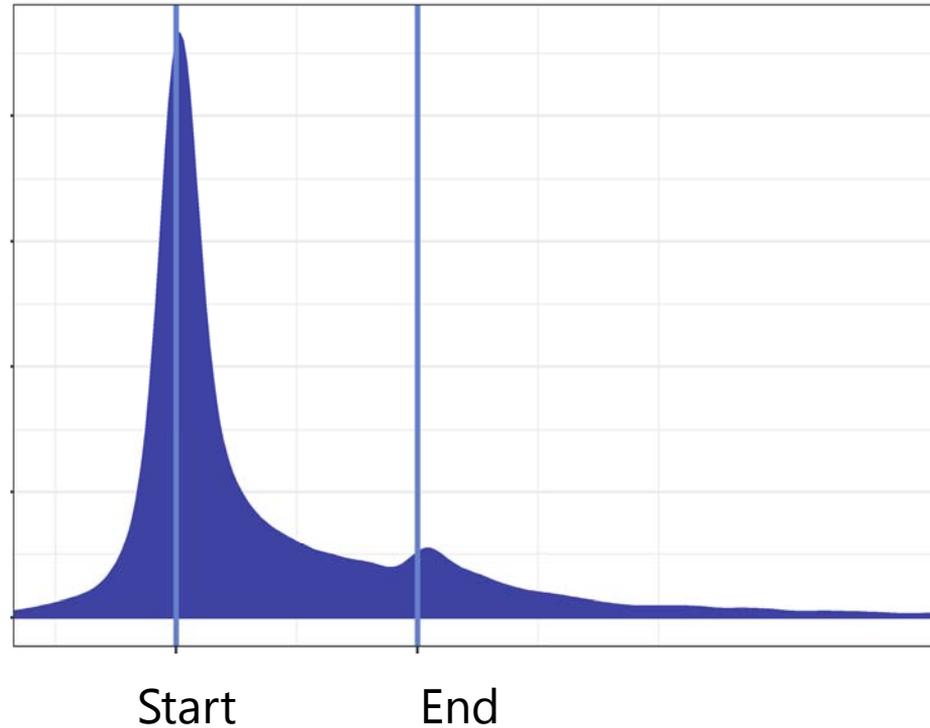


Inclusions



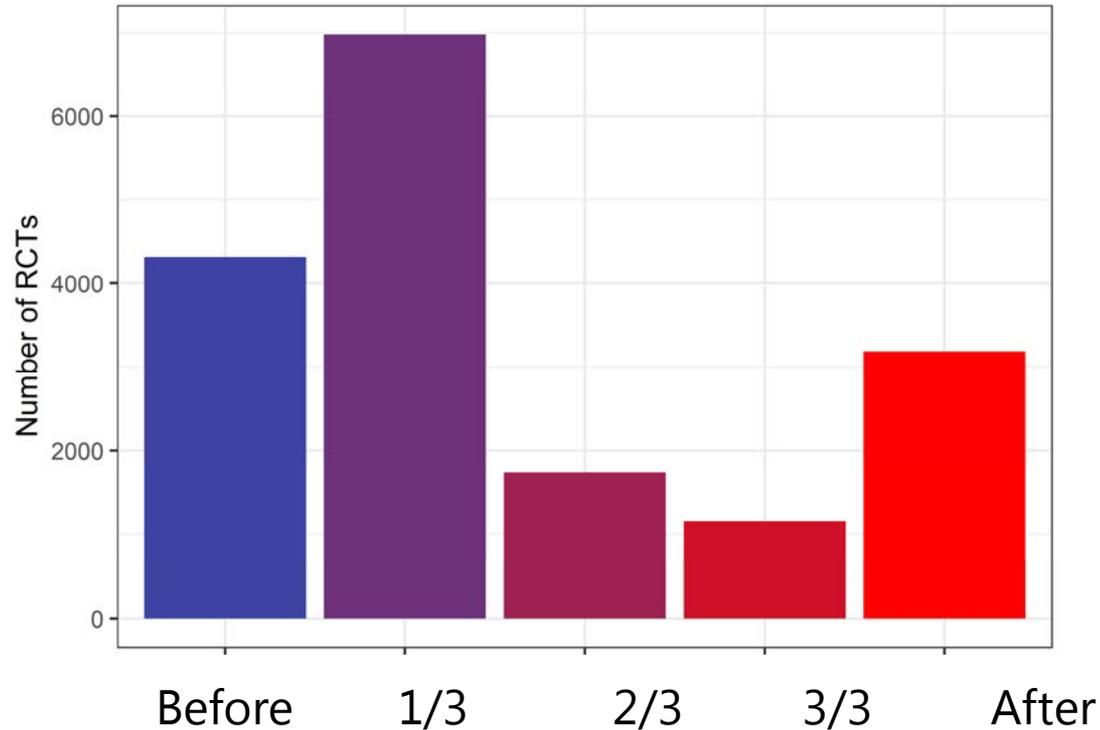
Finding 1

Most studies upload protocol around the starting date



Finding 1

Most studies upload protocol around the starting date



Finding 2

Primary outcome changed in one of three studies

any change: 31%

added:

6%

deleted:

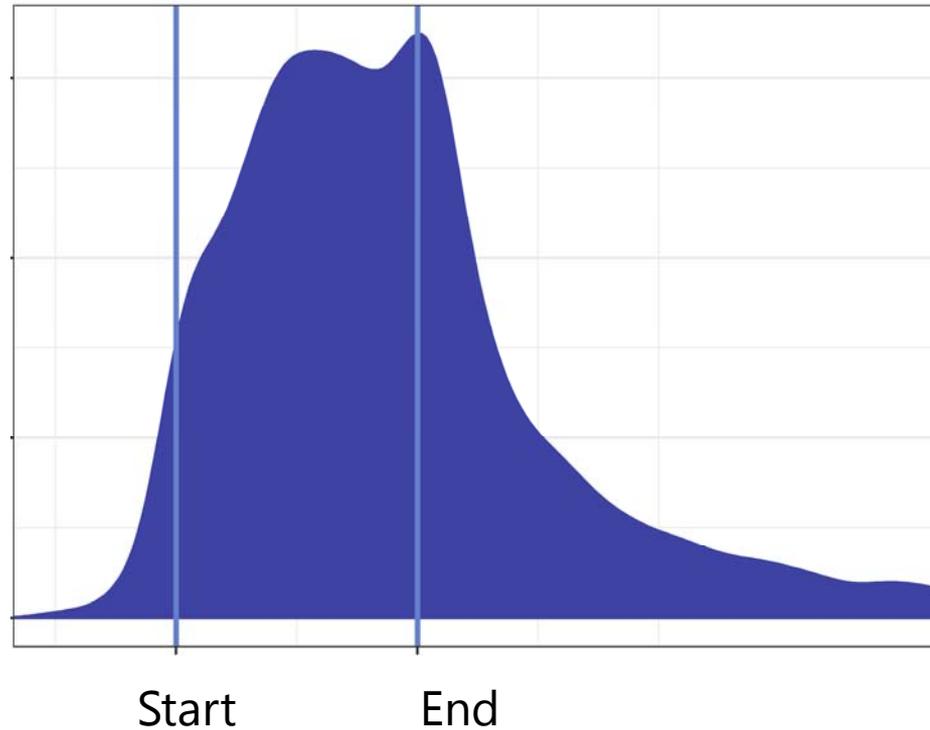
3%

changed:

26%

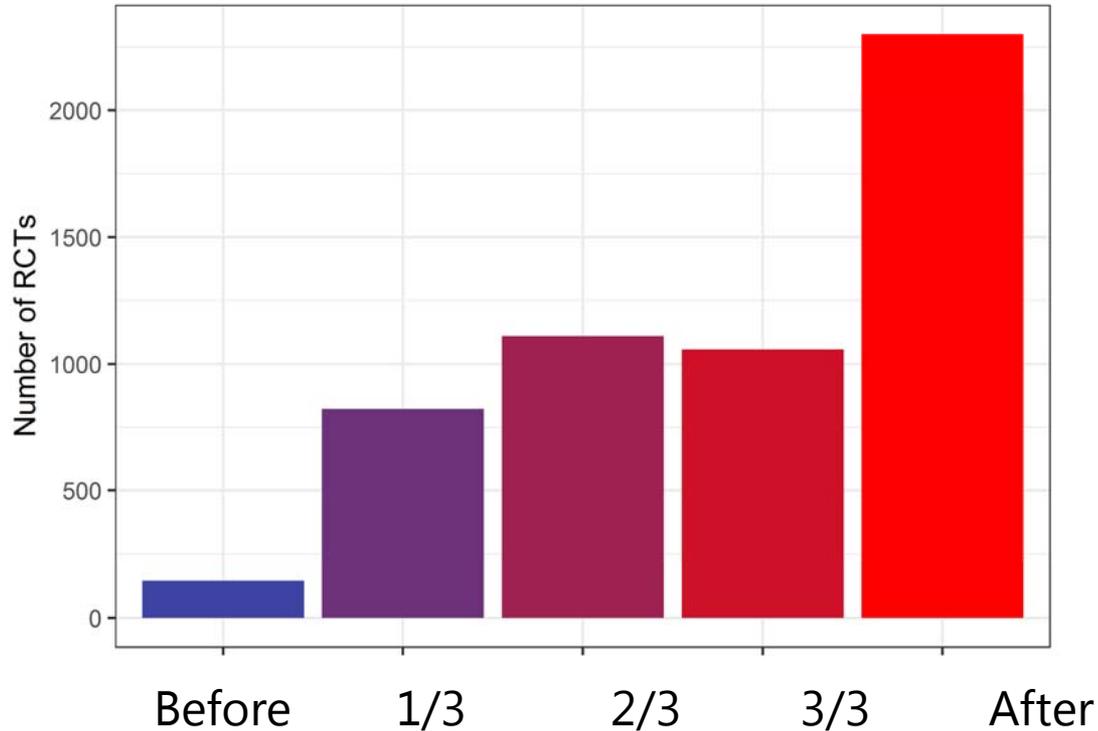
Finding 3

Most changes in primary outcome are made around the end



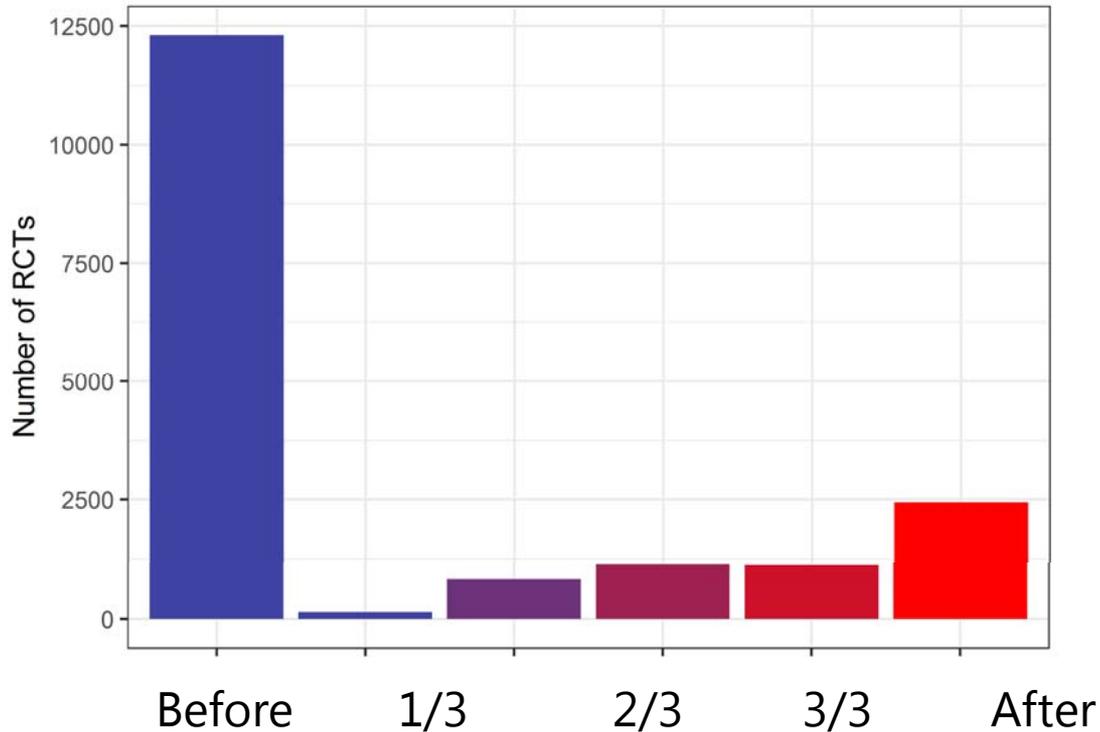
Finding 3

Most changes in primary outcome are made around the end



Finding 3

Most changes in primary outcome are made around the end



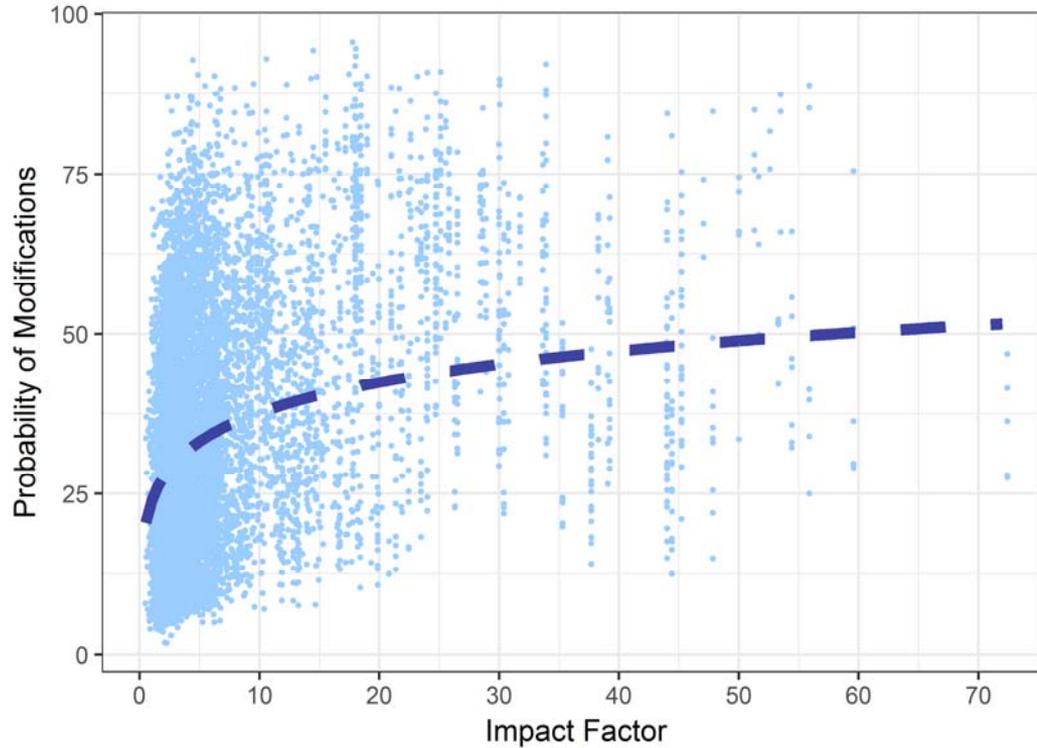
Finding 4

Year, phase, funding, results, journal category & IF matter

	OR	[95% CI]
Year study start	0.80	[0.79, 0.82]
Phase 1,2,4 vs 3	0.75 to 0.89	
Results posted on CT.gov	1.59	[1.44, 1.76]
Journal IF (log2 scale)	1.22	[1.17, 1.27]
Journal category vs anesthesiology	0.27 to 1.45	
Registered in WHO trial registry	1.08	[0.88, 1.31]

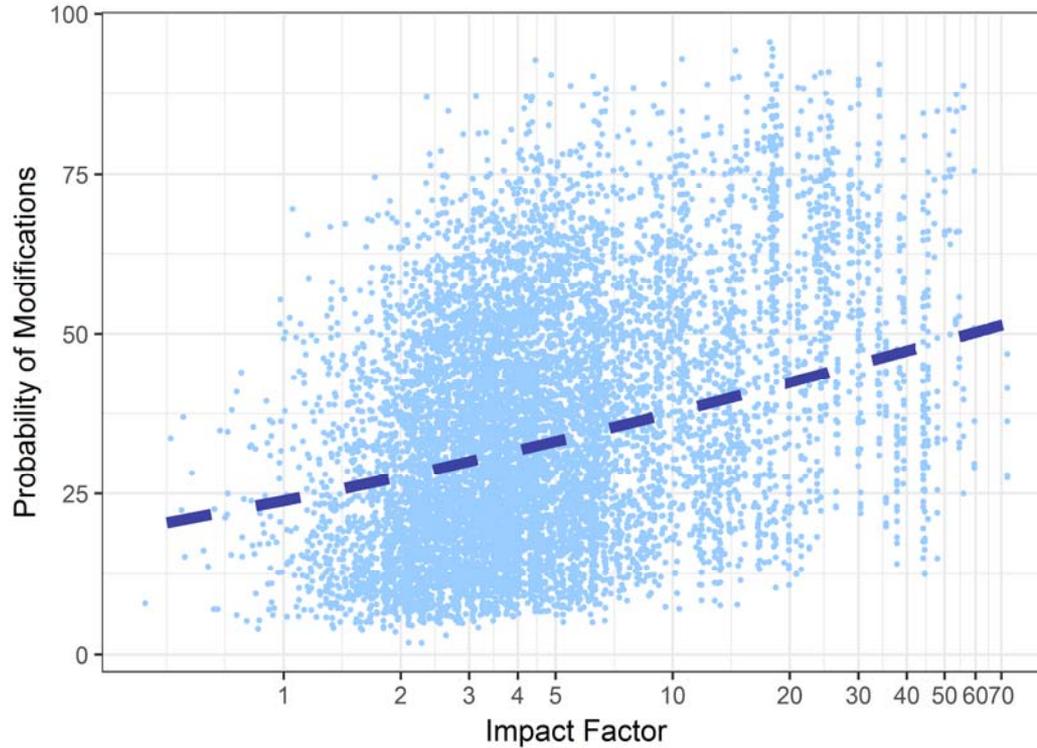
Finding 5

Higher impact factor is associated with more changes



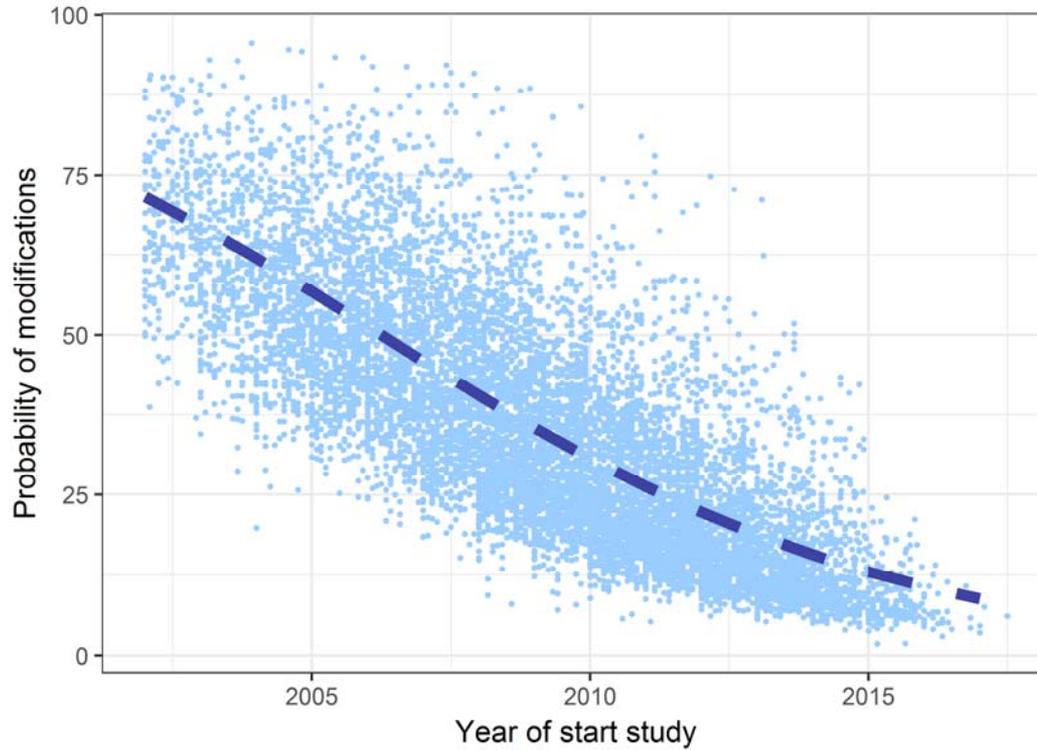
Finding 5

Higher impact factor is associated with more changes



Finding 6

Less changes are made over time



Summary

1. 31% of studies changed the primary outcome
2. mostly after trial completion
3. higher journal IF – more changes
4. later trials – less changes

Discussion

- amendments not necessarily misconduct
- amendments not necessarily questionable
- only published trials

Discussion

Relation to higher IF

? quality journals stricter

? potential questionable practice from researchers

Time trends

? better pre-registration practices

Thank you!

Core team



Anneke Damen



Pauliene Heus



Herm Lamberink



Joeri Tijdink



Lotty Hooft



Wim Otte



Christiaan Vinkers

Collaborators

Lex Bouter

Daniele Fanelli

David Moher

Rob Scholten

Paul Glasziou



supported by



grant number 445001 002