Selective outcome reporting in psychotherapy for depression

Clara Miguel
Eirini Karyotaki
Pim Cuijpers
Ioana A. Cristea

Evaluating interventions

Meta-analyses: gold-standard for examining effects

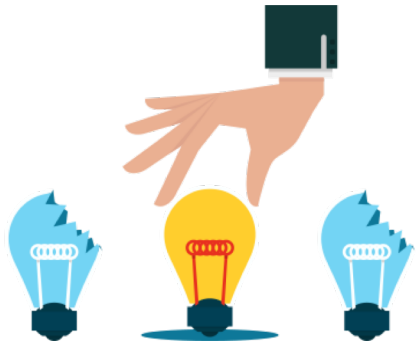
Potential sources of bias:

- Low quality of RCTs
- Researcher allegiance
- Publication bias, etc.

OVERESTIMATION OF TREATMENT EFFECTS

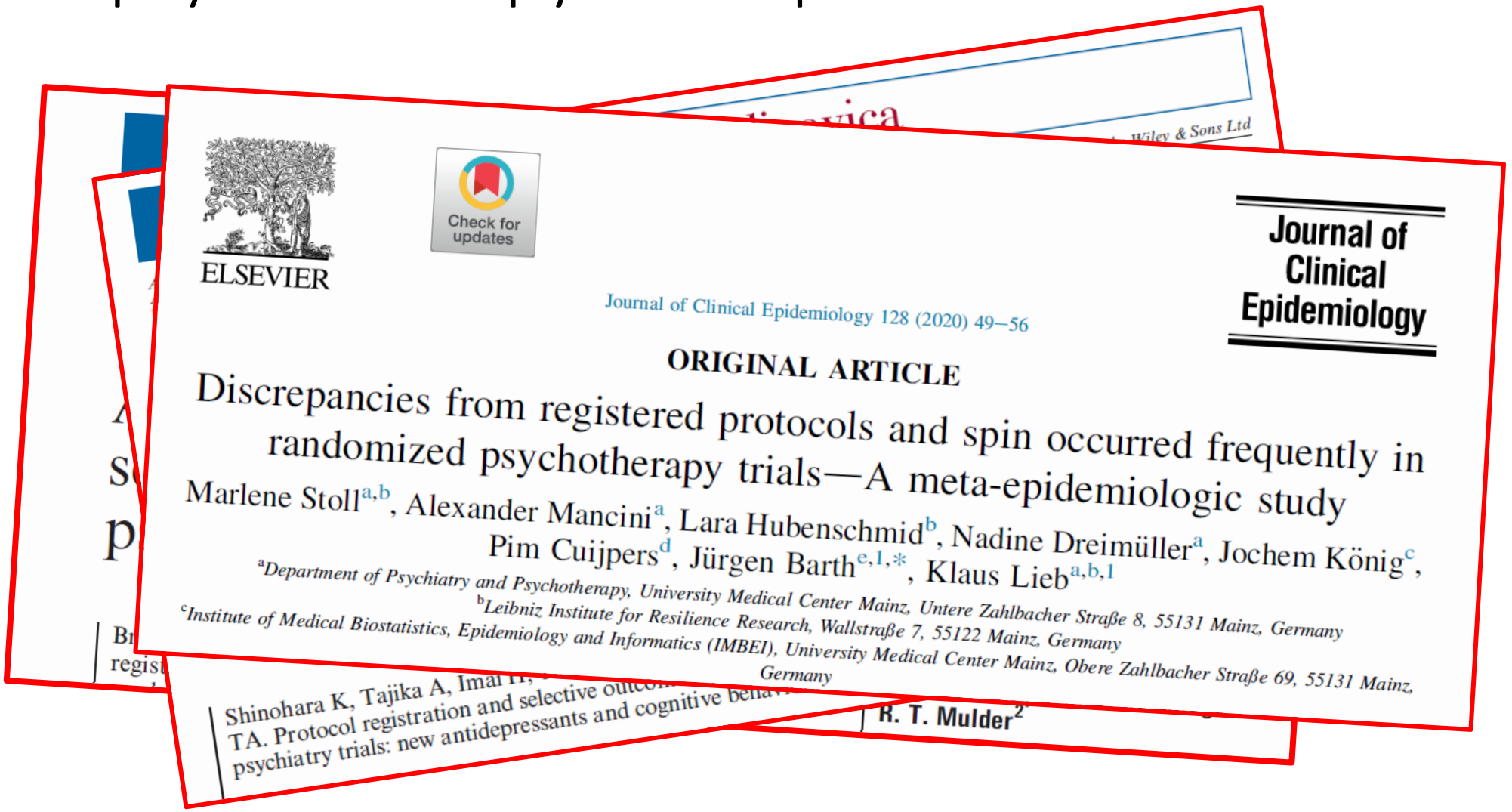
Selective outcome reporting (SOR)

Publication of **selected outcomes** within a study



Positive or **significant** outcomes have double the chance of being correctly reported

SOR in psychotherapy for depression



SOR in psychotherapy for depression

However:

- Previous studies examined SOR in a small and selected samples of trials
- Difficult to reliably estimate the prevalence of selective reporting
- Still unclear whether and by what extent it can influence the estimation of psychotherapy effects

Objectives

Estimate the **prevalence** of SOR across a complete cohort of trials of psychotherapy for depression

Examine the **influence** of SOR on psychotherapy effects

How did we examine SOR?

How did we examine SOR?

Trial publications

Meta-analytic database RCTs psychotherapy for depression

After July 2005

Trial registrations

Protocols from public clinical registries

Prospectively registered

How did we examine SOR?

Meta-analytic database (N= 353 RCTs)

- *Registered?*
  - *Publication*
  - *Searches in registries*

- *Prospectively registered?*
  - *Within 1 month enrollment start*

RESEARCH ARTICLE Open Access

Psychotherapy effectiveness for major depression: a randomized trial in a Finnish community

Hannu P. Saloheimo[1*], John Markowitz[2], Tuija H. Saloheimo[1], Jarmo J. Laitinen[1], Jari Sundell[4], Matti O. Huttunen[5], Timo A. Aro[6], Tuitu N. Mikkonen[3] and Heikki O. Katila[5]

Abstract

Background: The purpose of this study is to assess the relative effectiveness of Interpersonal Psychotherapy (IPT), Psychoeducative Group Therapy (PeGT), and treatment as usual (TAU) for patients with Major Depressive Disorder (MDD) in municipal psychiatric secondary care in one Finnish region.

Methods: All adult patients ($N = 1515$) with MDD symptoms referred to secondary care in 2004-2006 were screened. Eligible, consenting patients were assigned randomly to 10-week IPT ($N = 46$), PeGT ($N = 42$), or TAU ($N = 46$) treatment arms. Antidepressant pharmacotherapy among study participants was evaluated. The Hamilton Depression Rating scale (HAM-D) was the primary outcome measure. Assessment occurred at 1, 5, 3, 6, and 12 months. Actual amount of therapists' labor was also evaluated. All statistical analyses were

Conclusion: All three treatments notably benefited highly co 3 months, 42 % in r 12 months, these secondary care unit.

s. Statistically tcome measures

ublic sector

Trial registration: ClinicalTrials.gov NCT02314767 (09.12.2014).

NIH U.S. National Library of Medicine

ClinicalTrials.gov

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Home > Search Results > Study Record Detail

ClinicalTrials.gov Identifier: NCT02314767

Recruitment Status : Completed

First Posted : December 11, 2014

Last Update Posted : December 11, 2014

A Finnish Community Randomized Psychothera

The safety and scientific validity of this study is the responsibility of the study
investigators. Listing a study does not mean it has been evaluated by the U.
Government. Read our disclaimer for details.

First Posted : December 11, 2014

Last Update Posted : December 11, 2014

Sponsor:

Helsinki University Central Hospital

Information provided by (Responsible Party):

HSaloheimo, Helsinki University Central Hospital

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

Assessing selective outcome reporting

Trial publications

Primary outcome

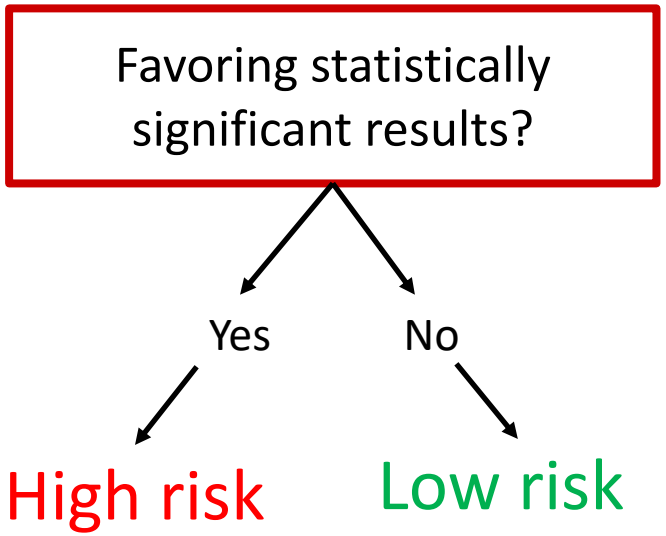
≠

Prospective Trial registrations

Assessing selective outcome reporting

≠ **DISCREPANCIES**

- Omission of registered primary outcome (non-reporting)
- Addition of new, not registered, primary outcome
- Downgrading of registered primary outcome to secondary
- Upgrading of secondary registered outcome to primary
- Assessment time point changes
- Analysis method changes



Statistical analyses

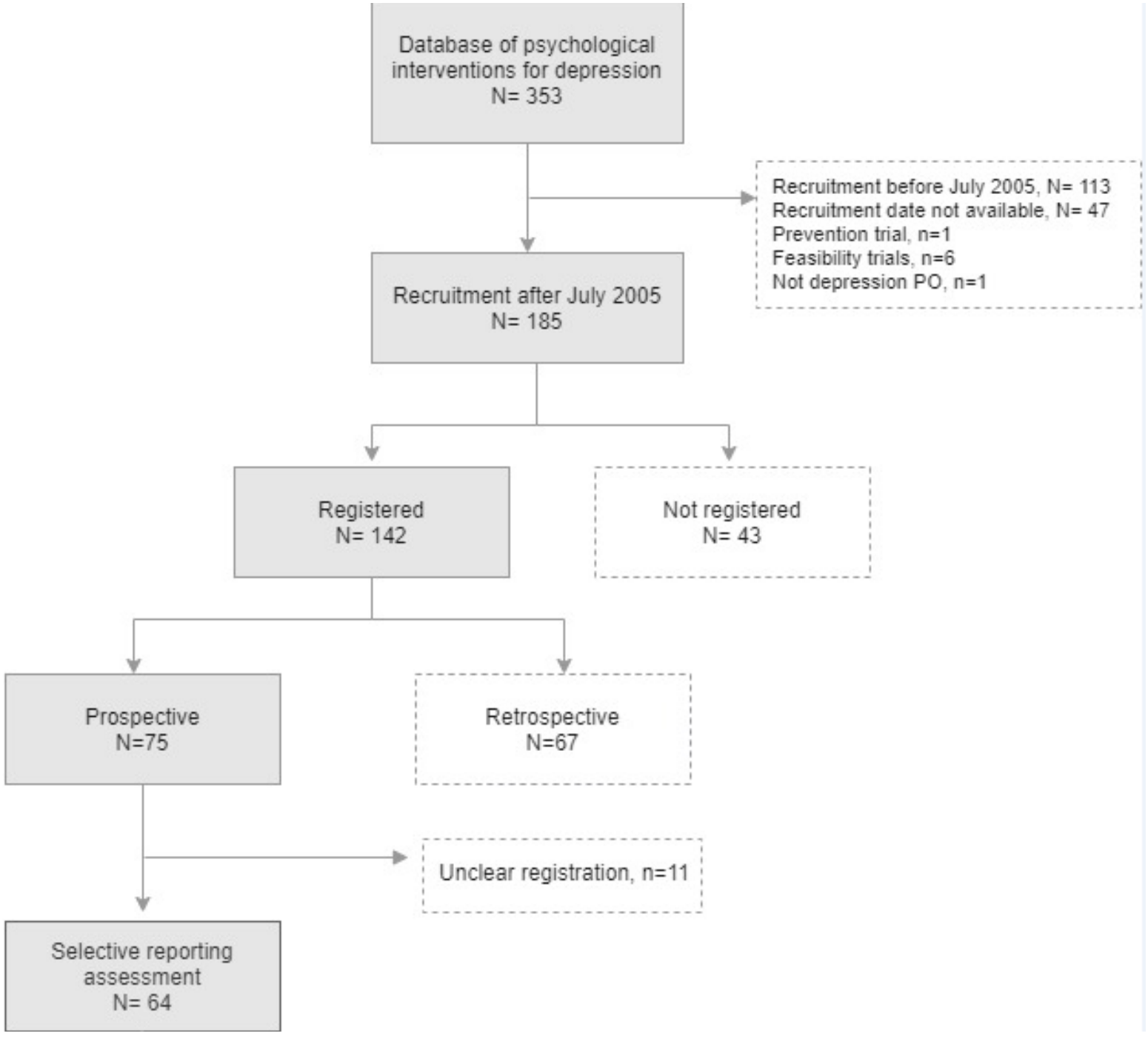
Counts and proportions

Standardized mean differences (SMD) based on reported primary outcome

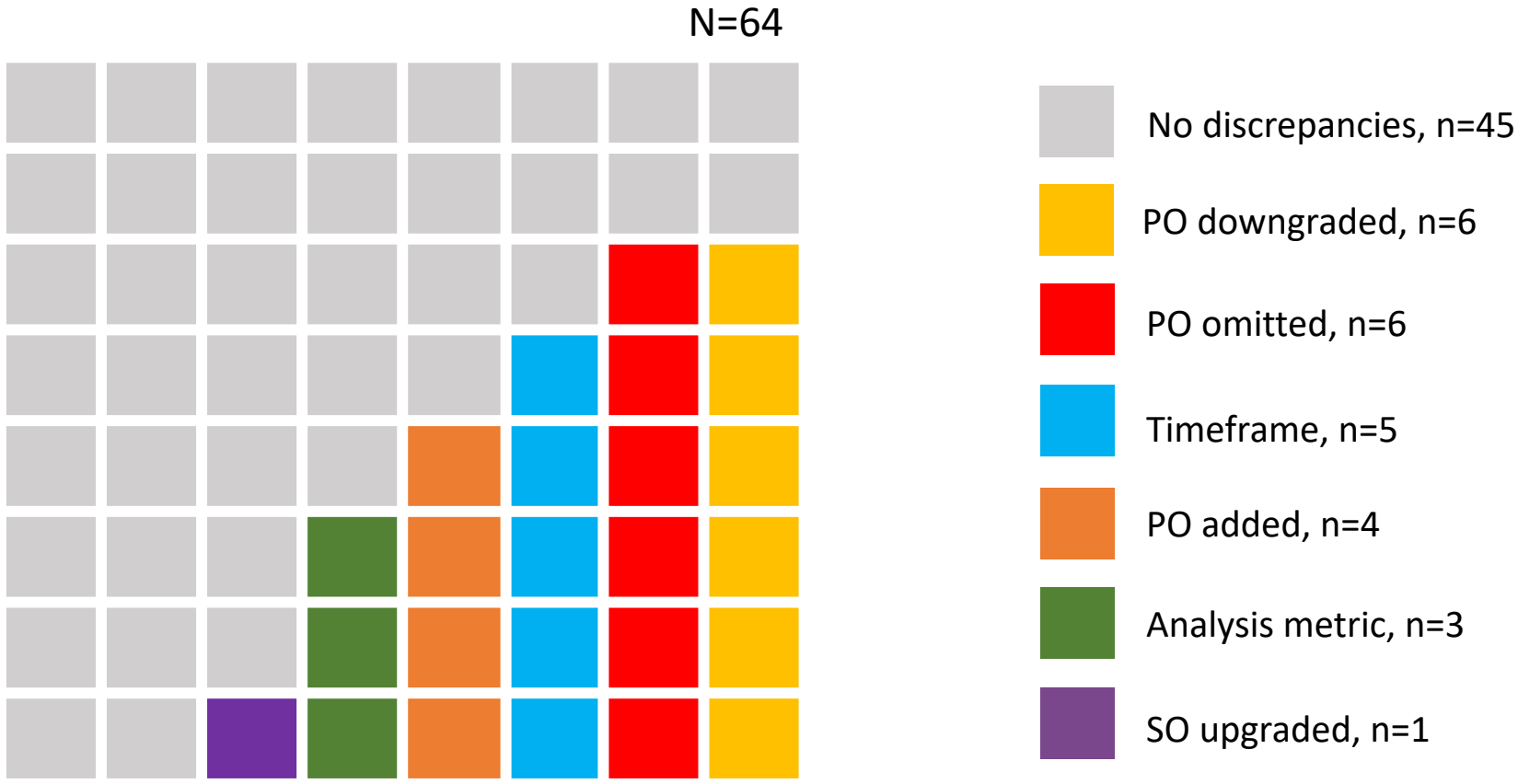
Pooled using robust variance estimation (RVE)

Stata/SE 16.1

Results

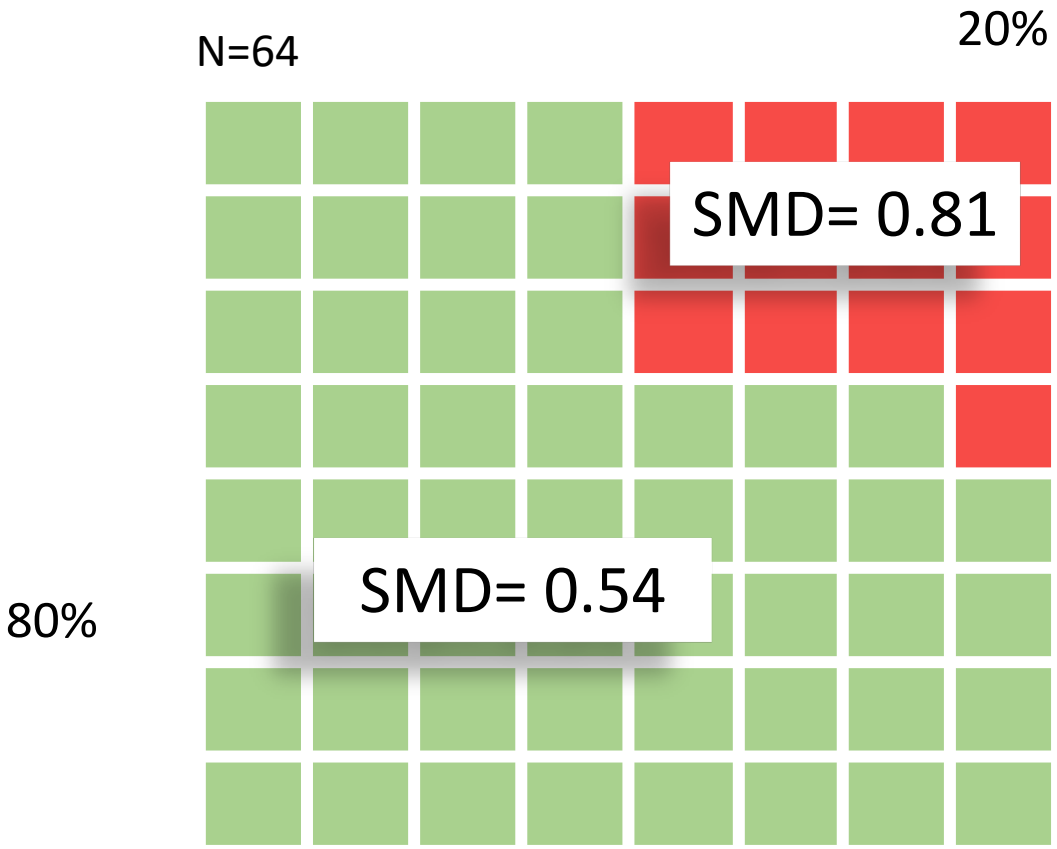

Database of psychological interventions for depression
N= 353
Recruitment before July 2005, N= 113
Recruitment date not available, N= 47
Prevention trial, n=1
Feasibility trials, n=6
Not depression PO, n=1
Recruitment after July 2005
N= 185
Registered
N= 142
Not registered
N= 43
Prospective
N=75
Retrospective
N=67
Unclear registration, n=11
Selective reporting assessment
N= 64

Discrepancies



30% showed at least one type of discrepancy, n=19

Selective outcome reporting



High risk of SOR, n=13

Low risk of SOR, n=51

Self-report and unblinded outcomes, SMD= 1.02!

Discussion

- Evidence of SOR on psychotherapy research for depression
- Almost 1 in every 3 trials had changes in the primary outcome
- High risk of SOR was associated with inflated treatment effects (+ 0.27 SMD)
- Trials with non-reported outcome or addition of non-registered outcomes were the main drivers of inflation

Limitations

Availability bias (16% analyzed)

Imprecise registrations & changes in analysis method

Conclusion

Trial registration and other practices for increasing transparency

Considering SOR when examining treatment effects

Best evidence for decision-making

Thank you for your attention

Clara Miguel – clara.miguelsanz@vu.nl
Eirini Karyotaki
Pim Cuijpers
Ioana A. Cristea