FOUNDATIONS BUILT ON SAND: EXPLORING UNDERLYING BIAS IN SYSTEMATIC REVIEWS OF PSYCHOLOGICAL THERAPIES FOR DEPRESSION

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Background

Systematic review and meta-analysis is considered the 'gold standard' for evidence-based practice. However, the process is not immune to the impact of studies that carry a high risk of bias (and low internal validity). Further, it is often assumed that all populations in the underlying studies are identical. There is, therefore, a risk that findings lack generalisability to a typical clinical population and estimates of effect size may be susceptible to bias.

Methods

Studies included in a recent systematic review of Cognitive Behavioural Therapy for depression (Cuijpers *et al*, 2013) were reviewed and assessed for risk of bias. Non-English studies and those that could not be obtained were excluded (N=9).

We extracted data on: study design; type of therapy; patient demographics; numbers in each study; and depression severity at baseline (which was converted to a score on the 17-item Hamilton Depression Rating Scale).

Each study was assessed using the Cochrane Collaboration risk of bias tool (Higgins, 2009), by both authors. Any disagreement was resolved by discussion.

Results

Study and participant characteristics

We reviewed 106/115 (92%) of all studies, comprising 11,160 patients. Year of publication ranged from 1977-2010.

Although the systematic review was of CBT, face-to-face CBT was the primary intervention for only 62% of studies. Other interventions are shown below.

The majority of participants were community-based (50%) or outpatients (45%). Control groups include: medication (15%); another therapy (52%); and treatment-as-usual or waiting list (31%).

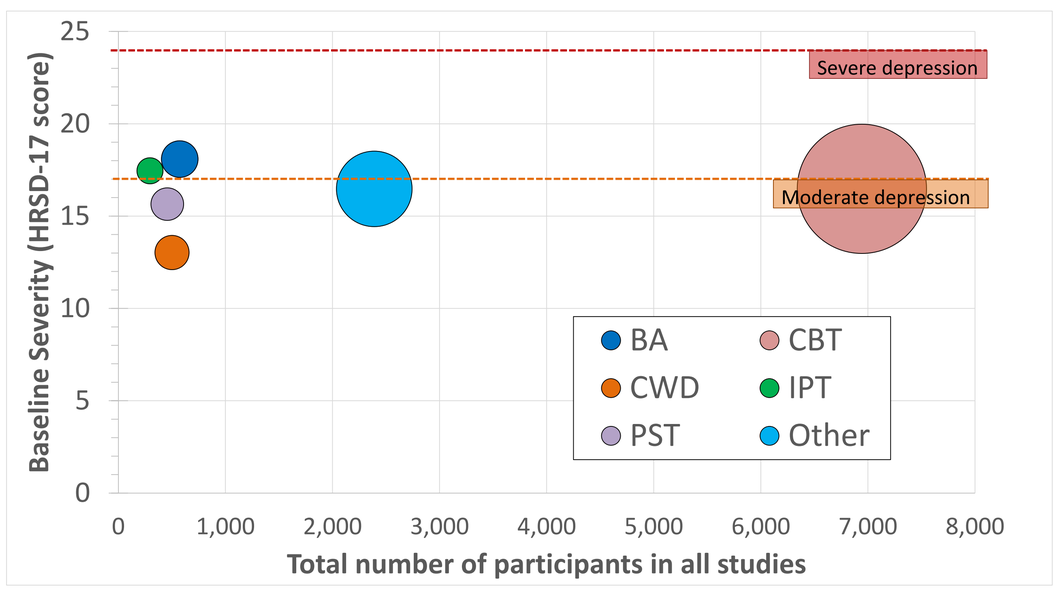
The majority of studies (97%) used psychological therapy as an active treatment, with 3% of studies using it as relapse-prevention.

Eighty-five percent of patients were between the ages of 18-65. The majority (71%) were female.

Depression severity

Forty-six percent of participants had major depressive disorder diagnosed. The rest had either mild or unspecified depression. The mean ± SD on the 17-item Hamilton Depression Rating Scale of all patients included was 16.4 ± 3.3.

The total no. of participants for each therapy and the baseline severity of depression is shown below, with dotted lines representing moderate and severe depression.



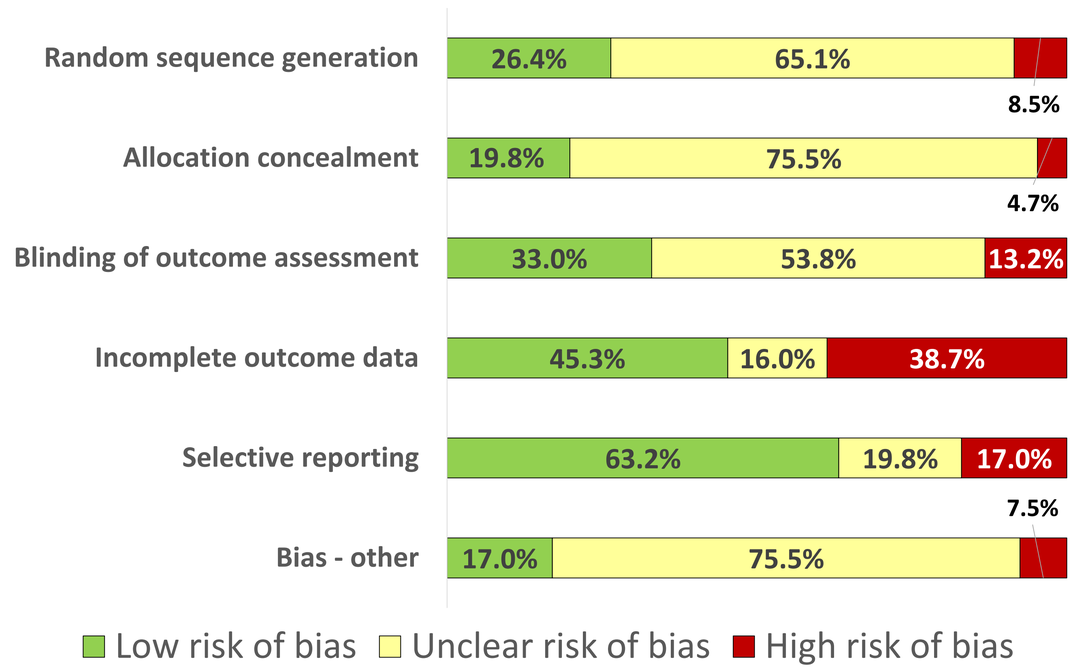
Where reported, an average of 35% of participants had chronic depression. Previous treatment included: pharmacological treatment (29%); psychological treatment (40%).

Ratings of bias

The authors dual-rated 98 studies (92%). Initial concordance ranged from 71%- 88% over each of the bias domains. Average agreement was 81% prior to reconciliation.

Risk of bias in included studies

The risk of bias for each domain in the Cochrane Risk of Bias tool for all included studies (N=106) is shown below. 'Blinding of participants' is not reported here because no studies were able to achieve effective blinding of participants for the intervention received.



Key findings

There was evidence of high risk of bias in almost 4-in-10 studies with regards to incomplete outcome data. These studies typically used a 'completer' sample which inflates the estimated effect because those who do not respond are more likely to drop out. Only 1-in-3 studies had low risk of bias in blinding of outcome assessment.

Only 6/106 studies (5.6%) were rated as low risk on all key domains relating to: randomisation; 'blinding of outcome assessment'; and 'incomplete outcome data'.

Discussion

Our review found significant levels of bias within the individual studies included in a large a systematic review and meta-analysis of CBT for depression. Preliminary examination of other systematic reviews has identified similar levels of bias.

This raises concerns about the validity of systematic reviews and meta-analyses of studies of psychological therapy.

Less than 50% of studies included participants with moderate depression, and only one study had participants with a mean severity in the severe range.

Further, these studies do not automatically provide evidence to support treatment in patients who have: moderate-severe depression; those not recruited from the community; and those who may have significant comorbidity. There is currently little evidence to support the use of psychological therapy in inpatients or those with severe forms of illness, for example.

We would argue that before generalising findings from meta-analyses to their patients, clinicians should have an understanding of the validity of the underlying studies.

P. Cuijpers, *et al*. 2013. *Can J Psychiatry*; 58: 376-385; J.P.T. Higgins, et al. 2009. *Cochrane Handbook for Systematic Reviews of Interventions*. John Wiley & Sons, Ltd: Chichester, UK

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