

Study protocol

Differences between psychotherapy and pharmacotherapy trials for treatment of depression.

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Background:

There is an ongoing debate as to whether depressive patients should be treated with medication or psychotherapy. Recent overview of reviews analyzing efficacy of pharmacotherapy and psychotherapy found higher effect sizes for psychotherapy, but also elevated risk of bias and lower baseline severity of illness as compared to pharmacotherapy (1). This suggests that further differences in methodology and patient characteristics of individual trials of psycho- and pharmacotherapy for depression exist and could account for the differences in efficacy.

Objective:

- (A) To elucidate the source of possible dissimilarities between psychotherapy and pharmacotherapy trials;
- (B) Investigate whether patients in psychotherapy studies are categorically different from those in drug treatment trials;
- (C) Clarify the big differences in efficacy found in meta-analyses of these two treatments;
- (D) Establish whether the general efficacy of these two treatment strategies could be meaningfully compared.

Methods:

We compared a number of methodological, study and patient characteristics of clinical trials of pharmacological and psychotherapy interventions for depression. Specifically, we analyzed all individual trials from two well-established meta-analyses of pharmacotherapy (2) and psychotherapy (3) for the treatment of depression. These meta-analyses were identified following a systematic selection procedure that can be found elsewhere (1). Differences between psychotherapy and pharmacotherapy trials will be analyzed descriptively and statistically.

Data items:

We read all the individual articles in full to extract the following information:

- Affiliation of the authors
- Age
- Baseline characteristics
- Baseline severity (including the Clinical Global Impression Scale, Beck Depression Inventory and the Hamilton Rating Scale for Depression / The Montgomery-Åsberg Depression Rating Scale)
- Clinical populations, general populations or other
- Control group
- Country

- Details of the diagnosis (diagnostic criteria used, severity of symptoms, type of depression)
- Duration of illness
- Education level
- Funding by pharmaceutical company, psychotherapy center or a public organization and the name of sponsor
- Gender
- Inclusion and exclusion criteria defining study participants
- Inpatients, outpatients or mixed
- Items for the Cochrane Risk of Bias tool (randomization, allocation concealment, blinding, attrition and reporting bias based on reporting of dropouts/ dropout rates and type of data analysis – completers versus intention to treat)
- Marital status
- Measurement scales
- Name of journal where the article was published
- Number of hospitalizations
- Number of study centers
- Primary outcome
- Psychotherapy or pharmacotherapy type
- Race
- Study population (specific target group)
- Supporting interventions
- Total number of participants
- What kind of data the article provided and what was their quality as regards meta-analytic calculations
- Whether follow-up data after the trial endpoint were collected

References

1. Huhn M, Tardy M, Spineli LM, Kissling W, Forstl H, Pitschel-Walz G, et al. Efficacy of pharmacotherapy and psychotherapy for adult psychiatric disorders: a systematic overview of meta-analyses. *JAMA psychiatry*. 2014;71(6):706-15. Epub 2014/05/03.
2. Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R. Selective publication of antidepressant trials and its influence on apparent efficacy. *The New England journal of medicine*. 2008;358(3):252-60. Epub 2008/01/18.
3. Cuijpers P, Smit F, Bohlmeijer E, Hollon SD, Andersson G. Efficacy of cognitive-behavioural therapy and other psychological treatments for adult depression: meta-analytic study of publication bias. *The British journal of psychiatry : the journal of mental science*. 2010;196(3):173-8. Epub 2010/03/03.