Psychotherapy and Pharmacotherapy Randomized Controlled Trials are Equally Likely to Report a Positive Outcome

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Abstract

A very high proportion of controlled trials of psychotropic drugs report a positive outcome. To determine if the population of positive outcome in psychotherapy trials is as high as reported, a cohort of consecutive randomized controlled trials published in four internal psychiatry journals over a five-year period were analyzed. Chi square test and descriptive analysis were conducted. A total of 237 trials were included. Out of 188 pharmacotherapy trials, 164 (88%) reported a positive outcome. Out of 49 psychotherapy trials, 44 (90%) reported a positive outcome. The difference between above reported population was not statistically significant on chi-square test (p=0.626). It was concluded that positive outcome reports in published psychotherapy trials are as common as in pharmacotherapy trials.

Introduction

Psychotherapy is as important a treatment modality in this part of the world as in the West.1 Recently there has been a lot of emphasis on developing as strong an evidence base for psychotherapeutic treatments as required for drug therapy.2 Randomized Controlled Trials (RCT), and Systematic Reviews and Meta-analyses based on these RCTs, are the gold standard for establishing the efficacy of a treatment intervention. However, concerns have been raised about both internal and external or 'real world' validity of RCTs.3

Publication bias has been described as the phenomenon in which "positive results have a better chance of being published, are published earlier, and are published in journals with higher impact factors.4 A recent observational study established that a high proportion of published RCTs of psychotropic drugs favoured the experimental drug.5 To our knowledge no such estimates are available for psychotherapy trials. The main objective of this study was to assess the probability that the proportion of positive outcome reported in psychotherapy trials might be as high as pharmacotherapy trials.

A major methodological issue in psychotherapy RCTs is the use of appropriate control groups.2 The concern is that unless all the groups are treated equally in terms of time spent with the therapist, it is difficult to ascertain whether the observed improvement was a specific effect of the intervention or just an attention artifact because of the extra time and attention given by the therapist(s) to one group but not the other. The second objective of this study was to find out if psychotherapy RCTs that did not control for 'therapists' time' were more likely to report a positive outcome than trials which did control for the therapists' time.

The reported outcomes of industry-funded trials are significantly more likely to favour the sponsoring company's drug over the control treatment.3,6 It has also been reported that authors do not always report their financial ties with the sponsor of the trial.7 Therefore, 'declaration of interest' and 'funding information' provided with psychotherapy RCTs was also reviewed in order to identify authors that may financially benefit as a result of publication.

Methods and Results

A review of all RCTs published in four major international psychiatry journals during July 1998-June 2003 was conducted. The Journals list included Acta Psychiatrica Scandinavica, American Journal of Psychiatry, Archives of General Psychiatry and British Journal of Psychiatry to include two prominent journals each from America and Europe. The details of the search and selection of RCTs have been reported in an earlier study.5

The data on psychotherapy trials outcome were independently extracted by two researchers (k= 0.90), who classified the trial outcome as positive or negative. The data on pharmacotherapy trials outcome were previously obtained in the same manner.

Psychotherapy RCTs were appraised and were classified independently according to "controlling for therapist's time" and "not controlling for therapist's time". The explicit operational criterion used was whether both the groups had spent the same amount of time with the therapist during the trial or not. For example if a trial compared eight 1-hourly one-to-one sessions of Cognitive Behaviour
Therapy with waiting list controls, it was declared as not controlling for therapist's time, but if a trial compared the above treatment with eight 1-hourly one-to-one befriending sessions, then it was declared as having controlled for therapist's time. Any ambiguities were discussed by two senior researchers, and were resolved with consensus.

The data on psychotherapy trials funding and acknowledgement of any other financial interests were obtained independently of the above mentioned data collection.

SPSS 13 was used for data analysis. Descriptive statistics is reported. Chi-square test was used to compare the difference in proportion of positive and negative outcomes reported in psychotherapy and pharmacotherapy trials. Chi-square test was also applied to answer whether psychotherapy trials that do not ‘control for therapist's time’ are more likely to be reported ‘positive’ in comparison to trials that ‘control for therapist's time’. However, the total number of trials with negative results was too small to generate any meaningful statistical testing for this particular question.

A total of 306 RCTs were published in the four journals over a 5-year period. Of these 215 RCTs evaluated at least one drug, while 91 RCTs compared non-pharmacological treatments only. Of the 215 drug RCTs, 188 were included in the study, the reasons for exclusion of the other 27 RCTs have already been reported. Among the non-pharmacotherapy RCTs, only 49 had evaluated at least one form of psychotherapy, the others evaluated treatments like Trans-Magnetic Stimulation (TMS), light therapy, Electro Convulsive Therapy (ECT) or exercise. Thus a total of 237 RCTs were included in this study, 188 drug RCTs and 49 psychotherapy RCTs.

Out of 188 pharmacotherapy trials 164 (88%) reported a positive outcome while 24 (12%) reported a negative outcome. Out of 49 psychotherapy trials, 44 (90%) reported a positive outcome and 5 (10%) reported a negative outcome. The difference between above reported proportions was not statistically significant (p= 0.626).

Thirty one (63%) psychotherapy trials were assessed to have not controlled for therapist's time. Out of these, 2 (6%) trials reported having a negative outcome. Eighteen (37%) trials were assessed to have controlled for therapist's time, out of which 3 (16%) trials reported a negative outcome. The number of trials was too small to do a meaningful statistical analysis.

Funding details were available for 46 (94%) psychotherapy trials. Forty three trials were supported by grants from research charities, universities and governmental bodies. Two trials were supported by grant from insurance companies and 1 trial was supported by grant from a pharmaceutical company. It was not readily apparent whether any author(s) would have financially benefited from a positive outcome of the trials. No other financial interests were declared with any of the psychotherapy trials.

Conclusions

It was observed that psychotherapy trials are as likely to report a positive outcome as pharmacotherapy trials and that the proportion of trials reporting a negative outcome remains rather low in both groups.

Association of financial conflict of interest with a positive outcome in psychotherapy trials remains rather unclear despite the finding that the size of positive outcome reported was as high as pharmacotherapy trials. One question that this study raised is whether journals apply relatively different policies to declaration of interest with psychotherapy trials?

References