

PROTOCOL AMENDMENTS

Protocol

Prospective protocol registration and selective outcome reporting in recent psychiatry trials: new antidepressants and cognitive-behavior therapies

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The original study protocol was uploaded in on our homepage

(<http://ebmh.med.kyoto-u.ac.jp/r-ebm.html>)

Changes from the protocol

We did not search the WHO portal site when we could not obtain registry information from the trial report or the author because identifying the targeted trial registry entity was not always possible using the portal service. In the study protocol, we planned to compare primary outcomes only when a trial had specified primary outcomes in both the publication and the registry, as was done in a previous study. However, we found that several trials showed some evidence of discrepancy in their primary outcomes that met the former criteria, even when they were not registered properly or the primary outcomes were not specified. Therefore, we decided to also examine all the registered trials for any discrepancies. Also, we did not conduct subgroup analyses regarding the following factors.

- i) The number of primary outcomes in publication: because determining the number of primary outcomes was often difficult, as the authors did not always declare them.
- ii) Trials with statistically significant primary outcomes: guessing the author's desired direction was difficult if a trial had multiple primary outcomes. Instead, we checked whether discrepancies favored statistically significant results.
- iii) Endorsement of ICMJE by each journal: because this information was not easily accessible to readers of the medical literature.