

Primary outcome

The primary [outcome](#) measure is the outcome that an investigator considers to be the most important among the many outcomes that are to be examined in the study. The primary outcome needs to be defined at the time the study is designed. There are 2 reasons for this: it reduces the risk of false-positive errors resulting from the statistical testing of many outcomes, and it reduces the risk of a false-negative error by providing the basis for the estimation of the sample size necessary for an adequately powered study.

The article of Andrade discusses the setting of the primary outcome measure, the need for it, the increased risk of false-positive and false-negative errors in secondary outcome results, how to regard articles that do not state the primary outcome, how to interpret results when secondary outcomes are statistically significant but not the primary outcome, and limitations of the concept of a primary outcome measure in clinical trial research ¹⁾.

¹⁾

Andrade C. The primary outcome measure and its importance in clinical trials. J Clin Psychiatry. 2015 Oct;76(10):e1320-3. doi: 10.4088/JCP.15f10377. PMID: 26528658.

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Last update: **2025/04/29 20:29**

