

AS29-03 - WHY PLACEBO-CONTROLLED RESEARCH IS NECESSARY IN THE EVALUATION OF ANTIDEPRESSANTS

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Considering the traditional experimental methodology of clinical psychopharmacology the best way to test efficacy of an antidepressant to placebo and at the same time taking into account the demand of EAM and FDA is the randomised controlled double-blind trial. Of course, such a trial has to be performed in the best methodological approach possible, avoiding all kinds of bias and confounders, avoiding especially statistical errors of different kinds etc.

The final result of a trial should never be seen as a final answer. The empirical methodology of clinical psychopharmacology demands confirmation by at least one other trial. Even then, the empirical process is not finished and e.g. the second trial might generate a negative result, thus conflicting with the two other positive results. This induces questions as to what might be the background for the inconsistent results and then possibly lead again to one or two other studies trying to support the former positive evidence. This is a way of empirical thinking in the sense of falsifications or confirmations. In the time of EBM, meta-analysis has become the preferred method to combine the outcomes of all informative, putatively conflicting studies on the question, whether a certain drug A is superior to a drug B or to placebo. However, it has to be understood that meta-analysis, depending on the applied methodology and depending on the inclusion or exclusion of certain studies can come to inconsistent results, although principally focussing on the same data base.