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STATISTICAL POWER AND REPORTING OF SAMPLE SIZE CALCULATIONS IN RANDOMIZED CONTROLLED TRIALS.

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Purpose: Statistical power and sample size calculations are important in planning and interpreting "negative" studies. Insufficient statistical power may lead one to erroneously conclude that a given intervention is ineffective when, in fact, the study may have had insufficient power to detect a clinically meaningful result (type II error). The purpose of this study is to evaluate statistical power and reporting of sample size calculations in randomized controlled trials (RCTs).

Methods: We evaluated all 174 RCTs published in *JAMA*, *Lancet* and the *New England Journal of Medicine* in 1995. Negative studies with two-group parallel design and a dichotomous or continuous primary outcome were evaluated for the presence of sample size calculations. The ability of a study to detect, with 80% power, a 25% or 50% relative difference between groups was calculated. Results were compared with a review by Moher et al¹ of RCTs published between 1975 and 1990.

Results: Fifty-five "negative" studies were identified, 34 with two-group parallel design and a dichotomous or continuous primary outcome.

Table: Statistical Power of RCTs and Results of Sample Size Calculations

Year	RCTs with power to detect		RCTs (%) reporting a sample size calculation
	25% difference	50% difference	
1975	2/16 (12%)	4/16 (25%)	0/22 (0%)
1980	2/15 (13%)	7/15 (47%)	7/22 (32%)
1985	1/15 (7%)	4/15 (27%)	10/21 (48%)
1990	6/24 (25%)	10/24 (42%)	16/37 (43%)
1995	10/34 (29%)	19/34 (56%)	36/55 (65%)

Conclusions: The frequency of sample size calculation reporting has increased in recently published trials. Still, about one-third did not report such calculations. The ability of studies to detect potential clinically significant differences between treatment and control groups has improved only modestly. A priori power calculations and utilizing larger sample sizes through multi-institutional studies could reduce the frequency of type II errors and result in more effective utilization of limited research funds.

¹ Moher D, Dulberg CS, Wells GA. Statistical power, sample size, and their reporting in randomized controlled trials. *JAMA*. 1994;272:122-124.

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