

Generalizability of findings from Randomized Controlled Trials in the Leading General Medical Journals

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Objective: To document reporting of study characteristics of RCTs reported in the four leading general medical journals using a novel Benchmarking method (BM); and to appraise the generalizability of the evidence.

Methods: All RCTs in BMJ, JAMA, Lancet and NEJM from January to September 2017 were searched by hand, and data was extracted according to the Benchmarking method (Malmivaara, A. BMC Medical Research Methodology 2018;18:91; Malmivaara, A. Scand J Med Sci Sports 2018;1-12).

Results: 161 RCTs were found. Of the single country trials 79% were conducted in Europe or in North America. Pharmacological therapy was compared in 67% of the trials. Main study characteristics in Table 1.

Table 1. Appropriate reporting (% of at least one item) on generalizability of evidence in the single subject randomized controlled trials.

Year, Study, country → ↓Study characteristics	BMJ (N=4) (%)	JAMA (N=50) (%)	Lancet (N=71) (%)	NEJM (N=36) (%)
<i>Selection of patients, health care system features</i>				
1.1. Patients' path	25	33	7	3
1.2. Reasons for exclusions	100	82	65	25
1.3. Patients declining participation	100	72	66	22
1.4. Health care settings	75	60	8	0
<i>Baseline characteristics</i>				
2.1. Disorder specific clinical data	100	100	97	94
2.2. Functioning and health related quality of life	50	54	49	42
2.3. Comorbidity, (at least two comorbid conditions)	25	50	26	47
2.4. Behavioral factors	25	50	58	47
2.5. Environmental factors	25	14	11	3
2.6. Potential inequity	50	68	52	28
<i>Interventions</i>				
3.1. Completed index intervention(s)	75	88	87	84
3.2. Completed control intervention	75	87	84	83
3.3. Cross over to index intervention more than 5%	75	4.3	3	3
3.4. Cross over to control intervention more than 5%	75	2,1	6	3
3.5. Co-interventions reported	25	10.0	10	5.6
<i>Follow-up</i>				
4.1. Follow-up percentage	75	90	88	88
4.2. Reasons for drop-outs reported	75	100	97	39

Conclusions: Almost all of the RCTs show deficiencies in description of patient selection and study setting; and in reporting of patient characteristics related to functioning, co-morbidities, and to behavioral, environmental and inequity factors. The findings indicate that generalizability of this evidence may be limited.