Is Accrual Higher for Patients Randomized to Pragmatic versus Exploratory Randomized Clinical Trials? A systematic review and meta-analysis

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Background

- Patient recruitment and retention in surgical trials can be particularly challenging
- All studies lie on a spectrum of pragmatic (usual care) to explanatory (ideal conditions) design
- Pragmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2) is a validated tool using 9 elements of trial design to determine where study lies on this spectrum

Objectives

To determine the effect of a pragmatic or explanatory trial design on accrual and retention rates

To identify elements of trial design that can help with patient accrual and retention

Methods

- Conducted in accordance with PRISMA
- MEDLINE and EMBASE database searched Jan 2016-Aug 2019 (to avoid impact of COVID-19)
- Inclusion: Published RCTs studying an intraoperative surgical intervention involving gastrointestinal or hepatobiliary system
- Exclusion: studies including <150 patients
- PRECIS-2 scores of all studies averaged with one standard deviation above and below mean to be considered pragmatic and explanatory, respectively
- Independent samples T-test and multi-variable linear regression used

Results

- 129 RCTs for PRECIS-2 scoring, mean 30.2, SD 3.5
- Determined ≥34 as pragmatic and ≤27 as explanatory
- 22 explanatory and 14 pragmatic studies included

Retention Rate	Accrual rate
• Pooled: 92.3% in explanatory, 94.1% in pragmatic studies • No significant effect for type of study on retention rate t(24)=0.001, p=0.99 • **More pragmatic follow up (B=0.039, t=3.34, p=0.003) and explanatory settings (academic centres) (B=-0.037, t=-4.244, p=0.0003) associated with higher retention rate**	• Pooled: 81.6% in explanatory, 92.7% in pragmatic • No significant effect for type of study on accrual rates t(20)=-0.318, p=0.75 • More pragmatic primary outcomes trended toward higher accrual rates (B=0.08, t=1.82, p=0.604)

Accrual rate: number of patients consented over number of patients eligible for inclusion

Retention rate: number of patients present at follow up over all patients consented at start of trial

Conclusion

More pragmatic follow-up (i.e., no more than usual follow up appointments in frequency and intensity) **in explanatory settings** (i.e., specialized trial or academic centres) **significantly associated with higher patient retention rate.**

More pragmatic primary outcomes (i.e., outcomes that are of obvious importance to patients) trend toward higher accrual rates.