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Pragmatic clinical trial

A pragmatic clinical trial (PCT), sometimes called a practical clinical trial (PCT), is a clinical trial that focuses on correlation between treatments and outcomes in Real-World Health Care practice rather than focusing on proving causative explanations for outcomes, which requires extensive deconfounding with inclusion criteria and exclusion criteria so strict that they risk rendering the trial results irrelevant to much of real-world practice

Clinical trials have been the main tool used by the health sciences community to test and evaluate interventions. Trials can fall into two broad categories: pragmatic and explanatory.

Pragmatic trials are designed to evaluate the effectiveness of interventions in real-life routine practice conditions, whereas explanatory trials aim to test whether an intervention works under optimal situations. Pragmatic trials produce results that can be generalized and applied in routine practice settings.

Clinical uncertainty and equipoise are vague notions that play important roles in contemporary problems of medical care and research, including the design and conduct of pragmatic trials ¹⁾.

Pragmatic care trials have been designed to provide optimal neurovascular care in the presence of uncertainty. The feasibility, benefits, and drawbacks of using this novel approach remain unknown.

Methods: We report the progress of 9 randomized trials integrated into routine practice to guide the endovascular or surgical treatment of intracranial aneurysms, arteriovenous malformations, and acute stroke. We review the criticisms and commentaries we have received and discuss the corresponding ethical and scientific concepts that need to be revised to practice outcome-based neurovascular care.

Results: Pragmatic care trials were used to address long standing dilemmas regarding rival management options or to offer innovative treatments for 1212 neurovascular patients recruited in an elective or acute care context. Adopting care trial methodology had an immediate impact on clinical practice, replacing unrepeatable treatment decisions by 1:1 randomized allocation whenever reliable knowledge about best management was not available. The care trial approach transformed unfounded medical practice into verifiable outcome-based medical care and reserved authoritative recommendations for care options that had previously been validated. Criticisms we have encountered include mainly the pragmatic trial design choices, with insufficient selection of patients and clinicians, too-flexible protocols, lack of funding and feasibility.

Conclusion: Care trials can be integrated into neurovascular practice. Although they remain a work in progress, the approach curtails the practice of unverifiable medicine and offers patients optimal care in the presence of uncertainty ²⁾.

1)

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