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PRAGMATIC CLINICAL TRIAL A REVIEW

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ABSTRACT

A pragmatic clinical trial is one that addresses questions of major public health importance, and whose results can inform decisions made every day by patients, clinicians, and health system leaders. Pragmatic clinical trials provide evidence-based research that translates directly into clinical practice. They differ from traditional clinical trials in that they reflect real-world clinical settings, and are designed to provide actionable information. Pragmatic clinical trials provide crucial evidence needed for health care decision-making, giving healthcare workers the tools to deliver effective interventions. The current paper is attempted to explore pragmatic clinical trial through reviewing published data on this topic.

KEYWORDS: Pragmatic trial, Clinical trial, evidence-based research, patients, clinicians.

INTRODUCTION

The word pragmatic was tossed firstly by Schwartz and Lellouch back in 1967, coined the terms “explanatory” and “pragmatic” to differentiate trials. A pragmatic clinical trial (PCT) sometimes called a practical clinical trial.[1] PCT is a clinical trial that focused on correlation between treatments and outcomes in real world health system practice rather than focusing on proving causative explanations for outcomes, which requires extensive deconfounding with inclusion and exclusion criteria so strict that they risk rendering the rial results irrelevant to much of real-world practice.[2,3]

Pragmatic clinical trials (PCTs) bridge the gap between research and clinical practice by examining interventions in real-world settings. This innovative trial design holds promise for accelerating the translation of research into quality patient care. While explanatory trial used to describe efficacy of intervention in ideal controlled setting, whereas the term pragmatic was used for trials designed to test the effectiveness of the intervention in a broad routine clinical practice. Pragmatic trials may test the same intervention as an explanatory trial, but they are conducted in real-world clinical practice settings, with typical patients and by qualified clinicians, who may not, however, have a research background. Often, the positive results from explanatory trials have been found to be less effective in practice than they were in the lab, because several factors not present in the controlled setting can affect the eventual outcomes.

PCTs are designed to evaluate interventions in real-world settings, measuring outcomes that matter to patients, providers, and policymakers. Unlike traditional randomized controlled trials (RCTs), PCTs prioritize external validity over internal validity, allowing for greater generalizability and implementation of findings. The current paper is attempted to explore pragmatic clinical trial through reviewing published data on this topic.

MATERIALS AND METHOD

Research articles and online data were reviewed thoroughly.

DISCUSSION

Advantages

Higher external validity: - external validity examines whether the findings of a study can be generalized to other contexts.[4] In Pragmatic clinical trials diverse populations receive intervention in real word setting with broad inclusive criteria irrespective of age, sex, class, culture etc so higher external validity is established.

Greater generalizability: - The results of a study are broadly applicable to many different types of people or situations; the study is said to have good generalizability.

Efficient enrolment and data collection: - as selection of patient for such study is with broad inclusive criteria, a greater number of patients are enrolled.

Disadvantages

Greater risk of bias and confounding: - Bias is the systematic distortion of the estimates due to poor design, conduct, or analysis of a trial.[5]

Reduced internal validity: - Internal validity is defined as the extent to which the observed results represent the truth in the population we are studying.[6]

The internal validity of a study can be threatened by many factors, Internal validity reduced due to errors in measurement or in the selection of participants in the study.

Complexity of design and implementation: - Pragmatic trials have high rates of loss to follow-up, nonadherence to study intervention, unblinded treatment and patient self-assessment, which can potentially create bias. often requiring large sample sizes to detect small treatment effects in heterogeneous populations.[7]

Logistical challenges

1) Selection of diverse population for trial and then obtaining informed consent from them for study and along with this ensuring adherence to the intervention can be challenging in real-world settings.
2) Data management challenges: - Accessing all data from various centre analysing, and integrating data from various sources can present unique challenges.
3) Resource challenges Funding, staffing, and infrastructure can limit the feasibility of PCTs

Some Examples of PCT's

1. Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness.
2. Randomized Pragmatic Trial of Pacemaker Versus Implantable Cardiac Monitor in Syncope and Bifascicular Block
3. Efficacy of topical tranexamic acid within a blood-saving programme for primary total hip arthroplasty: a pragmatic, open-label randomised study
4. Randomized Pragmatic Trial of Stroke Transitional Care; The COMPASS Study.
5. The clinical effectiveness of evidence-based interventions for depression: A pragmatic trial in routine practice.

Ethical Considerations

Respecting patient autonomy, ensuring informed consent, and minimizing harm are essential ethical considerations in PCTs. Balancing the desire for high-quality data with patient rights and safety can present unique challenges.

CONCLUSION

PCTs have the potential to accelerate the translation of research into meaningful improvements in clinical practice and patient outcomes. While challenging, the practicality and rigor of PCTs are well worth the effort, given their potential to promote patient-centered, evidence-based care.

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