

How to Read a Clinical Trial Paper: A Lesson in Basic Trial Statistics

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Abstract: While the number of clinical trials performed yearly is increasing, the application of these results to individual patients is quite difficult. This article reviews key portions of the process of applying research results to clinical practice. The first step involves defining the study population and determining whether these patients are similar to the patients seen in clinical practice in terms of demographics, disease type, and disease severity. The dropout rate should be compared between the different study arms. Design aspects, including randomization and blinding, should be checked for signs of bias. When comparing studies, clinicians should be aware that the outcomes being studied may vary greatly from one study to another, and some outcomes are much more reliable and valuable than others. The definition of clinical response should also be scrutinized, as it may be too lenient. Surrogate outcomes should be viewed cautiously, and their use should be well justified. Clinicians should also note that statistical significance, as defined by a *P*-value cutoff, may be the result of a large sample size rather than a clinically significant difference. The treatment effect can be estimated by calculating the number needed to treat, which will demonstrate whether changes in clinical practice are worthwhile. Finally, this article discusses some common issues that can arise with figures.

In the last decade, the number of publications dedicated to research in gastroenterology has expanded dramatically.¹ In parallel, the number of clinical trials has been increasing, with more than 18,000 ongoing clinical trials in the United States alone.² With this rapid growth in research, clinicians find themselves trying to keep up with wave after wave of studies and trying to determine how these studies apply to their patients. As researchers learn more about disease processes, clinical trial design is also changing and becoming more complex. Medical school and subsequent clinical training provide limited education on how to evaluate these stud-

Keywords

Statistics; clinical trials; randomized controlled trials; outcomes; clinical research

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Patrick Vollmar



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Table of Contents **Methods Trial Papers**

1. Understanding the eBook **Methods Trial Papers**
 - The Rise of Digital Reading **Methods Trial Papers**
 - Advantages of eBooks Over Traditional Books
2. Identifying **Methods Trial Papers**
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an **Methods Trial Papers**
 - User-Friendly Interface
4. Exploring eBook Recommendations from **Methods Trial Papers**
 - Personalized Recommendations
 - **Methods Trial Papers** User Reviews and Ratings
 - **Methods Trial Papers** and Bestseller Lists

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 - Methods Trial Papers Public Domain eBooks
 - Methods Trial Papers eBook Subscription Services
 - Methods Trial Papers Budget-Friendly Options
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 - Methods Trial Papers Compatibility with Devices
 - Methods Trial Papers Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Methods Trial Papers
 - Highlighting and Note-Taking Methods Trial Papers
 - Interactive Elements Methods Trial Papers
8. Staying Engaged with Methods Trial Papers
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Methods Trial Papers
9. Balancing eBooks and Physical Books Methods Trial Papers
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Methods Trial Papers
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Methods Trial Papers
 - Setting Reading Goals Methods Trial Papers
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Methods Trial Papers
 - Fact-Checking eBook Content of Methods Trial Papers
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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