

Box 14-1 Clinical Trials Registries

Clinical trials registries are Web-based resources that catalog information on publicly and privately supported clinical studies. In the United States, *ClinicalTrials.gov* includes more than 300,000 trials.⁶ Registries are also available in more than 20 countries.⁷ The database was developed by NIH through the National Library of Medicine (NLM) in collaboration with the Food and Drug Administration (FDA), allowing broad availability of information to those with medical conditions, members of the public, healthcare providers, and researchers.

The intent of a clinical registry is to help patients find trials for which they may be eligible, to enhance the design of clinical trials, and to prevent duplication of unsuccessful or unsafe trials. It is also intended to improve the evidence base that informs clinical

care, increase efficiency of drug and device development, improve clinical research practices, and build public trust in clinical research.⁸

Researchers can voluntarily register their studies when they begin using a Web-based entry system called the *Protocol Registration and Results System (PRS)*.⁹ Not all studies must be registered, but those involving drug or device interventions are required to do so, and must also submit their results.¹⁰ Researchers are responsible for updating and maintaining accuracy of information, such as when the study is recruiting subjects, when results are obtained, and when the study is complete. Protocols for trials are also published, giving details about study methods. Trials are assigned a number which can be used to search for specific studies and will be identified in PubMed citations.

**FUN FACT**

I actually participated in the original polio trial when I was in the first grade. I can remember standing outside the gym waiting in line for my shot with the other kids, feeling really nervous. Mostly I remember the lollipop I got and a little blue card stating that I was a "Polio Pioneer." Of course, I was bummed to find out later that I got the placebo and had to come back for another shot! But at least I got another lollipop!



Source unknown.

The Randomized Controlled Trial

The randomized controlled trial (RCT) is considered the gold standard for experimental research because its structure provides a rigorous balance to establish

cause-and-effect relationships. From an evidence-based practice perspective, the RCT is generally considered the highest form of evidence to support an intervention.

The basic structure of an RCT includes two groups, each getting a different treatment condition, with measurements taken before and after intervention to compare outcomes (see Fig. 14-1). The different groups within an RCT may be designated as experimental and control groups. They are also referred to as the **treatment arms** of the study. When two independent groups are compared in this way, the design is also considered a **parallel group study**. **An RCT qualifies as a true experiment because of three requisite design characteristics: manipulation of independent variables, random assignment, and the use of a control group.**

Several variations of the RCT are possible, and these will be described in Chapter 16.

■ Manipulation of Variables

Manipulation of variables refers to a deliberate operation performed by the investigator, imposing a set of predetermined experimental conditions, the independent variable, on at least two groups of subjects. The

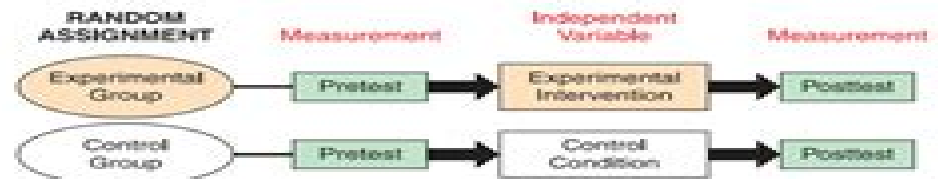


Figure 14-1 Basic structure of an RCT.

Rct Study Guide

A Loxley



Rct Study Guide:

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Table of Contents Rct Study Guide

1. Understanding the eBook Rct Study Guide
 - The Rise of Digital Reading Rct Study Guide
 - Advantages of eBooks Over Traditional Books
2. Identifying Rct Study Guide
 - 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 Rct Study Guide
 - User-Friendly Interface
4. Exploring eBook Recommendations from Rct Study Guide
 - Personalized Recommendations
 - Rct Study Guide User Reviews and Ratings
 - Rct Study Guide and Bestseller Lists

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

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

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- Integration of Multimedia Elements
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