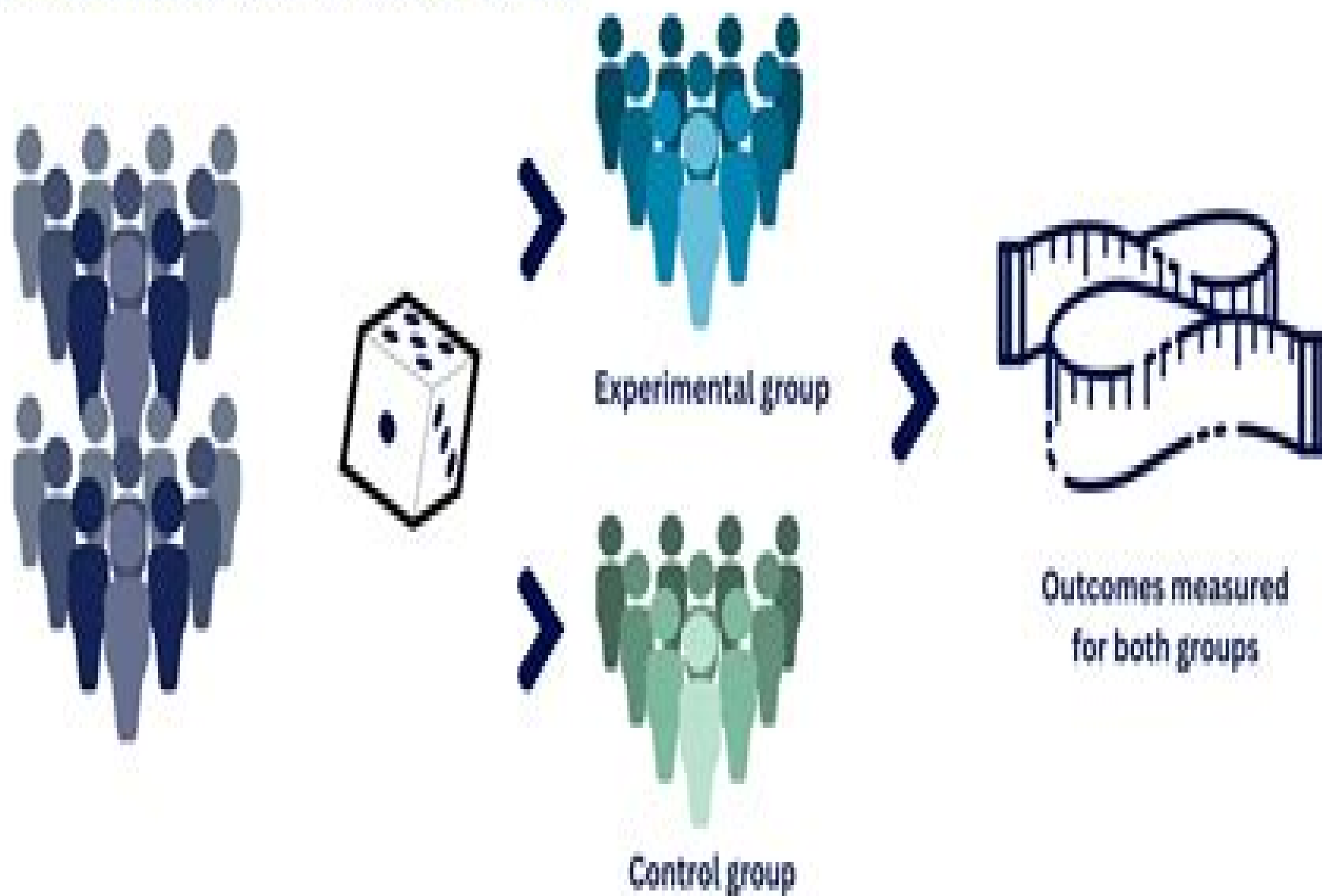


# Randomised controlled trial



# Randomised Controlled Trials

**Christopher J. Bulpitt**



## **Randomised Controlled Trials:**

*Randomized Controlled Trials* Alejandro R. Jadad, Murray W. Enkin, 2008-04-15 Randomized controlled trials are one of the most powerful and revolutionary tools of research This book is a convenient and accessible description of the underlying principles and practice of randomized controlled trials and their role in clinical decision making Structured in a jargon free question and answer format each chapter provides concise and understandable information on a different aspect of randomized controlled trials from the basics of trial design and terminology to the interpretation of results and their use in driving evidence based medicine The authors end each chapter with their musings going beyond the evidence or citations and sometimes even beyond orthodox correctness to share their thoughts and concerns about different aspects of randomized controlled trials and their role within the health system Updated to include insights from the last decade this second edition challenges over reliance on randomized controlled trials by debating their strengths and limitations and discussing their optimal use in modern healthcare It also includes a new and increasingly relevant chapter on the ethics of randomized trials World renowned writers and thinkers Drs Jadad and Enkin bring you this invaluable book for busy health professionals who wish to understand the theory of randomized controlled trials and their influence on clinical research or policy decisions

*Handbook of Statistical Methods for Randomized Controlled Trials* KyungMann Kim, Frank Bretz, Ying Kuen K. Cheung, Lisa V. Hampson, 2021-08-23 Statistical concepts provide scientific framework in experimental studies including randomized controlled trials In order to design monitor analyze and draw conclusions scientifically from such clinical trials clinical investigators and statisticians should have a firm grasp of the requisite statistical concepts The Handbook of Statistical Methods for Randomized Controlled Trials presents these statistical concepts in a logical sequence from beginning to end and can be used as a textbook in a course or as a reference on statistical methods for randomized controlled trials Part I provides a brief historical background on modern randomized controlled trials and introduces statistical concepts central to planning monitoring and analysis of randomized controlled trials Part II describes statistical methods for analysis of different types of outcomes and the associated statistical distributions used in testing the statistical hypotheses regarding the clinical questions Part III describes some of the most used experimental designs for randomized controlled trials including the sample size estimation necessary in planning Part IV describe statistical methods used in interim analysis for monitoring of efficacy and safety data Part V describe important issues in statistical analyses such as multiple testing subgroup analysis competing risks and joint models for longitudinal markers and clinical outcomes Part VI addresses selected miscellaneous topics in design and analysis including multiple assignment randomization trials analysis of safety outcomes non inferiority trials incorporating historical data and validation of surrogate outcomes

*Reading Randomised Controlled Trials* Amy Fox, Robert Savage, Anneka Dawson, Helen Gray, Clare Huxley, 2025-03-03 A behind the scenes look at a large scale reading intervention trial exposing the human decisions and real world challenges that shape

educational research Reading Randomised Controlled Trials presents an illuminating exploration of how large scale educational trials unfold in real world settings displaying the often overlooked human decisions that shape their outcomes Using the Flexible Phonics trial an ambitious study involving nearly 3 000 children in 118 schools across England as a case study the authors examine the practical and ethical problems with conducting randomized controlled trials RCTs in education Unlike pharmaceutical trials educational RCTs operate in dynamic environments where factors such as teacher decision making and school culture play a crucial role This book depicts the inner workings of education research and also underlines its broader significance particularly in the wake of school closures during the COVID 19 pandemic By focusing on early childhood literacy and the long term impact of evidence based interventions Reading Randomised Controlled Trials provides important insights for educators and researchers seeking to bridge the gap between rigorous research and meaningful classroom practice A must read for those invested in improving educational outcomes this book contests assumptions about what works in education and why

*Introduction to Randomized Controlled Clinical Trials* John N.S. Matthews, 2006-06-26 Evidence from randomized controlled clinical trials is widely accepted as the only sound basis for assessing the efficacy of new medical treatments Statistical methods play a key role in all stages of these trials including their justification design and analysis This second edition of *Introduction to Randomized Controlled Clinical Trials* provides a comprehensive and easily accessible single volume the book also adds new perspectives and insights to the conversation crucially the book considers the limits of their usefulness and applicability in education raising a range of largely unexplored concerns about their use Chapters include discussions on The impact of complexity theory and chaos theory Design issues and sampling in randomized controlled trials Learning from clinical trials Data analysis in randomized controlled trials Reporting evaluating and generalizing from randomized controlled trials Considering key issues in understanding and interrogating research evidence this book is ideal reading for all students on Research Methods modules as well as those interested in undertaking and reviewing research in the field of education

**Reading Randomised Controlled Trials** Robert Savage, Amy Fox, Anneka Dawson, Helen Gray, Clare Huxley, 2025-03-03 In early 2021 22 the Flexible Phonics reading intervention a large scale randomised controlled trial took place in 118 schools in England and involved nearly 3 000 children This study aimed to provide valuable insights into the success of largely school based

education trials The Flexible Phonics trial proved to be not only an important experiment in improving children's literacy but a case study in which the methodology of single randomised controlled trials in education can be considered Reading Randomised Controlled Trials investigates the complexities of conducting randomised controlled trials in the field of education and how they can be seen as a cultural activity The book emphasises the human operations decision making and actions that drive such trials which are often overlooked in published reports Through the case study of Flexible Phonics the book highlights the key differences between scaled educational trials and other types of trials such as pharmaceutical trials The additional focus on early childhood literacy is of significant educational importance particularly in the context of UK school partial closures in 2020 and 2021 during the Covid 19 pandemic Reading Randomised Controlled Trials is ultimately a unique resource on the implementation of randomised controlled trials in authentic school contexts and for the sustained improvement of practice in education

*Using Randomised Controlled Trials in Education* Paul Connolly, Andy Biggart, Dr. Sarah Miller, Liam O'Hare, Allen Thurston, 2017-07-03 The use of randomised controlled trials RCTs most commonly a medical sciences research tool is a hotly debated topic in Education This book examines the controversial aspects of RCTs in Education and sets out the potential and pitfalls of the method Drawing on their own extensive experience of running RCTs and their work at the Centre for Evidence and Social Innovation CESI at Queen's University Belfast the authors provide a thorough practical introduction to the use of randomised controlled trials in education Using real data sets chapters equip the reader with all of the key knowledge and skills required to design run analyse and report an RCT Coverage includes Step by step guidance on analysing data How to assess the reliability and validity of results Advice on balancing the demands of various stakeholders Essential reading for postgraduate and more experienced researchers as well as teachers and educationalists seeking to increase their knowledge and understanding of the use of such methods in education

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**Randomized Controlled Trials** Alejandro R. Jadad, 2007

Randomised Controlled Clinical Trials Christopher J. Bulpitt, 2013-03-08 Bradford Hill has defined a clinical trial as A

carefully and ethically designed experiment with the aim of answering some precisely framed question 1 This definition specifies a careful design and requires the provision of adequate controls Random allocation of treatments to subjects is important to ensure is entitled that the treated and control groups are similar Therefore this book Randomised Controlled Clinical Trials We can define a randomised controlled trial by rewriting Bradford Hill s definition as follows A carefully and ethically designed experiment which includes the provision of adequate and appropriate controls by a process of randomisation so that precisely framed questions can be answered I am a firm advocate of Randomised Controlled Clinical Trials but intend to give a balanced view of the advantages and disadvantages of these ethical experiments This book is directed primarily at the medical research worker although certain chapters may find a wider application When discussing a randomised controlled trial it is neither practicable nor desirable to divorce theory from practice however the first ten chapters concentrate mainly on theory and the remainder focus on practice The segment on trial design is followed by sections on writing the protocol designing the forms conducting the trial and analysing the results This book is meant to serve both as a reference manual and a practical guide to the design and performance of a trial

*A Medical Educator's Guide to Thinking Critically about Randomised Controlled Trials: Deconstructing the "Gold Standard"* Margaret MacDougall, 2024-05-30 Drawing on the statistical and philosophical expertise of its authors this book is designed to improve understanding and use of randomised controlled trials RCTs among health professionals It is intended for use primarily by medical educators involved in teaching statistics and evidence based medicine EBM to medical students junior doctors and other health professionals However each of the chapters serves a wider range of interests including the practical needs of physicians in interpreting research evidence to support clinical decision making and the teaching needs of philosophers of medicine who want to more fully appreciate how RCTs work in practice and provide engaging examples for their students Rather than compete with the proliferating methodological literature on RCT designs this book focuses on cultivating a healthy skepticism among developing health professionals to support critical appraisal of their own and published work on RCTs at a fundamental level including through a more informed understanding of the place of subgroup analyses in sound statistical inference Management of the positive predictive value in the statistical analysis of RCT findings is included as an important topic for contemporary medical curricula In comparing RCTs with non randomised studies a search for empirical evidence for the superiority of RCTs is initiated pointing to the need for further work to confirm what form this evidence should take Medical educators will find a wealth of reasons to encourage their students to think more critically about how the RCT operates in practice as a gold standard

**Randomised Controlled Clinical Trials** Christopher J. Bulpitt, 2013-04-17 Bradford Hill has defined a clinical trial as A carefully and ethically designed experiment with the aim of answering some precisely framed question 1 This definition specifies a careful design and requires the provision of adequate controls Random allocation of treatments to subjects is important to ensure is entitled that the treated and control groups are similar

Therefore this book Randomised Controlled Clinical Trials We can define a randomised controlled trial by rewriting Bradford Hill's definition as follows A carefully and ethically designed experiment which includes the provision of adequate and appropriate controls by a process of randomisation so that precisely framed questions can be answered I am a firm advocate of Randomised Controlled Clinical Trials but intend to give a balanced view of the advantages and disadvantages of these ethical experiments This book is directed primarily at the medical research worker although certain chapters may find a wider application When discussing a randomised controlled trial it is neither practicable nor desirable to divorce theory from practice however the first ten chapters concentrate mainly on theory and the remainder focus on practice The segment on trial design is followed by sections on writing the protocol designing the forms conducting the trial and analysing the results This book is meant to serve both as a reference manual and a practical guide to the design and performance of a trial

*Basic Epidemiology* R. Bonita, R. Beaglehole, Tord Kjellström, World Health Organization, 2006 Basic epidemiology provides an introduction to the core principles and methods of epidemiology with a special emphasis on public health applications in developing countries This edition includes chapters on the nature and uses of epidemiology the epidemiological approach to defining and measuring the occurrence of health related states in populations the strengths and limitations of epidemiological study designs and the role of epidemiology in evaluating the effectiveness and efficiency of health care The book has a particular emphasis on modifiable environmental factors and encourages the application of epidemiology to the prevention of disease and the promotion of health including environmental and occupational health

**Randomised Controlled Clinical Trials** Christopher Bulpitt, 2014-01-15 **Can randomised controlled trials end poverty?** Taibat Hussain, 2020-08-20 Essay from the year 2020 in the subject Economics Macro economics general grade 67 0 School of Oriental and African Studies University of London language English abstract This essay provides an overview of randomized controlled trials RCTs and their meteoric rise Then the author discusses key limitations to the use of RCTs from a theoretical and methodological lens and provides a country study example In recent times randomized controlled trials RCTs as a method of impact evaluation of the effectiveness of development interventions have sparked enthusiasm and optimism among a wide range of stakeholders Evidence from randomized evaluations is increasingly being used to understand and address poverty related problems To that extent advocates of RCTs labeled the randomistas as proffer RCTs the gold standard for developing effective poverty reduction policies Gold standard in this sense being the best and most accurate method without restriction to designing development interventions and assessing what works and what does not

Achieving Evidence-Based Practice Susan Hamer, Gill Collinson, 2005-11-23 This title is directed primarily towards health care professionals outside of the United States This book provides a practical introduction to and overview of the development and implementation of evidence based practice It focuses on how to look for and appraise the available evidence how to apply the evidence using a variety of approaches and in different organisational contexts and how to

understand different dimensions of personal and organisational change and its ethical components Numerous examples from practice and case studies clarify theory Very readable writing style and user friendly format with checklists of key issues Opportunities for reflective learning Update on current policy and regulatory frameworks Role of clinical governance in evidence based practice considered

A Practical Guide to Using Qualitative Research with Randomized Controlled Trials Alicia O'Cathain, 2018 Researchers measure the effectiveness of new interventions using randomized controlled trials RCTs They are increasingly using qualitative research with these RCTs to explain the results of RCTs or facilitate the viability and efficiency of RCTs A Practical Guide to Using Qualitative Research with Randomized Controlled Trials is a how to book about the use of qualitative research with RCTs Divided into three parts this book covers the process of using qualitative research with RCTs from start to finish Section one outlines overarching issues such as the many contributions qualitative research can make to generating evidence of effectiveness section two provides practical guidance from writing a proposal through to publishing qualitative research undertaken with RCTs and the final section guides the reader on how to engage with relevant stakeholders Each chapter focuses on the key steps of undertaking qualitative research in RCTs giving examples of how to write a proposal select research questions integrate qualitative and quantitative components and much more A Practical Guide to Using Qualitative Research with Randomized Controlled Trials is ideal for researchers who are leading undertaking or planning to use qualitative research with RCTs With its detailed explanations and inspiring examples this book is also useful for postgraduate students wishing to conduct qualitative research in the context of an RCT

*Essential Concepts in Clinical Research* Kenneth Schulz, David A. Grimes, 2018-07-19 This practical guide speaks to two audiences those who read and those who conduct research Clinicians are medical detectives by training For each patient they assemble clinical clues to establish causes of signs and symptoms The task involves both clinical acumen and knowledge of medical research This book helps guide clinicians through this detective work by enabling them to make sense of research and to review medical literature critically It will also be invaluable to researchers who conduct clinical research particularly randomized controlled trials Building on previously published peer reviewed articles from The Lancet this handbook is essential for busy clinicians and active researchers interested in research methods Written by leaders in the field of clinical research who have published extensively with authorship of hundreds of articles in medical journals The authorship includes one of the three authors of the CONSORT guidelines for the reporting of randomized controlled trials The book presents the essential concepts to a wide array of topics including randomized control trials descriptive studies cohort studies case control studies bias and screening tests The book utilises a readable and humorous prose style lightening what can be a difficult area for clinical readers Derived from decades of teaching clinical research in seminar settings the book will empower clinicians to make sense of and critically appraise current medical research and will enable researchers to enrich the quality of their work For this Second Edition the authors have revised and updated the original 16 chapters and added six new chapters For busy clinicians and



active researchers interested in research methods this book provides helpful tools to derive satisfaction indeed fun from clinical science      **Research** Elaine R. Monsen, Linda Van Horn, 2007-09 A comprehensive guide for survey planning study and questionnaire design and execution and presentation of research Topics include evidence based practice appetite assessment estimating sample size economic analysis using DRIs to assess intake and creating consumer research nutrition messages This book is invaluable for practicing professionals and students      **Analysis of Data from Randomized Controlled Trials** Jos W.R. Twisk, 2021-10-15 This book provides a practical guide to the analysis of data from randomized controlled trials RCT It gives an answer to the question of how to estimate the intervention effect in an appropriate way This problem is examined for different RCT designs such as RCTs with one follow up measurement RCTs with more than one follow up measurement cluster RCTs cross over trials stepped wedge trials and N of 1 trials The statistical methods are explained in a non mathematical way and are illustrated by extensive examples All datasets used in the book are available for download so readers can reanalyse the examples to gain a better understanding of the methods used Although most examples are taken from epidemiological and clinical studies this book is also highly recommended for researchers working in other fields

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