# Randomised controlled trial



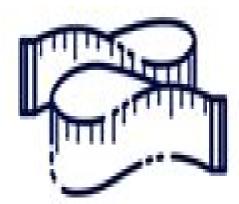








Control group



Outcomes measured for both groups

# **Randomised Controlled Trials**

**Christopher Bulpitt** 

#### **Randomised Controlled Trials:**

Randomized Controlled Trials Alehandro 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 Handbook of Statistical Methods for Randomized Controlled Trials KyungMann Kim, Frank policy decisions 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 prov

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 Taming Randomized Controlled Trials in Education Keith Morrison, 2020-07-07 There is a recent surge in the education use of randomized controlled trials RCTs within education globally with disproportionate claims being made about what they show what works and what constitutes the best evidence Drawing on up to date scholarship from across the world Taming Randomized Controlled Trials in Education critically addresses the increased use of RCTs in education exploring their benefits limits and cautions and ultimately questioning the prominence given to them While acknowledging that randomized controlled trials do have some place in education the book nevertheless argues that this place should be limited Drawing together all arguments for and against RCTs in 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

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 ethi cally designed experiment which includes the provision of adequate and ap propriate 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 con centrate 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 Randomised Controlled Clinical Trials Christopher J. Bulpitt, 2013-04-17 RCT operates in practice as a gold standard 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 ethi cally designed experiment which includes the provision of adequate and ap propriate controls by a process of randomisation so that precisely framed questions can be answered I am a firm advocate ofRandomised 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 con centrate 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

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Randomised Controlled Clinical Trials Christopher Bulpitt, 2014-01-15 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 Randomized Controlled Trials Alejandro R. Jadad, 2007 Elaine R. Monsen, Linda Van Horn, 2007-09 A comprehensive guide for survey planning study and guestionnaire 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 **Mixed Methods Research** for Nursing and the Health Sciences Sharon Andrew, Elizabeth J. Halcomb, 2009-09-24 Mixed methods research combines quantitative and qualitative research methods in a single study. The use of mixed methods research is increasingly popular in nursing and health sciences research This growth in popularity has been driven by the increasing complexity of research

problems relating to human health and wellbeing Mixed Method Research for Nursing and the Health Sciences is an accessible practical guide to the design conduct and reporting of mixed method research in nursing or the health sciences Each chapter stands alone describing the various steps of the research process but contains links to other chapters Within the text real life examples from the published literature doctoral theses and the unpublished work of the authors illustrate the concepts being discussed Places mixed methods research within its contemporary context Includes international contributions from UK Australia NZ and USA Provides an accessible introduction to theoretical and philosophical underpinnings Demystifies strategies for analysing mixed methods data Examines strategies for publishing mixed methods research Includes learning objectives and exemplars in each chapter Final chapters provide real life examples of applied research About the Authors Sharon Andrew is Head of Program Postgraduate and Elizabeth J Halcomb is Senior Lecturer School of Nursing Midwifery University of Western Sydney Also of Interest The Research Process in Nursing Fifth Edition Edited by Kate Gerrish and Anne Lacey 978 14051 3013 4 Research Handbook for Healthcare Professionals Mary Hickson 978 14051 7737 5 Real World Research A Resource for Social Scientists and Practitioner Researchers Second edition Colin Robson 978 0631 21305 5 Reviewing Research Evidence for Nursing Practice Systematic Reviews Edited by Christine Webb and Brenda Roe 978 14051 4423 0

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