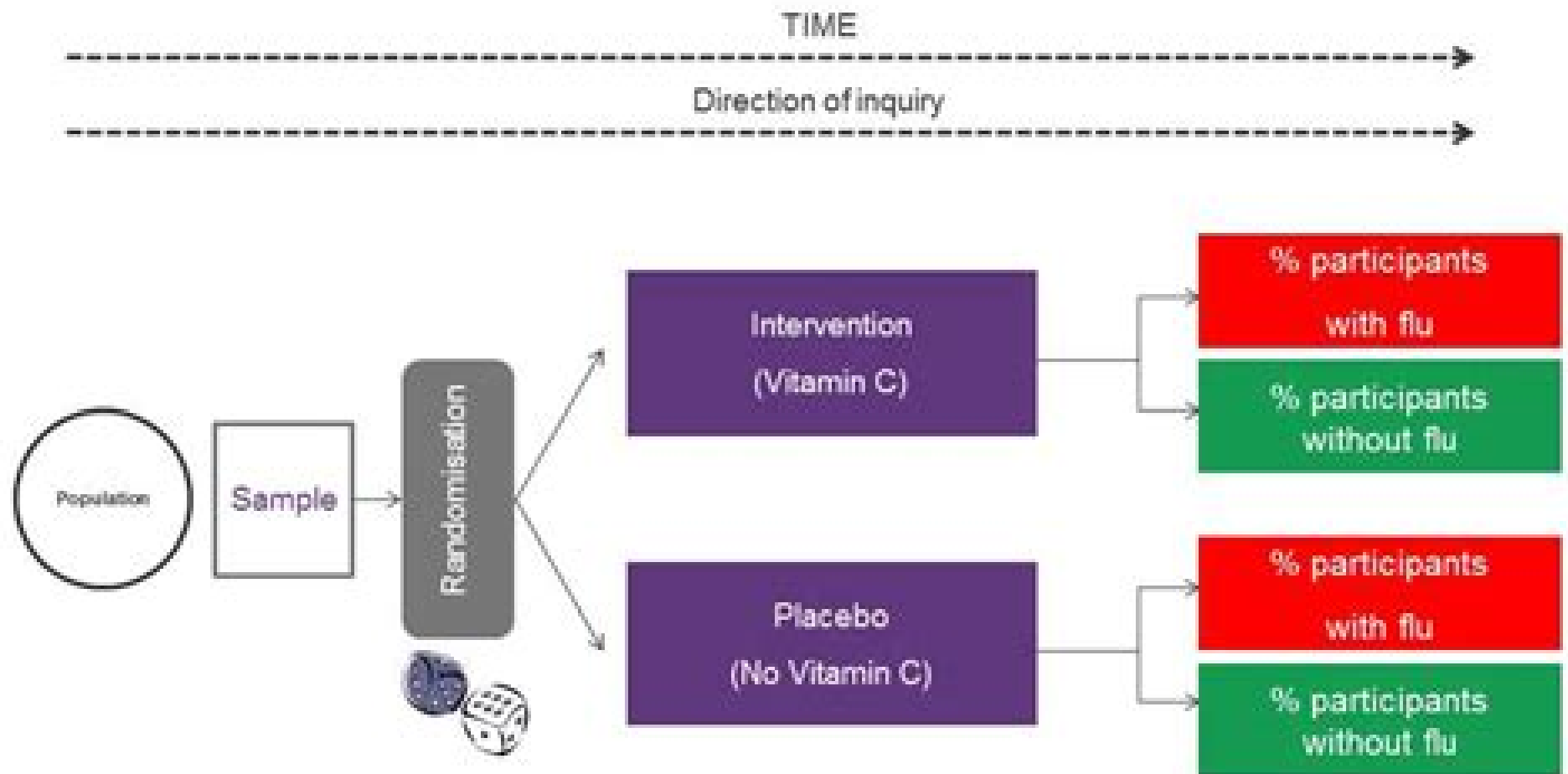


# Randomised controlled trial



# Randomised Controlled Clinical Trials

**Alejandro R. Jadad, Murray W. Enkin**



## **Randomised Controlled Clinical Trials:**

*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 accessible description of the underlying principles and practice of randomized controlled trials and their role in clinical decision making. Structured in a 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.

**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. This definition specifies a careful design and requires the provision of adequate controls. Random allocation of treatments to subjects is important to ensure that the treated and control groups are similar. Therefore, this book, *Randomised Controlled Clinical Trials*, defines 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.

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**Randomised Clinical Trials** David Machin, Peter M. Fayers, Bee Choo Tai, 2021-05-12 Randomised Clinical Trials Design Practice and Reporting provides a detailed overview of the methodology for conducting clinical trials including developing protocols data capture randomisation analysis and reporting Assuming no prior background this user friendly resource describes the statistical regulatory and practical components required for conducting randomised clinical trials Numerous examples and case studies from industry academia and the research literature help readers understand each stage of the clinical trial process This second edition contains extensively revised material throughout including new chapters covering designs for repeated measures non inferiority cluster and stepped wedge trials Other new chapters describe data and safety monitoring biomarker studies and feasibility studies Updated and expanded sections discuss situations where multiple organs different body locations or competing risks are involved subgroup analysis and multiple outcomes Written by an author team with extensive experience in conducting clinical trials this book Provides comprehensive coverage of randomised clinical trials ranging from basic to advanced Features several new chapters updated case studies and examples and references to changes in regulations Explains basic randomised trials including the parallel two group controlled trial with a single outcome measure Covers paired trial designs and trials with more than two interventions Includes a chapter on miscellaneous topics such as adaptive designs large simple trials Bayesian methods for very small trials alpha spending functions and the predictive probability test Randomised Clinical Trials is essential reading for clinicians nurses data managers and medical statisticians involved in clinical trials and for health practitioners responsible for direct patient care in a clinical trial setting Taming Randomized Controlled Trials in Education Keith Morrison, 2020-07-07 There is a recent

surge in the 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

**Randomized Controlled Trials** Alejandro R. Jadad, Murray W. Enkin, 2007-07-23 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

**Randomized Controlled Trials in Evidence-Based Dentistry** Richie Kohli, Harjit S. Sehgal, Peter Milgrom, 2024-04-16 This book reviews the role of randomized controlled trials RCTs in clinical dentistry explains how to successfully conduct RCTs related to dentistry and provides detailed information on the use of RCTs within each of the dental specialties Although RCTs represent the gold standard in evidence based dentistry for evaluation of the effects of an intervention a textbook on the subject has to date been lacking Randomized Controlled Trials in Evidence Based Dentistry will fill this educational gap and improve the confidence of dental providers researchers and their multidisciplinary teams in

conducting high quality RCTs in a variety of settings and different parts of the world In particular it will enable readers to implement a suitable step by step approach to RCTs identify possible solutions to common challenges when performing RCTs in individual dental specialties and apply these solutions to their own RCT projects *Clinical Trials* Curtis L. Meinert, Susan Tonascia, 1986 The definitive reference work on clinical trials this book presents a wealth of detailed practical information on the design conduct and analysis of both single center and multicenter trials No other book on clinical trials offers as much detail as Meinert does on such issues as sample size calculation stratification and randomization data systems design consent form development publication policies preparation of funding requests and reporting procedures **Introduction to**

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*"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 *Pragmatic Randomized Clinical Trials* Cynthia J. Girman, Mary E. Ritchey, 2021-04-08 Pragmatic Randomized Clinical Trials Using Primary Data Collection and Electronic Health Records addresses the practical aspects and challenges of the design implementation and dissemination of pragmatic randomized trials also sometimes referred to as practical or hybrid randomized trials While less restrictive and more generalizable than traditional randomized controlled trials such trials have specific challenges which are addressed in this book The book contains chapters encompassing common designs along with advantages and limitations of such designs analytic aspects in planning trials and estimating sample size and how to use patient partners to help design and operationalize pragmatic randomized trials Pragmatic trials conducted using primary data collection and trials embedded in electronic health records including electronic medical records and administrative insurance claims are addressed This comprehensive resource is valuable not only for pharmacoepidemiologists biostatisticians and clinical researchers but also across the biomedical field for those who are interested in applying pragmatic randomized clinical trials in their research Addresses typical designs and challenges of pragmatic randomized clinical trials pRCTs Encompasses analytic aspects of such trials Discusses real cases on operational challenges in launching and conducting pRCTs in electronic health records

*Health Research Fundamentals* P Manickam, Tarun Bhatnagar, 2024-02-07 Are you aspiring or pursuing a career in health research Are you inquisitive about how health research is planned and implemented You could be a student a physician or surgeon a public health practitioner a health counsellor a research associate a nurse a pharmacist a data manager a project manager an ethics committee member or just curious Health Research Fundamentals is the book to start with to be a competent public health researcher This book is a primer on health research methods with an effective combination of theoretical foundation and practical experiences Fully appreciative of the fact that there may not always be a single best approach to health research the goal here is to provide you with an overview of the principles and steps involved in biomedical and health research This book will Walk you through the systematic process of conceptualising designing planning proposing conducting and reporting a health research study Give you a head start whether you are concerned with clinical research and clinical trials patient oriented research epidemiologic studies behavioral science translational research or health services related research Get onboard to a stimulating journey of demystifying health research fundamentals A Practical Guide to Cluster Randomised Trials in Health Services Research Sandra Eldridge, Sally Kerry, 2012-01-09 Cluster randomised trials are trials in which groups or clusters of individuals are randomly allocated to different forms of treatment In health care these trials often compare different ways of managing a disease or promoting healthy living in contrast to conventional randomised trials which randomise individuals to different treatments classically comparing new drugs with a

placebo They are increasingly common in health services research This book addresses the statistical practical and ethical issues arising from allocating groups of individuals or clusters to different interventions Key features Guides readers through the stages of conducting a trial from recruitment to reporting Presents a wide range of examples with particular emphasis on trials in health services research and primary care with both principles and techniques explained Topics are specifically presented in the order in which investigators think about issues when they are designing a trial Combines information on the latest developments in the field together with a practical guide to the design and implementation of cluster randomised trials Explains principles and techniques through numerous examples including many from the authors own experience Includes a wide range of references for those who wish to read further This book is intended as a practical guide written for researchers from the health professions including doctors psychologists and allied health professionals as well as statisticians involved in the design execution analysis and reporting of cluster randomised trials Those with a more general interest will find the plentiful examples illuminating Handbook of Community Cancer Care Mark N. Gaze, Mark Gaze, Isobel M.

Wilson, 2003-01-04 An authoritative handbook covering the management of all types of cancer with an emphasis on those aspects of care of the cancer patient which are of particular interest in the community for example the presentation of cancer and palliative care The specialist management of different types of cancer is also covered with particular regard being paid to the requirements of shared care in the community and the supportive care needed for the treatment of side effects and complications

**Successful Randomized Trials** Michael J. Domanski, Sonja McKinlay, 2009 This handbook is a ready reference on the theory and operation of modern large multicenter randomized clinical trials which have come to be the basis of evidence based medicine Written in a concise engaging style geared to physicians the book explains the rationale and theoretical foundations for clinical trials the components of modern clinical trials including their functions and interactions and practical considerations in the design and implementation of these studies including an introduction to the economics and business aspects **Journal of the Royal Army Medical Corps**, 1999

*Immunotherapies Against Infectious Diseases* Saba Tufail, Mohammad Asif Sherwani, Najmul Islam, 2024-11-08 Infectious diseases have jeopardized human health significantly as evidenced by the ongoing Covid 19 pandemic In recent years the world has witnessed outbreaks of many emerging and re emerging infections such as SARS most recent by SARS CoV 2 Ebola Zika MERS dengue which in addition to taking millions of lives have posed major health issues in recovered individuals Moreover several infectious agents like hepatitis B and C viruses human papillomavirus human immunodeficiency virus type 1 Epstein Barr virus human T cell leukemia lymphoma virus type 1 Kaposi sarcoma associated herpesvirus Helicobacter pylori and Streptococcus bovis have been found to cause different types of cancers since the action mechanism of these agents sometimes transforms an infected cell into a cancer cell As these infections are difficult to treat with available drugs owing to their lower efficacy toxicity and emergence of drug resistance immunotherapy is viewed as a viable option Immunotherapy is manipulating body



s defense mechanism to treat manage disease Threats of emerging and reemerging infectious diseases in addition to dangers of developing cancer due to cancer causing infectious agents combined with lack of effective treatment modalities has shifted focus of scientific community to immunotherapy Advancements in immunotherapies comprising vaccines monoclonal antibodies cytokines T cells and checkpoint inhibitors have shown immense promise in combating not only cancer but infectious diseases as well Through this Research Topic we aim to discuss recent advances in immunotherapy based treatment management of infectious diseases We aim to include studies that evaluate how different forms of immunotherapies including vaccines have been can be exploited for preventing treating managing infectious diseases We welcome Original Research Articles Reviews and Mini reviews discussing the following main themes Vaccines against emerging re emerging diseases Vaccine design components technologies such as adjuvants delivery systems administration route dosage Targeted therapy Cancer immunotherapy using but not limited to monoclonal antibodies cytokines T cells and checkpoint inhibitors Monoclonal antibodies including nanobodies against SARS COV 2 for the treatment and prevention of COVID 19 Immunotherapies for infectious diseases using but not limited to monoclonal antibodies cytokines T cells and checkpoint inhibitors Authors are encouraged to submit manuscripts elaborating the use of delivery systems nanoparticles nanomaterials for the aforementioned theme themes **Clinical Trials, Practice and Design in Gastrointestinal Cancers** Alberto Puccini,Edouard Auclin,Jorg Kleeff,2023-11-07

## Unveiling the Power of Verbal Beauty: An Psychological Sojourn through **Randomised Controlled Clinical Trials**

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