

*DESIGN AND ANALYSIS OF*

**CLUSTER  
RANDOMIZATION  
TRIALS**

*IN HEALTH RESEARCH*

ALLAN DONNER  
& NEIL KLAR

# Design And Analysis Of Cluster Randomization Trials In Health Research

**Sandra Eldridge, Sally Kerry**



## **Design And Analysis Of Cluster Randomization Trials In Health Research:**

Design and Analysis of Cluster Randomization Trials in Health Research Allan Donner, Neil Klar, 2010-05-17 A cluster randomization trial is one in which intact social units or clusters of individuals are randomized to different intervention groups Trials randomizing clusters have become particularly widespread in the evaluation of non therapeutic interventions including lifestyle modification educational programmes and innovations in the provision of health care The increasing popularity of this design among health researchers over the past two decades has led to an extensive body of methodology on the subject This is the first book to present a systematic and united treatment of this topic it contains distinctive chapters on the history of cluster randomized trials ethical issues and reporting guidelines

**Design and Analysis of Pragmatic Trials** Song Zhang, Chul Ahn, Hong Zhu, 2023-05-16 This book begins with an introduction of pragmatic cluster randomized trials PCTs and reviews various pragmatic issues that need to be addressed by statisticians at the design stage It discusses the advantages and disadvantages of each type of PCT and provides sample size formulas sensitivity analyses and examples for sample size calculation The generalized estimating equation GEE method will be employed to derive sample size formulas for various types of outcomes from the exponential family including continuous binary and count variables Experimental designs that have been frequently employed in PCTs will be discussed including cluster randomized designs matched pair cluster randomized design stratified cluster randomized design stepped wedge cluster randomized design longitudinal cluster randomized design and crossover cluster randomized design It demonstrates that the GEE approach is flexible to accommodate pragmatic issues such as hierarchical correlation structures different missing data patterns randomly varying cluster sizes etc It has been reported that the GEE approach leads to under estimated variance with limited numbers of clusters The remedy for this limitation is investigated for the design of PCTs This book can assist practitioners in the design of PCTs by providing a description of the advantages and disadvantages of various PCTs and sample size formulas that address various pragmatic issues facilitating the proper implementation of PCTs to improve health care It can also serve as a textbook for biostatistics students at the graduate level to enhance their knowledge or skill in clinical trial design

**Key Features** Discuss the advantages and disadvantages of each type of PCTs and provide sample size formulas sensitivity analyses and examples Address an unmet need for guidance books on sample size calculations for PCTs A wide variety of experimental designs adopted by PCTs are covered The sample size solutions can be readily implemented due to the accommodation of common pragmatic issues encountered in real world practice Useful to both academic and industrial biostatisticians involved in clinical trial design Can be used as a textbook for graduate students majoring in statistics and biostatistics

A Practical Guide to Cluster Randomised Trials in Health Services Research Sandra Eldridge, Sally Kerry, 2012-02-20 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 [The Handbook of Clinical Trials and Other Research](#) Alan Earl-Slater,2002 This practical handbook includes all the main clinical trial and general research terms and is illustrated with real life examples diagrams and tables It also includes material on research ethical committees and incorporates recent international developments such as the EU Clinical Trials Directive The research methods and issues identified are universal crossing countries and disciplines It can be used as a reference tool an introduction to learning about clinical trials as a refresher to those involved in clinical research or to check that the correct terms are being used in the correct context Readily available references are included that can be used by the reader to further support their own work

**Clinical Trials** Duolao Wang,Ameet Bakhai,2006 This book explains statistics specifically for a medically literate audience Readers gain not only an understanding of the basics of medical statistics but also a critical insight into how to review and evaluate clinical trial evidence **How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research** Michael J. Campbell,Stephen J. Walters,2014-03-28 A complete guide to understanding cluster randomised trials Written by two researchers with extensive experience in the field this book presents a complete guide to the design analysis and reporting of cluster randomised trials It spans a wide range of applications trials in developing countries trials in primary care trials in the health services A key feature is the use of R code and code from other popular packages to plan and analyse cluster trials using data from actual trials The book contains clear technical descriptions of the models used and considers in detail the ethics involved in such trials and the problems in planning them For readers and students who do not intend to run a trial but wish to be a critical reader of the literature there are sections on the CONSORT statement and exercises in reading published trials Written in a clear accessible style Features real examples taken from the authors extensive practitioner experience of designing and analysing clinical trials Demonstrates

the use of R Stata and SPSS for statistical analysis Includes computer code so the reader can replicate all the analyses Discusses neglected areas such as ethics and practical issues in running cluster randomised trials How to Design Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research provides an excellent reference tool and can be read with profit by statisticians health services researchers systematic reviewers and critical readers of cluster randomised trials

Handbook Of Health Research Methods: Investigation, Measurement And Analysis Bowling, Ann,Ebrahim, Shah,2005-06-01 Handbook of Health Research Methods is an essential tool for researchers and postgraduate students taking masters courses or undertaking doctoral programmes in health services evaluation health sciences health management public health nursing sociology socio biology medicine and epidemiology However the book also appeals to health professionals who wish to broaden their knowledge of research methods in order to make effective policy and practice decisions

Cluster Randomised Trials Richard J. Hayes, Lawrence H. Moulton,2017-07-06 Cluster Randomised Trials Second Edition discusses the design conduct and analysis of trials that randomise groups of individuals to different treatments It explores the advantages of cluster randomisation with special attention given to evaluating the effects of interventions against infectious diseases Avoiding unnecessary mathematical detail the book covers basic concepts underlying the use of cluster randomisation such as direct indirect and total effects In the time since the publication of the first edition the use of cluster randomised trials CRTs has increased substantially which is reflected in the updates to this edition There are greatly expanded sections on randomisation sample size estimation and alternative designs including new material on stepped wedge designs There is a new section on handling ordinal outcome data and an appendix with descriptions and or generating code of the example data sets Although the book mainly focuses on medical and public health applications it shows that the rigorous evidence of intervention effects provided by CRTs has the potential to inform public policy in a wide range of other areas The book encourages readers to apply the methods to their own trials reproduce the analyses presented and explore alternative approaches

*Sample Size Calculations in Clinical Research* Shein-Chung Chow,Jun Shao,Hansheng Wang,Yuliya Lokhnygina,2017-08-15 Praise for the Second Edition this is a useful comprehensive compendium of almost every possible sample size formula The strong organization and carefully defined formulae will aid any researcher designing a study Biometrics This impressive book contains formulae for computing sample size in a wide range of settings One sample studies and two sample comparisons for quantitative binary and time to event outcomes are covered comprehensively with separate sample size formulae for testing equality non inferiority and equivalence Many less familiar topics are also covered Journal of the Royal Statistical Society *Sample Size Calculations in Clinical Research* Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development A comprehensive and unified presentation of statistical concepts and practical applications this book includes a well balanced summary of current and emerging clinical issues regulatory requirements and recently developed statistical

methodologies for sample size calculation Features Compares the relative merits and disadvantages of statistical methods for sample size calculations Explains how the formulae and procedures for sample size calculations can be used in a variety of clinical research and development stages Presents real world examples from several therapeutic areas including cardiovascular medicine the central nervous system anti infective medicine oncology and women s health Provides sample size calculations for dose response studies microarray studies and Bayesian approaches This new edition is updated throughout includes many new sections and five new chapters on emerging topics two stage seamless adaptive designs cluster randomized trial design zero inflated Poisson distribution clinical trials with extremely low incidence rates and clinical trial simulation

**Oxford Textbook of Global Public Health** Roger Detels, Martin Gulliford, Quarraisha Abdool Karim, Chorh Chuan Tan, 2017 Sixth edition of the hugely successful internationally recognised textbook on global public health and epidemiology comprehensively covering the scope methods and practice of the discipline [Journal of the National Cancer Institute](#), 2008

[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

*Discrete Event Simulations* Aitor Goti, 2010-08-18 Considered by many authors as a technique for modelling stochastic dynamic and discretely evolving systems this technique has gained widespread acceptance among the practitioners who want to represent and improve complex systems Since DES is a technique applied in incredibly different areas this book reflects many different points of view about DES thus all authors describe how it is understood and applied within their context of work providing an extensive understanding of what DES is It can be said that the name of the book

itself reflects the plurality that these points of view represent The book embraces a number of topics covering theory methods and applications to a wide range of sectors and problem areas that have been categorised into five groups As well as the previously explained variety of points of view concerning DES there is one additional thing to remark about this book its richness when talking about actual data or actual data based analysis When most academic areas are lacking application cases roughly the half part of the chapters included in this book deal with actual problems or at least are based on actual data Thus the editor firmly believes that this book will be interesting for both beginners and practitioners in the area of DES

**Encyclopedia of Biopharmaceutical Statistics - Four Volume Set** Shein-Chung Chow, 2018-09-03 Since the publication of the first edition in 2000 there has been an explosive growth of literature in biopharmaceutical research and development of new medicines This encyclopedia 1 provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process 2 gives a well balanced summary of current regulatory requirements and 3 describes recently developed statistical methods in the pharmaceutical sciences Features of the Fourth Edition 1 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters 2 Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review approval process and statistical designs and methodologies 3 Additional topics include multiple stage adaptive trial design in clinical research translational medicine design and analysis of biosimilar drug development big data analytics and real world evidence for clinical research and development 4 A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics About the Editor Shein Chung Chow Ph D is currently an Associate Director Office of Biostatistics U S Food and Drug Administration FDA Dr Chow is an Adjunct Professor at Duke University School of Medicine as well as Adjunct Professor at Duke NUS Singapore and North Carolina State University Dr Chow is the Editor in Chief of the Journal of Biopharmaceutical Statistics and the Chapman Hall CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers He was elected Fellow of the American Statistical Association in 1995

**Handbook of Health Research Methods: Investigation, Measurement and Analysis** Ann Bowling, Shah Ebrahim, 2005-06-16 an ideal set text Angela Scriven Course Leader Brunel University Which research method should I use to evaluate services How do I design a questionnaire How do I conduct a systematic review of research This handbook helps researchers to plan carry out and analyse health research and evaluate the quality of research studies The book takes a multidisciplinary approach to enable researchers from different disciplines to work side by side in the investigation of population health the evaluation of health care and in health care delivery Handbook of Health Research Methods is an essential tool for researchers and postgraduate students taking masters courses or undertaking doctoral programmes in health services evaluation health sciences health management public health nursing sociology socio biology medicine and epidemiology However the book also appeals to health professionals who wish to broaden their knowledge of

research methods in order to make effective policy and practice decisions Contributors Joy Adamson Geraldine Barrett Jane P Biddulph Ann Bowling Sara Brookes Jackie Brown Simon Carter Michel P Coleman Paul Cullinan George Davey Smith Paul Dieppe Jenny Donovan Craig Duncan Shah Ebrahim Vikki Entwistle Clare Harries Lesley Henderson Kelvyn Jones Olga Kostopoulou Sarah J Lewis Richard Martin Martin McKee Graham Moon Ellen Nolte Alan O'Rourke Ann Oakley Tim Peters Tina Ramkalawan Caroline Sanders Mary Shaw Andrew Steptoe Jonathan Sterne Anne Stiggelbout S V Subramanian Kate Tilling Liz Twigg Suzanne Wait

*Practical Transfusion Medicine* Michael F. Murphy, David J. Roberts, Mark H. Yazer, 2017-03-22 The fifth edition of this practical textbook on transfusion medicine has been thoroughly revised with the latest in scientific and technological developments and edited by a leading team of international expert haematologists including new co editor Mark H Yazer MD A succinct and user friendly resource of transfusion medicine for clinicians scientists and trainees with key points charts and algorithms Discusses practice in blood centres and hospitals including regulatory aspects transfusion safety production and storage donor care and blood transfusion in a global context Coverage of cellular and tissue therapies and organ transplantation including stem cell collection and haematopoietic stem cell processing and storage Review of the development of the evidence base for transfusion medicine Content on the clinical practice for transfusion and alternatives to transfusion

**Fundamentals of Evidence-Based Health Care and Translational Science** Francesco Chiappelli, 2014-03-18 Comparative effectiveness research the conduct and synthesis of systematic research in order to compare the benefits and harms of alternative treatment options is of critical importance in enabling informed health care decisions to be made This user friendly practical handbook examines in depth how best to perform such comparative effectiveness research A wide range of topics and methods are discussed including research synthesis sampling analysis assessment of evidence design systematic evaluation of statistical analysis and meta analysis The discussion extends well beyond the fundamentals by encompassing complex systematic reviews cumulative meta analyses and logic based versus utility based decision making Health care providers researchers instructors and students will all find this to be an invaluable reference on the compelling current issues and important analytical tools in comparative effectiveness research

*Advances in Clinical Trial Biostatistics* Nancy L. Geller, 2003-10-21 From aspects of early trials to complex modeling problems *Advances in Clinical Trial Biostatistics* summarizes current methodologies used in the design and analysis of clinical trials Its chapters contributed by internationally renowned methodologists experienced in clinical trials address topics that include Bayesian methods for phase I clinical trials adaptive two stage clinical trials and the design and analysis of cluster randomization trials trials with multiple endpoints and therapeutic equivalence trials Other discussions explore Bayesian reporting methods incorporating compliance in treatment evaluation and statistical issues emerging from clinical trials in HIV infection

**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

*Guidelines for Reporting Health Research* David Moher, Douglas Altman, Kenneth Schulz, Iveta Simera, Elizabeth Wager, 2014-08-06 *Guidelines for Reporting Health Research* is a practical guide to choosing and correctly applying the appropriate guidelines when reporting health research to ensure clear transparent and useful reports This new title begins with an introduction to reporting guidelines and an overview of the importance of transparent reporting the characteristics of good guidelines and how to use reporting guidelines effectively in reporting health research This hands on manual also describes over a dozen internationally recognised published guidelines such as CONSORT STROBE PRISMA and STARD in a clear and easy to understand format It aims to help researchers choose and use the correct guidelines for reporting their research and to produce more completely and transparently reported papers which will help to ensure reports are more useful and are not misleading Written by the authors of health research reporting guidelines in association with the EQUATOR Enhancing the QUALity and Transparency Of health Research Network *Guidelines for Reporting Health Research* is a helpful guide to producing publishable research It will be a valuable resource for researchers in their role as authors and also an important reference for editors and peer reviewers

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