Design And Analysis Of Cluster Randomization Trials In Health Research 1st Edition

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Cluster Randomised Trials - Richard J. Hayes 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.

A Practical Guide to Cluster Randomised Trials in Health Services Research - Sandra Eldridge 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.

Handbook of Statistical Methods for Randomized Controlled Trials - KyungMann Kim 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.

Design and Analysis of Clinical Trials - Shein-Chung Chow 2013-09-30

Praise for the Second Edition: “...a grand feast for biostatisticians. It stands readyto satisfy the appetite of any pharmaceutical scientist with arespectable statistical appetite.” —Journal of ClinicalResearch Best Practices The Third Edition of Design and Analysis of ClinicalTrials provides complete, comprehensive, and expanded coverageof recent health treatments and interventions. Featuring a unifiedpresentation, the book provides a well-balanced summary of currentregulatory requirements and recently developed statistical methodsas well as an overview of the various designs and analyses that areutilized at different stages of clinical research and development.Additional features of this Third Edition include: • New chapters on biomarker development and targetclinical trials, adaptive design, trials for evaluating diagnosticdevices, statistical methods for translational medicine, andtraditional Chinese medicine • A balanced overview of current and emerging clinicalissues as well as newly developed statistical methodologies • Practical examples of clinical trials that demonstrateeveryday applicability, with illustrations and examples to explainkey concepts • New sections on bridging studies and global trials, QTstudies, multinational trials, comparative effectiveness trials,and the analysis of QT/QTc prolongation • A complete and balanced presentation of clinical andscientific issues, statistical concepts, and methodologies forbridging clinical and statistical disciplines • An update of each chapter that reflects changes inregulatory requirements for the drug review and

approval processand recent developments in statistical design and methodology forclinical research and development Design and Analysis of Clinical Trials, Third Editioncontinues to be an ideal clinical research reference for academic,pharmaceutical, medical, and regulatory scientists/researchers,statisticians, and graduate-level students.

Field Trials of Health Interventions - Peter G. Smith 2015

"IEA, International Epidemiological Association, Welcome Trust."

Sample Sizes for Clinical Trials - Steven A. Julious 2009-08-26

Drawing on various real-world applications, Sample Sizes for Clinical Trials takes readers through the process of calculating sample sizes for many types of clinical trials. It provides descriptions of the calculations with a practical emphasis. Focusing on normal, binary, ordinal, and survival data, the book explores a range of trials, including superiority, equivalence, non-inferiority, bioequivalence, and precision for both parallel group and crossover designs. The author discusses how trial objectives impact the study design with respect to the derivation of formulae for sample size calculations. He uses real-life studies throughout to show how the concepts and calculations can be employed. This work underscores the importance of sample size calculation in the design of a clinical trial. With useful calculation tables throughout, it enables readers to quickly find an appropriate formula, formula application, and associated worked example. Watch the author speak about this book at JSM 2012 in San Diego.

Design and Analysis of Cluster Randomized Trials with Application to HIV Prevention and Treatment - Laura Balzer 2015

This dissertation is focused on the development of the optimal design and analysis for cluster randomized trials. Specifically, we tackle three common questions: whether or not to pair-match clusters, which causal parameter best captures the intervention effect, and how to select the adjustment set for the analysis. We begin by introducing a formal framework for causal inference in Chapter 1. Throughout, the Sustainable East Africa Research in Community Health (SEARCH) trial serves as the motivating example (NCT01864603). SEARCH is an ongoing community randomized trial to evaluate the impact of immediate and streamlined antiretroviral therapy on HIV incidence in rural East Africa. In Chapter 2, we consider pair-matching, an intuitive design strategy to protect study validity and to potentially increase power in randomized trials. In a common design, candidate units are identified, and their baseline characteristics are used to create the best n/2 matched pairs. Within the resulting pairs, the intervention is randomized, and the outcomes are measured at the end of follow-up. We consider this design to be adaptive, because the construction of the matched pairs depends on the baseline covariates of all candidate units. As a consequence, the observed data cannot be considered as n/2 independent, identically distributed (i.i.d.) pairs of units, as common practice assumes. Instead, the observed data consist of n dependent units. Chapter 2 explores the consequences of adaptive pair-matching in randomized trials for estimation of the conditional average treatment effect (CATE): the intervention effect, given the measured covariates of the n study units. We contrast the unadjusted estimator with TMLE and show substantial efficiency gains from matching and further gains with adjustment. In Chapter 3, we compare three causal parameters: the population, conditional and sample average treatment effects. Using a structural causal model, we explicitly define each parameter, discuss interpretation, and formally examine identifiability. To the best of our knowledge, Chapter 3 is the first to propose using TMLE for estimation and inference of the sample effect. In most settings, the sample parameter will be estimated more efficiently than the conditional parameter, which will, in turn, be estimated more efficiently than the population parameter. Finite sample simulations illustrate the potential gains in precision and power from selecting the sample effect as the target of inference. Finally

in Chapter 4, we discuss adjustment for measured covariates during the analysis to reduce variance and increase power in randomized trials. To avoid misleading inference, the analysis plan must be pre-specified. However, it is often unclear a priori which baseline covariates (if any) should be included in the analysis. In the SEARCH trial, for example, there are 16 matched pairs of communities and many potential adjustment variables, including region, HIV prevalence, male circumcision coverage and measures of community-level viral load. In Chapter 4, we propose a rigorous procedure to data-adaptively select the adjustment set, which maximizes the efficiency of the analysis. Specifically, we use cross-validation to select from a pre-specified library the candidate TMLE that minimizes the estimated variance. For further gains in precision, we also propose a collaborative procedure for estimating the known exposure mechanism. Our small sample simulations demonstrate the promise of the methodology to maximize study power, while maintaining nominal confidence interval coverage. Our procedure is tailored to the scientific question (sample vs. population treatment effect) and study design (pair-matched or not) and alleviates many of the common concerns.

A Practical Guide to Cluster Randomised Trials in Health Services Research - Sandra Eldridge 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.

The Ethics of Biomedical Research - Baruch A. Brody 1998

Examines the many ethical issues related to biomedical research, including the use of animals in research, research on human subjects, clinical trials, international research ethics policies, and other related topics.

Pragmatic Randomized Clinical Trials - Cynthia J. Girman 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

How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research - Michael J. Campbell 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.

Designing Randomised Trials in Health, Education and the Social Sciences - D. Torgerson 2008-03-13

The book focuses on the design of rigorous trials rather than their statistical underpinnings, with chapters on: pragmatic designs; placebo designs; preference approaches; unequal allocation; economics; analytical approaches; randomization methods. It also includes a detailed description of randomization procedures and different trial designs.

Symbolic Data Analysis - Lynne Billard 2012-05-14

With the advent of computers, very large datasets have become routine. Standard statistical methods don't have the power or flexibility to analyse these efficiently, and extract the required knowledge. An alternative approach is to summarize a large dataset in such a way that the resulting summary dataset is of a manageable size and yet retains as much of the knowledge in the original dataset as possible. One consequence of this is that the data may no longer be formatted as single values, but be represented by lists, intervals, distributions, etc. The summarized data have their own internal structure, which must be taken into account in any analysis. This text presents a unified account of symbolic data, how they arise, and how they are structured. The reader is introduced to symbolic analytic methods described in the consistent statistical framework required to carry out such a summary and subsequent analysis. Presents a detailed overview of the methods and applications of symbolic data analysis. Includes numerous real examples, taken from a variety of application areas, ranging from health and social sciences, to economics and computing. Features exercises at the end of each chapter, enabling the reader to develop their understanding of the

theory. Provides a supplementary website featuring links to download the SODAS software developed exclusively for symbolic data analysis, data sets, and further material. Primarily aimed at statisticians and data analysts, Symbolic Data Analysis is also ideal for scientists working on problems involving large volumes of data from a range of disciplines, including computer science, health and the social sciences. There is also much of use to graduate students of statistical data analysis courses.

Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research - Chul Ahn 2014-12-09

Accurate sample size calculation ensures that clinical studies have adequate power to detect clinically meaningful effects. This results in the efficient use of resources and avoids exposing a disproportionate number of patients to experimental treatments caused by an overpowered study. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research explains how to determine sample size for studies with correlated outcomes, which are widely implemented in medical, epidemiological, and behavioral studies. The book focuses on issues specific to the two types of correlated outcomes: longitudinal and clustered. For clustered studies, the authors provide sample size formulas that accommodate variable cluster sizes and within-cluster correlation. For longitudinal studies, they present sample size formulas to account for within-subject correlation among repeated measurements and various missing data patterns. For multiple levels of clustering, the level at which to perform randomization actually becomes a design parameter. The authors show how this can greatly impact trial administration, analysis, and sample size requirement. Addressing the overarching theme of sample size determination for correlated outcomes, this book provides a useful resource for biostatisticians, clinical investigators, epidemiologists, and social scientists whose research involves trials with correlated outcomes. Each chapter is self-contained so readers can explore topics relevant to their research projects without having to refer to other chapters.

Running Randomized Evaluations - Rachel Glennerster 2013-11-24

This book provides a comprehensive yet accessible guide to running randomized impact evaluations of social programs. Drawing on the experience of researchers at the Abdul Latif Jameel Poverty Action Lab, which has run hundreds of such evaluations in dozens of countries throughout the world, it offers practical insights on how to use this powerful technique, especially in resource-poor environments. This step-by-step guide explains why and when randomized evaluations are useful, in what situations they should be used, and how to prioritize different evaluation opportunities. It shows how to design and analyze studies that answer important questions while respecting the constraints of those working on and benefiting from the program being evaluated. The book gives concrete tips on issues such as improving the quality of a study despite tight budget constraints, and demonstrates how the results of randomized impact evaluations can inform policy. With its self-contained modules, this one-of-a-kind guide is easy to navigate. It also includes invaluable references and a checklist of the common pitfalls to avoid. Provides the most up-to-date guide to running randomized evaluations of social programs, especially in developing countries Offers practical tips on how to complete high-quality studies in even the most challenging environments Self-contained modules allow for easy reference and flexible teaching and learning Comprehensive yet nontechnical

Design and Analysis Methods for Cluster Randomized Trials with Pair-matching on Baseline Outcome - Misook Park 2006

Practical Issues in the Design and Analysis of Stepped Wedge Cluster Randomized Trials - Erin Leister Chaussee 2018

The stepped wedge (SW) design is a variation on the cluster randomized trial (CRT) in which all clusters receive both the control and intervention conditions. Clusters begin the trial at the

same time, and all participants are assigned to the control condition during this initial phase in the study. At sequential time periods, individual clusters or groups of clusters cross over to the intervention condition based on a randomly assigned cluster order. The SW design is becoming increasingly popular due to its advantages over CRTs when intra-cluster correlation is high, and because it is a useful design in the field of implementation science. This research focused on three different design issues that statisticians and researchers are currently facing: (1) variability in cluster size and enrollment over time leading to imbalance in number of participants by treatment arm, and subsequent effects on statistical power, (2) covariate-constrained randomization as a way to mitigate potential covariate imbalance across treatment arm, and (3) efficient control group selection procedures from electronic medical records. Some of our research questions were inspired by the DECIDE-LVAD trial, which employed a SW design, and summary data from this trial are used in examples throughout. SW designs can end up with an imbalance in the number of participants by treatment arm if the clusters are of variable size, or if participants do not enroll at a constant rate across time period within cluster. We explored the effects of variable cluster size, variable enrollment over time and treatment group imbalance on the power of SW designs. We found that increasing cluster size variability and enrollment variability across time period led to decreased power relative to designs with equal cluster-period sample sizes. To understand the difference in power between complete SW designs and those with a washout period prior to intervention implementation, we derived an expression for the variance of the treatment effect in the presence of a washout period. This showed that the difference in power between complete and washout designs is dependent on the number of treatment sequences in the SW design. Covariate-constrained randomization is commonly used in the CRT setting if there are concerns about potential confounding due to differing cluster level covariates or individual-level covariates where the distributions vary by cluster. We developed a method for covariate-constrained randomization in SW designs that is easy to implement, including shareable code. We evaluated this method by comparing treatment effect estimation, power, and type I error across analysis methods and using different constraint thresholds. We compared analysis methods in two ways: (a) linear mixed model analyses vs. permutation tests, and (b) unadjusted vs. adjusted for potential confounders. We observed consistently good results when the covariate-constrained randomization procedure was used to rule out a small set of potential randomizations with the worst balance and final statistical analyses were adjusted for potential confounders. Recently, questions have been raised regarding efficient control group selection methods in a situation when participants in the intervention arm of the SW design will be enrolled as usual, but all outcome data will be collected from electronic health records. In this setting, control group participants would not need to be enrolled. This design variant is of interest to researchers due to the potential cost savings of enrolling a smaller group of participants. Research questions include (a) how to select the potential controls to match the risk profile of the intervention group participants, and (b) how to analyze the data after control participants are selected. First, we modified a propensity score (PS) matching technique that has been used in the clustered data setting for use in SW, and compared its matching properties to the greedy nearest neighbor matching algorithm. Next, we compared results of statistical analyses after selecting the control group using the matching methods to analysis methods which made use of the entire pool of potential controls (PS weighting, covariate adjustment). We observed that the analysis methods which employed covariate adjustment on the sample of intervention participants and the entire pool of potential controls were the most robust, even in the presence of cluster-level unmeasured confounding. This research will be of use to researchers who are

considering employing the SW design in a future trial. Our findings demonstrate the sensitivity of the power to cluster-period sample size variability, emphasize the importance of considering all potential confounders prior to cluster order randomization, and describe appropriate methods for design and analysis in the presence of potential confounding.

Design and Analysis of Group-randomized Trials - David M. Murray 1998

This text provides the most comprehensive treatment of the design and analytic issues involved in group-randomized trials. GRTs are comparative studies conducted to evaluate the effect of a health promotion intervention in which the units of assignment are identifiable groups (e.g., schools, worksites) and the units of observation are members of those groups (e.g., students, workers). The book reviews the underlying issues, the most widely used research designs, and analytic strategies. There is an emphasis on mixed-model regression, with two chapters illustrating the analytic methods in SAS PROC MIXED and GLIMMIX. There is also a detailed chapter on power analysis and sample size calculation.

Principles of Research Design and Drug Literature Evaluation - Rajender R. Aparasu 2014-03-07

Principles of Research Design and Drug Literature Evaluation is a unique resource that provides a balanced approach covering critical elements of clinical research, biostatistical principles, and scientific literature evaluation techniques for evidence-based medicine. This accessible text provides comprehensive course content that meets and exceeds the curriculum standards set by the Accreditation Council for Pharmacy Education (ACPE). Written by expert authors specializing in pharmacy practice and research, this valuable text will provide pharmacy students and practitioners with a thorough understanding of the principles and practices of drug literature evaluation with a strong grounding in research and biostatistical principles. Principles of Research Design and Drug Literature Evaluation is an ideal foundation for professional pharmacy students and a key resource for pharmacy residents, research fellows, practitioners, and clinical researchers. FEATURES * Chapter Pedagogy: Learning Objectives, Review Questions, References, and Online Resources * Instructor Resources: PowerPoint Presentations, Test Bank, and an Answer Key * Student Resources: a Navigate Companion Website, including Crossword Puzzles, Interactive Flash Cards, Interactive Glossary, Matching Questions, and Web Links From the Foreword: "This book was designed to provide and encourage practitioner’s development and use of critical drug information evaluation skills through a deeper understanding of the foundational principles of study design and statistical methods. Because guidance on how a study’s limited findings should not be used is rare, practitioners must understand and evaluate for themselves the veracity and implications of the inherently limited primary literature findings they use as sources of drug information to make evidence-based decisions together with their patients. The editors organized the book into three supporting sections to meet their pedagogical goals and address practitioners’ needs in translating research into practice. Thanks to the editors, authors, and content of this book, you can now be more prepared than ever before for translating research into practice." L. Douglas Ried, PhD, FAPhA Editor-in-Chief Emeritus, Journal of the American Pharmacists Association Professor and Associate Dean for Academic Affairs, College of Pharmacy, University of Texas at Tyler, Tyler, Texas

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.

Data Monitoring Committees in Clinical Trials - Susan S. Ellenberg 2003-01-17

There has been substantial growth in the use of data monitoring committees in recent years, by both government agencies and the pharmaceutical industry. This growth has been brought about by increasing recognition of the value of such committees in safeguarding trial participants as well as protecting trial integrity and the validity of conclusions. This very timely book describes the operation of data monitoring committees, and provides an authoritative guide to their establishment, purpose and responsibilities. * Provides a practical overview of data monitoring in clinical trials. * Describes the purpose, responsibilities and operation of data monitoring committees. * Provides directly applicable advice for those managing and conducting clinical trials, and those serving on data monitoring committees. * Gives insight into clinical data monitoring to those sitting on regulatory and ethical committees. * Discusses issues pertinent to those working in clinical trials in both the US and Europe. The practical guidance provided by this book will be of use to professionals working in and/or managing clinical trials, in academic, government and industry settings, particularly medical statisticians, clinicians, trial co-ordinators, and those working in regulatory affairs and bioethics.

Design and Analysis of Cluster Randomization Trials in Health Research - Allan Donner 2000-10-10

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.

A Simulation Study to Evaluate the Effect of Constrained Randomization for the Design and Analysis of Stepped Wedge Cluster Randomized Trials - Peiyan Gao 2020

In this study, we conducted simulations to evaluate the effect of constrained randomization on testing the treatment effect in terms of type I error and power with data generated from a stepped wedge cluster-randomized design, under the presence of cluster-level covariates. We considered two cases, one with a single binary co- variate and the other with a mixture of continuous and categorical covariates. For case one we used stratified randomization to achieve perfect covariate balance whereas for case two we constrained the randomization space by setting scores based on different balance criteria. For each case we consider eight different scenarios, and apply model-based and permutation-based inference to estimate and test for the treatment effect, both adjusted and unadjusted for covariates in the analysis phase. We found that the type I error is close to the nominal level most of the time except for permutation inference with constrained randomization and unconstrained analysis, where it drops down towards zero. In general, we see that constrained randomization can slightly increase power when covariates are also included at the analysis phase, and such increase is more visible in case one with a single binary covariate than case two with multiple covariates. Overall, although we discovered some advantages of doing constrained randomization in terms of power, such gain is only marginal and its impact in practice is likely to be

much smaller than under traditional cluster-randomized design. Therefore, controlling for covariates in the analysis phase is still considered to be a more effective way to attain higher testing power under stepped wedge setting.

Health Services Research Methods - Nick Black 1998-11-09

An up to date account of all that is known about the key methods used in health services research. It describes the uses and limitations of the principal methods based on the findings of the NHS Health Technology Assessment Programme. Each chapter makes suggestions for best practice.

Oxford Textbook of Global Public Health - Roger Detels 2017

Sixth edition of the hugely successful, internationally recognised textbook on global public health and epidemiology, with 3 volumes comprehensively covering the scope, methods, and practice of the discipline

Design and Analysis of Cluster Randomization Trials in Health Research - Allan Donner 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.

Antenatal Care - A. Donner 1998

Design and Analysis of Cluster Randomized Trials - Michael J. Campbell 2001

Oxford Textbook of Public Health - 2002

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

Power Analysis of Trials with Multilevel Data - Mirjam Moerbeek 2015-07-01

Power Analysis of Trials with Multilevel Data covers using power and sample size calculations to design trials that involve nested data structures. The book gives a thorough overview of power analysis that details terminology and notation, outlines key concepts of statistical power and power analysis, and explains why they are necessary in trial de

Cochrane Handbook for Systematic Reviews of Interventions - Julian P. T. Higgins 2008-11-24

Healthcare providers, consumers, researchers and policy makers are inundated with unmanageable amounts of information, including evidence from healthcare research. It has become impossible for all to have the time and resources to find, appraise and interpret this evidence and incorporate it into healthcare decisions. Cochrane Reviews respond to this challenge by identifying, appraising and synthesizing research-based evidence and presenting it in a standardized format, published in The Cochrane Library (www.thecochranelibrary.com). The Cochrane Handbook for Systematic Reviews of Interventions contains methodological guidance for the preparation and maintenance of Cochrane intervention reviews. Written in a clear and accessible format, it is the essential manual for all those preparing, maintaining and reading Cochrane reviews. Many of the principles

and methods described here are appropriate for systematic reviews applied to other types of research and to systematic reviews of interventions undertaken by others. It is hoped therefore that this book will be invaluable to all those who want to understand the role of systematic reviews, critically appraise published reviews or perform reviews themselves.

Small Clinical Trials - Institute of Medicine 2001-01-01

Clinical trials are used to elucidate the most appropriate preventive, diagnostic, or treatment options for individuals with a given medical condition. Perhaps the most essential feature of a clinical trial is that it aims to use results based on a limited sample of research participants to see if the intervention is safe and effective or if it is comparable to a comparison treatment. Sample size is a crucial component of any clinical trial. A trial with a small number of research participants is more prone to variability and carries a considerable risk of failing to demonstrate the effectiveness of a given intervention when one really is present. This may occur in phase I (safety and pharmacologic profiles), II (pilot efficacy evaluation), and III (extensive assessment of safety and efficacy) trials. Although phase I and II studies may have smaller sample sizes, they usually have adequate statistical power, which is the committee's definition of a "large" trial. Sometimes a trial with eight participants may have adequate statistical power, statistical power being the probability of rejecting the null hypothesis when the hypothesis is false. Small Clinical Trials assesses the current methodologies and the appropriate situations for the conduct of clinical trials with small sample sizes. This report assesses the published literature on various strategies such as (1) meta-analysis to combine disparate information from several studies including Bayesian techniques as in the confidence profile method and (2) other alternatives such as assessing therapeutic results in a single treated population (e.g., astronauts) by sequentially measuring whether the intervention is falling above or below a preestablished probability outcome range and meeting predesigned specifications as opposed to incremental improvement.

Public Health Research Methods - Greg Guest 2014-03-03

Providing a comprehensive foundation for planning, executing, and monitoring public health research of all types, this book goes beyond traditional epidemiologic research designs to cover technology-based approaches emerging in the new public health landscape.

How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research - Michael J. Campbell 2014-05-27

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.

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.

Randomization in Clinical Trials - William F. Rosenberger 2015-10-28

Praise for the First Edition “All medical statisticians involved in clinical trials should read this book...” - Controlled Clinical Trials Featuring a unique combination of the applied aspects of randomization in clinical trials with a nonparametric approach to inference, Randomization in Clinical Trials: Theory and Practice, Second Edition is the go-to guide for biostatisticians and pharmaceutical industry statisticians. Randomization in Clinical Trials: Theory and Practice, Second Edition features: Discussions on current philosophies, controversies, and new developments in the increasingly important role of randomization techniques in clinical trials A new chapter on covariate-adaptive randomization, including minimization techniques and inference New developments in restricted randomization and an increased focus on computation of randomization tests as opposed to the asymptotic theory of randomization tests Plenty of problem sets, theoretical exercises, and short computer simulations using SAS® to facilitate classroom teaching, simplify the mathematics, and ease readers’ understanding Randomization in Clinical Trials: Theory and Practice, Second Edition is an excellent reference for researchers as well as applied statisticians and biostatisticians. The Second Edition is also an ideal textbook for upper-undergraduate and graduate-level courses in biostatistics and applied statistics. William F. Rosenberger, PhD, is University Professor and Chairman of the Department of Statistics at George Mason University. He is a Fellow of the American Statistical Association and the Institute of Mathematical Statistics, and author of over 80 refereed journal articles, as well as The Theory of Response-Adaptive Randomization in Clinical Trials, also published by Wiley. John M. Lachin, ScD, is Research Professor in the Department of Epidemiology and Biostatistics as well as in the Department of Statistics at The George Washington University. A Fellow of the American Statistical Association and the Society for Clinical Trials, Dr. Lachin is actively involved in coordinating center activities for clinical trials of diabetes. He is the author of Biostatistical Methods: The Assessment of Relative Risks, Second Edition, also published by Wiley.

Cluster Randomised Trials - Richard J. Hayes 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.

Introduction to Randomized Controlled Clinical Trials, Second Edition - 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 concise presentation of the principles applied in this area. It details the concepts behind randomization and methods for designing and analyzing trials and also includes information on meta-analysis and specialized designs, such as cross-over trials, cluster-randomized designs, and equivalence studies. This latest edition features new and revised references, examples, exercises, and a new chapter dedicated to binary outcomes and survival analysis. It also presents numerous examples taken from the medical literature, contains exercises at the end of each chapter, and offers solutions in an appendix. The author uses Minitab and R software throughout the text for implementing the methods that are presented. Comprehensive and accessible, Introduction to Randomized Controlled Clinical Trials is well-suited for those familiar with elementary statistical ideas and methods who want to further their knowledge of the subject.

Bayesian Design and Analysis of Cluster Randomized Trials - Shan Xiao 2017

Cluster randomization is frequently used in clinical trials for convenience of inter ventional implementation and for reducing the risk of contamination. The opera tional convenience of cluster randomized trials, however, is gained at the expense of reduced analytical power. Compared to individually randomized studies, cluster randomized trials often have a much-reduced power. In this dissertation, I consider ways of enhancing analytical power with historical trial data. Specifically, I introduce a hierarchical Bayesian model that is designed to incorporate available information from previous trials of the same or similar interventions. Operationally, the amount of information gained from the previous trials is determined by a Kullback-Leibler divergence measure that quantifies the similarity, or lack thereof, between the histor ical and current trial data. More weight is given to the historical data if they more closely resemble the current trial data. Along this line, I examine the Type I error rates and analytical power associated with the proposed method, in comparison with the existing methods without utilizing the ancillary historical information. Similarly, to design a cluster randomized trial, one could estimate the power by simulating trial data and comparing them with the historical data from the published studies. Data analytical and power simulation methods are developed for more general situations of cluster randomized trials, with multiple arms and multiple types of data following the exponential family of distributions. An R package is developed for practical use of the methods in data analysis and trial design.