

Design and Analysis of Group-Randomized Trials: A Review of Recent Practices

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We reviewed group-randomized trials (GRTs) published in the *American Journal of Public Health* and *Preventive Medicine* from 1998 through 2002 and estimated the proportion of GRTs that employ appropriate methods for design and analysis.

Of 60 articles, 9 (15.0%) reported evidence of using appropriate methods for sample size estimation. Of 59 articles in the analytic review, 27 (45.8%) reported at least 1 inappropriate analysis and 12 (20.3%) reported only inappropriate analyses. Nineteen (32.2%) reported analyses at an individual or subgroup level, ignoring group, or included group as a fixed effect.

Hence increased vigilance is needed to ensure that appropriate methods for GRTs are employed and that results based on inappropriate methods are not published. (*Am J Public Health*. 2004;94:393–399)

DURING THE PAST 25 YEARS, increased attention has been devoted to exploring the impact of intraclass correlation (ICC) in the design and analysis of group-randomized trials (GRTs) and to identifying appropriate methods for these trials. Despite this attention, periodic reviews of published GRTs have found that many investigators employed methods that do not account for the ICC properly.

A 1990 review of GRTs published in medical and epidemiological journals between 1979 and 1989¹ found that only 3 (19%) of the 16 reviewed articles accounted for ICC properly in sample size calculations, and only 8 (50%) accounted for ICC in the analysis. A meta-analysis of evaluations of 8 separate trials of a school-based program to

prevent drug use reported that only 2 (25%) accounted for ICC in the analysis.² Simpson et al.³ reviewed all GRTs published in the *American Journal of Public Health* and *Preventive Medicine* between 1990 and 1993; they reported that only 4 (19%) of 21 articles included power calculations and only 12 (57%) included analyses that took ICC into account. A more recent review of community health interventions⁴ included 8 GRTs; only 1 (12%) reported taking ICC into account properly in sample size calculations, though 7 (88%) accounted for ICC in the analysis.

In the meantime, methodologists have continued to focus attention on valid methods for estimating sample size and analyzing data from GRTs; a summary of

the work published in the last 5 years is provided in another article in this issue.⁵ However, no recent review of published GRTs has examined the effect of this increased attention on the practices of investigators who conduct GRTs.

It is important to continue to monitor the published literature to determine the impact of recent methodological developments. Such reviews enable methodologists to determine the extent to which issues of clustering are recognized among investigators and to identify areas that may need further attention. They also alert investigators to attend more closely to the issues that they are missing. The goals of this study were to review GRTs recently published in the *American Journal of Public Health* and *Preven-*

Design And Analysis Of Group Randomized Trials

Noel S. Weiss, Thomas D. Koepsell



Design And Analysis Of Group Randomized Trials:

Design and Analysis of Group-randomized Trials David M. Murray, 1998 Community or group randomized trials which are usually done to evaluate the effect of health promotion efforts It reviews the underlying issues describes the most widely used research design and presents the many approaches to analysis that are now available *Design and Analysis of Group-randomized Trials* David M. Murray, 2023 This comprehensive text on the design and analysis of group randomized trials is intended to help those involved in trials to improve their ability to plan fund conduct analyze and interpret them

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 Journal of the National Cancer Institute ,2008 *Methods and Applications of Statistics in Clinical Trials, Volume 1* Narayanaswamy Balakrishnan, 2014-03-05 A complete guide to the key statistical concepts essential for the design and construction of clinical trials As the newest major resource in the field of medical research *Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs* presents a timely and authoritative review of the central statistical concepts used to build clinical trials that obtain the best results The

reference unveils modern approaches vital to understanding creating and evaluating data obtained throughout the various stages of clinical trial design and analysis Accessible and comprehensive the first volume in a two part set includes newly written articles as well as established literature from the Wiley Encyclopedia of Clinical Trials Illustrating a variety of statistical concepts and principles such as longitudinal data missing data covariates biased coin randomization repeated measurements and simple randomization the book also provides in depth coverage of the various trial designs found within phase I IV trials Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs also features Detailed chapters on the type of trial designs such as adaptive crossover group randomized multicenter non inferiority non randomized open labeled preference prevention and superiority trials Over 100 contributions from leading academics researchers and practitioners An exploration of ongoing cutting edge clinical trials on early cancer and heart disease mother to child human immunodeficiency virus transmission trials and the AIDS Clinical Trials Group Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs is an excellent reference for researchers practitioners and students in the fields of clinical trials pharmaceuticals biostatistics medical research design biology biomedicine epidemiology and public health **Principles and Practice of Clinical Trials** Steven

Piantadosi, Curtis L. Meinert, 2022-07-19 This is a comprehensive major reference work for our SpringerReference program covering clinical trials Although the core of the Work will focus on the design analysis and interpretation of scientific data from clinical trials a broad spectrum of clinical trial application areas will be covered in detail This is an important time to develop such a Work as drug safety and efficacy emphasizes the Clinical Trials process Because of an immense and growing international disease burden pharmaceutical and biotechnology companies continue to develop new drugs Clinical trials have also become extremely globalized in the past 15 years with over 225 000 international trials ongoing at this point in time Principles in Practice of Clinical Trials is truly an interdisciplinary that will be divided into the following areas 1 Clinical Trials Basic Perspectives 2 Regulation and Oversight 3 Basic Trial Designs 4 Advanced Trial Designs 5 Analysis 6 Trial Publication 7 Topics Related Specific Populations and Legal Aspects of Clinical Trials The Work is designed to be comprised of 175 chapters and approximately 2500 pages The Work will be oriented like many of our SpringerReference Handbooks presenting detailed and comprehensive expository chapters on broad subjects The Editors are major figures in the field of clinical trials and both have written textbooks on the topic There will also be a slate of 7 8 renowned associate editors that will edit individual sections of the Reference 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 **SAGE Quantitative Research**

Methods W Paul Vogt, 2011-01-01 For more than 40 years SAGE has been one of the leading international publishers of works on quantitative research methods in the social sciences This new collection provides readers with a representative sample of the best articles in quantitative methods that have appeared in SAGE journals as chosen by W Paul Vogt editor of other successful major reference collections such as *Selecting Research Methods* 2008 and *Data Collection* 2010 The volumes and articles are organized by theme rather than by discipline Although there are some discipline specific methods most often quantitative research methods cut across disciplinary boundaries Volume One Fundamental Issues in Quantitative Research Volume Two Measurement for Causal and Statistical Inference Volume Three Alternatives to Hypothesis Testing Volume Four Complex Designs for a Complex World Design and Analysis of Vaccine Studies M. Elizabeth Halloran, Ira M. Longini, Jr., Claudio J. Struchiner, 2009-10-27 As well as being a reference for the design analysis and interpretation of vaccine studies the text covers all design and analysis stages from vaccine development to post licensure surveillance presenting likelihood frequentists and Bayesian approaches **Analyzing data from nonrandomized group studies**

Jeremy W. Bray, William E. Schlenger, Gary A. Zarkin, Deborah Galvin, 2008-11-03 Researchers evaluating prevention and early intervention programs must often rely on diverse study designs that assign groups to various study conditions e g intervention versus control Although the strongest designs randomly assign these groups to conditions researchers frequently must use nonrandomized research designs in which assignments are made based on the characteristics of the groups With nonrandomized group designs little guidance is available on how best to analyze the data We provide guidance on which techniques work best under different data conditions and make recommendations to researchers about how to choose among the various techniques when analyzing data from a pre test post test nonrandomized study We use data from the Center for Substance Abuse Prevention's Workplace Managed Care initiative to compare the performance of the various methods commonly applied in quasi experimental and group assignment designs *How To Do Primary Care Research* Felicity Goodyear-Smith, Robert Mash, 2018-10-10 This practical How To guide talks the reader step by step through designing conducting and disseminating primary care research a growing discipline internationally The vast majority of

health care issues are experienced by people in community settings who are not adequately represented by hospital based research There is therefore a great need to upskill family physicians and other primary care workers and academics to conduct community based research to inform best practice Aimed at emerging researchers including those in developing countries this book also addresses cutting edge and newly developing research methods which will be of equal interest to more experienced researchers

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

Epidemiologic Methods Noel S. Weiss, Thomas D. Koepsell, 2014-07-03 This second edition of Epidemiologic Methods offers a rigorous introduction to the concepts and tools of epidemiologic research Aimed chiefly at future epidemiologists the book offers clear descriptions practical examples and question answer sections for each of the science s key concepts Authored by two award winning epidemiology instructors this book is ideally suited for use as a text in a graduate level course sequence in epidemiologic methods The book s chapters are organized around three main themes general concepts and tools of epidemiology major study designs and special topics including screening outbreak investigations and use of epidemiology to evaluate policies and programs With additional exercises at the end of each chapter and expanded attention to topics such as confounding this new edition of Epidemiologic Methods is an indispensable resource for the next generation of epidemiologic study

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

Introduction to Power Analysis E. C. Hedberg, 2017-12-05 Introduction to Power Analysis Two Group Studies provides readers with the background examples and

explanation they need to read technical papers and materials that include complex power analyses This clear and accessible guide explains the components of test statistics and their sampling distributions and author Eric Hedberg walks the reader through the simple and complex considerations of this research question Filled with graphics and examples the reader is taken on a tour of power analyses from covariates to clusters seeing how the complicated task of comparing two groups and the power analysis can be made easy Handbook of Education Policy Research Janelle Scott,2025-07-17 The second edition of the Handbook of Education Policy Research the largest volume published in AERA s history addresses a variety of policy and contextual issues in early childhood K 12 and postsecondary education that have received extensive empirical attention during the past 15 years With the pandemic and social turmoil as a backdrop the editors build on the breadth and depth of the first edition while expanding the scope of the project to include subjects methods theories and analyses that have contributed powerfully to the study of education policy and politics in the 2010s and 2020s The field has become more comprehensive and inclusive and the authors represent a diversity of racial ethnic and gender identities and intellectual and disciplinary orientations Most chapters come from multiple authors reflecting the multi sourced development of research in education policy since the first volume was published This compilation consists of 70 chapters and nine commentaries that map past present and future directions of the field and richly attend to critical issues of interest to students researchers policy makers and practitioners Design and Analysis of Clinical Trials Shein-Chung Chow,Jen-Pei Liu,2013-09-30 Praise for the Second Edition a grand feast for biostatisticians It stands ready to satisfy the appetite of any pharmaceutical scientist with a respectable statistical appetite Journal of Clinical Research Best Practices The Third Edition of Design and Analysis of Clinical Trials provides complete comprehensive and expanded coverage of recent health treatments and interventions Featuring a unified presentation the book provides a well balanced summary of current regulatory requirements and recently developed statistical methods as well as an overview of the various designs and analyses that are utilized at different stages of clinical research and development Additional features of this Third Edition include New chapters on biomarker development and target clinical trials adaptive design trials for evaluating diagnostic devices statistical methods for translational medicine and traditional Chinese medicine A balanced overview of current and emerging clinical issues as well as newly developed statistical methodologies Practical examples of clinical trials that demonstrate everyday applicability with illustrations and examples to explain key concepts New sections on bridging studies and global trials QT studies multinational trials comparative effectiveness trials and the analysis of QT QTc prolongation A complete and balanced presentation of clinical and scientific issues statistical concepts and methodologies for bridging clinical and statistical disciplines An update of each chapter that reflects changes in regulatory requirements for the drug review and approval process and recent developments in statistical design and methodology for clinical research and development Design and Analysis of Clinical Trials Third Edition continues to be an ideal clinical research reference for academic pharmaceutical

medical and regulatory scientists researchers statisticians and graduate level students **The Handbook of Research Synthesis and Meta-Analysis** Harris Cooper, Larry V. Hedges, Jeffrey C. Valentine, 2009-02-05 Praise for the first edition

The Handbook is a comprehensive treatment of literature synthesis and provides practical advice for anyone deep in the throes of just teetering on the brink of or attempting to decipher a meta analysis Given the expanding application and importance of literature synthesis understanding both its strengths and weaknesses is essential for its practitioners and consumers This volume is a good beginning for those who wish to gain that understanding

Chance Meta analysis as the statistical analysis of a large collection of results from individual studies is called has now achieved a status of respectability in medicine This respectability when combined with the slight hint of mystique that sometimes surrounds meta analysis ensures that results of studies that use it are treated with the respect they deserve

The Handbook of Research Synthesis is one of the most important publications in this subject both as a definitive reference book and a practical manual

British Medical Journal When the first edition of The Handbook of Research Synthesis was published in 1994 it quickly became the definitive reference for researchers conducting meta analyses of existing research in both the social and biological sciences

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source of information for researchers undertaking meta analysis today In response to the increasing use of research synthesis in the formation of public policy the second edition includes a new chapter on both the strengths and limitations of research synthesis in policy debates Translational Sports Medicine Jeffrey A. Bakal, Steve DeFroda, Brett D. Owens, Adam E.M. Eltorai, 2023-08-14 Translational Sports Medicine covers the principles of evidence based medicine and applies these principles to the design of translational investigations This title is an indispensable tool in grant writing and funding efforts with its practical straightforward approach that will help aspiring investigators navigate challenging considerations in study design and implementation It provides valuable discussions of the critical appraisal of published studies in translational sports medicine allowing the reader to learn how to evaluate the quality of such studies with respect to measuring outcomes and to make effective use of all types of evidence in patient care In short this practical guidebook will be of interest to every medical researcher or sports medicine clinician who has ever had a good clinical idea but not the knowledge of how to test it Readers will come to fully understand important concepts including case control study prospective cohort study randomized trial and reliability study Medical researchers will benefit from greater confidence in their ability to initiate and execute their own investigations avoid common pitfalls in translational sports medicine and know what is needed in collaboration Focuses on the principles of evidence based medicine and applies these principles to translational investigations within sports medicine Details discussions of the critical appraisal of published studies in translational sports medicine supporting evaluation with respect to measuring outcomes and making effective use of all types of evidence in patient care Written by experts in the sports medicine field **Examining the Experimental Designs and Statistical Power of Group Randomized Trials Funded by the Institute of Education Sciences** Jessaca K. Spybrook, 2007

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