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Undertaking multi-centre randomised controlled trials in primary care: learnings and recommendations from the PULsE-AI trial researchers

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Abstract

Background Conducting effective and translational research can be challenging and few trials undertake formal reflection exercises and disseminate learnings from them. Following completion of our multicentre randomised controlled trial, which was impacted by the COVID-19 pandemic, we sought to reflect on our experiences and share our thoughts on challenges, lessons learned, and recommendations for researchers undertaking or considering research in primary care.

Methods Researchers involved in the Prediction of Undiagnosed atrial fibrillation using a machine learning Algorithm (PULsE-AI) trial, conducted in England from June 2019 to February 2021, were invited to participate in a qualitative reflection exercise. Members of the Trial Steering Committee (TSC) were invited to attend a semi-structured focus group session. Principal Investigators and their research teams at practices involved in the trial were invited to participate in a semi-structured interview. Following transcription, reflexive thematic analysis was undertaken based on pre-specified themes of recruitment, challenges, lessons learned, and recommendations that formed the structure of the focus group/interview sessions, whilst also allowing the exploration of new themes that emerged from the data.

Results Eight of 14 members of the TSC, and one of six practices involved in the trial participated in the reflection exercise. Recruitment was highlighted as a major challenge encountered by trial researchers, even prior to disruption due to the COVID-19 pandemic. Researchers also commented on themes such as the need to consider incentivisation, and challenges associated with using technology in trials, especially in older age groups.

Conclusions Undertaking a formal reflection exercise following the completion of the PULsE-AI trial enabled us to review experiences encountered whilst undertaking a prospective randomised trial in primary care. In sharing our

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Randomised Controlled Trials And Multi Centre Research

Martin Lipscomb



Randomised Controlled Trials And Multi Centre Research:

Randomised Controlled Trials and Multi-centre Research Martin Underwood, Philip Hannaford, Anne Slowther, 2000

Randomized Controlled Trials in Evidence-Based Dentistry Richie Kohli, Harjit S. Sehgal, Peter Milgrom, 2024-04-16

This book reviews the role of randomized controlled trials RCTs in clinical dentistry explains how to successfully conduct RCTs related to dentistry and provides detailed information on the use of RCTs within each of the dental specialties Although RCTs represent the gold standard in evidence based dentistry for evaluation of the effects of an intervention a textbook on the subject has to date been lacking Randomized Controlled Trials in Evidence Based Dentistry will fill this educational gap and improve the confidence of dental providers researchers and their multidisciplinary teams in conducting high quality RCTs in a variety of settings and different parts of the world In particular it will enable readers to implement a suitable step by step approach to RCTs identify possible solutions to common challenges when performing RCTs in individual dental specialties and apply these solutions to their own RCT projects

A Medical Educator's Guide to Thinking Critically about Randomised Controlled Trials: Deconstructing the "Gold Standard" Margaret MacDougall, 2024-05-30 Drawing on the statistical and philosophical expertise of its authors this book is designed to improve understanding and use of randomised controlled trials RCTs among health professionals It is intended for use primarily by medical educators involved in teaching statistics and evidence based medicine EBM to medical students junior doctors and other health professionals However each of the chapters serves a wider range of interests including the practical needs of physicians in interpreting research evidence to support clinical decision making and the teaching needs of philosophers of medicine who want to more fully appreciate how RCTs work in practice and provide engaging examples for their students Rather than compete with the proliferating methodological literature on RCT designs this book focuses on cultivating a healthy skepticism among developing health professionals to support critical appraisal of their own and published work on RCTs at a fundamental level including through a more informed understanding of the place of subgroup analyses in sound statistical inference Management of the positive predictive value in the statistical analysis of RCT findings is included as an important topic for contemporary medical curricula In comparing RCTs with non randomised studies a search for empirical evidence for the superiority of RCTs is initiated pointing to the need for further work to confirm what form this evidence should take Medical educators will find a wealth of reasons to encourage their students to think more critically about how the RCT operates in practice as a gold standard

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 **An**

Introduction to Clinical Trials Jonathan A. Cook, 2023 An Introduction to clinical trials is a concise step by step guide to the principles and practices of clinical trials for those studying clinical trials or new to working on one Clinical trials are critical to the progress of medicine and improving healthcare as they evaluate whether new treatments and interventions work They are also complex multidisciplinary projects that integrate science ethics and legal requirements in the conduct of medical research Starting with the research question An Introduction to clinical trials explains study design sample size determination study set up study conduct statistical analysis and dissemination of the results The book primarily focusses on randomised controlled trials as the ultimate clinical trial It demystifies the terminology used in clinical trials research and presents the underlying scientific and statistical concepts Real life examples are used throughout to bring concepts to life Written by an experienced medical statistician An Introduction to clinical trials will benefit readers of all backgrounds from postgraduate and medical students trainee doctors and healthcare professionals to others working on clinical trials in a professional capacity This book aims to help readers gain a fuller and more rounded understanding of clinical trials

Exploring Evidence-based Practice Martin Lipscomb, 2015-07-30 Despite sustained debate and progress the evolving thing that is evidence based nursing or practice EBP continues to dangle a variety of conceptual and practical loose threads Moreover when we think about what is being asked of students and registered or licenced practitioners in terms of EBP it is difficult not to concede that this ask is in many instances quite large and occasionally it may be unachievable EBP has and continues to improve patient client and user care Yet significant questions concerning its most basic elements remain unresolved and if nurses are to contribute to the resolution or reconfiguration of these questions then as a first step we must acknowledge their existence From a range of international standpoints and perspectives contributors to this book focus on aspects of EBP that require development This focus is always robust and at times it is unashamedly provocative Contributors challenge readers to engage with anomalies that surround the subject and readers are asked to consider the often precarious

assumptions that underpin key aspects of EBP While both conflict and concord are evident among the various offerings presented here the book nonetheless creates and sustains a narrative that is bigger or more substantial than the sum of individual parts And across contributions a self assuredly critical stance towards EBP as currently practiced conceptualized and taught coexists alongside respectful admiration for all who make it happen Exploring Evidence based Practice Debates and Challenges in Nursing should be considered essential reading for academics and postgraduate students with an interest in evidence based practice and nursing research

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

Cumulated Index Medicus, 1980

Multi-Center Phase III Clinical Trials and NCI Cooperative Groups Institute of Medicine, National Cancer Policy Forum, 2009-01-30 The NCI sponsored cooperative groups have made important contributions to improving treatment for many types of cancer including breast ovarian colorectal and childhood cancers Cooperative group research has been instrumental in establishing innovative treatments that improve outcomes and quality of life Despite these successes the Cooperative Group Program has faced a number of challenges that threaten its effectiveness To address this problem the National Cancer Policy Forum NCPF convened a workshop titled Multi Center Phase III Clinical Trials and NCI Cooperative Groups in Washington DC on July 1 2 2008 The purpose of the workshop was to outline the challenges that the public clinical cancer research enterprise faces and to identify possible solutions to these challenges

Randomised Clinical Trials David Machin, Peter M. Fayers, Bee Choo Tai, 2021-05-12 Randomised Clinical Trials Design Practice and Reporting provides a detailed overview of the methodology for conducting clinical trials including developing protocols data capture randomisation analysis and reporting Assuming no prior background this user friendly resource describes the statistical regulatory and practical components required for conducting randomised clinical trials Numerous examples and case studies from industry academia and the research literature help readers understand each stage of the clinical trial process This second edition contains extensively revised material throughout including new chapters covering designs for repeated measures non inferiority cluster and stepped wedge trials Other new chapters describe data and safety monitoring biomarker studies and feasibility studies Updated and expanded sections discuss situations where multiple organs different body locations or competing risks are involved subgroup analysis and multiple outcomes Written by an author team with extensive experience in conducting clinical trials this book Provides comprehensive coverage of randomised clinical trials ranging from basic to advanced Features several new chapters updated case studies and examples and references to changes in regulations

Explains basic randomised trials including the parallel two group controlled trial with a single outcome measure Covers paired trial designs and trials with more than two interventions Includes a chapter on miscellaneous topics such as adaptive designs large simple trials Bayesian methods for very small trials alpha spending functions and the predictive probability test Randomised Clinical Trials is essential reading for clinicians nurses data managers and medical statisticians involved in clinical trials and for health practitioners responsible for direct patient care in a clinical trial setting **Cochrane**

Handbook for Systematic Reviews of Interventions Julian P. T. Higgins, James Thomas, Jacqueline Chandler, Miranda Cumpston, Tianjing Li, Matthew J. Page, Vivian A. Welch, 2019-09-23 The revised edition of the Handbook offers the only guide on how to conduct report and maintain a Cochrane Review The second edition of The Cochrane Handbook for Systematic Reviews of Interventions contains essential guidance for preparing and maintaining Cochrane Reviews of the effects of health interventions Designed to be an accessible resource the Handbook will also be of interest to anyone undertaking systematic reviews of interventions outside Cochrane and many of the principles and methods presented are appropriate for systematic reviews addressing research questions other than effects of interventions This fully updated edition contains extensive new material on systematic review methods addressing a wide range of topics including network meta analysis equity complex interventions narrative synthesis and automation Also new to this edition integrated throughout the Handbook is the set of standards Cochrane expects its reviews to meet Written for review authors editors trainers and others with an interest in Cochrane Reviews the second edition of The Cochrane Handbook for Systematic Reviews of Interventions continues to offer an invaluable resource for understanding the role of systematic reviews critically appraising health research studies and conducting reviews *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 *Pleural Disease,*

An Issue of Clinics in Chest Medicine, E-Book David Feller-Kopman,2021-11-16 Pleural Disease An Issue of Clinics in Chest Medicine E Book **Diabetes: New Insights for the Healthcare Professional: 2011 Edition** ,2012-01-09 Diabetes New Insights for the Healthcare Professional 2011 Edition is a ScholarlyEditions eBook that delivers timely authoritative and comprehensive information about Diabetes The editors have built Diabetes New Insights for the Healthcare Professional 2011 Edition on the vast information databases of ScholarlyNews You can expect the information about Diabetes in this eBook to be deeper than what you can access anywhere else as well as consistently reliable authoritative informed and relevant The content of Diabetes New Insights for the Healthcare Professional 2011 Edition has been produced by the world s leading scientists engineers analysts research institutions and companies All of the content is from peer reviewed sources and all of it is written assembled and edited by the editors at ScholarlyEditions and available exclusively from us You now have a source you can cite with authority confidence and credibility More information is available at [http www ScholarlyEditions com](http://www.ScholarlyEditions.com) **Encyclopedia of Health Services Research** Ross M. Mullner,2009-05-15 Today as never before healthcare has the ability to enhance the quality and duration of life At the same time healthcare has become so costly that it can easily bankrupt governments and impoverish individuals and families Health services research is a highly multidisciplinary field including such areas as health administration health economics medical sociology medicine political science public health and public policy The Encyclopedia of Health Services Research is the first single reference source to capture the diversity and complexity of the field With more than 400 entries these two volumes investigate the relationship between the factors of cost quality and access to healthcare and their impact upon medical outcomes such as death disability disease discomfort and dissatisfaction with care Key Features Examines the growing healthcare crisis facing the United States Encompasses the structure process and outcomes of healthcare Aims to improve the equity efficiency effectiveness and safety of healthcare by influencing and developing public policies Describes healthcare systems and issues from around the globe Key Themes Access to Care Accreditation Associations Foundations and Research Organizations Biographies of Current and Past Leaders Cost of Care Economics Finance and Payment Mechanisms Disease Disability Health and Health Behavior Government and International Healthcare Organizations Health Insurance Health Professionals and Healthcare Organizations Health Services Research Laws Regulations and Ethics Measurement Data Sources and Coding and Research Methods Outcomes of Care Policy Issues Healthcare Reform and International Comparisons Public Health Quality and Safety of Care Special and Vulnerable Groups The Encyclopedia is designed to be an introduction to the various topics of health services research for an audience including undergraduate students graduate students and general readers seeking non technical descriptions of the field and its practices It is also useful for healthcare practitioners wishing to stay abreast of the changes and updates in the field **Healthcare-Associated Infections in Australia** Ramon Z. Shaban,Brett G. Mitchell,Deborah Macbeth,Philip Russo,2023-04-01 Infection prevention and control IPC is everybody s responsibility

Healthcare associated Infections in Australia is the first Australian text to address the challenges posed by infectious diseases and healthcare associated infections HAIs for all members of the multidisciplinary healthcare team Drawing on the expertise of a wide author team and based on current research this important and comprehensive text provides a clear pathway for the reader to increase their knowledge and understanding of IPC The text is designed for both students and practising clinicians and is presented in two sections Principles and Practice for ease of use With IPC principles and guidelines now embedded into all health related curricula and mandated by standards and guidelines across all areas of healthcare this is a book no health professional should miss Includes practice tips case studies and video based learning materials providing real life examples across more than 20 health professions Suitable for increasing IPC knowledge across all members of the multidisciplinary team Content is pitched at different levels with examples ranging from novice to expert Aligned to the Australian National Infection Control Guidelines 2019 and the NSQHS Standard Preventing and Controlling Healthcare Associated Infections as well as the nine hospital acquired complication HAC HAIs addressed in specific chapters Endorsed by the Australian College for Infection Prevention and Control ACIPC and the Australian Society for Infectious Diseases ASID Supported by a companion text Epidemiology of Healthcare associated Infections in Australia providing data on the epidemiology of healthcare associated surveillance in Australia Instructor and Student resources on Evolve Multiple Choice Questions Case Studies Abbreviations and Glossary Useful Websites Resources Video based learning materials

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Pediatric Critical Care in Resource-Limited Settings Krishan Chugh,Ndidi Musa,Phuc Huu Phan,Srinivas Murthy,Yves Ouellette,2019-07-11 Millions of children are dying each year with preventable and reversible critical illness including circulatory shock and respiratory failure According to the World Health Organization in 2015 the under five mortality rate in low income countries was 76 deaths per 1000 live births about 11 times the average rate in high income countries 7 deaths per 1000 live births There is limited data about the nature of the delivery of critical care in resource limited regions The care of critically ill children in low resource settings is challenging contributing factors include limitations in the existing infrastructure lack of resources and low numbers of appropriately trained healthcare workers Meeting these challenges requires clinical evidence pertinent to the local settings adequate number of well trained personnel quality improvement activities and the ongoing development of preventative measures In addition approaches to prevent worsening critical illness in at risk hospitalized patients are needed We are presenting 15 state of the art manuscripts from international experts from all settings involved in the care of critically ill children in resource limited settings This collection of manuscripts covers topics including education research clinical experience and infectious diseases We hope that we are providing a window into the future of critical care delivery for all children around the world

The Direct Anterior Approach to Hip Reconstruction B. Bal, Lee Rubin, Kristaps Keggi, 2024-06-01 Total hip arthroplasty has steadily evolved to improve patient outcomes and safety One innovation has been to incorporate less invasive surgical methods such as the direct anterior surgical approach The Direct Anterior Approach to Hip Reconstruction is a comprehensive reference text that addresses contemporary surgeon interest in innovation and less invasive surgery This resource will help with introductory learning intermediate technical development and advanced revision total hip skills using the direct anterior technique Accordingly the text is structured into three sections as follows Basic concepts Surgical hip anatomy patient selection and placement of single multiple and extensile incisions for primary total hip arthroplasty Intermediate concepts Adoption of imaging and navigation technologies use of traction tables to enhance positioning and presentation of unique instruments and custom devices that have evolved specifically for the direct anterior approach Advanced concepts Using the direct anterior approach for bearing and liner exchanges acetabular revisions femoral component revisions and both component revisions Drs B Sonny Bal Lee E Rubin and Kristaps J Keggi have combined their unique perspectives along with those of a renowned group of North American and European experts in the anterior hip reconstruction surgery to create this reference Dr Keggi was among the first to recognize the benefits of the direct anterior approach in hip reconstruction this text is based on his 50 plus years of experience as a clinician and pioneer surgeon The Direct Anterior Approach to Hip Reconstruction

provides a stepwise learning process for surgeons interested in mastering total hip arthroplasty using the direct anterior approach with detailed chapters and video instruction contributed by a distinguished group of international experts in the field. The chapters focus on using the direct anterior approach to address a variety of hip problems well beyond performing total hip arthroplasty for osteoarthritis. The unique applications of the direct anterior approach within the orthopedic subspecialties are addressed in chapters covering the fields of pediatrics, sports medicine, trauma, and tumor surgery. Other chapters address subjects like femoroacetabular impingement, hip preservation surgery, and postoperative rehabilitation protocols designed to improve patient outcomes. The final section of the text reviews the evidence-based outcomes related to direct anterior total hip arthroplasty, addressing evolving implant design concepts specific to this approach and outlining directions for educating the next generation of surgeons who will continue to develop and refine these techniques. Complementing the written text is a website with educational videos to further enhance the learning experience. To date, no other reference has addressed the need for comprehensive education for the orthopedic resident, fellow, or surgeon seeking to learn about the direct anterior approach for hip reconstruction. This resource should be invaluable to orthopedic surgeons worldwide and will contribute to improving patient safety, reducing complications, and better surgical outcomes. Indeed, this landmark publication is truly the world's first comprehensive text on anterior hip surgery.

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former india captain sachin tendulkar was unveiled at his home ground a splash of colourful confetti and the rhythmic beats of the dhol gave a festive fervour to the ceremony as a rather emotional tendulkar who was

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