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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

**KyungMann Kim, Frank Bretz, Ying
Kuen K. Cheung, Lisa V. Hampson**



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

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

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 **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

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 Cumulated Index Medicus ,1980

Advances in Back Pain Research and Treatment: 2011 Edition ,2012-01-09 Advances in Back Pain Research and Treatment 2011 Edition is a ScholarlyBrief that delivers timely authoritative comprehensive and specialized information about Back Pain in a concise format The editors have built Advances in Back Pain Research and Treatment 2011 Edition on the vast information databases of ScholarlyNews You can expect the information about Back Pain 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 Advances in Back Pain Research and Treatment 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>

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Research Methods for Nurses and Midwives Merryll Harvey,Lucy Land,2021-11-10 This book walks you step by step through the whole research process so you can get up to speed understanding and doing your own research In their friendly down to earth style the authors lay the theoretical foundations you need to consume and critique research before showing how to translate this into action when tackling your own literature review or research project This second edition Draws on a wealth of examples from midwifery four fields of nursing including mental health nursing and child nursing and a range of health care specialities Covers new and updated NMC professional education standards and maps all relevant policy and law Supports your learning

with reflective exercises online activities and quizzes that enable you to be confident in your understanding and develop your thinking Whether you re encountering research and evidence based practice for the first time or refreshing your methods knowledge this is the ideal research companion for nurses and midwives pre registration post registration and beyond

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

Textbook of Clinical Neurology Christopher G. Goetz, MD
MD, 2007-09-12 Organized to approach patient problems the way you do this best selling text guides you through the evaluation of neurologic symptoms helps you select the most appropriate tests and interpret the findings and assists you in effectively managing the underlying causes Its practical approach makes it an ideal reference for clinical practice Includes practical evidence based approaches from an internationally renowned team of authors Zeroes in on what you really need to know with helpful tables that highlight links between neurological anatomy diagnostic studies and therapeutic procedures Offers a logical clinically relevant format so you can find the answers you need quickly Features a new updated design for easier reference Includes new full color images and updated illustrations to facilitate comprehension of important concepts Features updated chapters on the latest genetic and immunologic based therapies advances in pharmacology and new imaging techniques Includes an expanded and updated CD ROM that allows you to view video clips of patient examinations download all of the book s illustrations and enhance exam preparation with review questions

Wall & Melzack's Textbook of Pain E-Book Stephen B. McMahon, Martin Koltzenburg, Irene Tracey, Dennis Turk, 2013-03-01 Apply the latest scientific and clinical advances with Wall Melzack s Textbook of Pain 6th Edition Drs Stephen McMahon Martin Koltzenburg Irene Tracey and Dennis C Turk along with more than 125 other leading authorities present all of the latest knowledge about the genetics neurophysiology psychology and assessment of every type of pain syndrome They also provide practical guidance on the full range of today s pharmacologic interventional electrostimulative physiotherapeutic and psychological management options Consult this title on your favorite e reader with intuitive search tools and adjustable font sizes Elsevier eBooks provide instant portable access to your entire library no matter what device you re using or where you re located Benefit from the international multidisciplinary knowledge and experience of a who s who of international authorities in pain medicine neurology neurosurgery neuroscience psychiatry psychology physical medicine and rehabilitation palliative medicine and other relevant fields Translate scientific findings into clinical practice with updates on the genetics of pain new pharmacologic and treatment information and much more Easily visualize important scientific concepts with a high quality

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presented with emphasis on the most promising therapies currently being tested Experts discuss disease and symptom management for MS subtypes including neuromyelitis optica and pediatric MS In addition key scientific advances in MS pathology genetics immunology and epidemiology are presented The fourth edition has been extensively revised featuring more than 50% new material All chapters have been substantially updated to provide current information on rapidly evolving topics and this volume contains 15 new chapters reflecting the growth of the field in recent years This book is an essential reference for practitioners caring for MS patients investigators planning or conducting clinical trials and clinical trial sponsors Index Medicus ,2004 Vols for 1963 include as pt 2 of the Jan issue Medical subject headings Introduction to Research Methodology for Specialists and Trainees P. M. Shaughn O'Brien,Fiona Broughton Pipkin,2017-08-17 Health centred research has changed hugely over the last ten years from the importance of computing software to the NHS becoming more involved in research The expectations of grant awarding bodies ethics committees and publishers have evolved and increased in many senses This new edition is designed for trainee clinicians not only those preparing for membership of the Royal College of Obstetricians and Gynaecologists MRCOG but also higher degree candidates and aspiring clinical academics Chapter authors with extensive expertise make the path to embarking on research direct straightforward and most importantly fun and interesting particularly aiming to support those who trained clinically and are now undertaking a research project or beginning an academic career There remains no single book with so much relevant information gathered in a single succinct volume This edition now covers the wide spectrum of modern research methods for all specialities with five supplementary chapters on major obstetric and gynaecological subspecialties **Recent Advances in Surgery 40** Michael Douek,Rachel Hargest,2021-09-30 Recent Advances in Surgery 40 is the latest volume in the recognised series reviewing current topics in general surgery and its major subspecialties Divided into eight sections the book begins with topics of general interest to surgeons and surgical training The following sections cover subspecialty surgeries including transplant vascular head and neck breast and abdominal The final section reviews recent clinical trials

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

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