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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

**Alessio Martucci, Carlo Nucci, Maria
Dolores Pinazo-Duran**



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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

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 *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 Cumulated Index Medicus ,1999 *Advances in Back Pain Research and Treatment: 2011 Edition* ,2012-01-09

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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 **HIV/AIDS: New Insights for the Healthcare Professional: 2011 Edition**, 2012-01-09 HIV AIDS New Insights for the Healthcare Professional 2011 Edition is a ScholarlyEditions eBook that delivers timely authoritative and comprehensive information about HIV AIDS The editors have built HIV AIDS New Insights for the Healthcare Professional 2011 Edition on the vast information databases of ScholarlyNews You can expect the information about HIV AIDS 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 HIV AIDS 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>

Researchers and Their 'subjects' Marie Smyth, Emma Williamson, 2004-10-13 Offering an insight into research participants perspectives and discussing the ethical regulations and guidance governing researchers in different disciplines this work analyses case studies of innovative research projects where ethics have been central to the researcher subject relationship **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 [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 Evidence-Based Gastroenterology and Hepatology John W. D. McDonald, Andrew K. Burroughs, Brian G. Feagan, 2008-04-15 Traditional textbooks in this field have emphasized the basic sciences of pathology biochemistry and physiology Evidence based Gastroenterology and Hepatology covers all the major diseases of the gastrointestinal tract and liver utilizing clinical epidemiology to present the strongest and most current evidence for interventions This second edition is edited and written by leading gastroenterologists from around the world each chapter summarizes the evidence so that better informed decisions will be made about which treatments to offer to patients It provides practising Gastroenterologists and Surgeons with clear information regarding the diagnosis and treatment of pancreatic diseases giving clear evidence and experience based material that is immediately relevant to clinical practice Also contains a list of recommended reading at the end of each chapter Take a look at up to date information at www.evidbasedgastro.com **Research Methods for Nurses and Midwives** Merryl 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

Youmans and Winn Neurological Surgery E-Book H. Richard Winn, 2022-01-21 Widely regarded as the definitive reference in the field Youmans and Winn Neurological Surgery offers unparalleled multimedia coverage of the entirety of this complex specialty Fully updated to reflect recent advances in the basic and clinical neurosciences the 8th Edition covers everything you need to know about functional and restorative neurosurgery deep brain stimulation stem cell biology radiological and nuclear imaging and neuro oncology as well as minimally invasive surgeries in spine and peripheral nerve surgery and endoscopic and other approaches for cranial procedures and cerebrovascular diseases In four comprehensive volumes Dr H Richard Winn and his expert team of editors and authors provide updated content a significantly expanded video library and hundreds of new video lectures that help you master new procedures new technologies and essential anatomic knowledge in neurosurgery Discusses current topics such as diffusion tensor imaging brain and spine robotic surgery augmented reality as an aid in neurosurgery AI and big data in neurosurgery and neuroimaging in stereotactic functional neurosurgery 55 new chapters provide cutting edge information on Surgical Anatomy of the Spine Precision Medicine in Neurosurgery The Geriatric Patient Neuroanesthesia During Pregnancy Laser Interstitial Thermal Therapy for Epilepsy Fetal Surgery for Myelomeningocele Rehabilitation of Acute Spinal Cord Injury Surgical Considerations for Patients with Polytrauma Endovascular Approaches to Intracranial Aneurysms and much more Hundreds of all new video lectures clarify key concepts in techniques cases and surgical management and evaluation Notable lecture videos include multiple videos on Thalamotomy for Focal Hand Dystonia and a video to accompany a new chapter on the Basic Science of Brain Metastases An extensive video library contains stunning anatomy videos and videos demonstrating intraoperative procedures with more than 800 videos in all Each clinical section contains chapters on technology specific to a clinical area Each section contains a chapter providing an overview from experienced Section Editors including a report on ongoing controversies within that subspecialty Enhanced eBook version included with purchase Your enhanced eBook allows you to access all of the text figures and references from the book on a variety of devices

Methods in gastrointestinal cancers Shuyun Rao, Imayavaramban Lakshmanan, Shantibhusan Senapati, Zhendong Jin, 2023-05-16

The ASCRS Textbook of Colon and Rectal Surgery Scott R. Steele, Tracy L. Hull, Neil Hyman, Justin A. Maykel, Thomas E. Read, Charles B. Whitlow, 2021-11-20

This book serves as a valuable resource for surgeons and health care providers at all stages of their career caring for patients with colorectal disease This edition provides all newly written chapters organized around the pillars of colorectal disease perioperative including endoscopy anorectal disease benign disease including inflammatory bowel disease malignancy pelvic floor disorders and a miscellaneous section that covers aspects both inside and beyond the operating room Chapters are formatted to follow that of a how to manual as well as an algorithm based guide to allow the reader to understand the thought process behind a proposed treatment strategy By making use of evidence based recommendations each chapter includes not only background information and diagnostic therapeutic guidelines but also provides operative technical details

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Critical Care Medicine Joseph E. Parrillo, MD, FCCM, R. Phillip Dellinger, MD, MS, 2013-12-05 Take the best possible care of adult critical care patients with Critical Care Medicine Principles of Diagnosis and Management in the Adult Editors Dr Joseph Parrillo and Dr Phillip Dellinger two of the most respected names in critical care medicine combine their extensive knowledge with that of hundreds of top authorities in the field to bring you expert state of the art answers to any clinical question you may face in the intensive care unit Offer your adult critical care patients the most effective care with practical evidence based guidance from many of the most trusted experts in critical care medicine Learn from the best ICU specialists worldwide with contributions from an increased number of international authorities Effectively manage common complications in the ICU with updated coverage of severe sepsis septic shock surgical infections neurogenic and anaphylactic shock severe heart failure acute coronary syndromes and Acute Respiratory Distress Syndrome Access the complete contents online at Expert Consult along with an image bank and instructional videos

Key Topics in Surgical Research and Methodology Thanos Athanasiou, H. Debas, Ara Darzi, 2010-02-28 Key Topics in Surgical Research and Methodology represents a comprehensive reference text accessible to the surgeon embarking on an academic career Key themes emphasize and summarize the text Four key elements are covered i e Surgical Research Research Methodology Practical Problems and Solutions on Research as well as Recent Developments and Future Prospects in Surgical Research and Practice

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