ICTMC 2019 5th International Clinical Trials Methodology Conference

6 – 9 October, Brighton, UK

Educational Workshops

Sunday 6th October – 09:00 – 13:00		
Pre-Conference Workshop 1.1	**Pre-Conference Workshop 1.2**	**Pre-Conference Workshop 1.3**
Using Studies Within A Trial (SWATs) to increase the evidence-base for trial process decisions: how to select, design and run them	Design and analysis of clinical trials in the era of precision medicine	Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols
Sunday 6th October 14:00 – 18:00		
Pre-Conference Workshop 2.1	**Pre-Conference Workshop 2.2**	**Pre-Conference Workshop 2.3**
Missing data in randomised trials: concepts and design	Strategies for optimising recruitment to challenging randomised controlled trials: the QuinteT approach	Finding and critically appraising a core outcome set (COS) for your trial
Wednesday 9th October – 14:00 – 17:30		
Post-Conference Workshop 3.1	**Post-Conference Workshop 3.2**	**Post-Conference Workshop 3.3**
Close Out and Archiving - a CTU guided workshop and discussion session on processes and procedures to conclude a trial	Practical Implementation of Bayesian Adaptive Designs for Single-arm, Randomised, Basket and Platform Phase II Trials, with real-world case studies	A hands-on introduction to health economics analysis plans (HEAPs)

Using Studies Within A Trial (SWATs) to increase the evidence-base for trial process

Prof Shaun Treweek[1], Dr Catherine Arundel[2], Prof Peter Bower[3], Prof Declan Devane[4], Dr Katie Gillies[1], Miss Karen Innes[1], Dr Adwoa Parker[2], Prof David Torgerson[2]

[1]University Of Aberdeen, UK, [2]University of York, UK, [3]University of Manchester, UK, [4]NUI Galway, Ireland

Pre-Conference Workshop 1.1, October 6, 2019, 9:00 AM - 1:00 PM

Introduction

Randomised trials are at the heart of clinical guidelines affecting the care of millions of people around the world and are central to evidence-based health care systems. It is odd then that the evidence available to trial teams to inform their own decisions about trial design, conduct and dissemination is so sparse. This is true for trial processes from choice of research question through to the dissemination of results.

This interactive workshop will give a brief overview of the trial process evidence problem and then devote the rest of the time to a key tool in the methods evaluation armoury– the Study Within A Trial (SWAT). The workshop will give practical, hands-on advice about how to select, design, run and report SWAT studies. Moreover, we will explain the need for coordinated and collaborative work so that high quality evidence is generated in a few years not decades as is currently the case.

Goals of the session

Participants will:

1. Gain an overview of the lack of trial process evidence and the harm it does.
2. Learn about SWATs as a way of increasing trial process evidence.
3. Have a hands-on session to discuss issues around designing and running SWATs in participants' own fields and institutions.

Structure of the workshop

Part 1

1. Introduction and learning about participants and what they want from the workshop. (20 mins)
2. A tool to increase the evidence base for trial processes: the Study Within A Trial (SWAT). (10 mins)
3. Small group work #1. Discussion of two SWAT examples (one qualitative, one quantitative). (25 mins)
4. Individual group feedback. (15 mins)
5. A Trials Unit's experience of running SWATs. (15 mins)
6. Case studies (20 mins):

a) The Christmas card SWAT (Karen Innes)
b) Case study from Liverpool (TBC)
c) Experience from the MRC START study (Peter Bower)
d) Post It Note SWATs (Catherine Arundel)

Break (15 mins)

Part 2

1. Why would a trial chief investigator be interested in SWATs? (10 mins)
2. The ethics of SWATs. (15 mins)
3. The PRIORITY prioritisation projects for recruitment and retention. (10 mins)
4. Small group work #2. Discuss questions coming from PRIORITY 1 and 2 and potential SWATs that could address these. (25 mins)
5. Discussion and open Q&A (25 mins) to cover:

a) Feedback from small group work #2.

b) Discuss the things raised in Part 1.

6. Summing up (5 mins).

Target audience
Anyone interested in improving the evidence base for trial process decision-making.

Beyond the CONSORT extension for pilot trials: guideline, planning, abstracts and protocols

Associate Professor Sally Hopewell[1], Professor Sandra Eldridge[2], Professor Christine Bond[3], Professor Mike Campbell[4], Professor Lehana Thabane[5], Professor Gillian Lancaster[6], Claire Chan[2]

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Pre-Conference Workshop 1.3, October 6, 2019, 9:00 AM - 1:00 PM

Introduction

Pilot and feasibility trials are an essential part of trial preparation, particularly for the planning of complex interventions. However, they often suffer from publication bias and a lack of clarity in the objectives and methodological focus. There are also misunderstandings about the purpose of pilot / feasibility trials including confusion about their definitions. This workshop is based on the work of the Pilot and Feasibility Studies (PAFS) collaboration, which is an international research group working on the reporting and conduct of pilot and feasibility studies. The group has established a framework for defining these studies [1] and published the CONSORT extension to randomised pilot and feasibility trials in 2016 [2].

Goals of the session

1. An understanding of the different views espoused by different organisations and individuals about pilot and feasibility studies and to explain how these can be organised into an overarching conceptual framework.
2. Familiarity with the CONSORT extension for pilot trials and its differences from the main CONSORT statement, with an understanding of the reasons for the major differences.
3. An understanding of good practice in relation to design, conduct and analysis of pilot and feasibility trials, particularly where this differs from the practice for definitive trials.

Structure of Workshop

This interactive workshop is made up of a series of short lectures, group work and discussion sessions.

1. Welcome and introduction.
2. Small Group: Participants to introduce own pilot and feasibility study examples. (15 mins)
3. Framework for defining pilot and feasibility studies. (10 mins)
4. Small group work: Discussion of how own examples fit within framework. (15 mins)
5. CONSORT extension for pilot and feasibility trials – overview of checklist items. (15 mins)
6. Objectives of pilot and feasibility studies. (10 mins)
7. Small group work: Focusing on participants' examples and how different parts of the CONSORT extension would work for different trials. (20 mins)
   BREAK
8. Sample size, progression criteria and analysis. (10 mins)

9. Small group work: focusing on participants' examples and how different parts of the CONSORT extension would work for different trials. (20 mins)
10. Guidance on flow diagrams and writing abstracts. (10 mins)
11. Group Exercise: Using the CONSORT extension to assess completeness of pilot trial reporting. (30 mins)
12. Guideline on planning pilot and feasibility studies and writing study protocols. (10 mins)
13. Future plans and close. (10 mins)

Target Audience

This half-day workshop is for anyone (health professionals, clinicians, epidemiologists, statisticians, PhD Students, NIHR Fellows etc.) interested in planning or reporting a pilot or feasibility study. Participants are strongly encouraged to come with their own examples of pilot trials so that these can be used in the discussions as outlined above.

References

1. PLoS ONE 2016; 11(3):e0150205.
2. BMJ 2016; 355:i5239; Pilot and Feasibility Studies 2016; 2:64.

Design and analysis of clinical trials in the era of precision medicine

Prof James Wason[1,2], Dr Haiyan Zheng[1]
[1]Newcastle University, Newcastle upon Tyne, United Kingdom, [2]MRC Biostatistics Unit, University of Cambridge, Cambridge, United Kingdom

Pre-Conference Workshop 1.2, October 6, 2019, 9:00 AM - 1:00 PM

Introduction

This tutorial focuses on novel clinical trial designs for precision medicine.

Precision medicine is about going beyond assessing whether a new treatment works on average to predicting which subgroups of patients receive benefit and to what extent. When the subgroups, often defined by biomarkers, genetic, phenotypic or psychosocial characteristics, are associated with a treatment's efficacy or toxicity, precision medicine offers substantial advantages to patients, trial sponsors, and the wider healthcare system. However, a barrier to realising the promise of precision medicine is the inappropriate use of traditional clinical trial design and analysis, which rely on estimates of population-averaged effects.

In this course we introduce the concept of precision medicine and cover some innovative approaches, including basket, umbrella, Bayesian hierarchical modelling, adaptive signature and adaptive enrichment designs. These approaches have all been developed to improve power and patient benefit provided by clinical trials. Examples from a wide variety of therapeutic areas will be discussed, with implementation in the OpenBUGS and R software. Perspectives will be given on the future development of design, conduct and analysis of clinical trials in the field.

Goals of the session

1. To learn how traditional clinical trials are not always appropriate in the context of precision medicine.
2. To learn about new quantitative approaches for clinical trials where the aim is to find which groups of patients a treatment works well for.
3. To explore how to design and analyse these trials using R and OpenBUGS.
4. To hear about some future directions of the area.

Structure of the workshop

1. Precision medicine and the need for novel statistical approaches. (35 mins)
   a. Precision medicine
   b. Traditional clinical trials and their limitations
   c. Subgroup analyses

2. Basket trials and using Bayesian methods for borrowing of information. (40 minutes)
   a. Basket trials in oncology
   b. Borrowing of information between modules in a basket trial

c. Bayesian hierarchical models for robust borrowing
d. Extending beyond oncology trials

3. Practical 1: Computer-based practical session to guide participants through issues raised in lectures 1 and 2. (45 mins, including break)

4. Adaptive designs for using subgroup information prospectively during clinical trials. (35 mins)
   a. Adaptive enrichment designs
   b. Umbrella designs

5. Developing signatures from high-dimension subgroup information. (40 minutes)
   a. High-dimensional information and its increasing role in clinical trials
   b. Retrospective analysis of high-dimensional subgroup information
   c. Adaptive signature design and extensions
   d. Future research

6. Practical 2: Computer based practical session with topics from lectures 3 and 4. (45 mins)

Target audience

Students and professionals with some knowledge of clinical trials and statistics are welcome. Statisticians will benefit the most from this course. Clinicians and trialists with good knowledge of statistics and computing will follow much of the course and will be exposed to a range of potential new methods. With the practicals, participants will have a chance to implement the novel methods in concrete examples. Some of the course will be difficult to follow for individuals without a good knowledge of statistical theory or R software but as much intuition will be given as possible.

Missing data in randomised trials: concepts and design

Dr Ian White[1], Dr Finbarr Leacy[2]
[1]MRC Clinical Trials Unit At UCL, London, United Kingdom, [2]Health Products Regulatory Authority, Dublin, Republic of Ireland

Pre-Conference Workshop 2.1, October 6, 2019, 2:00 PM - 6:00 PM

Introduction

Most trials suffer from missing outcome data, despite trialists' best efforts. This course aims to equip trialists with a conceptual understanding of why missing data matter and how they can be tackled. Topics to be covered include the impact of missing data, key assumptions encountered when analysing datasets with missing values, the ideas of multiple imputation and other analysis methods, and how to design trials both to reduce the amount of missing data and to aid the analysis and interpretation of the trial.

Goals of the session

1. Explain why missing outcome data are a problem in clinical trials.
2. Describe the principles behind some common statistical methods for handling missing data in clinical trials.
3. Identify steps that can be taken in trial design to reduce the extent of missing data.
4. Identify steps that can be taken in trial design to reduce the impact of missing data on statistical analysis.

Structure of the workshop

1. Understanding missing data: why does it matter and how is it handled in analysis? (60 mins).

2. Designing trials: how can we reduce the extent and impact of missing data? (60 mins).

Both speakers will encourage opportunities for discussion with other participants during presentations.

3. Small Group Practical 1: Designing a trial in weight loss (45 mins).

4. Small Group Practical 2: Critiquing a published trial in weight loss (45mins).

Target audience

All trialists. Specialist knowledge of statistics or of missing data methods is not assumed.

Strategies for optimising recruitment to challenging randomised controlled trials: the QuinteT approach

Dr Nicola Mills[1], Dr Leila Rooshenas[1], Dr Marcus Jepson[1]
[1]*University of Bristol, Bristol, United Kingdom*

Pre-Conference Workshop 2.2, October 6, 2019, 2:00 PM - 6:00 PM

Introduction
Randomised controlled trials (RCTs) can provide high quality evidence about the effectiveness of health care interventions but can be challenging to deliver. Slow or sub-optimal patient recruitment is one of the biggest threats to successful trial delivery, with difficulties leading to underpowered trials, costly extensions, administrative burden, delayed reporting or early trial closure. Empirically-based and widely transferable strategies for overcoming recruitment issues are important to the successful delivery of RCTs and improvements in patient care.

The Quintet Recruitment Intervention (QRI) is a flexible, broadly applicable intervention to rapidly understand and address sources of recruitment difficulty in an RCT as recruitment proceeds. Developed by the UK's QuinteT research group from over two decades of empirical research, it has been embedded in over 40 challenging RCTs, revealing common and often hidden factors that undermine recruitment, and demonstrating effective strategies for overcoming these. Growing evidence indicates that the QRI, and its associated recruiter training, increases recruiters' confidence and improves recruitment.

Goals of the session
To improve attendees' awareness and understanding of some of the more hidden barriers to recruitment and equip them with techniques to overcome them.

Structure of workshop

This workshop aims to equip attendees with knowledge and insight into the hidden challenges of RCT recruitment, as well as sharing evidence-based strategies informed by the QuinteT research programme to overcome them. There will be a blend of lectures including recruitment data from 'real-life' RCTs, interactive discussion and small group practical work, with attendees encouraged to share their experiences of RCT recruitment.

Sessions will be delivered by QuinteT group members: Dr Nicola Mills, Dr Leila Rooshenas and Dr Marcus Jepson.

1. Challenges of RCT recruitment and the QuinteT Recruitment Intervention. (40 mins)
   Includes 20-minute small group exercise for participants to share their recruitment experiences.

2. Maximising the pool of eligible patients. (40 mins)
   Includes reflection exercise on how these tips/techniques may be applied to randomised trials.

3. Information provision to potential trial participants. (2 hrs 15 mins)
   Includes presentations and short exercises for each section a-c.
   a) *Conveying equipoise*

b) *Engaging with patients' treatment preferences*
c) *Communicating RCT terminology*

6. Summary/wider discussion (25 mins)

Target audience

Academics, trial co-ordinators, and health care professionals involved in the design/delivery of RCTs, particularly those who organise or undertake recruitment in trials that are deemed difficult to recruit to.

Finding and critically appraising a core outcome set (COS) for your trial

Dr Elizabeth Gargon[1], Professor Paula Williamson[1], Dr Sara Brookes[2]
[1]University Of Liverpool, Liverpool, United Kingdom, [2]University Of Birmingham, Birmingham, United Kingdom

Pre-Conference Workshop 2.3, October 6, 2019, 2:00 PM - 6:00 PM

Introduction

A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in a specific condition. They are also suitable for use in research other than randomised trials that report on health-related outcomes. This allows research to be compared and combined as appropriate, and ensures that all studies provide usable information. The COMET Initiative provides and maintains a database of COS, as well as carrying out methodological research and producing guidelines for COS development.

Many organisations now actively endorse the use of COS and the COMET database, including health research funders who have included reference to COMET and COS in their grant application guidelines; referring applicants to check the COMET database for the existence of a COS. Funders include NIHR (HTA, PGfAR, RfPB), HRB, HRA, Deutsche Forschungsgemeinschaft (DFG), KCE: Belgian Health Care Knowledge Centre, Horizon2020 and ARUK.

For example, The NIHR Health Technology Assessment funding body in the UK has added the following statement to its application form:
'Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives.
- Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.'

It is important that relevant stakeholders are involved in the development of COS to ensure that COS appropriately reflect outcomes that are important to those groups, particularly patients, health care professionals and those that will use the COS in their research. The use of COS in clinical trials will ensure that outcomes important to patients, trialists and health care professionals are considered. High quality COS can aid trialists in selecting outcomes for inclusion in their trials, and COMET makes it easier for trialists to identify and use COS.

Goals of the session

1. To describe the rationale for using COS in clinical trials, and demonstrate how the COMET database helps to facilitate this.
2. To describe the issues to consider when deciding whether a COS is applicable to a trial, and the minimum standards for development that have been established that can help users of COS decide if a COS has been developed using reasonable methods.

Structure of the workshop

1. Introduction to workshop. (10 mins)
2. Group discussion: How do you [as trialists] currently choose the outcomes, and how to measure them, for your trials? (15 mins)
3. COS, The COMET Initiative, and the relevance to trialists. (20 mins)
4. Demonstration of the COMET database. (10 mins)
5. Uptake of COS in NIHR HTA applications submitted between January 2012 and December 2015. (15 minutes)
6. Discussion. (15 mins)
   Break (15 mins)
7. Introduction to group work. (10 mins)
8. Group work 1: Work through examples of COS. Consider assessing whether an existing COS is relevant to your trial – what might you need to think about? Scope, how, where, and who? What challenges might you encounter? (30 mins)
9. Bring discussions together and go through issues to consider and COS minimum standards. (25 minutes)
   Break (15 mins)
10. Group work 2: Applying minimum standards criteria to COS. (30 mins)
11. Discussion of group work 2. (20 mins)
12. Summary and take home points. (10 mins)

Target audience:
Trialists, researchers, patients, clinicians, academia, students, HTA agencies, policy makers, review authors, review editors, consumers, statisticians, methodologists.

Close Out and Archiving - a CTU guided workshop and discussion session on processes and procedures to conclude a trial

Dr Gordon Fernie[1], Ms Karen Innes[1], Dr Suzanne Breeman[1], Dr Lynda Constable[1], Ms Claire Cochran[1], Mrs Tracey Davidson[1], Mrs Alison Mcdonald[1], Ms Kath Starr[1]
[1]*Centre for Healthcare Randomised Trials, Health Services Research Unit, University Of Aberdeen, Aberdeen, United Kingdom*

Post-Conference Workshop 3.1, October 9, 2019, 2:00 PM - 5:30 PM

Introduction
Aim: Share knowledge about and experience of closing and archiving trials.

The successful and timely completion of multi-centre clinical trials requires that close out and archiving are completed effectively. When the trial end date is looming multiple tasks compete for priority within a congested and interdependent task timeline. The time spent trying to resolve difficulties at trial sites can sometimes disrupt the overall progress of completing the trial. Many trial managers have experience of deadlines slipping due to multiple factors including lack of stakeholder engagement and recruitment centres not responding to data queries.

This workshop will draw on the experience of an experienced trial management team working in a busy clinical trial unit. We will use group exercises to stimulate discussion about strategies and possible solutions for managing problems which can occur during close out and archiving publicly funded trials.

Goals of the session
In this workshop we will demonstrate and discuss how task assignment, setting and enforcing deadlines, and engaging stakeholders whose input you require can be managed. By employing effective strategies to mitigate or resolve such difficulties quickly trial teams can minimize disruption without increasing pressure on all involved stakeholders.

Structure of the workshop

1. Introduction. (10 mins)

2. Discuss group expectations and questions. (10 mins)

3. Small group work to undertake the following tasks a-c:

   2a. Chronology and project management (45 mins): Create a timeline for close out and archiving a trial.

   2b. Archiving activity (30 mins): Demonstrate some considerations when planning archiving and discuss what needs to be considered.

   Break (20 mins)

2c. Trouble-shooting (60 mins): Consider problems encountered during trial close down and archiving. A group discussion will follow.

4. Group expectations revisited and questions. (20 mins)

5. Summary and conclusion. (10 mins)

Target audience

All stakeholders in the project management group of clinical trials will benefit from attendance at this workshop including but not limited to chief investigators, academic grant-holders, statisticians, health economists, trial managers and coordinators.

Practical Implementation of Bayesian Adaptive Designs for Single-arm, Randomised, Basket and Platform Phase II Trials, with real-world case studies

Professor Christina Yap[1], Professor Ying Yuan[2]
[1]The Institute of Cancer Research, United Kingdom, [2]University of Texas MD Anderson Cancer Center, United States

Post-Conference Workshop 3.2, October 9, 2019, 2:00 PM - 5:30 PM

Introduction

Numerous Bayesian early phase adaptive designs have been proposed to improve the efficiency, flexibility and success rate of phase II trials. These designs, however, are still rarely translated into practice. The main barriers include the lack of (1) understanding of the methodology, (2) real-world experience on applying those novel methods, and (3) more importantly user-friendly software to implement the designs. One of our key objectives of this workshop is to remove those barriers.

A distinct feature of this workshop is that it centres on real-world case studies to motivate the applications of Bayesian adaptive designs. Using an array of user-friendly design software at www.trialdesign.org, delegates will work in sets of 2-3 (grouped to have a mix of expertise) to implement Bayesian adaptive designs they have learnt in the lectures during the interactive practical sessions. Differences between frequentist and bayesian approaches will be highlighted throughout.

Goals of the session

1. Understand basic concepts of Bayesian adaptive designs.
2. Design several Phase II real-world case studies using Bayesian approaches with user-friendly software (www.trialdesign.org).
3. Gain knowledge to choose and implement efficient, adaptive Bayesian designs tailored to their applications.
4. Learn about extensions to more complex scenarios such as hierarchical modelling in platform trials.

Structure of the workshop

1. Introduction to Bayesian Adaptive Designs. (30 mins)
   a. Basic concepts
   b. Differences compared to Frequentist Adaptive Designs
   c. Learn and demonstrate Bayesian inference and posterior update using www.trialdesign.org

2. Single arm, randomised 2-arm designs. (70 mins including practical)

   Practical: Using case studies to explore how to re-design the trials using Bayesian approaches with www.trialdesign.org.

Break (30 mins)

3. Randomised Multi-arm Multi-stage selection designs.
   a. Concepts of Response-adaptive randomisation
   b. Case study 3.

c. Learn the dynamic process of the response-adaptive randomisation using www.trialdesign.org

4. Interactive session. (30 mins)
   a. Discuss advantages and challenges – why use Bayesian?
   b. What information should be included in grant applications and protocol?

5: Introduction to Basket and Platform Designs illustrated by two case studies, with highlights on statistical and operational efficiency. (40 mins)

7. Closing Remarks. (10 mins)

Target Audience

Clinicians, trialists and students with good knowledge of clinical trials and statistics, and statisticians will benefit from this course and be exposed to a range of Bayesian designs. No knowledge of statistical programming is required as the practical will be conducted using a user friendly interface software.

A hands-on introduction to health economics analysis plans (HEAPs)

Dr Joanna C Thorn[1], Professor William Hollingworth[1], Dr Melina Dritsaki[2]
[1]University of Bristol, , United Kingdom, [2]University of Oxford, , United Kingdom

Post-Conference Workshop 3.3, October 9, 2019, 2:00 PM - 5:30 PM

Introduction

Health economics analysis plans (HEAPs) are detailed documents pre-specifying the key features of a proposed economic analysis. Pre-specification of a HEAP prior to conducting the analysis aims to reduce bias in the results of economic evaluations conducted alongside randomised controlled trials (RCTs) by reducing selective reporting and prohibiting undeclared post hoc analyses. The Network of Hubs for Trials Methodology Research funded a project to conduct an international Delphi survey among health economists to seek consensus on the essential content of HEAPs. The project concluded by identifying 58 items (such as the measurement of resource-use data, and key assumptions) that should be included in a HEAP, and a further 9 items that could be considered optional, resulting in a template HEAP. The template was introduced to a group of 25 early-career researchers in a hands-on workshop held in Bristol earlier this year. The participants responded positively to the workshop, which has now been adapted to deliver to further groups of students.

Goals of the session

The aim of the workshop will be to offer a hands-on training session in writing a HEAP, supported by sessions covering the background and rationale for adopting HEAPs (and the HEAP template in particular). We aim to give participants a thorough understanding of the framework in which a HEAP is created, and to allow them protected time to make a start on (or further develop) their own HEAP.

Structure of the workshop

1. Background: Why do we need HEAPs? (30 mins)
2. Development of the HEAP template: expert Delphi consensus survey. (15 mins)
3. Practical session: turning a protocol into a HEAP. (60 mins)
4. Group discussion of any difficulties. (30 mins)
5. HEAPs in the real world – issues and challenges. (15-30 mins)
6. Second practical session. (60 mins)
7. Next steps: what to do with your HEAP. (15 mins)

Target audience

The workshop will be aimed at early career health economists who are writing analysis plans for economic evaluations conducted alongside RCTs. However, the content may also be of interest to more senior health economists, and to trial unit staff who wish to gain an overview of HEAPs.