Basic Workshop on Randomised Controlled Trials
20 hours

This workshop is aimed to participants with no / limited experience in Randomised Controlled Trials (RCTs). Lectures (of 30 to 40 minutes each) will take place in the morning, followed by practical activities in the afternoon. This practical component could be of two types depending on whether attendants have or do not have a research question suitable for developing an RCT:

- If they have a question, each individual or group could work in the afternoon developing the question, according to the topics covered during the morning

- If they do not have one, a question may be set out for all the groups to work on it.

Day 1

Introduction to the Workshop

Welcome, introduction and goals. Workshop structure (bound to the development of a protocol), learning in small groups

Topic 1. Overview of Randomised Controlled Trials (RCTs)

- What is an RCT? History.
- Alternative research methodologies.
- Why it is important to conduct RCTs.
- Main components of a RCT with two parallel groups (selection of participants, allocation, experimental and control interventions, follow-up, outcome assessment, analysis)

Topic 2. The Question

- Main (primary) question and secondary questions.
- Elements of the clinical research question.
- The research question and pragmatic RCTs.

Topic 3. RCT Population

- Selection of participants
- Eligibility criteria (inclusion and exclusion criteria)
- Generalisation of results
- Enrolment methods
- Information to potential participants

Topic 4. Allocation of Interventions

- What is randomisation?
- Justification for randomisation
- Stratified randomisation and randomisation in blocks
- Methods of randomisation (simple, stratified or in blocks, cluster (concept))
- Software for randomisation
- Open and concealed allocation
- Method for concealment of allocation

Topic 5. Interventions

- Interventions in the experimental group.
- Interventions in the control group (other treatment, placebo, usual care).
- Administration of interventions to participants.
- Introduction to blinding issues (will talk about in more depth on Day 2)

Group Work/Debate.

Day 2

Topic 6. Measurement/Assessment and data collection

- Baseline assessment.
- Clinical outcome measurements (end-points) -primary and secondary.
- Open and blinded trials (simple, double, triple).
- Follow-up strategies.
- Withdrawal of participants.
- Data collection methods (paper, electronic, routine, non-routine)

Topic 7. Compliance or adherence

- Definitions.
- Considerations before subject's enrolment.
- Methods to measuring compliance.
- Strategies to ensuring participants' adherence.

Topic 8. Sample Size

- Basic clinical concepts: event baseline frequency, clinically meaningful difference.
- Basic statistical concepts: type I and II errors, alpha and beta probabilities, study power.
- Software for sample size calculation.

Topic 9. Analysis Strategies

- General aspects of analysis (baseline comparison, result comparison).
- Dummy tables in a RCT.
- General analysis strategies: intention to treat, per protocol.
- Association measurements for dichotomy variables (ARR, RR, RRR).
- Confidence intervals and hypothesis testing.
- Introduction to analysing cluster randomised trials.
- Software for data analysis

Topic 10. Protocol Deviations

- Inclusion of non-eligible subjects.
- Management of subjects with poor adherence.
- Missing or poor-quality data.
- Competitive events.

Group Work/Debate

Day 3

Topic 11. Ethical Aspects of the RCTs

- Clinical balance (equipoise) concept.
- Informed Consent.
- Special populations (minors, handicapped, vulnerable populations).
- Risks and benefits for participants.
- Disclosure of conflicting interests.

Topic 12. RCT Management/Conduction

- RCT co-ordination.
- Good Clinical Practice.
- Getting your research funded.
- Authorship.

Discussion and Evaluation of the Projects

And potentially: accompanying research, qualitative research methods, economic evaluations, quality of life assessment.

Closing remarks