

# Nuts & Bolts of RCT Venue – KEM Hospital Coordinator – Dr Kadam

| No. | Topic                                    | What will be covered                                                                                                                                                                                                                                                                                                          | Duration | Start time | End time |
|-----|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|------------|----------|
| 1   | Overview of randomized controlled trials | When is an RCT justified and when not justified, advantages over observational studies, broad overview of the types of RCTs, major sections of RCT                                                                                                                                                                            | 30       | 09:00 AM   | 09:30 AM |
| 2   | Framing a research hypothesis            | PICO, time and effect size of the outcome                                                                                                                                                                                                                                                                                     | 30       | 09:30 AM   | 10:00 AM |
| 3   | Deciding on the outcome                  | Patient-centric versus intermediate or surrogate outcomes; all-cause versus cause-specific; outcome measurement by sensitive versus specific criteria; composite outcomes                                                                                                                                                     | 20       | 10:00 AM   | 10:20 AM |
| 4   | Tea break                                |                                                                                                                                                                                                                                                                                                                               | 20       | 10:20 AM   | 10:40 AM |
| 5   | Sample size calculation                  | Binary versus continuous outcomes, assumptions that go into sample size calculation, factors that increase or decrease sample size requirement, binary outcome expressed as a ratio measure or difference measure- implications for sample size; <b>practical demo</b> using a sample size calculator                         | 50       | 10:40 AM   | 11:30 AM |
| 6   | Deciding on eligibility criteria         | Screening criteria, inclusion versus exclusion criteria, external validity                                                                                                                                                                                                                                                    | 15       | 11:30 AM   | 11:45 AM |
| 7   | Randomisation and allocation concealment | Biases avoided due to randomisation; simple versus restricted randomisation; minimisation; implementation of random allocation sequence- SNOSE, central computer/telephone; <b>practical demo</b> of using a randomisation website; <b>practical demo</b> of converting a stratified, block randomisation sequence into SNOSE | 60       | 11:45 AM   | 12:45 PM |
| 8   | Lunch break                              |                                                                                                                                                                                                                                                                                                                               | 50       | 12:45 PM   | 01:35 PM |
| 9   | Blinding                                 | Biases avoided, Terminology, methods of blinding, PROBE studies                                                                                                                                                                                                                                                               | 20       | 01:35 PM   | 01:55 PM |
| 10  | Interim analysis and stopping rules      | Need for interim analysis and stopping rules; pros and cons of common stopping rules; implications for sample size                                                                                                                                                                                                            | 30       | 01:55 PM   | 02:25 PM |
| 11  | Analysis                                 | ITT versus per protocol; meaning of RR, OR, RD, NNTB, NNTH, mean difference, median difference; pros and cons of RR vs OR vs RD; 95% CI of ratio measures versus difference measures.<br>How to handle missing data; sensitivity analysis                                                                                     | 60       | 02:25 PM   | 03:25 PM |
| 12  | Tea break                                |                                                                                                                                                                                                                                                                                                                               | 20       | 03:25 PM   | 03:45 PM |
| 13  | Confounders and effect modifiers         | What are they? how to recognise them? how to handle them in design and analysis?                                                                                                                                                                                                                                              | 25       | 03:45 PM   | 04:10 PM |
| 14  | Subgroup analysis                        | What kind of subgroups deserve subgroup analyses? Pitfalls of analysing subgroup separately. Tests of interaction and their p values?                                                                                                                                                                                         | 25       | 04:10 PM   | 04:35 PM |
| 15  | Practical issues and useful checklists   | Trial registration, participant information sheet, informed consent form, clinical trial insurance, CDSCO approval<br>SPIRIT 2025 guidelines for writing proposal, CONSORT 2025 guidelines for writing manuscript, CASP for critical appraisal                                                                                | 55       | 04:35 PM   | 05:30 PM |

**Final  
Workshop  
faculty:**  
**Dr Kabra**  
**Dr Kadam**  
**Dr Datta**  
**Dr Lobo**  
**Dr Patole**