## Day 1 (Tuesday 19th November 2024) – Lead for the day Ed Roddy

**Key principles and designs of RCTs**

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| **Time** | **Content** | **Tutor** |
| 9.30- 10.15 | Welcome and Introductions  ***Live session*** | Ed Roddy |
| 10.15- 11.30 | Principles of Randomised Controlled Trials (RCTs)  ***Pre-recorded session 10.15-11.15***  ***Live Q&A 11.15-11.30*** | Julius Sim |
| 11.30-11.45 | **Break** |  |
| 11.45- 12.15 | Patient and Public Involvement and Engagement (PPIE) in RCTs  ***Live session*** | Adele Higginbottom, Alice Moult  **PPIE Rep TBC** |
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| 12.15-13.00 | **Break** |  |
| 13.00- 14.15 | Randomised Controlled Trials: Research designs, consort statement and SPIRIT guidance  ***Live session 13.00-14.00***  ***Live Q&A 14.00-14.15*** | Ivonne Solis-Trapala |
| 14.15- 14.45 | Designing Implementation into your Randomised Controlled Trial  ***Live session*** | **TBC** |
| 14.45-15.00 | **Break** |  |
| 15.00- 16.15 | Pitch Your PICO  Discussion and agreement of RCT question  ***Live small group work*** | Ed Roddy  Mel Holden  Martyn Lewis |

## Day 2 (Wednesday 20th November 2024) – Lead for Day Mel Holden

## Managing Clinical Trials: Key issues from protocol to implementation

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| **Time** | **Content** | **Tutor** |
| 9.30 - 10.15 | Research Governance  ***Pre-recorded session 9.30-10.00***  ***Live Q&A 10.00-10.15*** | Jo Simon |
| 10.15 -11.10 | Trial Set-up: Participant information, recruitment, consent, randomisation and blinding, maximising follow-up  ***Pre-recorded session 10.15-10.30***  ***Live practical workshop and Q&A 10.30-11.10*** | Kendra Cooke |
| 11.10 -11.25 | **Break** |  |
| 11.25 -12.30 | RCT design and operationalisation (1)  ***Live small group work*** | Ed Roddy  Mel Holden  Martyn Lewis |
| 12.30-13.15 | **Break** |  |
| 13.15-13.40 | Recruiting and training clinical research partners  ***Pre-recorded session & Live Q & A*** | **TBC** |
| 13.50- 14.45 | Evaluating and monitoring the progress and conduct of the trial  ***Pre-recorded session 13.50-14.25*** *Live practical workshop and Q&A 14.25-14.45* | Ruth Beardmore & Nicola Halliday |
| 14.45- 15.00 | **Break** |  |
| 15.00-  16.00 | RCT design and operationalisation (2)  ***Live small group work*** | Ed Roddy  Mel Holden  Martyn Lewis |

## Day 3 (Thursday 21st November 2024) Lead for the Day Martyn Lewis

## Data issues in the implementation and analysis of clinical trials

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| **Time** | **Content** | **Tutor** |
| 9.30- 10.15 | Key statistical principles for Clinical Trials  ***Pre-recorded session 9.30-10.00***  ***Live Q&A 10.00-10.15*** | Elaine Nicholls |
| 10.15- 10.45 | Sample size  ***Pre-recorded session*** | Martyn Lewis |
| 10.45-11.00 | **Break** |  |
| 11.00- 12.00 | Analysis and presentation of data – examples  ***Live session*** | Julius Sim |
| 12.00 – 12.15 | Live Panel Q&A | Elaine Nicolls, Julius Sim, Martyn Lewis |
| 12.15 – 13.00 | **Break** |  |
| 13.00- 14.00 | Economic evaluation alongside clinical trials  ***Pre-recorded session 13.00-13.45***  ***Live Q&A 13.45-14.00*** | Jesse Kigozi |
| 14.00 – 14.15 | Break |  |
| 14.15-16.00 | RCT data issues (randomisation, outcomes, sample size, blinding, methods of analysis, health economics)  ***Live small group work*** | Ed Roddy  Mel Holden  Martyn Lewis  **TBC**  **Kieran Bromley**  **Royes Joseph** |

## Day 4 (Friday 22nd November 2024) – Lead for the Day Ed Roddy

## Qualitative methods and presentation of developed RCTs

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| **Time** | **Content** | **Tutor** |
| 9.30- 10.30 | Qualitative methods in RCTs  ***Pre-recorded session 9.30-10.15***  ***Live Q&A 10.15-10.30*** | Julius Sim |
| 10.30- 10.45 | Break |  |
| 10.45- 12.45 | Finalising RCT plans and presentations for funding panel  ***Live small group work*** | Ed Roddy  Mel Holden  Martyn Lewis |
| 12.45- 13.30 | Break |  |
| 13.30- 15.00 | Presentation of sample RCTs to the funding panel, with questions and answers  Funding Panel: Chair - Jonathan Hill, Elaine Nicholls, **PPIE Rep TBC** | All and funding panel |
| 15.00- 15.30 | Course feedback, panel deliberation  Funding decision  Close | Ed Roddy  Funding panel |