Planning a Randomised Controlled Trial (RTC) – Points to Consider

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In this section

Planning an RCT takes time, and should include all aspects of the design, conduct and reporting. The following summarises issues that should be considered during planning, although not all will apply to all trials.

Support for most of these is offered by UKCRC Registered CTUs and in England, The NIHR Research Design Service (RDS).

Choosing the right question

- Is it relevant, to the NHS and to patients and their families?
- Is it an identified research gap (is there a systematic review)?

Protocol development

- Clearly stated hypothesis
- Patient and public involvement
- Realistic recruitment strategy
- Clearly defined primary outcome (see Comet Initiative)
- Clearly defined intervention and control
- Appropriately referenced and justified sample size estimates
- Appropriate statistical analysis plan, including any interim analysis
- Risk assessment and appropriate monitoring strategy (for data quality, protocol compliance, and safety of participants)

- Appropriate strategy for independent trial management and oversight (Trial Management Group, Trial Steering Group, Data Monitoring Committee, Research & IP Management Group)
- Protocol publication, trial registration

Study set up

- Submission of protocol for necessary approvals: Ethics, NHS R&D, MHRA
- Negotiate contracts with participating organisations (including intellectual property and commercialisation agreements)
- Study sponsor, insurance and indemnity
- Develop and agree data collection tools
- Agree statistical analysis plan, including dummy tables for final results
- Staff training: clinical sites, co-ordinating centre

Trial intervention: CTIMPs or other medication trials

- Procurement of drug and control, packaging and distribution
- Stock control and quality checking
- Appropriate pharmacovigilance
- Emergency code break

Trial Intervention: Devices trials

- Procurement or development of device
- CE status of device and requirement for MHRA approval
- Control arm – treatment as usual or ‘sham’ device
- Supply of device, operational manual and quality checking
- Adverse event/adverse reaction assessments

Trial Intervention: Therapy or other complex intervention trials

- Manualisation of therapy and fidelity checks, if appropriate

- Availability of therapists to deliver interventions
- Control arm – treatment as usual or non-therapeutic intervention
- Level of therapist experience and expertise appropriate to the trial
- Inter-rater reliability, therapist training and supervision
- Adverse event / adverse reaction assessments

Study conduct:

- Selecting recruitment sites
- Randomisation process: monitor eligibility and stratification errors
- Database development and maintenance: computer system validation
- Site set up: training, awareness raising
- Recruitment: monitoring, incentives, recruitment fatigue
- Data management: data collection, collation and confirmation
- Study monitoring: site visits (source data verification, investigator site file and pharmacy file checks), central monitoring
- Study marketing: investigator meetings, newsletters (participants, clinicians), logo
- Project management: Trial Management Group, Trial Steering Committee, Data Monitoring Committee, Research & IP Management Group
- Follow up: Minimise missing data and attrition, prioritise safety & primary outcome data
- Interventions: Success of blinding, accidental unblinding, compliance with allocated treatment
- Analyses: interim, final (intention to treat and per protocol)
- Preparing routine, interim and final reports, and publications of results: funders, journal articles, presentations, information for study participants. CONSORT is intended to improve the reporting of a randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results.
- Archiving