

Study Development



Advice Available from BCTU

Idea Stage

Support and advice can be provided on the following aspects:

- Formulation of a research question – population, intervention, control or comparison arm, outcome measures;
- Literature searching – either we can provide a comprehensive guide to literature searching or we can search the literature and summarise the results of the search from abstracts or full papers where freely available.

You need to provide a little information at this point other than that requested on the [SUPPORT & ADVICE REQUEST FORM \(/Documents/college-mds/trials/bctu/BCTU-documents/BCTU-Support-and-Advice-Request-Form-v3.docx\)](#). If you wish us to conduct a literature search for you, you will first meet with one of the Unit's systematic reviewers to define the search strategy. Once this is complete and the information has been reviewed, an appointment with a statistician will be made to discuss the study design.

Study & Protocol Development Stage

Many researchers have a fairly clearly defined idea and need help with the next steps, such as study design, protocol development and application to a funding body.

Advice available from BCTU Statisticians

[Open all sections](#)

- Study design and methodology
- Sources of funding and grant applications
- Sample size calculation
- Randomisation procedures
- Endpoints and outcome measures
- Analysis methods

Advice available from BCTU Senior Trial coordinators

- Trial/ Study management
- Sources of funding and grant applications
- Appropriate resources for running the study (including advice on NHS costs)
- Regulatory requirements
- Drafting a protocol and developing case report forms

Advice available from BCTU Senior Programmers

- Form design (paper & electronic)
- IT needs for clinical studies
- Database system development and design

Information will need to be provided in advance of any meeting with a BCTU member of staff by completing the [SUPPORT & ADVICE REQUEST FORM \(/Documents/college-mds/trials/bctu/BCTU-documents/BCTU-Support-and-Advice-Request-Form-v3.docx\)](#), and provision of a draft protocol and relevant literature if available.