Centre for Healthcare Randomised Trials

Proposal Outline

Thank you for your approach to CHaRT. Please send a brief description of your proposed trial, using the headings provided below as guidance, to CHaRT Research Managers; Kirsty McCormack - k.mccormack@abdn.ac.uk and/or Ruth Thomas – r.e.thomas@abdn.ac.uk .

1. Title of proposed trial

2. What is your research question?

Your research question should usually identify the intervention to be evaluated, the comparator, main outcome and the relevant population.

3. Why is a trial needed now?

a) Importance of the health problem

Please describe the frequency and importance of the health problem in the population and, if possible, its impact on the individual, the health care provider (ie the NHS), and wider society.

b) Summary of the current evidence:

Please describe any systematic reviews, RCTs, or other relevant studies evaluating the intervention(s) or treatment(s) to be studied. Describe current knowledge and ongoing research. How will your proposed research add to what is already known? How will the results of this trial be used?

4. Brief trial description

a) Population/participants

Please describe the "population" ie your trial participants – the group for whom you think it is important to evaluate the intervention(s) or treatment(s).

b) Interventions

Please describe the intervention(s) or treatment(s) that you wish to compare. Please provide a description of the setting and the health professionals involved? What are the perceived advantages and disadvantages of each? Which, if any, of the interventions or treatments is current practice?

c) Outcomes

What outcomes would you use to measure the effects (benefits and harms) of the intervention(s) or treatment(s) (e.g. quality of life, treatment complications, resource use) and why? At what time points would you measure these outcomes? Which of these outcomes do you consider the most important?

5. Is the trial feasible?

Have you (or a statistician) calculated a sample size for the trial, if so please give details. How will you identify potential trial participants?
How many potential participants would you treat in your centre? Please give details of any other centres willing to be involved.
Do you have any estimates of their potential participant numbers?
Please outline any potential barriers to, or problems that you foresee with, either recruiting participants and centres or retaining them within the study?

6. Are you planning a pilot/feasibility stage? If so, please give brief details.

7. Does the study intervention carry 'additional risks' to the patient?

8. Please could you give some details about yourself and any other proposed applicants or collaborators (name, discipline/speciality, and/or expertise, institution?)

9. Please could you explain why this proposal will enhance the strategic plan of the University of Aberdeen e.g. by facilitating trials in clinical areas recognised as a strength.

10. Have you been directed to a particular funding stream/call? If so, please give brief details.

11. What level of support are you seeking from CHaRT (i.e randomisation service only or CHaRT as the supporting Clinical Trials Unit)?

Please send us a maximum of 5 key references for the proposed area of research including a systematic review, if available.