

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](mailto:k.mccormack@abdn.ac.uk) and/or Ruth Thomas – [r.e.thomas@abdn.ac.uk](mailto: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 problem**

*What is the problem or gap in knowledge that your study will address? Please describe the frequency and importance of the problem in the population and, if possible, its impact on the individual, the health care provider (i.e. 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?*

**c) Patient and Public Involvement and Engagement (PPIE)**

*Briefly describe how patients, service users, or carers have informed the research question, outcomes, and design, and how their input supports the need for the trial at this time.*

**4. Brief trial description**

**a) Population/participants**

*Please describe the “population” i.e. your trial participants – the group for whom you think it is important to evaluate the intervention(s) or treatment(s). Include consideration of research inclusion and diversity, outlining how the proposed population reflects the demographics of those affected by the condition and how you will ensure equitable access to participation.*

**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? Where relevant, comment on any inclusion or accessibility considerations that may influence acceptability or delivery across diverse groups.*

**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? Please also consider whether the outcomes are relevant and meaningful across diverse participant groups, including those typically under-represented in research.*

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

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

**9. 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.***