Improving Recruitment into Clinical Trials

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Background

- **Embedding research in clinical services** is a core function of the NHS. National policy states that all NHS patients should be offered the opportunity to participate in clinical research. Currently, patients with common mental health problems do not get this chance. Most trials recruit less than 10% of eligible patients and only 30% of trials for depression recruit to target.
- **DiReCT** is a pilot study testing the ethical and practical feasibility of a unique 'Cohort Multiple RCT' (cmRCT)[1] method for recruiting patients with common mental health problems into clinical trials. This recruitment method has been recently suggested to tackle problems associated with pragmatic effectiveness of trial designs such as recruitment, sampling bias and patient preferences.
- **The cmRCT method** establishes a prospective cohort of participants who agree to be randomly selected and offered treatments in clinical trials should they meet eligibility criteria. Control group patients continue to receive treatment as usual and are assessed as part of the longitudinal cohort, providing comparative data for the experimental groups.

Objectives

The **DiReCT** proof of principle will comprise of three phases; the 'ethics test', 'recruitment test' and 'trials test' and will test the following questions:

1. **How ethically acceptable is the cmRCT system?**
2. **What proportion of NHS patients with common mental health problems will agree to join the DiReCT cohort?**
3. **How many patients in the DiReCT cohort would consent to being randomly selected to receive new treatments?**

This study will establish the feasibility of future work in this area to establish a health research cohort and provide much needed clinical trial recruitment infrastructure in Devon.

Methodology

Participants: all patients with common mental health problems presenting for assessment at the Depression and Anxiety Service (DAS) of Devon Partnership NHS Trust for a period of four months.

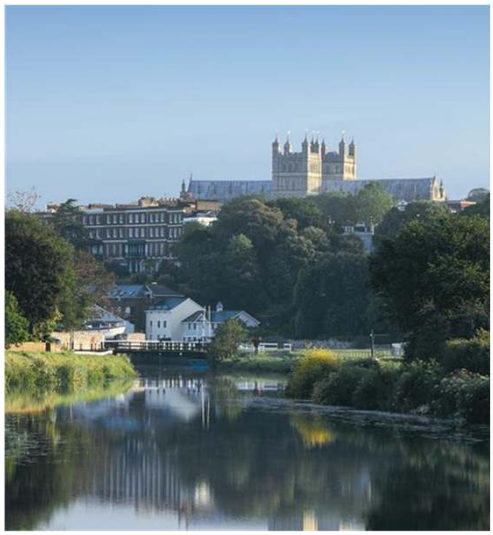
Procedure: clinicians working for DAS will ask patients if they wish to participate in the DiReCT study. They will be given a participant information sheet and consent form. The consent form will ask patients if they wish to consent to a) participate in a health research cohort and b) being randomly selected to be offered treatments tested in randomised controlled trials (RCT's).

Measures: we will record the total number of assessments conducted and the numbers of patients offered participation by the assessing clinician. We will record the number of patients consenting to involvement in the cohort; in their medical records being reviewed; and in the random selection to clinical trials.

Analysis: we will report frequencies of the number of patients (1) attending for assessment who are offered participation compared to the total number of attendees; (2) consenting to involvement in the cohort compared to the number offered participation; (3) confirming consent to be randomly selected to be offered treatment trials via a follow up call compared to those consenting via the consent form.

Benefits

- Provide an exemplar proof of concept test of the cmRCT idea and reduce resource waste by establishing a more efficient clinical infrastructure for recruiting participants into multiple trials.
- Allow for the publication of regular cohort data following the implementation science theme previously undertaken by David Richards[2] to inform treatment development and access work.
- Reduce the need for repetitive investment in participant identification for RCT's.
- Deliver a stronger evidence base for newly developed treatments to inform health services improvement.
- Increase funding opportunities for clinical trial and health care research work in Devon.



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[1] **Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomized controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ* 2010**

[2] **Richards, D.A. and Borglin, G. (2011). Implementation of Psychological Therapies for Anxiety and Depression in Routine Practice: Two Year Prospective Cohort Study. *Journal of Affective Disorders***

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