

# Conducting a Randomised Controlled Trial of an Intervention for Depression for People with Comorbid Heart Disease and/or Diabetes in Primary Care: Learning Points from the COINCIDE trial

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## What is the COINCIDE trial?

- The COINCIDE trial is a cluster-randomised controlled trial looking at the cost- effectiveness of collaborative care for depression in people with comorbid heart disease and/or diabetes in primary care.
- The trial is funded by the Greater Manchester CLAHRC which aims to undertake high quality health research focused on the needs of patients and supports the translation of research findings into NHS practice.

## Study design and processes

- Delivery of the COINCIDE trial, with its multi-component intervention, involved engaging GP practices to agree to take part in the study, IAPT workers and practice nurses to deliver the intervention and patients.
- COINCIDE aimed to recruit 30 practices across the Northwest (15 in each arm) , and 450 patients. The COINCIDE study began in Jan 2012 and is running until Dec 2013.
- Once recruited, practices were randomised sequentially into either the collaborative care or usual care arm of the study.
- Figure 1 shows the processes involved in the trial and the numbers eventually recruited.

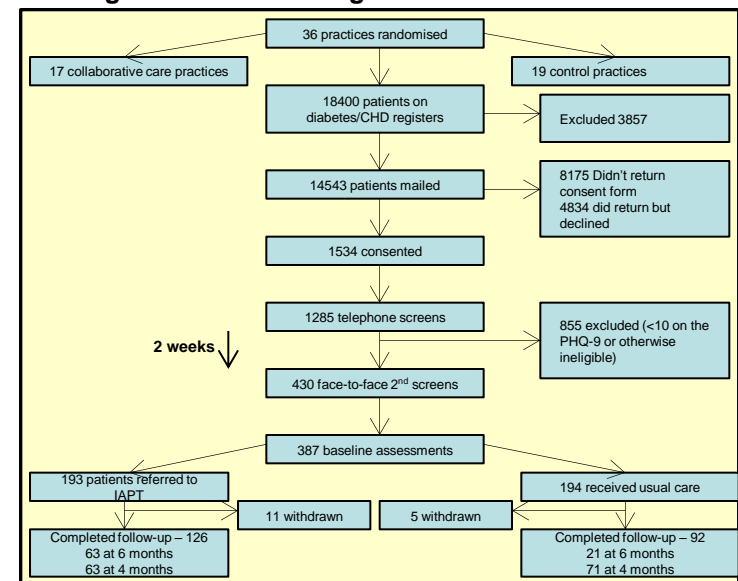
## What worked well?

- IAPT teams were supportive of our study as developing more integrated services for people with long term conditions and common mental health problems is key priority of IAPT.
- We worked with the Primary Care Research Network (PCRN), who supported us in recruiting practices, and the MHRN, who supported patient recruitment by conducting mail-outs.
- Working successfully with the networks required close working relationships, an understanding of roles and ways of working of the networks, and providing them with clear information to explain our research to health professionals and patients.
- Creating and maintaining a database of GP practices in the targeted recruitment areas helped us keep on track with GP recruitment.
- Professionally produced patient and professional materials with a strong 'brand identity' seemed to help to engage both professionals and patients.

## What didn't work so well?

- Unexpected delays in GP recruitment delayed mail-outs from practices in some cases.
- We also experienced a low response rate from practices with small numbers.

**Figure 1: Consort diagram for the COINCIDE trial**



- However as we picked this up early we were able to adjust timelines and number of clusters (GP practices) in the study and were therefore able to still recruit to target.

## What have we learnt?

1. Research networks can be very useful in facilitating recruitment into trials.

2. Making use of independent monitoring and advice is a good idea
3. Recruitment targets can be met following judicious changes to the study protocol
4. However it is important to ensure that any such changes to protocol are published.