Background
All randomised controlled trials (RCTs) lie on a continuum from completely explanatory to fully pragmatic.
Most RCTs are the former, but calls for pragmatic randomised studies in mental health have been increasing.
There are, however, still only a few examples of studies truly grounded in real-world practice.
The Cochrane Schizophrenia Group has a successful programme of such studies in psychiatry.

Methods
- High grade systematic reviews precede design of the trials.¹
- Working collaboratively, studies are planned with
  - participants recognisable to everyday care
  - practical, accessible interventions
  - outcomes relevant to everyone concerned
- An International RCT number (INRCTN) is gained for the trial at protocol stage
- Detailed protocols, including explicit details of how analyses are to be undertaken, are published before anyone is randomised²³

Results
Over 4 years we have randomised 1786 people into 6 different trials

Local
1. Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) Project – community®
   Buprenorphine vs dihydrocodeine opiate detoxification regimens for homeless people, N=60, 100% follow up
2. Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) Project – Armley*
   Buprenorphine vs dihydrocodeine opiate detoxification regimens for people in prison, N=90, 100% follow up
3. PROMPTS for psychiatric out-patient attendance*
   Prompting letter vs standard system for people due to attend psychiatric OPD for the first time, N=764, 97% follow up

National
1. Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) Project – UK Prisons
   Buprenorphine vs methadone opiate detoxification regimens for people in prison, estimated N=300, start late 2005

International
1. TREC-Rio-1* •
   IM Haloperidol + promethazine vs midazolam for acutely aggressive people, N=301, 100% follow up.
2. TREC-Vellore-1**
   IM Haloperidol + promethazine vs lorazepam for acutely aggressive people, N=200, 100% follow up.
3. TREC-Rio-2®
   IM Haloperidol + promethazine vs haloperidol for acutely aggressive people, N=316, 100% follow up.
4. TREC-Vellore-2
   IM Haloperidol + promethazine vs IM olanzapine for acutely aggressive people, estimated N=200, recruiting now, n=45.

Discussion
All trials have been undertaken on shoe-string budgets
Nevertheless, commitment to, and expertise in, design and conduct of this type of research is increasing
The rewards of working in a productive, truly collaborative, local/national/international network are great
- published studies from this network are recognised as “the only trials of high methodological quality in the area”⁴

References
1. For example: Gillies D, Beck A, McCloud A, Rathbone J. Benzodiazepines alone or in combination with antipsychotic drugs for acute psychosis. The Cochrane.

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