WORKSHOP
Randomised trials in primary care — tips for success

Facilitators: PACT (Primary care Alliance for Clinical Trials Group), including A/Prof Jane Gunn, Dr Marie Pirotta, A/Prof Bruce Arroll, Dr Raina Elley, Prof Paul Glasziou, Prof Justin Beilby, Ms Patty Chondros, A/Prof Nicholas Glasgow, Dr Nabil Sulaiman, Dr Mark Nelson

Well-conducted randomised trials provide the most rigorous evidence of effectiveness of primary health care interventions. Trials can be expensive and require planning and persistence to be successful. This workshop was the first official face-to-face gathering of the PACT network. Thirty-five participants met to share experiences and to discuss key challenges commonly encountered when undertaking randomised trials in the primary health care setting.

Our afternoon began with an address from Professor Judith Lumley, Centre for the Study of Mothers’ and Children’s Health. Judith is a medical graduate and epidemiologist who spoke with us about her involvement in clinical trials. Using examples from her experience we heard about the challenges and rewards of conducting trials.

We then divided into groups to discuss:

► When is an intervention ready to be tested in a randomised trial? [Facilitators — Jane Gunn and Nabil Sulaiman]

Participants in this small group participated in a decision making process about whether or not a complex intervention was ready to trial. This activity highlighted the principles behind the development and implementation of complex interventions within RCTs in primary care.

► Measuring meaningful outcomes in RCTs [Facilitators — Bruce Arroll and Justin Beilby]

Participants in this group debated the issues around measuring meaningful outcomes in RCTs. They discussed issues such as: should we be measuring changes in mean scores on scales or should we be measuring clinically meaningful outcomes such as the % of people recovered from condition X?

► Cluster versus individual randomisation — more than a sample size issue [Facilitators — Raina Elley and Patty Chondros]

Participants in this group debated the issues in deciding whether to randomise at the individual or practice level.

► Undertaking large-scale multi-practice randomised trials in primary care — tips for success [Facilitators — Marie Pirotta, Nicholas Glasgow and Mark Nelson]

Participants in this group explored the methods required to ensure the success of multi-centred trials in the context of Australian primary care. The facilitators drew upon their own experiences of such trials, one successfully completed and two under way, to prompt discussions about the challenges of ethics committees, recruitment and retention of both practices and subjects over time.
Following our small group work we participated in a ‘Tea and Trials’ session. During this time we sipped tea and talked about our current trials — using posters to assist our discussion. We heard snippets about more than 20 participants’ current work!

Finally Paul Glasziou facilitated a session of open discussion where we discussed:

- Should we form an informal trials network — PACT — that would function as an email list and meet at least once a year in conjunction with a primary care research conference?
- How can we foster multicentre-GP trials (including across states and National borders)?
- How can we develop and inform each other about new trial methods (a ‘community of practice’ model)

**Outcomes of Workshop**

The workshop was a great success and received overwhelmingly positive evaluations from the participants. We agreed that the PACT network would continue to function and that we would organise another network meeting for 2004, establish a website and email list. Jane Gunn and Maria Potiriadis agreed to continue these activities as an ongoing part of the PHC RED program at the Department of General Practice, University of Melbourne. The facilitators agreed to write up the proceedings from their small groups and to submit these papers to a journal for publication and dissemination.

If you are interested in joining the PACT network please email: gp-phcred@unimelb.edu.au