

Review of Clinical Trials talk by Janet Dunn, Warwick Clinical Trials Unit given at ICPV Summer School, Brighton, 4th July 2014.

Janet started by reminding us what a clinical trial is and why it is important that they are conducted properly. She gave us one or two lessons from history to show that properly conducted trials can refute what is otherwise considered to be self-evident from anecdotal evidence. For example in the 20's and 30's gold therapy for TB was thought to be of great value in treating patients, until it was shown that results were no better than previous treatments.

We were asked to think about why randomisation in trials is important, and the problems that can arise through bias, and insufficient sample size. Getting the design right is so important because we wish to make statistical inference from the results. That is we will use our results to infer how all the population will behave.

We then went on to hear about the differences between Phase I,II, III and IV trials, and the practical stages required to run a clinical trial from defining the aims, through design, funding, running and monitoring, to analysis and dissemination.

Some issues of design were covered, introducing us to factorial design, the Zelen method, and the even more challenging 2x2 factorial design. We also had some great examples of real trials that have used these techniques.

Finally the highlight of the afternoon was a chance to try and design our own trials. We were divided into three groups, and each was given an example of a recent funding call for applications to run a trial in a specific area. We had to discuss as a group how we would design a proposal, looking at factors such as eligibility, design, primary and secondary outcome factors. In the short time available we could only scratch the surface of these issues, but the examples caused much debate between us.

So thank you to Janet for giving us such a fascinating talk and workshop, which will help us as we read through and comment on real trial proposals.

Comment written by Hilary Stobart, ICPV member 7th June 2014