

Understanding *randomisation* during teaching of RCTs in EBM

Background

I am responsible for teaching medical students about Evidence Based Medicine. One of the challenges is to explain the several ways in which randomisation can be compromised in randomised controlled trials (RCTs).

The problem

It is difficult for students to grasp how critical is for randomisation to be conducted properly, and of the ways in which it can be disrupted, (breaking the *blinding*, *attrition*, *drop-outs*, and failure to analyse by *intention to treat*), leading to introduction of bias. Each item is individually easy to grasp, but the problem is making the whole process appear practical and not a distant theoretical concern.

The educational solution

Students are handed an envelope as they enter the lecture theatre for a session introducing randomised controlled trials. They are asked not to open it until instructed.

The lecture proceeds. At the point when randomisation is discussed, the students are invited to supply some information about themselves: how many are female; live inter-state, have ever smoked etc. The data are written up on a white board in a Table. Then I ask if anyone has already opened their envelope (almost invariably 1-2% have), and these data are also tabulated, also checking their state and past smoking status. I also ask if anyone has been able to work out what the envelopes contain: explaining that we put in two types of confectionery (popular brands of either a boiled, or minty, sweet). Some know, and I record this into the Table.

And I ask how they were able to check (usually they have held the envelope to the light, or simply palpated its contents and guessed), recording this also. I ask them to check if they were right by fully opening their envelopes, recording how many guessed correctly (usually most). I invite everyone to open their envelope and consume their contents. Finally, I ask how many have swapped theirs with a neighbour because of preferences (usually surprisingly many).



The following discussion

After the commotion has settled down, I open a discussion, and ask the students to help me draw up a CONSORT statement of the outcomes of this RCT. The breaking of blinding is recorded, together with the attrition to the 'other treatment', and we use the previously collected data about the students to test if the randomisation was successful (the *Baseline Table* of so many reported RCTs).

Follow up

I test knowledge and understanding by means of multiple choice questions in the end of year exams to check there is some persistent understanding. I also revisit the teaching session the following year when we start to critically appraise randomised controlled trials, pausing to talk about randomisation. This enables a spiral of learning re-enforcement.

Where the idea came from

Sandy Pirozzo was a lecturer in the Masters of Public Health program at the University of Queensland who was extremely original in her teaching ideas, and she devised these techniques.