

Solutions to the exercises

1. FFFFF

Controls should be treated in the same place at the same time under the same conditions as the treatment group (except for the treatment).

2. FTFTF

Random allocation is done to obtain comparable groups that subsequently receive different treatments (or control).

3. TFFFT

Patients ideally do not know their treatment (blind) but they usually know that they are in a trial.

4. FFFFF

Vaccinated and refusing children are self-selected. We analyse by intention to treat.

5. TFTTT

The order is randomized.

6. FFTTT

The purpose of placebos is to make different treatments to appear similar (not always possible: try to give a placebo open heart surgery). Only in randomized trials can we rely on comparability, but there will still be some random variation.

2E

1. It was hoped that women in the KYM group would be more satisfied with their care. The knowledge that they would receive

continuity of care was an important part of the treatment, and so the lack of blindness is essential.

More difficult is that the women were given a choice and may therefore be more committed to the scheme they had chosen than did the control group.

2. The study has to be analysed by Intention to Treat. As often happens, the refusers did worse than the volunteers, and also

worse than the control group. When we compare all those allocated to KYM with the control there is very little difference.

3. Women expected to receive standard care. Those allocated to the control group thus received what they expected.

Those

allocated to KYM had the choice between KYM and the standard care. Apart from the questionnaires (which could be refused

as well) no extra procedures were performed. It is thus hard to find ethical problems in this case.