Case Studies

# Chapter 7: Randomised controlled trials

Blessing is completing an assignment to design a randomised controlled trial. For her subject, she chooses the impact of antitussives (cough suppressants) on alertness. She selects one of the most common antitussives to base her RTC on and forms the hypothesis that: *‘5 ml dosages of Dextromethorphan administered at 4 hour intervals over a 12 hour period increases response time by 50%*’. This is the H1 statement of her two-tailed hypothesis. The H0 statement is: *‘5 ml dosages of Dextromethorphan administered at 4-hour intervals over a 12 hour period does not increase response time by 50%’.*

For her study population, Blessing proposes a sample size of 100 adults, setting eligibility criteria as follows: Adults aged between 18 and 65, with no diagnosed cognitive impairment, no current or pre-existing health condition that affects cognition, and not taking any other medication. Participants should not have a cough or cold at the time of the experiment, as it will be impossible to extract whether levels of alertness are impacted by the Dextromethorphan or the underlying virus.

Alertness levels will be measured (in seconds) by asking participants to respond to shapes appearing on a computer screen by pressing a button.

The trial will take a triple-blind approach to reduce potential bias or the placebo effect.

* Do you think Blessing’s hypothesis has eliminated all other possibilities and is quantifiable as a statement of cause and effect? Will her outcome measure make a difference in practice?
* Are there any types of bias or chance which haven’t been identified in Blessing’s eligibility criteria or approach?
* Design your own randomised controlled trial plan (you do not have to conduct the actual trial). Include the following: Hypothesis, study population and size, method, and data collection approach. Be mindful of bias and chance. What follow-up research or other outcomes do you think your RCT could produce?