CHAPTER 3:

QUANTITATIVE RESEARCH DESIGN

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CHAPTER OVERVIEW

Quantitative research uses large samples and, as such, the findings of well-conducted studies can often be generalised to larger populations. However, it is important that studies are well-designed to avoid errors in their interpretation and/or the reporting of inaccurate results. Misleading results from quantitative studies can have serious negative implications such as wasting public money on flawed policies and subjecting service users to ineffective or harmful treatments. This chapter explores descriptive and experimental quantitative research designs and examines, through case examples, the difference between cross-sectional, longitudinal and cohort studies. Factors leading to poorly and well-constructed studies are explored, along with a discussion of the key features of well-designed randomised controlled trials, the gold-standard design for testing treatment effectiveness.

LEARNING OBJECTIVES

By the end of this chapter you should be able to:

1. Explain the importance of well-designed quantitative studies
2. Explore descriptive and experimental quantitative designs
3. Identify the key features of a randomised controlled trial

INTRODUCTION

Quantitative research generally uses large numbers of participants. This is because it seeks to draw accurate conclusions about, for example, how common a health problem is within a population, what factors increase a person's likelihood of developing a health problem (e.g. weight, gender, wealth, employment, education etc.), or whether a medicine or other intervention is effective in treating a health problem. Without larger numbers of people included in studies with these aims, conclusions are less likely to be accurate because they may not reflect how things actually are in the target population. There are two types of quantitative design, descriptive and experimental. This chapter will introduce descriptive and experimental quantitative designs using case examples to bring them to life.

Descriptive quantitative designs

Descriptive studies measure things as they are without intervention from researchers to change people's behaviour and experiences. **Case example A** in **Figure 9** provides an example of a descriptive design:

Figure 9

Case example A

Descriptive design

Paul is interested in looking at how common clinical depression is in people living in Bristol and what factors seem to increase the likelihood of people having depression. He sends out a questionnaire to everyone in Bristol measuring their levels of depression and collecting basic demographics such as age, gender, ethnicity, sexuality, accommodation and employment status. Paul hasn't changed anything within the population in order to assess its effect, he's simply described the frequency of depression in that population and some of the characteristics of people with and without depression at a particular point in time.

There are different types of descriptive quantitative research designs. These produce different types of findings, and which type to use depends on the question being asked.

Consider again **case example A**. This type of study is called a **cross-sectional study**, which means it involves researchers taking a snapshot of a population at a single point in time. So **case example A** might give us some useful information about the prevalence of depression in Bristol at that point in time and suggest some possible factors that might increase the likelihood of people having depression. It is a useful design for describing what a situation is, but it is less useful in telling us why the situation is as it is or how stable that situation is over time.

Imagine Paul had distributed his questionnaire to all the people of Bristol once every year from 1997 to 2017. This would be a **longitudinal study**. This design would enable Paul to examine how rates of depression change over time and generate further **hypotheses** (possible explanations to be proven or disproven) about the factors that seem to increase the prevalence of depression in the population or explain differences in the prevalence of depression in different subgroups (e.g. age, gender and ethnic groups). These factors might, for example, include things like changes in mental health policy, funding or service provision during this time. However, a longitudinal study cannot prove relationships between these different factors. It cannot establish **causal relationships**. It can only observe possible relationships (called **associations**), i.e. events that seem to happen at the same time. So Paul might be able to say that, based on his longitudinal study, when policy change X occurs, outcome Y also seems to occur. He cannot say conclusively that X has caused Y because there may have been another factor, unknown to Paul, that was actually responsible for the change in rates of depression.

Some descriptive designs can generate stronger indications of relationships between events than others. In a **longitudinal cohort study**, for example, researchers identify two groups (or cohorts) of people that are broadly similar to each other, except for the fact that one group has been exposed to a particular circumstance and the other has not. They then collect data from both groups at multiple time points and examine differences in outcomes between the two. **Case example B** in **Figure 10** provides an example of a longitudinal cohort study.

Figure 10 Case example B Longitudinal cohort design

Debbie is interested in the relationship between children's psychological well-being and grammar school systems. She knows that Trafford borough has a grammar school system and Manchester does not. This provides an opportunity to analyse differences between the two groups as a result of the different school systems the children have experienced. Debbie asks every school-starting child in Trafford and Manchester to complete a questionnaire measuring their psychological well-being and repeats the questionnaire annually throughout each of their school years (4-16).

Debbie wants to ensure, as far as she can, that any differences she observes in psychological well-being between the two groups is a result of differences in the school system they have experienced. Because of this, she identifies further information about each child who completes the questionnaires, including: parental income, education, relationship status and whether English is their first language, the level of social deprivation in the area where the child lives and whether the child has special educational needs. Collecting this information allows Debbie to adjust her analysis to ensure that differences between the two groups (Manchester and Trafford children) other than the school system they have experienced are not accounting for the differences (if any) she observes in psychological well-being.

Debbie has made great efforts to ensure that the differences she observes between the two groups in psychological well-being are a result of the different school systems between Manchester and Trafford. Her study therefore may make a contribution to understanding a possible relationship between different education systems and children's psychological well-being. However, Debbie was still observing differences between two naturally occurring groups. Therefore, despite her efforts to control for differences in her analysis, Debbie cannot be certain that the differences in outcomes she observed were not due to an unknown factor that she had not identified. This is why a longitudinal cohort study cannot provide evidence of a causal relationship between different events.

Experimental designs

In an **experimental** study, you take some measurements, provide some sort of treatment or intervention, then take some measurements again to assess what kind of impact the new treatment/intervention has had. **Case example C** in **Figure 11** provides an example of an experimental design.

Figure 11

Case example C

Experimental design

Dave is interested in testing the effectiveness of a new self-help book for depression. He includes participants who have clinical depression according to their score on a depression questionnaire that he gets participants to complete at the beginning of the study. He then provides them with the self-help book and asks them to use it for three months. He then asks them to complete the depression questionnaire again to compare scores before participants used the book to after they had used it. This enables Dave to assess the effect of the self-help book on participant depression symptoms.

Discussion point 1: Read through **case example C** in **Figure 11** again.

What do you think were the problems with the design of Dave's project that would have made it difficult to prove his self-help book had resulted in reduced depression?

Dave measured people's depression scores before and after providing them with his new depression self-help book. Dave's study could be described as an **uncontrolled pre- and post- (or pre-post) design**. Dave didn't compare the pre- and post- effects of his self-help book on depression scores with another group of people with depression who had not used his self-help book. In an experimental design, the comparison group of participants that do not receive the new treatment/therapy are known as the **control group**. If Dave had used a control group his design would be called a **controlled pre- and post- (or pre-post) design**.

Using a controlled pre- and post- (or pre-post) design, Dave could demonstrate:

- a) that there was a greater improvement in depression scores in the people who had used his self-help book than in those in the control group who hadn't used it.
- b) that the average improvement in depression scores over the control group had not occurred by chance (this is calculated using statistical calculations, see Chapter 4. Generally, if researchers can demonstrate that there was less than 5% chance the difference occurred by chance, the result is accepted as **significant**).

Using this approach, Dave would have some evidence of a link between his self-help book and reduced depression. However, even if Dave could say that he had met these two requirements, he could not say that there were not important differences between those who received his book and those in the control group that might explain the differences in depression scores at the end of the study (rather than the benefit of his self-help book). Dave could have ensured that both groups were the same by randomly allocating people to either receive his book or to the control group at the beginning of the study. This process is called **randomisation** which is a process of allocating participants to the treatment or control group effectively on the basis of a coin-toss. Along with the use of a control group, randomisation is one of the key features of a **randomised controlled trial**.

The randomised controlled trial

The randomised controlled trial (RCT) is considered the 'gold-standard' design for determining whether a **cause-effect relationship** exists between a treatment and outcomes. **Figure 12** provides a more detailed description of the features of an RCT, but the key steps involved are:

1. Select participants
2. Measure **baseline variables** (e.g. using **case example C** this would be the score on the depression questionnaire, but you would also, as a minimum, collect basic demographics such as age, gender etc.)
3. Randomise (to treatment or control group)
4. Apply intervention (e.g. using **case example C** providing participants in the treatment group with the depression self-help book)
5. Measure follow-up outcomes (e.g. using **case example B** this would involve repeating the depression questionnaire with participants in both the treatment and control groups following the three months that the treatment group used the self-help book)
6. Analyse the data

Figure 12 Key features of RCTs

There are two key benefits of randomisation. Firstly, it reduces bias by preventing researchers from influencing which participants receive the treatment and which are allocated to the control group. Secondly, it helps to minimise the effect of **confounding variables** (e.g. extra variables that the researchers didn't account for which can ruin an experiment by giving them incorrect results) through evening out different participant attributes between the intervention and control group. So, again, we will use Dave's self-help book as an example to make this point more clearly. If Dave was conducting a controlled study of his self-help book, a potential problem might be that he had people with more severe depression and more patients on antidepressant medication in his treatment group than in his control group. Dave could address this problem by only including people who scored as having moderate depression according to their baseline depression questionnaire and excluding anyone who was on anti-depressant treatment – but this might mean he could exclude people he was trying to help. The beauty of randomisation is that, provided you have a large enough sample (i.e. enough randomisations/coin-tosses), the laws of probability dictate that these varying attributes within your sample will gradually begin to even out, until you have two equivalent groups to compare treatment effects.

Researchers often measure the effect of a new treatment against many different outcomes, asking participants to complete many different questionnaires at baseline and at follow-up data collection points. Earlier, we discussed how researchers will accept up to 5% probability that a significant result has occurred by chance. Researchers must accept this 5% probability across all of their outcomes. Clearly then, the more outcomes researchers use, the greater the chance of getting **false-positive results**. This is why, for an RCT, researchers must select a single **primary outcome** to measure the success of their treatment/intervention against. The remaining outcomes of interest should be considered **secondary outcomes**.

The primary outcome is also used to calculate the sample size required for the trial. First, researchers must work out what would represent a **clinically significant effect** of the intervention. For example, this might be a change on a depression scale that moved a person from severe to moderate depression, or from moderate to mild depression. Once this has been agreed, researchers conduct a statistical test called a **power calculation**. This calculates the minimal sample size required to detect a significant difference between the treatment and control groups.

The final key feature of an RCT yet to be covered is the need for researchers to conduct an **intention-to-treat analysis**. This refers to the need to include all participants randomised in the final analysis of data, regardless of whether they withdrew from the trial or failed to complete questionnaires. After all, it makes sense that participants who failed to complete the study may have had less favourable experience of the intervention, so failing to include any data from these individuals provides an important source of bias in favour of the intervention. The intention-to-treat analysis works by inputting estimates of what the missing data was likely to be – this is based on earlier scores on the questionnaires that participants completed.

PPI stories from EQUIP

Next Andrew discusses his experiences of being involved in quantitative research.

ANDREW'S STORY

One of the studies in the EQUIP research programme was an RCT of a training intervention for community mental health and social care professionals to help them improve service user and carer involvement in care planning. We compared teams trained through a new training course (our intervention) with teams who did not receive this training (our control). Service users rated different aspects of the services they received from these teams before and after training.

RCTs are a quantitative research design. Study design and data analysis were led by the research team but I played a major role in developing and delivering the new training intervention for our trial. Our team met to co-design our intervention using information gathered from a literature review (Bee et al., 2015a) and from focus groups and interviews with service users, carers and professionals (Bee et al., 2015b; Cree et al., 2015; Grundy et al., 2015).

We agreed the content and format of our training intervention and co-developed a training manual and presentation slides for a two-day training course.

I was an integral member of the team who delivered this training course to the community mental health and social care professionals participating in our trial. To prepare me for my role, I attended a 'train the trainers' course (Fraser et al., 2017), which equipped me with the practical skills for training these professionals.

I ended up delivering our new training intervention to 18 different community mental health teams. It was important to me that I use my lived experience to do this. Other service users and the carers co-facilitated group work with me. We shared positive and negative experiences of care planning, and shared ideas around good and poor practice throughout the two days.

I co-facilitated follow-up supervision with teams who were trained in our trial, and I assisted some service users to complete our outcome measure pack. Sometimes I did this over the phone and sometimes it was in person. Supporting people to complete trial outcome measures is important because it can help to make sure these people aren't excluded from health research studies. It can make these studies less daunting and increase the number of people who want to take part in a trial.

REFLECTIVE EXERCISE

- **When and why might you use a randomised controlled trial?**
- **What are the key features of an experimental study?**
- **Describe an appropriate method of randomisation and describe the benefits of undertaking randomisation.**

REFERENCES AND FURTHER READING

Sibbald, B. and Roland, M. (1998) Understanding controlled trials: why are randomised controlled trials important? *British Medical Journal* 316:201.