Understanding Research for Nursing Students

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Peter Ellis

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About the author

Peter Ellis is an independent nursing and health and social care writer and consultant. He is also an Expert Witness for nursing and social care. Peter was most recently a Registered Manager and Nursing Director in the Hospice and social care settings. Prior to this, he was a senior lecturer and programme director at Canterbury Christ Church University where he taught understanding research, among other topics, to undergraduate and postgraduate nursing students. Peter is also an Honorary Senior Research Fellow of Canterbury Christ Church University and has a special interest, including ongoing research, in palliative and end-of-life care.

Foreword

Understanding Research for Nursing Students is a key text in facilitating readers' personal and professional development. On a personal level, it offers students opportunities to gain confidence by getting to grips with important aspects of the research process in nursing. On a professional level, it succinctly demonstrates how a wide range of research methods are used to generate knowledge that can be applied to enhance the quality of care that service users receive. It promotes an awareness of uncertainty, of what we do not know and what we need to find out in order to provide the best care possible. Each chapter is mapped against Standards of Proficiency for Registered Nurses (NMC, 2018a) encouraging readers to adopt a healthy, questioning, evidence-based approach in delivering safe and effective, person-centred nursing care.

A variety of case studies and scenarios provide practical real-life examples to help readers relate to the topic and apply relevant theory. There are also numerous learning activities to engage with, test out ideas and deepen understanding. Helpful additional learning resources are recommended at the end of each chapter, and a glossary is also provided for readers to clarify their understanding of the research terms used. This complements the author's informative, lucid, interactive and reader-friendly style which both nursing students and their lecturers have highly commended.

In the sixth edition of this very popular book, Peter Ellis has responded to feedback received and updated references and contents to reflect recent developments in researching health and social care research, such as Artificial Intelligence use in clinical settings and ethical issues in research. It highlights how the knowledge base informing nursing is continually developing and that nurses must be research-minded and keep up to date in order to enhance their practice. After reading this book, nursing students should have a good grasp of research that will help them in their academic work, and in delivering high-quality, evidence-based and person-centred nursing care.

Dr Mooi Standing, Series Editor

Introduction

The purpose of this book is to introduce the nursing student to the key concepts involved in nursing and healthcare research. The aim of introducing research is twofold: the first is to enable you to better understand the research you read in order to inform your practice and to make some judgements about its quality. The second aim is to prepare you to undertake research either as part of your role at work or as part of a course of study. Many nurses believe that understanding research, let alone undertaking research, is beyond them. The book sets out to explode this myth by demonstrating that the processes involved in the design and undertaking of research are easily understood.

Understanding Research for Nursing Students does not contain all that any budding researcher will need in order to design and carry out their own research, but it does provide a reasonable overview and suggests other sources of information that may help in the study design process. Clearly, books such as this present an idealistic view of research which, like clinical nursing, is subject to practical considerations and the realities of funding, experience and ability, and so rarely proceeds in a textbook manner.

Chapter 1 introduces what research in health and social care is about, and the sorts of questions that nursing research can be used to answer. It also introduces some of the philosophical assumptions that underpin research, including those that inform the quantitative and qualitative paradigms. The reader is introduced to the processes that a researcher might go through in order to generate a research question. The chapter also introduces the key ethical principles and ideas that inform all phases of the research process. It is important for any researcher to understand and take heed of these issues in the design of a research study in order to ensure that it is both realistic and ethical.

Chapters 2 and 3 introduce qualitative research methodologies and methods. Chapter 2 concentrates on identifying the qualitative research methodologies, the questions they set out to answer, the sampling methods they use and the key methods (data collection tools) they employ. Chapter 3 continues the qualitative theme, exploring in more detail the key methods used in qualitative data collection. It goes on to explore some of the issues in data management and analysis of qualitative data.

Chapters 4 and 5 explore the quantitative research methodologies and some research methods. Chapter 4 mirrors Chapter 2 in introducing the quantitative research methodologies, the research questions they set out to answer, the ways in which samples for

study are chosen and the key data collection methods they use. Chapter 4 concludes by introducing some of the key methods in data presentation and analysis used in the quantitative research methodologies. Chapter 5 continues to explore the quantitative theme, presenting some of the main methods nurses use when employing the quantitative methods in their research studies.

Chapter 6 examines the use of mixed methods and methodologies in research. It introduces the key ideas in evaluation research and the nature, scope and practice of action research in nursing, including data collection methods. This chapter establishes that there is often a need to employ mixed methodologies and methods in healthcare research in order to gain a more holistic view of some of the complex issues that surround the provision of nursing care.

The final chapter, Chapter 7, considers how the thoughtful use of research can inform both what you do as a student nurse in practice and how research might be assimilated into your academic work to add to its depth and credibility. It demonstrates that research is not a dry academic topic but one potential source of increased knowledge to guide thinking and nursing practice.

NMC Standards of Proficiency

This edition refers to the Nursing and Midwifery Council's *Future Nurse: Standards of Proficiency for Registered Nurses* (NMC, 2018a) as they pertain to your development as a nurse, although its content is not narrowly defined by these standards.

Learning features

Learning from reading text is not always easy. Therefore, to provide variety and to assist with the development of independent learning skills and the application of theory to practice, this book contains activities, case studies, concept summaries, further reading and useful websites to enable you to participate in your own learning. You will need to develop your own study skills and 'learn how to learn' to get the best from the material. The book cannot provide all the answers, but instead provides a framework for your learning.

The activities in the book will help you in particular to make sense of, and learn about, the material being presented. Some activities ask you to reflect on aspects of practice, or your experience of it, or the people or situations you encounter. *Reflection* is an essential skill in nursing, and it helps you to understand the world around you and often to identify how things might be improved. Other activities will help you develop key graduate skills such as your ability to *think critically* about a topic in order to challenge received wisdom, or your ability to *research a topic and find appropriate information*

and evidence, and to be able to make decisions using that evidence in situations that are often difficult and time-pressured. Communication and working as part of a team are core to all nursing practice, and some activities will ask you to think about your *communication skills* to help develop these.

All the activities require you to take a break from reading the text, think through the issues presented and carry out some independent study, possibly using the internet. Where appropriate, sample answers are presented at the end of each chapter, and these will help you to understand more fully your own reflections and independent study. You will gain most from the activities if you try to complete them yourself before reading the suggested answers. Remember, academic study will always require independent work; attending lectures will never be enough to be successful in your programme, and these activities will help to deepen your knowledge and understanding of the issues under scrutiny and give you practice at working on your own.

You might want to think about completing these activities as part of your personal development plan (PDP) or portfolio. After completing an activity write it up in your PDP or portfolio in a section devoted to that particular skill, then look back at it over time to see how far you have developed. You can also do more of the activities for a particular key skill that you have identified as a weakness, which will help build your skill and confidence in this area.

There is a glossary of terms at the end of the book that provides an interpretation of some of the terminology in the context of the subject of the book. Glossary terms are in **bold** in the first instance that they appear.

All chapters have further reading and useful websites listed at the end, with notes to show you why we think they will be helpful to you. The websites will also help you to remain up to date with developments in this aspect of practice as awareness of key issues grows and policies develop.

This, the sixth edition of *Understanding Research for Nursing Students,* has been updated and improved in response to feedback from earlier editions. We hope that this book will add to both your enjoyment and understanding of this topic area, and that you will find it helpful in developing your professional practice. We also hope it will challenge you to ensure you provide care and support that reduces the risk of vulnerability and promotes dignity, respect and a positive quality of life. Good luck with your studies.

Chapter 4 Overview of quantitative methodologies

NMC Future Nurse: Standards of Proficiency for Registered Nurses

This chapter will address the following platforms and proficiencies:

Platform 1: Being an accountable professional

At the point of registration, the registered nurse will be able to:

1.7 demonstrate an understanding of research methods, ethics and governance in order to critically analyse, safely use, share and apply research findings to promote and inform best nursing practice.

Platform 6: Improving safety and quality of care

At the point of registration, the registered nurse will be able to:

6.7 understand how the quality and effectiveness of nursing care can be evaluated in practice, and demonstrate how to use service delivery evaluation and audit findings to bring about continuous improvement.

Platform 7: Coordinating care

At the point of registration, the registered nurse will be able to:

7.7 understand how to monitor and evaluate the quality of people's experience of complex care.

7.11 demonstrate the ability to identify and manage risks and take proactive measures to improve the quality of care and services when needed.

Chapter aims

After reading this chapter, you will be able to:

- identify the main quantitative research methodologies used in health and social care;
- describe the type of research questions the different research methodologies can be used to answer;
- demonstrate awareness of how samples are chosen for quantitative studies;
- briefly describe the key methods of data collection used in each methodology.

Introduction

Epidemiology is the study of causes and consequences of disease in populations and is widely regarded as the major scientific discipline underpinning the practice of evidence-based medicine. For the most part, epidemiological studies are quantitative and employ fairly rigid and well-defined rules to ensure the accuracy of their findings. This chapter introduces you to the major quantitative methodologies (which are often termed epidemiological methodologies) and explains the theoretical and practical differences between them. It identifies the sorts of questions quantitative methodologies can be used to explore and the key characteristics of quantitative research. It then examines some of the main methodologies you will encounter in your nursing education and beyond. These are: quasi-experimental and experimental studies; randomised controlled trials (RCTs); cohort studies; case-control studies; and cross-sectional studies.

The chapter explores the strengths and weaknesses of each of these methodologies and considers which methodologies would be most suitable for different research questions. For example, when the research is seeking to prove **causality** (i.e. demonstrating cause and effect, as in exposure to asbestos causing mesothelioma or vaccination against influenza reducing the risk of disease), then only methodologies accepted to prove cause and effect (i.e. experimental and cohort studies) can be used. Other methodologies (case-control and cross-sectional) can be used to explore potential associations between a cause and effect (e.g. to explore a potential, but unproven, link between mobile phone use and brain tumours) or to measure the **prevalence** of an exposure or a disease (e.g. how many people with diabetes also have hypertension) but are not regarded as being of the right design to prove causality. The chapter also looks at the sampling methods (i.e. the ways in which study subjects are chosen) that can be used for each of the research methodologies identified.

The knowledge you gain from this chapter will enable you to identify quantitative research when you come across it in your own reading, and to evaluate and understand the methodologies used. It will also enable you to start thinking about how you

could use these research methodologies to improve your own practice, especially after registration, as highlighted in proficiency 1.7 of the NMC Standards of Proficiency identified at the start of the chapter.

Case study 4.1

Dr John Snow undertook the first major **epidemiological** study in 1854. An outbreak of cholera (an infectious diarrhoeal illness) was killing a large number of people living in the Soho area of London, England. At that time, it was widely believed that miasmas (invisible and infected vapours carried on the wind) were the cause of ill health and disease; bacteria and viruses had not yet been discovered. Snow mapped the homes of the people affected by the disease and was drawn to believe (although, other than his own extensive observations, he had no scientific reason for believing this) that a water pump on Broad Street was the source of the outbreak. Snow persuaded the city authorities to remove the handle from the pump so no water could be drawn from it and the number of infections and deaths fell away rapidly.

Key characteristics of quantitative research

Quantitative research methodologies are used to answer questions that have a numerical element to them, or that set out to prove an association between two variables (cause and effect). Essentially, quantitative methodologies fall into one of two broad classifications: those that are **interventional** (or **experimental**) and those that are **observational** (or **non-experimental**). Interventional studies seek to manipulate an **exposure** (the **independent variable**) in order to measure what effect it has on an outcome (the **dependent variable**) – for example, increasing education for people with diabetes (the independent variable or exposure) to improve their blood glucose levels (the dependent variable or **outcome**). Observational studies, on the other hand, seek to explore the associations between a naturally occurring independent variable (exposure) and a dependent variable (outcome) (Celentano and Szklo, 2019) or merely to quantify something in a population (e.g. how many student nurses smoke). This is because it is simply not always possible to be certain about what has caused something, often because there may be several potential causes contributing to an effect, some of which are known about and some of which are not, and it is necessary, therefore, to be more cautious about assigning a 'cause'. The terms **association** and sometimes **correlation** (although this also has a strict research meaning, as you will see in the glossary) are used instead. For example, there is an association between being obese and developing type 2 diabetes but the development of type 2 diabetes is also associated with a family history of the disease and other environmental and lifestyle factors.

Concept summary 4.1 Cause and effect

A cause is simply something that has an effect. In quantitative research terminology it is common for a number of terms to be used for cause and effect, but essentially quantitative research is interested in causes (independent variables or exposures) and effects (dependent variables or outcomes). So we could describe the same event in one of three ways.

1. A nosebleed (effect) may result from a punch to the nose (cause).
2. A nosebleed (dependent variable) may result from a punch to the nose (independent variable).
3. A nosebleed (outcome) may result from a punch to the nose (exposure).

The dependent variable is best thought of as occurring only if the independent variable has occurred. In this case the nosebleed is dependent on there having been a punch to the nose – if the punch had not been thrown, the nosebleed would not have happened. The independent variable is not affected by the dependent variable – obviously, a nosebleed will not cause a punch on the nose!

A small note of caution here: the dependent variable may sometimes arise as a result of the interplay of a number of independent variables, for example, a genetic predisposition to having diabetes and being obese (independent variables) may sometimes need to be in play to give rise to a dependent variable, in this case developing diabetes. Similarly, while a particular independent variable may give rise, or contribute, to a dependent variable, effect, it may not be the only possible explanation. For example, some people develop diabetes in later life but are not obese or even overweight.

Understanding independent and dependent variables

This may all seem a bit complicated, but it is essentially just the terminology and rules that are applied to the study of cause and effect in healthcare. Understanding the nature and realities of cause and effect allows health professionals to intervene in a meaningful way in the lives of their patients. For example, having an understanding of the fact that smoking is one of the causes of coronary heart disease, lung disease and cancer is useful for nurses who are seeking to engage in meaningful health promotion. Understanding that applying compression stockings after surgery reduces the occurrence of deep vein thromboses when compared to not using them equips nurses with information for practice that is potentially life-saving. Such evidence-based practice reflects a number of the NMC proficiencies.

The importance of quantitative research to nursing practice is clearly established in some of the preceding examples, but the fact nurses undertake little in the way of quantitative research is of some concern. Establishing the benefits, or not, of some

nursing practices would serve to advance nursing knowledge and practice and, more importantly, would be of great service to our patients. For example, using a randomised prospective study, Hoe and Nambiar (1985) famously demonstrated that the traditional nursing practice of shaving patients prior to surgery did not in fact reduce wound infection rates. Interestingly, a literature review by Bradshaw and Price (2007) demonstrated that the common practice of inserting rectal suppositories blunt end first – believed by many nurses to be evidence-based – relies on one questionnaire-based study published in *The Lancet* in 1991 that has not been subsequently verified. These examples identify the need for nurses both to understand the source of the ideas they read and to be able to critique the quality of the research which led to them before they use them to change their practice (more on this in Chapter 7).

There are a number of questions that quantitative research methods can be used to answer and, like qualitative methods, there are a number of issues the researcher has to take heed of before attempting to design a quantitative study. The key questions the methodologies explored in this chapter can answer are outlined in Table 4.1.

Table 4.1 Questions that different quantitative methodologies can be used to answer

Questions	**Methodology**
If *x* is done, what will happen? If *x* is done, how often will *y* happen?	Experiment/quasi-experiment/ randomised controlled trial
If a person is exposed to *x*, will that person develop outcome (disease) *y*? Does exposure to *x* cause outcome *y*?	Cohort study
This individual has outcome *y*, what exposure *x* might have caused it?	Case-control study
In this group of people, how many have been exposed to *x* or have outcome *y*? What is the prevalence of *x* or *y* in this group?	Cross-sectional study
The data show that when *x* increases in the population so too does *y* – might they be associated?	Ecological study

What is apparent from the table is that the sorts of questions quantitative methodologies can answer are highly interrelated. They tend towards asking questions about causes and effects and things that can be *measured* in one way or another, and they all have a *numerical* (quantifiable) element to them. It is important to bear in mind, however, that if practice is to be established or changed on the basis of some quantitative research, it is imperative the correct methodology is chosen and properly applied. Table 4.1 gives an indication of the sorts of theoretical questions that can be answered using the different approaches. What follows will expand on these and give you a deeper insight into the questions and answers the different methodologies can be used to ask and answer, as well as the key features of these methodologies.

Activity 4.1 Reflection

Stop and think about the area that you are currently working in or your last placement. What type of nursing questions might quantitative research be used to answer about the sort of patient problems encountered or the care delivery undertaken there?

There are some possible answers at the end of the chapter.

Experimental and quasi-experimental research

Key features

The type of experiment described here does not relate to experiments that take place in the laboratory, but to ones that involve the researcher (or experimenter) examining the relationship between two variables – for example, does giving sucrose reduce the perception of pain in neonates? These experiments are carried out **prospectively** (that is, data are collected in real time and do not rely on memory or old notes) in an attempt to prove cause and effect. The reason any experiment is conducted is because there is genuine uncertainty about which treatment is best for the participants. This is called the *uncertainty principle* (described in Chapter 1), and 'best' in this context might be taken to mean cheapest, safest, most effective or easiest to use.

Observational studies (such as case-control and cross-sectional studies, which are studies that involve no intervention on the part of the researcher and are described later in this chapter) often lead to the generation of ideas for testing using experimental study designs. Sometimes it is hard to know which of two variables in an observational study caused the other to happen (if, indeed, they are at all related). A good example of this is the debate around the use of cold remedies. If patients take a cold remedy and get better within a few days, they may think that the remedy 'cured' their cold, even though it is likely they would have recovered equally well without taking the remedy. You might then ask the question, 'If the patient took the remedy and got better, does it matter whether the remedy worked or not?' This is a reasonable response, but what if the remedy were toxic, expensive or potentially dangerous? Many modern medicines and treatments are expensive and many have a host of side effects, and sometimes the medication or treatment has no real effect. The question therefore becomes, 'Why undertake treatments or give medications that are costly and have no benefits, or that are actually worse than doing nothing at all?'

The rise in antibiotic resistance is a consequence of the fact that antibiotics were, and often are, given to people unnecessarily (World Health Organization, 2023). This demonstrates that there is a consequence to poor clinical practice that in turn is sometimes guided by poor research, poorly interpreted research, by ignoring the research or by giving in to pressure to do something.

Avoiding unnecessary expense and side effects provides one reason why it is important to undertake experimental studies into the usefulness of medications and other health-related interventions. Such questions require experimental approaches to answering them and demonstrate why these approaches are favoured in modern healthcare.

Case study 4.2

As an example of a clinical observation that was proven wrong by an RCT, the increased risk of cardiovascular events (especially stroke) in post-menopausal women taking hormone replacement therapy (HRT) was identified only during an RCT (an important experimental method, explained below) of HRT against a **placebo** (Writing Group for the Women's Health Initiative Investigators, 2002). Prior to this RCT, it had been thought that HRT actually protected women against cardiovascular events.

So experiments and quasi-experiments are types of research that are done to test cause and effect. The cause (independent variable) is manipulated, or introduced, by the researcher under carefully controlled conditions, and the effect (dependent variable) is then measured. Experiments and quasi-experiments are widely used to test, for example, the usefulness of: educational programmes in increasing understanding; clinical interventions in improving clinical outcomes; medicines in improving the management of disease; screening to identify disease; and the changing of methods of care delivery to improve the patient experience and satisfaction.

Hypotheses

When conducting an experiment it is good practice to start with a hypothesis. A hypothesis is literally an idea that is less than or below (*hypo*) a proposition or idea (*thesis*). That is, it is an idea that has yet to be tested or proven using the scientific method. Concept summary 4.2 shows the important characteristics of a hypothesis.

Concept summary 4.2 A hypothesis

Critical features of a hypothesis:

- suggest the relationship between the variables;
- identify the nature of the relationship;
- point to the research design to be used;
- indicate the population to be studied.

Hypotheses are often arrived at as the result of experience, clinical observation or observational research. Hypotheses remain theoretical until proven otherwise and even once 'proven' they remain open to further study; that is, something is only proven according to the ability of science at a given point in time and so what we 'know' today might change tomorrow (see Chapter 1, Concept summary 1.1: Empiricism).

We have seen that in an experimental study the researcher manipulates one or more independent variables to see what happens to the dependent variable. In their simplest form (Figure 4.1) this means manipulating one independent variable in one group of participants and measuring the change in a dependent variable (often called a pre–post-test or before-and-after study).

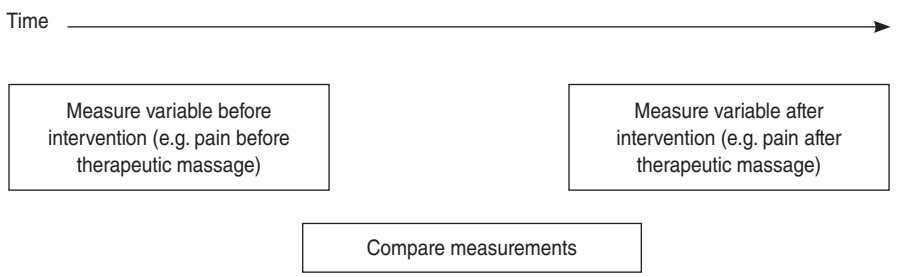

Figure 4.1 A simple experimental design

Weaknesses

There are a number of issues with this type of study, not least that there is nothing to compare the intervention to and the outcome (reduced muscle pain in the example in Figure 4.1) might have occurred anyway if the person had just been left alone. Or perhaps it was the attention being paid to the individual that reduced the pain, and not the massage itself. The first issue is an example of what is called a **temporal effect**. This means it is an effect that occurs over time. The second issue is an example of the **placebo effect –** a perceived or measurable improvement in a person's condition that is not due to any active intervention but is, rather, the result of what is probably a subconscious psychological response to having an intervention (Murray, 2021). It is worth noting here that the placebo effect is not a bad thing: some commentators regard the placebo effect which arises from positive interactions between clinicians and patients to be at the core of the healing relationship (Kaptchuk and Miller, 2015).

There are two other issues with this type of simple experimental design: first, **regression to the mean** and, second, **testing effects**. Regression to the mean occurs when individuals who have a variable measured for a second time in the post-test tend towards measurements that are more average than they were on the first occasion (e.g. satisfaction scores increase in those with initially low scores and decrease a little in those with initially high scores). This may happen regardless of the effects of the intervention (Walters et al., 2021). The other problem that may occur in this type of experiment

results from the effects of the testing itself. For example, people subjected to a test involving an educational intervention may go away from the pre-test and find out about gaps in their knowledge, so when they are retested after the educational intervention their scores will rise because of the combined effects of the education and their own research. One way to overcome this is to do the pre- and post-tests a long way apart; the other is to introduce a **control arm** to the experiment (see 'Randomised controlled trials', pp92–7).

Quasi-experiments

The term quasi-experiment can be applied to the observation and measurement of changes that occur naturally (sometimes called natural experiments). In their natural experimental study of the impact of having a friend who was a teenage mother, Yakusheva and Fletcher (2015) demonstrated that the likelihood of teenage pregnancy diminished by 6 per cent in those teenagers who had a friend who had been pregnant and given birth. It may seem odd to think of this as an example of an experiment, because there is no manipulation of any variable by the researcher. However, when you consider that it might be impossible, or unethical, to undertake experiments on many subjects/issues, observing naturally occurring events provides a good window on the world of events which might otherwise be unethical to study.

Figure 4.2 represents a quasi-experimental design diagrammatically.

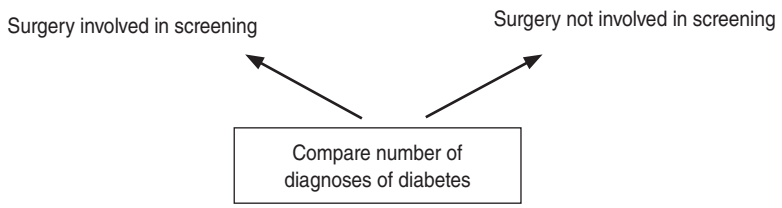

Figure 4.2 A quasi-experimental (natural experiment) design

A second form of quasi-experiment takes the methodology a little further. It examines two unrelated groups of people between which there is some difference in an independent variable. Measures are then taken of a suspected dependent variable, and the dependent variable for the two groups or **fixed cohorts** is compared. For example, in their quasi-experimental study of how likely a patient is to get a diagnosis of type 2 diabetes according to the level of participation of the GP practice in national screening initiatives, Palladino et al. (2017) demonstrated that patients in practices which actively engaged with national screening programmes were more likely to gain a diagnosis of type 2 diabetes than patients in those practices which were less engaged. This study is an example of a natural experiment comparing fixed cohorts – those practices whose engagement with national screening programmes was high, medium or low. The independent variable here is the level of engagement with the programme. Again, clearly this study might be considered to be unethical if undertaken as a prospective experiment,

whereas, as is the case here, collecting data without changing existing practice is an acceptable means of assessing the impact on diagnosis of incident type 2 diabetes according to the level of practice engagement.

The third variation of the quasi-experiment is the pre–post-test study. In their natural experimental study of the impact of a community empowerment and health provider capacity-building intervention on the uptake of antenatal, delivery and post-natal care and care practices of the newborn baby, Ekirapa-Kiracho et al. (2017) demonstrated improvements in all domains in the areas of Uganda where the intervention had been applied. In this form of quasi-experiment the subjects (or, in this case, health districts) effectively become their own **control**. This design of a quasi-experiment is very useful in health policy research as it allows researchers to gauge the effectiveness of new health-care policies on whole populations without disadvantaging any groups.

Quasi-experiments rely, therefore, on the measurement of unmanipulated independent and dependent variables. Because of this, and because there is no control over the environment in which the study takes place, there is a real danger that the outcomes of such experiments are affected by factors that are unknown to the researcher, and the results of such experiments therefore need to be treated with great caution. When working with such data, there is a real need to be certain that there is some plausibility to the associations being made – for example, health education changes health practices but increased availability of mobile phones does not.

Sampling in experimental and quasi-experimental research

The sample (that is, the individuals to be studied) chosen for an experimental study depends on the question posed in the hypothesis. Take the example of therapeutic massage and pain relief in Figure 4.1. First, it is important to define what constitutes pain and what part of the body is affected – let us say muscle pain in the thigh following sporting injury. There is a need to sample people from the population that exist with this condition, but there may well be a need to be more precise in defining the sample so that the effects of massage in a well-defined group are actually measured and described. The research sample may therefore consist of people experiencing a first soft-tissue injury of the leg with no broken bones. The outcome of the study would therefore apply only to people with the identified and described injury and not to other people experiencing a similar injury in their shoulder, say, or to people experiencing a second injury to the same thigh muscles or to those whose injury included a broken bone. Figure 4.3 gives a diagrammatic representation of sampling.

Once these criteria are met and a large population (that is, people with the relevant injury) is identified, individuals for the study may then be chosen from that population – this is called the study sample. When the selection process gives everyone in the larger population the same chance of being in the study (so long as they meet the other criteria),

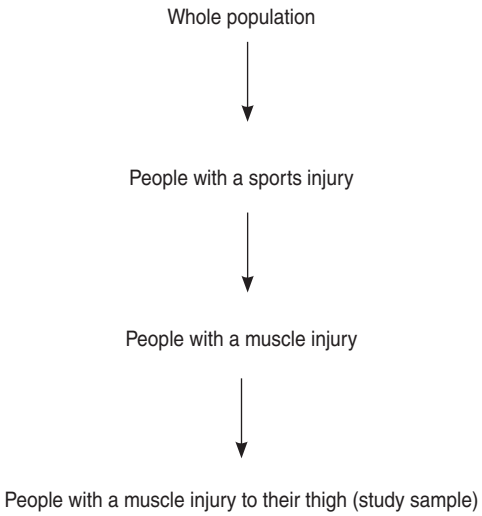

Figure 4.3 Sampling within an experimental study

this is called **probability sampling**, and when the sample size is big enough (often calculated using statistical formulae), a sample that is **representative** of the larger population has been produced.

Activity 4.2 Research and finding out

Start keeping a list of the new words and terminology you encounter in this chapter and elsewhere in this book and spend a little time finding out about them in more detail. You may find some explained well in the various chapters and others in the glossary, but the best way to get a really full understanding of research terminology is to study and find out about it for yourself. You might do this by undertaking online searches or by searching the index of this and other research textbooks. Write your own explanations of research terms and add a reference from an academic source; you may find this useful when drafting an essay at a later date.

In a natural experiment, the sample for the study is the people who have experienced, or are experiencing, the phenomenon being researched. In the simple natural experiment they are the whole population affected by the change, while in the fixed cohorts design they are chosen because they come from one or other of the two groups under study. Studies which identify the impact on health at population level of a health-modifying risk factor – for example, the impact of the rollout of Facebook on the mental health of college students (Braghieri et al., 2022) – are sometimes termed **ecological studies** as the risk of the outcome (psychoses) relates to the ecology (living conditions) of the people affected.

Methods used in data collection

Data collection in experimental and quasi-experimental studies depends on the exact question being investigated. The data collected can include data about the independent variable, such as demographic data (e.g. age, gender and ethnicity), which may be collected from pre-existing sources such as databases or from individuals themselves, and data on a phenomenon (such as a sports injury or natural disaster), which may exist in patient notes, be collected from news sources or be collected especially for the study by interview or questionnaire (as with the data about the existence of post-natal depression by Palladino et al., 2017). Outcome (dependent variable) data may also be collected from existing records (as in the data used in the study by Braghieri et al., 2022) or may be specially collected for the study using data collection methods such as interviews, questionnaires, physical examination or biological samples.

Randomised controlled trials

Key features

RCTs are widely considered to be the 'gold standard of proof' for a clinical intervention or the effectiveness of a medication. RCTs are conducted in a precise manner so that they are capable of answering a very specific question, or set of interrelated questions – for example: to determine the effects of vitamin D supplementation on mortality in older people (Neale et al., 2022); to evaluate the impact on cognitive impairment of early mobilisation in critical illness (Patel et al., 2023); and the impact of educating fathers on exclusive breastfeeding (Panahi et al., 2022). You may want to look up some of these in the library or online and explore how they have been undertaken.

RCTs are a very specific application of the experimental method identified above as they use techniques to explore the relationships between two (or often more) variables while maintaining direct control over other factors that may affect the **validity** and **reliability** of the findings.

Concept summary 4.3 Validity and reliability

Validity refers to the ability of a methodology (or data collection technique) to measure what it is supposed to be measuring. For example, we know that a thermometer (if placed correctly and for long enough) will measure temperature, but it is not easy to be certain that a questionnaire designed to measure quality of life does so, because it is not always easy to define what quality of life actually is and therefore to ask questions about it.

Reliability refers to whether a method of data collection, or a measurement, will repeatedly give the same results if used by the same person more than once or by two or more people (so-called **inter-rater reliability**) when measuring the same phenomenon.

Because RCTs regulate many of the independent variables that a simple experiment does not, they have found favour as a source of evidence in medicine and, as the examples given above show, also in wider health and social care research. To understand why RCTs are so highly regarded it is worth paying attention to the key features of their design. The following discussion relates to the best possible design for an RCT: the 'gold standard'. However, it should be remembered that RCTs are very often conducted with human subjects, so there are good practical and ethical reasons why not all RCTs contain all of the features discussed below. An example of this is **equivalence studies**, where the current treatment for a condition is used instead of a placebo or **sham treatment** for comparison (see below). This is because it would be unethical not to treat people in the control arm when a treatment which is in general use already exists for the condition.

A control arm for a study provides the researchers with a group of individuals whose outcomes can be compared to the outcomes for the individuals in the study arm. People in the control arm of a study are treated in an identical manner to people in the study arm but minus the intervention or drug being tested. By doing this, the researcher can be sure that it is the intervention or the drug being researched that has caused the outcome of interest and not merely the fact that the individual has been involved in a research study, or indeed that behaviours have changed as a result of being in the study (testing effects, as noted earlier in the chapter).

Concept summary 4.4 Control

The easiest way to understand why a control arm is important in a study is to consider what happens when a parent picks up a child who has fallen over and grazed its knee. The very act of picking up the child, saying 'there, there' and giving him/her a kiss is sufficient in most cases to make the child feel better. This is odd because no physical intervention has been offered to make the pain go away; it is merely the attention which has the effect. Similarly, in a study of smoking cessation and the use of nicotine replacement therapy (NRT), failing to have a control group that sees the nurse, gets the advice but does not get the nicotine replacement patches or gum leaves us with a question at the end of the study: 'Is it the NRT which is having the impact, or the attention and information received while being part of the study?'

RCTs are always conducted in a prospective manner, which, as discussed earlier in the chapter, means that data are collected in real time and do not rely on participant recall (which may lead to **recall bias**) or old notes or data. Prospective data collection also has the advantage of allowing researchers to collect the data they need rather than just that available to them after the event. This means both the type and quality of the data collected are better than that achieved using existing data sources (in most cases).

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The study question is sometimes posed as a hypothesis, and sometimes as a **null hypothesis** (or the opposite of the outcome that the researchers expect to see and what the study sets out to disprove or reject). The reasons for this relate to the statistics the study team will use and are not of great significance here. RCTs use one group of participants on whom a new intervention is tried, and at least one other group on whom the new intervention is not tried and with which the first group is compared. Both groups are treated in the same way, other than the intervention (the independent variable), so that the people conducting the RCT can demonstrate that the intervention, and nothing else, has caused the differences in outcomes (the dependent variable) between the groups. This is why they are an improvement on the simple experimental methodology described earlier. Figure 4.4 gives a diagrammatic representation of a simple RCT design.

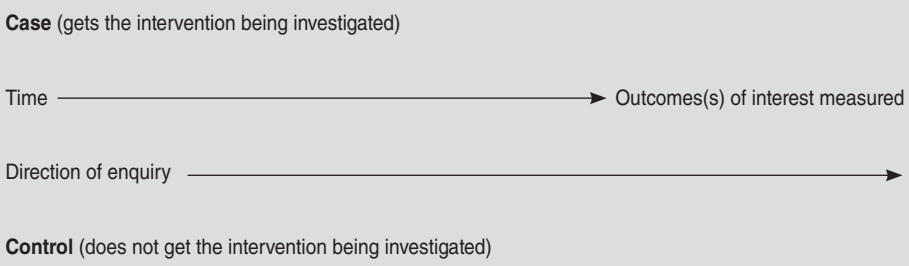

Figure 4.4 A simple randomised controlled trial design with one control group

Activity 4.3 Research and finding out

Consider the area in which you are working and some of the interventions you are involved with on a daily basis. Now consider what evidence might exist for these interventions and discuss these with your practice supervisor. Spend some time outside of work looking at whether you can find some evidence for the interventions. Do a search on a bibliographic database and/or look at the evidence contained in a NICE guideline and consider why much of this evidence is based on RCTs.

There are some possible answers at the end of the chapter.

Sampling in RCTs

The first problem with the above method, if we take it at face value, is to ensure the two groups (cases and controls) are alike at the start of the study. The simple solution to this issue might seem to be matching the two groups up for all the things that we can measure to make sure that this is the case. So, for example, if we wanted to test

the usefulness of a new drug for lowering high blood cholesterol levels, we could get together a group of people with high cholesterol and then split it into two groups. We could make sure that the two groups were evenly matched for age, gender, ethnicity, body mass index and whether they had high blood pressure or diabetes and thereby claim that the two groups starting the study were identical. Indeed, if we accept that the issues identified are important in determining how people might respond to the drug this might seem reasonable. Some studies do closely match cases and controls for known variables, usually because there are few participants available for the research and sample sizes are small.

Matching cases and controls for all *known* variables is not, however, always a good idea, since what this approach does not necessarily do is split the variables that we cannot see or measure – for instance, participant attitude and likely adherence to the trial regime, genetic make-up, social criteria and diet – evenly between the two groups. It is quite conceivable that these criteria are unevenly distributed among the participants and are affected by criteria we do not yet know about and lack the ability to measure. So the more usual way of dealing with the creation of the two groups is to allow them to be generated randomly, often by a computer or randomisation table.

RCTs start with participants that meet the inclusion criteria and are therefore similar in a number of ways. They are then randomly split into two groups so variables that can be seen and measured and variables that cannot be seen and measured are likely to be split evenly between the two groups (assuming that the number of participants included in the trial is large enough).

There is another reason why researchers do not split the participants into the two groups themselves: **selection bias**. Selection bias occurs when a researcher places a person in one arm of the study because they believe, perhaps subconsciously, that the person will benefit the most from the new intervention and/or that the individual is likely to show the new intervention in its best light.

Activity 4.4 Critical thinking

Imagine that you are involved in an RCT and are responsible for recruiting participants to the study and allocating them to be either cases or controls. Obviously you want the study to be a resounding success. What factors might affect the way in which you allocate people, assuming you have the choice about which arm of the study to put them into?

There are some possible answers at the end of the chapter.

The study is now at the point where the two groups have been determined and the new intervention is being applied in the case group and not in the control group. This gives rise to two new questions: 'Does it matter if participants can tell which group they are in?' and 'Does it matter if the researcher can tell which group each participant is in?'

Blinding in RCTs

The simple answer to these questions is that it is preferable that neither the participant nor the researcher can tell which group any individual participant is in. There are some good reasons for this. Participants are known to react differently if they know they are getting a new intervention. Returning to the cholesterol-lowering drug example, if the participants know they are on the cholesterol-lowering drug, they may choose to be less careful about their diet because, after all, they are getting the real thing; conversely, they may choose to increase their exercise and improve their diet because they want the study to work. Such **behavioural biases** (called the Hawthorne effect) will affect the confidence that can be placed in the study findings.

Activity 4.5 Reflection

Think back to your answers to Activity 3.2 in which you greeted some people by saying 'Are you all right?' and others by saying 'How are you today?' You will recall we observed that people will respond in the way they believe you want them to respond. In what way might similar additional behavioural biases be introduced to an RCT if the researchers know what group the participants are allocated to?

There is an explanation of this activity at the end of the chapter.

If researchers know what arm of a study a participant is in, this too may change their behaviour, either consciously or subconsciously, again because they want to be part of something successful. This may mean that in a trial of a new wound dressing they report improved wound healing for the new dressing; or in the cholesterol-lowering example, they may, without realising it, give the intervention group more education about diet, exercise and smoking cessation than they give to the control group. It is also always possible that their interactions and questioning about symptoms will not be the same between groups.

To avoid behavioural biases, gold-standard RCTs blind both the participants and researchers to which arm of the study each participant is on. This **blinding** (now sometimes called **masking**) is usually achieved by the use of a placebo in a drug trial or a sham intervention in a trial of a treatment. A placebo is a medication that looks exactly like the medication being trialled, but that does not contain the active drug. Sham interventions are harder to provide – for instance, it is hard to pretend to give a therapeutic massage or to hide which wound dressing is being used. One way round this is for the person delivering the intervention and the person recording the effectiveness of the intervention to be different so that prior knowledge of what treatment a patient is receiving does not bias the measurements being taken.

Methods used for data collection

RCTs use a number of methods for collecting the study data. These methods include clinical and non-clinical measurements (e.g. blood cholesterol levels, wound-healing rates, participant satisfaction and quality-of-life data). The methods used for data collection are determined by the outcomes that the study is measuring. All methods of data collection need to measure the variables concerned both accurately and clearly (Parahoo, 2014). This means that when designing research it is important to define what is being measured as well as how it is being measured, by whom and when, and to ensure that all researchers involved in the study (which may be taking place across many different sites, for example) follow precisely the same protocol (thus increasing the inter-rater reliability of the study).

Many RCTs collect data on more than one outcome, so they may use clinical measures and questionnaires simultaneously to obtain data to answer the research question. In order to maintain blinding, the results of clinical tests such as cholesterol levels are not known to either the researcher or the participant but are surveyed by a monitoring team that also has responsibility for making sure that the participants in a study are kept safe and that it is stopped if there are any unforeseen adverse consequences. Monitors may also stop a study early if the proof required of it is derived early, so-called 'stopping early for benefit', although doing this does risk the study's findings remaining subject to question.

Many of the questionnaires used in RCTs and other forms of quantitative research have been previously validated, that is, they have been tested on many occasions in several groups of individuals to make sure that the questions they contain gain a true picture of what people actually think or feel about an issue. A common example of such a questionnaire is the Short Form 36 (SF36), which is used to measure an individual's health and well-being as that person sees it (**https://orthotoolkit.com/sf-36/**) and which has been validated in different languages among people with different health conditions.

Activity 4.6 Research and finding out

Go online and identify some pre-validated questionnaires which might be used by researchers. Such questionnaires might ask questions about a person's general health, mental health, mobility, quality of life or social functioning. Read up about the questionnaires, how they were designed and validated and what they might be used for. Examples include: the Hospital Anxiety and Depressions Scale (HADS); the World Health Organization Quality of Life (WHOQOL); and the Social Functioning Questionnaire (SFQ).

Cohort studies

Key features

Cohort studies are usually prospective and follow a predetermined group of individuals through time and measure the **incidence** of predetermined outcomes. For example, cohort studies might be used to follow a group of workers in the asbestos industry for a period of years to determine the incidence of mesothelioma (a type of lung cancer associated with exposure to asbestos) in that group (Nicholson et al., 1982). The purpose of cohort studies is to link an exposure (independent variable or cause – in this case, asbestos) with an outcome (dependent variable or effect – in this case, mesothelioma). Cohort studies are said to be able to determine the causality of disease, that is, they are able to link exposure to a certain independent variable with a disease being researched.

Concept summary 4.5 Cohorts

To understand the concept of cohorts, think about the people with whom you trained or are training. They are your training cohort. Because you are training in a caring profession, you will share some characteristics: you are all likely to be similar as people, be caring and have broadly similar values. Because you are training or have trained together, you share similar skills because you have been exposed to similar classroom and clinical situations. As you are a cohort, it is likely therefore you will have some shared outcomes that result from your shared exposures.

Unlike the experimental study designs discussed earlier, cohort studies do not involve an intervention on the part of the researcher – they are purely observational. It is the fact these studies are, usually, undertaken prospectively and that they explain the biological reasons for the disease outcome that makes them able to determine the causality of disease. Figure 4.5 gives a diagrammatic representation of a simple cohort study.

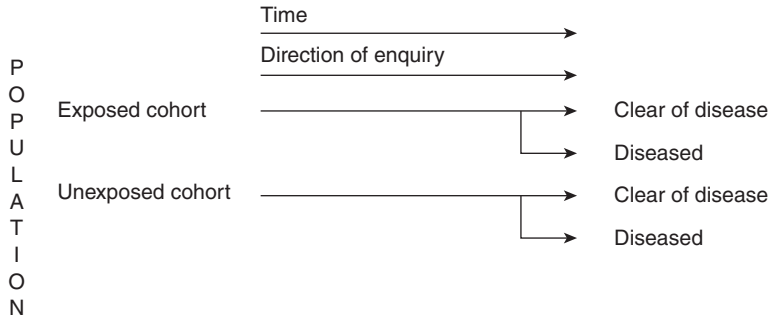

Figure 4.5 A simple cohort study design with one control group

What you will notice from Figure 4.5 is that some people get the disease even though they were not thought to be exposed to the cause of the disease. There are two main reasons for this. First, disease may have more than one cause and so the cohort study provides insight into how much disease is actually caused by the exposure under investigation rather than other environmental or lifestyle exposures. Second, people are often exposed to things they do not know about – for example, they may be exposed to asbestos in an old house or place of work, or, as is commonly recognised now, through handling and washing the overalls of a spouse who works directly with asbestos.

Some cohort studies are **retrospective** (that is, they look back in time) and try to collect data about an exposure (a potential cause of disease) and relate it to an outcome (often a disease). However, less faith is placed in the outcomes of these types of studies because they are not prospective and so rely on the recall of participants for things such as dietary or smoking history. This may cause recall bias, which leads to questions about whether the study does indeed demonstrate what it claims to demonstrate. Goodman et al. (2024) give the example of women with ovarian cancer having possibly incorrect recall of their use of talcum powder in the area of the perineum. Such recollections might cause the association between talc use and ovarian cancer to be overestimated in the research.

As well as cohort studies that follow well-defined groups of people over a period of time to collect data on the incidence of a particular disease (as in the asbestos and mesothelioma example), there is another form of prospective cohort study design that follows people over a period of time and collects data about their lifestyle, blood pressure, diet and working lives (exposures or independent variables) as well as collecting data about the development of disease and ill health (outcomes or dependent variables) in the cohort. The data collected on exposure, and indeed non-exposure, are then compared to data on outcomes, or not, in the cohort. Inferences are then made about the causes of disease and ill health. The benefit of this form of cohort study is that it does not have to start with any preconceptions and is therefore useful in identifying causes of disease that had not previously been thought of.

A number of famous cohort studies have given useful insights into what lifestyle choices, jobs and medication regimes give rise to increased likelihood of disease. Perhaps the most interesting studies for nurses are the massive and very productive Nurses' Health Studies that are taking place in the USA (see Case study 4.3).

Case study 4.3

The Nurses' Health Study cohort research project (NHS I) was started in 1976 and its scope and cohort size were further expanded in 1989 and 2010. In 1976 the study enrolled married registered nurses aged 30–55 who lived in the 11 US states where the state nursing

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boards had agreed to supply the nurses' names and addresses. Of the 170,000 nurses initially approached, approximately 122,000 nurses responded. Every two years since then, all members of the cohort have received a follow-up questionnaire regarding diseases and health-related topics, including smoking, hormone use and menopausal status. Every four years since 1980, the nurses have also received questions relating to their dietary habits, and since 1990 questions about quality of life have been added. Response rates to the questionnaires have been, and remain, high, at about 90 per cent, throughout the study's life (**www.nhs3.org/about/history/**).

A second study (NHS II) was started in 1989 with younger participants – aged 25–42 – in order to study emerging areas of interest such as contraception use, diet and more lifestyle data. The cohort for this study is somewhat smaller, at around 117,000 participants of whom 90 per cent are still involved.

NHS III is the newest study: it is web-based and started to roll out in 2010, again to a younger generation of nurses, and for the first time including men as well as Canadian nurses and nursing students. NHS III is collecting broader data than I and II to include environmental as well as mental health issues.

What is interesting about these studies is that they have taken an informed set of professionals and collected data in real time over many years. If an individual nurse enrolled in 1976 and is still participating in the study – as many are – then, to date, there are almost 50 years of data relating to the one individual. Given the size of the initial cohort, this means that NHS I has data relating to over 5 million years of nurses' lives, the things they are exposed to and the outcomes and diseases these might cause. To date, these studies have produced, and are still producing, many hundreds of research papers relating to disease risk factors for women. Some of the key findings from NHS I and NHS II are shown in Table 4.2. You may find that exploring the website for this study gives you some understanding of the nature of these types of study.

Activity 4.7 Research and finding out

Many good-quality cohort studies have contributed widely to our understanding of the causes of disease, whether those causes relate to lifestyle, diet, exercise, occupation or something else. Go online and find three or four other cohort studies and identify the key findings they have demonstrated which have improved our understanding of the factors contributing to good health and disease. A couple of examples which are of most interest include: Whitehall I and II (ongoing) and the British Doctors Study (analysis of which is still ongoing).

Table 4.2 Some of the major findings of the Nurses' Health Studies

Major findings of the Nurses' Health Studies
• Birth control pills do not increase non-smoking women's risk of heart disease.
• Women who take oral contraceptives for more than five years have less than half the risk of ovarian cancer than women who have never used birth control pills.
• Women who take oestrogen after menopause decrease their risk of heart disease, but raise their risk of developing breast cancer.
• Increased dietary calcium intake among post-menopausal women is not protective against fractures of the hip and wrist, although a positive relationship has been observed between protein intake and risk of fractures.
• A diet rich in red meat raises the risk of colon cancer.
• Women who drink moderate amounts of alcohol (one to three drinks per week) cut their risk of heart attack in half, but increase their risk of breast cancer by one-third.
• Limiting fat intake and eating more high-fibre foods does not reduce a woman's risk of breast cancer.
• Women who have taken multi-vitamin supplements that contain folic acid have a 75 per cent reduced risk of colon cancer.

Source: www.nhs3.org/about/publications/

Sampling in cohort studies

The sample selected for a cohort study is determined by the questions that the study sets out to answer. So, if the study is interested in specific outcomes for a specific group (such as individuals who work with asbestos), the people who meet the criteria of interest then constitute the study group or sample. If, however, the study is interested in determining several outcomes, especially where there is no suspicion of a particular disease in a group, then a more general group is chosen and followed up for a period of time, measuring a range of exposures and outcomes to see what arises (the Nurses' Health Studies would fall into this category).

As with RCTs, there remains the need for a comparison group so that it is possible to compare exposure in one group to non-exposure in the other and thus determine the extent to which the outcome of interest is caused by the exposure (demonstrating causality).

There are many issues relating to how and who is selected to be in the comparison group, as there is a need to keep the two groups as alike as possible in order that the one thing that is different between the groups can be said to be the exposure that has caused the outcome. In studies such as the Nurses' Health Studies, this is achieved by studying a large homogeneous (largely similar) group of nurses of similar ages and, when an outcome of interest arises, comparing the data on exposures between those who have the outcome (or disease) of interest and those who do not.

In more specific cohort studies, such as the asbestos workers example, the comparison group would be drawn from people who are largely similar to the group being investigated except they are not exposed to the potential cause being investigated. So a comparison group for people who work with asbestos might include other workers in the same factory or workers in similar jobs who live in the same community and have broadly similar lifestyles to the group under study.

Methods used for data collection

The most frequently used data collection method in cohort studies is self-completion questionnaires. The use of self-completion questionnaires is driven by the fact that these studies are so large and take place over such long periods of time that individual visits, or data collection by study staff, would be very expensive and time-consuming. Some studies collect additional data from some participants for analysis of subgroups or because there is a suspicion the extra data will yield some useful results. For example, for various purposes the NHS I study has collected toenail clippings (to examine mineral content) as well as blood samples (usually more than one sample, and some years apart) from many thousands of participants.

As with the RCT, some of the questionnaires used are previously validated while other questions and questionnaires are designed specifically for the study.

Case-control studies

Key features

Case-control studies are cheap and easy to do when compared with other quantitative research methods (they are not related to, nor do they answer similar questions to, RCTs). Case-control studies are backward looking (retrospective). They study people with an outcome (or disease – the dependent variable) of interest and try to determine past exposures (the independent variable) to things that might have caused the disease (Celentano and Szklo, 2019), or might predict the occurrence of an outcome. For example, in their study of sleep disturbance and stroke risk, McCarthy et al. (2023) identified that individuals who also had a history of sleep disturbance were at an increased risk of having a stroke; Sun et al. (2023) demonstrated in their case-control study that polypharmacy (the use of a lot of medications) and the use of antipsychotics were associated with an increased mortality risk in people with learning disabilities and epilepsy; and Jafari et al. (2022) demonstrated a link between eating ultra-processed foods and an increased risk of colorectal cancer.

Case-control studies cannot be used to prove causality because they do not collect data in a prospective manner and so there are many issues relating to **confounding** and bias that may affect the quality of the data they produce. People with the disease in question

may recall exposure to the causal agent better than people without the disease because they have thought about it. As explained earlier, this is called recall bias. A case-control study must have a hypothesis, or hypotheses, as this makes the design of the study easier and more understandable to people who might read it. Figure 4.6 gives a diagrammatic representation of a case-control study.

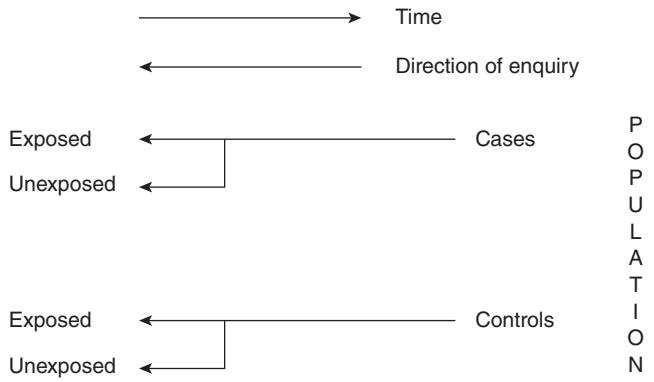

Figure 4.6 A case-control study

Concept summary 4.6 Confounding

Confounding occurs when alternative explanations for an outcome in a study are not accounted for. Confounding variables are always independently associated with both the exposure and the outcome being measured. For example, an increased risk of coronary heart disease (the outcome) is attributable to both smoking (the exposure/independent variable being studied) and high alcohol consumption (an exposure/independent variable not being studied); however, smokers are known to drink more than non-smokers generally so smoking and drinking are independently associated both with each other and the outcome of interest, coronary heart disease.

In the mesothelioma cohort study, if the control group used was very different from the study group – for example, if it was composed of office workers who are less likely to smoke than manual workers who work with asbestos – then smoking might be responsible for making the manual workers more susceptible to mesothelioma. So the risk of getting mesothelioma from exposure to asbestos might be overestimated if the levels of smoking in the two groups were not accounted for.

Sampling in case-control studies

The sample for a case-control study is taken by selecting people who have an outcome of interest – in our examples, having had a stroke, mortality and developing colorectal cancer – and matching them with appropriately matched individuals who do not have

the outcome of interest. Cases need to be well defined. It is not enough, for instance, to define your sample as 'people with hypertension' (high blood pressure); it is better to state what is meant by high blood pressure (e.g. 'greater than 150/85 mmHg on three consecutive occasions'). It is also important to define where the cases are from (their source), because this provides information about how representative they are of all people with the outcome of interest. At its simplest, all cases of liver cancer in one hospital in the UK may not be representative of all cases of liver cancer, especially if the hospital is in an area of high unemployment or social deprivation, for example. When subjects are drawn from prevalent cases (rather than incident ones) they may be different from the whole population of people with the disease. This may be because prevalence of the disease relies on people surviving with it, whereas using incident cases does not.

Concept summary 4.7 Prevalent and incident cases

Prevalent cases are people with a disease (or other outcome of interest) at a given point in time. Incident cases are new cases of a disease (or other outcome of interest) occurring during the course of the research study. So prevalent cases are existing cases and incident cases are new cases. The important issue is survival: if a study uses prevalent cases, but the disease has a high early **mortality rate**, then prevalent cases may not represent the majority of people who get the disease because many of them will have died.

Disease duration also affects the choice of prevalent or incident cases. If one is studying an outbreak of food poisoning, then one would study incident cases as the illness is short-lived. But when researching chronic diseases (such as diabetes or chronic kidney disease), the choice of prevalent or incident cases is influenced more by the research question than the disease duration.

Choosing controls for case-control studies is as much a matter of judgement as it is of science. Controls need to be chosen with care. If the aim of the study is to compare like with like, then the controls need to be very similar – in all respects other than not having the disease – to the case population.

A good example that demonstrates the need for good judgement is the study of a disease that is related to alcohol. If the cases are all people who have been admitted to hospital with alcohol-related liver disease, it may seem sensible to compare them to other people in the hospital at the same time who are of the same gender and age. There is a problem with this, however, since people who have alcohol-related accidents or alcohol-related diseases are admitted to hospital more often than people of the same age and gender in the general population. So a control group chosen like this would be less like the general population from which the cases are drawn than if it was drawn from the general population.

When next in practice, you may want to take note of the number of patients you see who smoke or have a history of excessive alcohol use. What you will note is that the percentage who smoke or who drink to excess is greater than the percentage of people in the general population who drink or smoke.

Methods used for data collection

Data collection for case-control studies is usually undertaken by studying medical, nursing and other documentary records, by interviewing (the cases and controls or their relatives) and by taking or using existing biological samples. One of the major problems with case-control studies – and a good reason why they are generally used to generate hypotheses that are later tested in prospective studies – is that they often rely on participant recall (which is open to recall bias). The other issue of note is that the use of retrospective data does not allow the researcher any control over what data are collected or its quality. This means there can be issues with both validity and reliability.

Cross-sectional studies

Key features

Cross-sectional studies are used to research the prevalence of an outcome or exposure in a given group. They are very common in healthcare research and are quick, cheap and easy to conduct. Cross-sectional studies allow researchers to generate hypotheses that can be tested using other quantitative methods such as RCTs and cohort studies.

Cross-sectional studies often use survey methods to find out any number of things, including demographic data, the presence or absence of disease, people's opinions and the way in which people plan to vote. It is usual practice for universities to collect data on students' opinions of the modules they are studying; this is a simple cross-sectional study usually undertaken for quality monitoring (audit) purposes.

Since data on exposures and outcomes are collected simultaneously, cross-sectional studies are not good at showing the sequence of events (the **temporal sequence**). For example, a cross-sectional study of mental illness and unemployment would be hard to interpret since it is likely that mental illness is both a cause and effect of being unemployed. Because of this they are the weakest of the epidemiological study designs discussed in this chapter.

Cross-sectional studies usually measure one of two types of prevalence: **point prevalence** ('Do you have a headache at the moment?') and **period prevalence** ('Have you had a headache in the last week?'). For chronic diseases (diseases that last a long time, such as asthma or diabetes) there is little difference between the two measures of prevalence, while for short-lived diseases (such as a cold or a headache) the two may be vastly different.

A cross-sectional study is essentially a snapshot of a phenomenon at a point in time and cannot, therefore, be used to demonstrate the incidence of an exposure or an outcome, unlike the prospective methods discussed earlier. Unless they are focused on high-risk groups, cross-sectional studies are not very useful for studying rare diseases. Cross-sectional studies can be useful for planning the delivery of a service and for estimating future need.

Some cross-sectional studies collect data on two phenomena of interest and examine whether there is an association (or correlation) between the two, although, because cross-sectional studies are not usually longitudinal, they are not able to demonstrate true cause and effect. One such study by Sharif et al. (2023) sought to examine the prevalence of anaemia in women in socially deprived and non-socially deprived groups in India.

Sampling in cross-sectional studies

The sample for a cross-sectional study is usually drawn from a population in which the exposures or outcomes of interest are known to be fairly prevalent. For example, Ellis and Cairns (2001) studied the period prevalence of renal disease among older people with hypertension and/or diabetes in two GP practices. The purpose of this study was to ascertain the prevalence of early renal disease in order to inform the debate about whether screening for renal disease among this population was a worthwhile exercise.

Methods used for data collection

Data for cross-sectional studies are often drawn from pre-existing data, such as blood test results, data held on hospital or GP databases, or data held by local authorities. Such data may be supplemented during the course of a study by taking biological samples, by using questionnaires or by conducting structured interviews. Again, as much of this data is collected outside of the study protocol it is subject to quality issues like validity, reliability and bias.

Chapter summary

This chapter has described the main quantitative methodologies used in healthcare research. It has identified that the choice of study design is influenced by a number of issues that include the nature of the question being asked, whether the study is attempting to show cause and effect (experimental designs and cohort studies) or whether it is interested in looking for potential associations (case-control) or merely measuring the prevalence of a phenomenon (cross-sectional studies).

We have seen that the samples used in various studies have to be carefully chosen and described in order to maintain the validity of the study and that various data collection

methods have to be used consistently (reliably) in order to generate the findings for a given research methodology.

The following chapter describes and explores in more detail the data collection methods used in quantitative research and when they might be used, as well as their strengths and weaknesses. It shows some of the methods used for describing the data found during a quantitative study and some of the statistical tests used to generate findings.

Activities: Brief outline answers

Activity 4.1 Reflection (p86)

Here are some types of questions that quantitative research might be used to answer.

- How can nurses effectively measure pain and the effects of analgesia?
- Is patient mortality linked to the nurse–patient ratio on the ward?
- Does using dressing X result in less wound infections for patients undergoing knee replacement?
- Does home birth result in fewer complications for the mother than hospital birth?

Activity 4.3 Research and finding out (p94)

RCTs are used to determine cause and effect and may be used to demonstrate the effectiveness of a drug or a therapeutic intervention. They are also used to compare new and old drugs or usual interventions. Example investigations might include the following.

- Does patient-controlled analgesia improve patient satisfaction with knee replacement surgery when compared to four-hourly injections?
- Do children admitted to the emergency department with an exacerbation of asthma respond as well to a reservoir spacing device as they do to a nebuliser?
- Do patients with arthritis report better mobility with the new drug X than they did with the old drug Y?

Problems with undertaking RCTs in the practice setting include time, making sure everyone follows the trial protocol and procedures properly, and keeping accurate records of interventions. You may discover that the findings of the RCT you have located are embedded in practice; if they are not, discuss with your practice supervisor why this might not be the case – for example, it is too expensive, the RCT does not reflect the findings of other studies, NICE have adopted other protocols.

Activity 4.4 Critical thinking (p95)

Any researcher might be tempted to put the sickest participants into the cases arm (group) as they might show the best response. It is also possible, depending on the study, that putting the least sick participants into the cases arm might achieve the best result. There might also be the temptation to put into the cases group the most articulate participants or those considered most likely to comply or try hardest to achieve the goals of the study. Such choices may be conscious decisions or made purely subconsciously. Either way, they mean that the study would not be comparing like with like.

Activity 4.5 Reflection (p96)

Most people like to be liked; one way that people ensure that they are liked is to behave in a way that they think you want them to behave. When you say ‘Are you all right?’, what they are hearing is,

'I want you to say that you are all right', but when you say 'How are you today?' they hear an open question that has no suggested response, so they feel more able to respond by saying how they actually feel. This is similar to the Hawthorne effect in that people are responding to what they think you want to hear, rather than saying what they actually want to say. If researchers know what group a participant is allocated to in a study, this may lead to them treating people in the two arms differently and asking the same questions in different ways, or in a different tone, when interacting with participants in the different groups.

Further reading

Gerrish, K and Lathlean, J (eds) (2015) *The Research Process in Nursing* (7th edn). Oxford: Wiley-Blackwell.

See Chapter 17 on experimental research, Chapter 18 on survey methods and Chapter 30 on questionnaire design and use.

Celentano, M and Szklo, DD (2019) *Gordis Epidemiology*. Philadelphia: Elsevier.

A classic and very accessible guide to all epidemiology, especially the research designs.

Parahoo, K (2014) *Nursing Research: Principles, Process and Issues* (3rd edn). London: Palgrave Macmillan.

See Chapter 3 on quantitative designs, Chapter 11 on experimental design and Chapter 13 on questionnaires.

Useful websites

https://conjointly.com/kb/

The *Research Methods Knowledge Base* is a comprehensive web-based textbook that addresses all the topics in a typical introductory undergraduate or graduate course in social research methods. The section on experimental and quasi-experimental design is quite useful.

www.casp-uk.net

The home of the Critical Appraisal Skills Programme and some great tools for checking the quality of research reports.