PRIMARY STUDY DESIGNS OVERVIEW

When looking for evidence you will find lots of different types of studies. This simple guide will help you to understand the key differences between study designs and introduce you to some of the terms that can be used. This useful flow chart from NICE might also help you decide which type of study design you are looking at.

Experimental Study Design

1. Randomised controlled trial (RCT)

RCTs are often felt to be the most trustworthy study design, as a lot of effort goes into making sure the results of the study have not been influenced by chance, bias or confounding. This means researchers can be more confident that the results are because of the thing they are looking at and not something else influencing the results. The RCT is a useful study design for investigating an intervention to see if something works, such as a drug to treat an illness. The term 'randomisation' refers to the way people taking part are divided into the two groups; undergoing a treatment (or intervention) or the control group. This occurs at random, so no one can predict which group they will be in, even the people conducting the research. The process of randomisation means that the people in each group will be similar and the only difference is the treatment (or intervention) they are given. This means the researchers will be even more confident that any differences between the two groups after the treatment (or intervention) has been given, is down to the treatment (or intervention), rather than some other factor, such as being male or over 50 years old, or being diabetic, or the fact that researchers put the worst patients in the intervention group as they thought they would benefit most. Another way a study can be influenced is by the way the researchers behave towards the people in the study, because of which group they are in. To avoid this, we can 'blind' people, so no one knows which group they are in. Sometimes, but not often, even the people in the study don't know which group they are in. If the research is looking at a drug for instance, it is easy to give everyone in both groups a tablet, but only one group will get the new drug which is being looked at. The other group will get a harmless, dummy tablet, called a placebo. This way neither the researchers, nor the people taking part, know which group they are in.

Sometimes instead of people being recruited and put into groups, schools or doctors surgeries are recruited – this is known as a cluster RCT. It works roughly in the same way as an RCT that uses people, but this time the whole school or doctors surgery are counted as one person.

The CONSORT statement is a useful set of reporting guidelines for people conducting an RCT to make sure it is robust and trustworthy. The Cochrane Collaboration and the Critical Appraisal Skills Programme (CASP) offer a quality assessment tool which can be used when reading a published article about an RCT to make sure the researchers did everything they could to reduce chance, bias and confounding. If they did as much as they could to reduce these, we can be more certain about the results they found.

Observational Study Designs

1. Cohort study

This type of study design is very useful for investigating the cause of something (called an exposure), such as a disease (called an outcome), and this study design uses groups of people that are as identical as possible, except that one group will have been exposed to something and the other group haven't. Researchers can then investigate if the exposure causes an outcome of interest, for instance if smoking causes cancer. Because this type of study looks at how many people in a group, or population, develop the disease or outcome, this type of study is great for looking at incidence rates.

A cohort study can be carried out in the past where researchers look backwards in time to see if people have been exposed to something or not (such as smoking) and then see if they developed the outcome of interest (such as cancer). This is known as a retrospective cohort study and researchers might use surveys to obtain the information they need. Or, alternatively, it can be carried out in the future, so a group of people are recruited and then followed for a period of time to see if they develop the outcome of interest. This is known as a prospective cohort study. This type of study is often undertaken over many decades and is very useful for learning about diseases. In the smoking and cancer example, people could be hired at a young age and then followed to see who started to smoke, and which of those got cancer. Researchers could also look for other exposures, such as if they eat chocolate, or go walking regularly to see if these also have a bearing on the disease, or outcome of interest. These exposures can then be compared to the people who didn't smoke, to see which group got the most cancer. They could also look to see if the other exposures appear to offer some protection or increase the disease, or outcome rate. For example, they might look to see if eating chocolate makes the cancer worse, or if walking regularly helps to prevent the cancer.

Because cohort studies involve large amounts of people and often over a long period of time, they gather a lot of useful information and can be used for many things, not just what they were initially set up for. For example, a famous cohort study is the British Doctors study, which ran from 1951 and was still collecting data in 2015. It sent out surveys to doctors asking about their smoking habits, and was central in demonstrating the link between smoking and lung cancer, which is what it was set up to do. However, the information they gathered has also been used for other types of research, such as cardiovascular disease research. More information about this important cohort study can be found here.

The STROBE statement is a really good guide on the things researchers need to include when writing up their report of a cohort study, and the Newcastle Ottowa Scale or the CASP checklist is used when looking at the results of a published cohort study to see if they thought about everything they should have done, which makes the results of their study more reliable, so we can trust them. This is known as a quality assessment or critical appraisal.

2. Cross-sectional study

A cross-sectional study can be used by researchers to look at one group of people at one point in time to investigate the number of people who have a disease (this is known as prevalence). This makes them useful for looking at the burden of disease and because they are quite quick and simple to set up, and they are often used to study whole populations. Researchers will often obtain the information they need from routinely collected population surveys, such as the Welsh Health Survey, thus they obtain a snapshot of the population at one particular time. Because of the type of data often used in cross-sectional studies, often entire populations can be studied, very cheaply. This type of study cannot tell us about which exposures can cause a disease, or outcome, but they can also tell us about associations. Because of this, they are useful when not much is understood about a disease and can be used to identify a cohort of people that can be followed-up in another study. Cross-sectional studies are not analytical, but descriptive and although they cannot be used to estimate cause and effect, they are useful for generating hypotheses. The STROBE statement is the main reporting guideline for cross-sectional studies, and the Joanna Briggs Institute offer a checklist for critical appraisal.

3. Case-control study

This type of study design is very useful for looking at associations, or possible risk factors of disease. A case-control study investigates the link between an exposure or

characteristic thought to be connected to a disease and the disease itself, such as smoking and cancer. It uses two groups of people, one with a disease or outcome of interest (cases), and one group of people without the outcome of interest (control). Researchers will try and match characteristics shared between the cases and controls as much as possible so the only difference between the two groups is the outcome. This is a process called 'matching' and involves finding a case participant and a control participant that have similar characteristics such as age, weight, height and occupation. The exact characteristics matched depend on what is being investigated, but age, gender and race are often used. This is because they are known to be common confounders to many diseases. A confounder is something that is connected to both the exposure and the outcome being studied. A commonly used example is the relationship between alcohol, smoking and heart disease. A study may be looking at the association between alcohol and heart disease. The results may suggest there is strong evidence that people who drink a lot of alcohol also seem to have higher rates of heart disease than those who do not drink. However, they also collect information on smoking, and notice that those who drink a lot of alcohol, also smoke more than those who do not drink alcohol. This shows that all three are connected, and smoking is confusing the results by making it appear that alcohol and heart disease are linked. Actually it is smoking and heart disease that are linked.

The two groups (cases and controls) are compared to see who has been exposed or has a certain characteristic. If they find more people in the diseased group have been exposed to something than the non diseased group (the control group), researchers may decide there is a strong relationship and this is a risk factor to the disease. For example, more smokers may develop lung cancer than non smokers, and therefore smoking could be a risk factor of lung cancer. This is an example of an exposure. Researchers might also find that more people with heart disease are obese compared to those without heat disease. This would be an example of a characteristic linked with a disease. Researchers will often look for lots of different characteristics or exposures of the participants and collect lots of different information, which makes this study design helpful when there are lots of different factors relating to a disease.

This type of study design is good for looking at causes of disease which take a very long time to develop from the point of exposure, such as many different types of cancer. This is called the latency period. It is also very valuable for rare diseases because it is easier to see a difference in a small number, and these studies can be cheap and quick to conduct. Sometimes people doing this type of research will use

information collected during a cohort study. This is known as a nested case control study. Because people often don't remember things that have happened in the past correctly, and this type of study collects information on things that have already happened, known as retrospective, this type of study is often seen to be of low strength.

The STROBE statement is the main reporting guideline for case-control studies, and the Newcastle Ottowa Scale or the CASP checklist is used for quality assessment.

4. Case series

These descriptive studies are very useful for rare diseases, and are used to follow a small group of people, those with a disease or outcome of interest, such as a medical procedure or treatment. This is a descriptive study which means no statistical measures can be taken from them. If researchers are investigating how effective a treatment is, they can see how effective the treatment is by looking at the people who have received it and make a judgement on how well the treatment works. They can then generate hypotheses which can be tested by other, more rigorous study designs. The STROBE statement is the main reporting guideline for case series, and the Joanna Briggs institute offer a checklist for quality assessment.

Qualitative Study Designs

1. Qualitative methods

Qualitative methods do not look at numbers or how effective something is, but they look at social interactions and people's behaviour and feelings. It embraces individuality and enables a range of views, or understandings to be explored which provide a rich and descriptive view of what it is being investigated. These aspects have an important role to play in healthcare. It can be very useful when looking at behaviour change as it allows researchers to understand how participants feel about something and why. It also enables the researchers to get an individual perspective on something. Often in-depth interviews or focus-groups are used to collect data from a small number of people. In contrast to quantitative research, qualitative research prefers to have small numbers of participants, but they dig deep and gather a lot of information from each of them. Often the interviews or focus groups are records, so a large amount of spoken word from each participant needs to be typed

up, and the researcher can look for common or important elements which are then developed into underlying themes by the researchers. Because people are allowed to talk at length about something, often new and exciting perspectives can be found which can be very enlightening. They also provide a very individual view. There are a variety of different approaches to qualitative methods and analysis which are outlined here. CASP have a useful tool for quality assessment.

NICE glossary of study designs

Extending an evidence hierarchy to include topics other than treatment (2009) additional file – levels of evidence according to research question