# Understanding Physiotherapy Research

# Understanding Physiotherapy Research

By

Chris Littlewood and Stephen May

CAMBRIDGE SCHOLARS

PUBLISHING

Understanding Physiotherapy Research,
by Chris Littlewood and Stephen May

This book first published 2013

Cambridge Scholars Publishing

12 Back Chapman Street, Newcastle upon Tyne, NE6 2XX, UK

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library



ISBN (10): 1-4438-4602-3, ISBN (13): 978-1-4438-4602-8

# TABLE OF CONTENTS

# LIST OF FIGURES

# LIST OF TABLES

# PREFACE

Why is there a need for another book about research? As experienced musculoskeletal physiotherapists involved in education and research we were aware of the difficulties that pre- and post-registration physiotherapists had in engaging with research evidence. In our experience, research is commonly treated as an add-on to physiotherapy educational curricula or clinical practice. The implications of research evidence are a concern only at the time of writing an assignment or preparing a presentation. It is something left largely to a minority with an interest. However, in an era of evidence based-practice, it is vital that all physiotherapists are aware of the inherent strengths and limitations of research studies and what this means for their practice. Despite this there is a dearth of physiotherapy specific texts that enable practising physiotherapists and students to effectively appraise and then apply research findings to their practice. Many generic research texts are available but, based upon our experience, this literature, which lacks a physiotherapy context, serves as a barrier to understanding and engaging with research.

To bridge this gap, this book presents a clinically focused range of methodological discussions in relation to specific research study designs in musculoskeletal physiotherapy. The intention of the book is to offer a platform upon which readers can develop their understanding of meaningful critical appraisal and hence gain confidence when reading published research. A focus on physiotherapy is preserved throughout the book to maintain engagement by discussing a topic of direct interest to the reader in a clinical language with which they are familiar. Our experience suggests that clinicians and students become lost when trying to apply abstract concepts from one topic to another. For those of you to which this sounds familiar, this book is for you. Our aim is to offer an introductory level text that is accessible and understandable to all those who appreciate the need to integrate research evidence into their practice, whether that is clinical, educational or managerial practice.

As with most substantial pieces of work, this book is not the product of the work of two individuals. We are indebted to our students, past and present, for asking the questions and subsequently stimulating the production of this book. We are also grateful to Ken Chance-Larsen, a friend and colleague, and Keith Hemsley, a friend and father-in-law, who

took the time to review drafts of this work and offer helpful comments along the way.

# CHAPTER ONE

# EVIDENCE-BASED PHYSIOTHERAPY

## Introduction

Everyone is now very familiar with the term evidence-based practice, a term that has been around for a number of years. Evidence-based medicine was a concept introduced in the 1990s and defined by one of its founders as "*the conscientious, explicit and judicious use of current best evidence*" (Sackett et al 1996). The background for this movement was that about only 15% of medical interventions were supported by solid scientific evidence, only 1% of articles were scientifically sound, and many treatments had never been assessed at all (Smith 1991). "*The weakness of the scientific evidence underlying (medical) practice is one of the causes of the wide variations that are well recognised in (medical) practice*" (Smith 1991). Subsequently the philosophy behind the concept was adopted by physiotherapists for very much the same reasons, and the term extended to become evidence-based practice / healthcare (Bury and Mead 1998).

It is important to make it clear from the start; evidence-based practice is not cook-book healthcare. Instead, evidence-based practice is about integrating the best available external evidence with clinical expertise and with patient preference (Sackett et al 1996). Thus external evidence is used but does not displace individual clinical expertise which should be used to determine if that evidence is relevant to the patient in front of you. It involves retrieving, appraising and, where appropriate, integrating that evidence to inform individual clinical decision making. As will become clear throughout this book, evidence does not just mean data obtained from randomised controlled trials and/or systematic reviews, though both are useful and important sources of evidence. The type of research evidence required will depend upon the clinical question being asked which in turn dictates the most appropriate form of research design required. If the question is about effectiveness of an intervention then, usually, a randomised controlled trial is the most appropriate research design; but if you want to find if a physical examination procedure is reliable between clinicians then a reliability study is necessary. If you want

to find out about risk or prognostic factors for a certain disease then cohort studies are required. To find out about the perceptions held by patients or therapists then a qualitative study is needed. To find out if a physical examination procedure really does what the textbooks say it does, cross sectional studies comparing the test to a gold standard way of making that diagnosis would be appropriate. All of these study designs can be summarised and appraised in systematic reviews, so, for busy clinicians, these are an essential first read to get an overview on a topic.

## Hierarchy of evidence

Sometimes the different study designs are ranked in a hierarchy of evidence, in which, for instance, systematic reviews are the strongest form of evidence, followed by randomised controlled trials, then cohort or case-control studies, then non-experimental studies, and lastly expert opinion (Gray 1997). Notice however that such hierarchies do not consider the type of question you are asking which, as stressed above, is central to the decision about the most appropriate study design to use. So, we suggest, it is best to take such hierarchies of evidence with a large pinch of salt, and "*you should never under any circumstances slavishly adopt or accept a hierarchy or grade of evidence*" (Earl-Slater 2002).

## Implementing evidence-based physiotherapy

The founders of evidence-based healthcare described five procedural stages (Sackett et al 1997):

1) Formulate a clear clinical question based upon a patient's problem
2) Retrieve evidence with maximum efficiency to find evidence that addresses the question
3) Critically appraise that evidence for its validity (trustworthiness) and usefulness (applicability to your clinical setting)
4) Implement the findings into practice
5) Evaluate the impact of the evidence.

Obviously the research question will depend very much on the topic of interest that a patient has raised. Factors that might be relevant in your research question are: the type of patient you are interested in; the reliable and valid tools that are available in their assessment; reliable and valid outcome measurements; and effectiveness of interventions. From the research question you will develop key words, which should be directly

relevant to the question, for instance, the type of patient group, the type of intervention, the outcomes of interest and the most applicable study design and so on. The acronym PICO (Higgins and Green 2008), sometimes supplemented with "S" to make PICOS, has been but forward as a useful reminder of these components and table 1.1 displays a basic search strategy structured around PICOS in response to the clinical question: *"Will mobilisation help my patient with low back pain return to work?"*

| | **Search terms** |
|---|---|
| (P)atient group | Low back pain OR spinal pain OR lumbago |
| (I)ntervention | Mobilisation OR manipulation OR manual therapy |
| (C)omparator | Usual care OR physiotherapy OR placebo |
| (O)utcome | Return-to-work OR quality of life OR function |
| (S)tudy design | Randomised controlled trial OR randomized controlled design OR clinical trial OR systematic review |

**Table 1.1 Simple search strategy structured using PICOS**

As seen from table 1.1, some key words and possible alternatives have been combined into search terms. It is appropriate to include as many synonyms as possible for each area of the search, and then combine them using the Boolean operator OR. This means that the electronic search will retrieve any papers that include these key words. The next step is to combine all the synonym terms with other aspects using the Boolean operator AND. This means that the electronic search should only retrieve papers that include the key words relating to the patient group **and** the intervention of interest **and** the outcome of interest etc. This is a way of restricting the search so that only potentially relevant papers are retrieved. Table 1.2 shows how this looks in practice.

Note in this example we have not included the terms for the comparator. In our experience of searching the physiotherapy-related literature this often significantly diminishes the return of the search meaning that important studies might be missed. By omitting the comparator terms, the worst-case scenario is that you will retrieve extra papers. In most cases this sensitive approach is preferable to one where a highly specific search excludes potentially relevant papers.

| |
|---|
| (low back pain OR spinal pain OR lumbago) |
| **AND** |
| (mobilisation OR manipulation OR manual therapy) |
| **AND** |
| (Return-to-work OR quality of life OR function) |
| **AND** |
| (Randomised controlled trial OR randomized controlled design OR clinical trial OR systematic review) |

**Table 1.2 Implementation of a simple search strategy**

In terms of identifying the key words to include in the search, your own knowledge and experience is a starting point. However, this should be supplemented by looking at the key words of published papers, reviewing the search strategies of relevant systematic reviews and also adopting the work of others who might have developed a search strategy specifically related to the question you are asking or at least an aspect of the question you are asking, for example the Cochrane highly sensitive search strategy for identifying randomised trials (Higgins and Green 2008).

Once search terms have been identified then the next step is to identify electronic databases in which to implement the search. Relevant databases include the Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Excerpta Medica Database (EMBASE). Other important sources of evidence include the Cochrane database, which has its own series of systematic reviews, a Database of Abstracts of Reviews of Effectiveness (DARE), and the Physiotherapy Evidence Base (PEDro) which is a very useful source for physiotherapy related research, but is exclusively related to intervention studies, and not a good source for other types of evidence. PEDro though does have the added advantage of critically appraising the studies on the site and giving them a score out of ten for their methodology. Often a study scoring six or more out of ten is deemed to be high quality. However, if we stop to think, you might recognise that there is a certain amount of arbitrariness about determining the quality of a study in terms of a score out of ten. Imagine two studies, both scoring six out of ten and therefore both regarded as being of similar high quality. Now, for simplicity, what if one study meets criteria one to six and the second study meets criteria five to ten (what these criteria actually are is irrelevant at this stage)? The point to recognise is that the studies have both scored six out of ten but have met very different criteria to attain this. How can we be sure that meeting criteria one to six is the

same in terms of study quality as meeting criteria five to ten? Currently we can't and this is why many have moved away from sole reliance on a quality score to determine the quality of a study.

Returning to the databases above; all are accessible online, although a subscription is required for some. We think it is useful to become familiar with the way they operate and their scope before commencing the search. A literature search of electronic databases, as described above, is frequently seen as a starting point by many and additional strategies, including contact with experts, searching the reference lists of the papers retrieved, hand-searching relevant journals and also citation-searching are useful complementary strategies to enhance the search.

Once the search has been implemented and the retrieved papers have been screened for relevance, the next stage is to undertake a critical appraisal. Critical appraisal refers to a process where you are asking: *"Can I trust the findings of these papers and if so are they applicable to my practice?"*

To facilitate the process of critical appraisal there are numerous published quality criteria available for all study designs (the PEDro tool for randomised controlled trials has been mentioned above). Currently it is unclear whether one quality appraisal tool or set of criteria is superior in a given situation. Despite this, there are some generally accepted quality issues that should be considered and these will be reviewed in subsequent chapters where relevant study designs are covered.

The next stage is implementation; straightforward in theory but potentially difficult in practice. Remember, evidence-based practice refers to integration of the best available external evidence with clinical expertise, and with patient preference. Consider a situation where a patient communicates a strong preference for ultrasound for the treatment of non-specific low back pain; "*it worked last time*." The research evidence points to exercise and restoration of function and cautions against the use of passive therapies, including ultrasound. You believe that ultrasound will do no harm but you also now believe that it will do no good. How do you proceed? The answer is not clear cut but attempts to prescribe an exercise programme to someone who does not believe in its potential, and hence is unlikely to engage with it, are unlikely to result in a favourable outcome. Clearly this is a challenge facing every clinician and one that has to be dealt with on an individual basis.

The final, or more accurately subsequent, stage of the evidence-based practice cycle is to evaluate impact. Remember, evidence-based practice is supposed to be superior to non-evidence-based practice. An on-going

process of measurement is necessary to evaluate the impact of any changes.

## Evidence-based physiotherapy in action

In this section we consider the use of therapeutic ultrasound and the evidence for its effectiveness. Therapeutic ultrasound is a modality taught at both undergraduate and postgraduate levels of physiotherapy and there is evidence from a number of studies from different countries that therapeutic ultrasound is considered a useful intervention. For instance, used by 8-22% of therapists in Britain, Ireland and Denmark for back pain (Foster et al 1999, Jackson 2001, Gracey et al 2002, Hamm et al 2003), 71% of therapists for back pain in Canada (Poitras et al 2005), 61% in Thailand (Pensri et al 2005), and about 5% in India (Fidvi and May 2010).

It has been claimed that therapeutic ultrasound has a number of properties, being both anti-inflammatory and an inflammatory stimulant at different intensities, and having the capacity to stimulate bone and soft-tissue healing (Norris 1997). The evidence for these properties comes largely from histological and tissue-based studies, rather than clinical practice. However, in the age of evidence-based practice, it is important to verify these claims in randomised controlled trials. Furthermore, unlike active physiotherapy interventions, such as exercise or manual therapy, blinding (the importance of this is discussed in subsequent chapters) of both patients and therapist is possible, and active ultrasound can be compared to placebo ultrasound. Thus the claims for its benefits should be scientifically verifiable.

Literature has been published relating to the effectiveness of ultrasound and twelve reviews are listed in table 1.3. It can be seen that the majority of reviews concluded that ultrasound was ineffective at treating soft tissue injuries, and compared to placebo had no effect on pain, swelling or healing times. The theoretical benefit from laboratory experiments did not carry over into the real world in a convincing way.

Remember, as stated at the outset of this chapter, the call for evidence-based practice arose from the weakness of scientific evidence for contemporary practice. So, in an era of evidence-based practice, why is therapeutic ultrasound still used when the weight of evidence provided over several decades demonstrates a lack of treatment effect compared to placebo? There are many possible reasons for this including patient and clinical preferences serving as barriers to implementation. However, a lack of confidence and technical ability in relation to critical appraisal are others. Thinking in relation to physiotherapy practice continues to evolve

and it is no longer appropriate to rely on what we were taught. It is important that physiotherapists are aware of the inherent strengths and limitations of research studies and what this means for their practice. It is here where the focus of this book lies. Subsequent chapters revolve around critical appraisal of physiotherapy related research with the intention of offering a platform upon which readers can develop their understanding of meaningful critical appraisal, and hence gain confidence when reading published research and implementing research evidence into practice.

## Conclusion

In this introductory chapter the aim has been to introduce or remind readers about some of the concepts behind research and evidence-based healthcare, and some of the motives for its introduction. We have examined an example of physiotherapy practice, therapeutic ultrasound, which has been retained in practice despite a lack of credible scientific evidence. As a profession it is important that our practice is truly evidence-based. The following chapters will review research evidence and different study designs with the aim of enhancing understanding and developing critical thought.

## References

Alexander L, Gilman D, Brown D, Brown J, Houghton P (2010). Exposure to low amounts of ultrasound energy does not improve soft tissue pathology: a systematic review. Physical Therapy, 90, 14-25.

Baker K, Robertson V, Duck F (2001). A review of therapeutic ultrasound: biophysical effects. Physical Therapy, 81, 1351-1358.

Brosseau L, Casimiro L, Robinson V, Milne S, Shea B, Judd M, Wells G, Tugwell P (2001). Therapeutic ultrasound for treating patellofemoral pain syndrome. Cochrane Database of Systematic Reviews, Issue 4.

Bury T and Mead J (1998). Evidence-based Healthcare. Butterworth Heinemann, Oxford.

Chinn N, Clough A, Clough P (2010). Does therapeutic ultrasound have a clinical evidence base for treating soft tissue injuries? International Musculoskeletal Medicine, 32, 178-181.

Cullum N, Nelson E, Flemming K, Sheldon T (2001). Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. Health Technology Assessment, 5, 9.

Earl-Slater A (2002). The Handbook of Clinical Trials and Other Research. Radcliffe Medical Press, Oxford.

Fidvi N and May S (2010). Physiotherapy management of low back pain in India – a survey of self-reported practice. Physiotherapy Research International, 15(3), 150-159.

Foster N, Thompson K, Baxter G, Allen J (1999). Management of nonspecific low back pain by physiotherapists in Britain and Ireland. Spine, 24, 1332-1342.

Gam A and Johannsen F (1995). Ultrasound therapy in musculoskeletal disorders: a meta-analysis. Pain, 63, 85-91.

Gracey J, McDonough S, Baxter G (2002). Physiotherapy management of low back pain. A survey of current practice in Northern Ireland. Spine, 27, 406-411.

Gray J (1997). Evidence-based Healthcare. How to Make Health Policy and Management Decisions. Churchill Livingstone, New York.

Hamm L, Mikkelsen B, Kuhr J, Stovring H, Munck A, Kragstrup J (2003). Danish physiotherapists' management of low back pain. Advances in Physiotherapy, 5, 109-113.

Higgins J and Green S (2008). Cochrane Handbook for systematic reviews of interventions. Wiley-Blackwell, Chichester.

Holmes M and Rudland J (1991). Clinical trials of ultrasound treatment in soft tissue injury: a review and critique. Physiotherapy Theory and Practice, 7, 163-175.

Jackson D (2001). How is low back pain managed? Physiotherapy, 87, 573-581.

Norris C (1997). Sports Injuries. Diagnosis and Management for Physiotherapists. Butterworth-Heinemann, Oxford.

Nussbaum E (1997). Ultrasound: to heat or not to heat – that is the question. Physical Therapy Reviews, 2, 59-72.

Pensri P, Foster N, Srisuk S, Baxter G, McDonough S (2005). Physiotherapy management of low back pain in Thailand: a study of practice. Physiotherapy Research International, 10, 201-212.

Poitras S, Blais R, Swaine B, Rossignol M (2005). Management of work-relates back pain: a population-based survey of physical therapists. Physical Therapy, 85, 1168-1181.

Robertson V and Baker K (2001). A review of therapeutic ultrasound: effectiveness studies. Physical Therapy, 81, 1339-1350.

Sackett D, Rosenberg W, Gray J, Haynes R, Richardson W (1996). Evidence based medicine: what it is and what it isn't. British Medical Journal, 312, 71-72.

Sackett D, Richardson W, Rosenberg W, Haynes R (1997). Evidence-based Medicine. How to Practice and Teach EBM. Churchill Livingstone, New York.

Smith R (1991). Where is the wisdom...? The poverty of medical evidence. British Medical Journal, 303, 798-799.

Van der Windt D, van der Heijden G, van den Berg S, ter Riet G, de Winter A, Bouter L (1999). Ultrasound therapy for musculoskeletal disorders: a systematic review. Pain, 81, 257-271.

Van der Windt D, van der Heijden G, van den Berg S, ter Riet G, de Winter A, Bouter L (2002). Therapeutic ultrasound for acute ankle sprains. Cochrane Database of Systematic Reviews, Issue 1.

Welch V, Brosseau L, Peterson J, Shea B, Tugwell P, Wells G (2001). Therapeutic ultrasound for osteoarthritis of the knee. Cochrane Database of Systematic Reviews, Issue 3.

| Reference | Remit | N | Conclusions |
|---|---|---|---|
| Holmes and Rudland 1991 | Soft tissue injury | 18 | Most studies were flawed, only one study with placebo found active US to be more effective. |
| Gam and Johannsen 1995 | Musculoskeletal disorders | 22 | From meta-analysis of 13 studies no evidence that active compared to sham US gave pain relief. |
| Nussbaum 1997 | Biophysical properties of US | Unclear | Evidence is contradictory and difficult to interpret. Efficacy of US still needs to be addressed. |
| Van der Windt et al 1999 | Musculoskeletal disorders | 38 | 11 / 13 placebo-controlled trials of good quality found no evidence that favoured US, except possibly lateral epicondylitis. |
| Baker et al 2001 | Biophysical effects | Unclear | Not proven to have a clinical effect or do not occur in vivo. |
| Brousseau et al 2001 | Patellofemoral pain | 1 | No clinical benefit. |
| Cullum et al 2001 | Chronic wounds | 10 | Insufficient reliable evidence to draw conclusions. |
| Robertson and Baker 2001 | Musculoskeletal disorders | 35 | 8 / 10 studies of good quality active no better than placebo US; two suggested possible effect in CTS and calcific tendinitis. |
| Welch et al 2001 | Osteoarthritis of the knee | 3 | 1 / 3 was placebo controlled; none showed benefit. |
| Van der Windt et al 2002 | Acute ankle sprains | 5 | 4 / 5 placebo controlled trials showed minimal effect. |
| Alexander et al 2010 | Soft tissue shoulder problems | 8 | Three studies showed significant benefit (two for calcific tendinitis); US at very high levels and long exposure. |
| Chinn et al 2010 | Soft tissue injuries | 7 | 2 / 7 placebo controlled trials showed benefit. |

**Table 1.3 Systematic reviews and reviews into the therapeutic effect of ultrasound (US); CTS = carpal tunnel syndrome**

# CHAPTER TWO

# RESEARCH DESIGN

## Introduction

Research design refers to the approach taken to answer a research question. In our experience deciding which research design to employ or deciding which research design has been used in a study presents a challenge to many. Most texts and critical-appraisal tools require that the reader has defined the research design before the relevant information can be accessed. For example, the Critical Appraisal Skills Programme (CASP) offers a range of critical-appraisal tools for a range of research designs; including the randomised controlled trial, cohort study, case-control study, qualitative study and others. However, this assumes that you are able to confidently recognise the research design before using or judging the quality of the study. Recognising the research design can be a challenge because a range of research designs are available to us but it is not always clear which designs should be used or have been used in published studies.

Different research designs have different roles and it is important that we recognise the relative merits of each. This might seem an obvious statement but the idea that the randomised controlled trial is the best research design to address all research problems is a common misconception that we encounter. Hence, this chapter will present some simple questions that any reader of research can ask to enable them to make a decision about the type of research design that should be or has been employed. Following this an overview of common research designs used within physiotherapy-related research will be presented as a means of introducing the forthcoming chapters. A schematic overview of these designs is presented in figure 2.1.

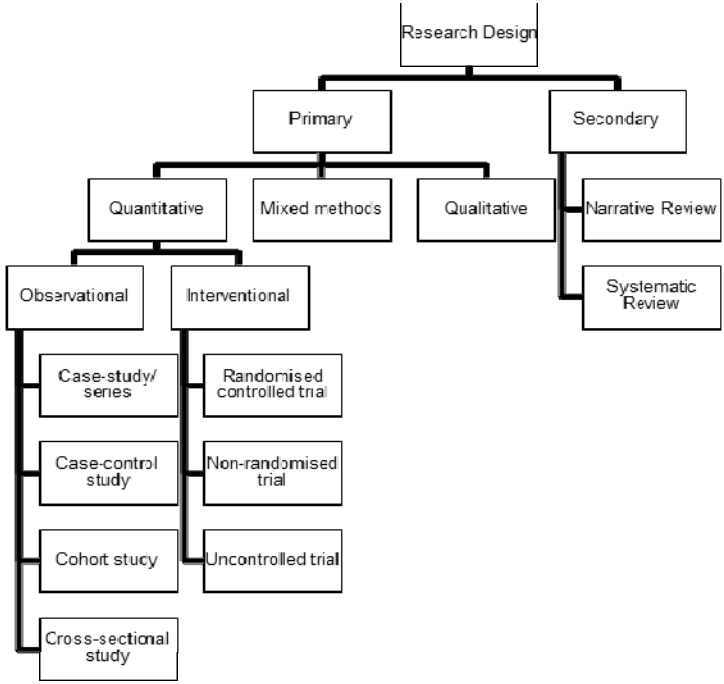


Figure 2.1 Overview of research designs

## Primary or secondary research?

The first question to ask is whether the research is primary or secondary. Primary research studies collect data/ information directly from research participants. An example would be where researchers are interested to know how pain, associated with osteoarthritis of the knee, fluctuates over a one-year period. The researchers could recruit a group of people diagnosed with osteoarthritis of the knee and ask them to complete a questionnaire measuring the extent of pain at the beginning of the year and then after every three months. This is an example of a primary research question because data has been collected directly from the research participants.

Secondary research studies take a different approach to collecting data. These studies, often called reviews, collect data from primary studies. Secondary studies are most frequently undertaken to summarise the primary research that has been undertaken to date. This can be useful

because it is important to understand what is already known before planning a primary study so that the study is capable of answering a useful research question and does not simply repeat what is already known. Also, because of the vast quantity of research that is produced, it is helpful to have a concise summary of research to enable clinicians to apply the evidence to their practice. So, a secondary research study could still aim to answer the same research question as a primary study but the approach to data collection is different. Hence the example of how pain associated with osteoarthritis of the knee fluctuates over a one year period could be a useful question upon which to base a secondary research study, but in this situation the study would identify primary studies that have investigated this area and summarise the findings from these studies.

Secondary research is further classified into either a narrative review or a systematic review (sometimes erroneously referred to as a meta-analysis). A narrative or non-systematic review is an approach where the author(s) selects primary studies, or possibly other reviews, to enable them to create their story. In contrast, the systematic review is expected to be conducted according to pre-specified methodological guidelines which the author(s) follows while constructing their review (Higgins and Green 2008). One of the key differences between these two types of reviews is that the author of a narrative review is not required to adhere to the same strict guidelines when selecting the studies they will use to inform their argument. Such freedom of selection leads many to question the validity or closeness to the truth of narrative reviews due to the high possibility of bias and it is mainly for this reason that fewer narrative reviews are now published.

## Primary research; quantitative, qualitative or mixed methods?

If it is decided that the study to be evaluated or undertaken is primary research, then the next step is to consider whether it is qualitative, quantitative or mixed methodology.

### Quantitative research

Quantitative data is straightforward to define and simply refers to the collection of numerical data; for example, age in years, weight in kilograms, exercise capacity in terms of maximum oxygen uptake, level of pain on a visual analogue scale. An example would be where researchers are interested to know whether physiotherapy reduces pain for people who

complain of shoulder dysfunction. A measure of pain, for example the visual analogue scale, could be taken before treatment and then repeated after treatment to see whether a worthwhile change has occurred. In this situation a person may rate their pain as nine out of ten before treatment and four out of ten after treatment and so a numerical value equating to a five point change has occurred.

In the above example it is easy to see that numerical data is generated and so the study is regarded as quantitative. However, some studies might confuse as they blur the boundary between what is qualitative and quantitative data. Many quantitative studies use questionnaires to collect data. Some of these questionnaires, for example the Short-Form 36 (Ware and Sherbourne 1992), which is the most commonly used general health status questionnaire, ask research participants to mark a statement which most closely relates to their current situation. For example, a question asks: "*Compared to one year ago, how would you rate your health in general now*?"

The possible responses include;

- *much better than one year ago*
- *somewhat better than one year ago*
- *about the same, etc.*

Clearly this is not numerical but the responses are converted to numbers. So, the first response would equate to a score of one, the second response would equate to a score of two etc. Here the qualitative statements have been used to inform the research participant of the range of responses but these responses are then assigned a numeric value and treated quantitatively.

## Qualitative research

Qualitative research has been defined by different people in different ways but essentially this approach refers to research where non-numerical data is collected. Most frequently this data comes in the form of observation of actions or the spoken word (Pope and Mays 2000). An example would be where researchers are interested to know physiotherapists' attitudes to hand washing on a general surgical ward. When the range of possible answers is unknown or unclear, the researchers could interview the physiotherapists to help understand the range of possible attitudes, for example; "*it's a good thing and I do it all the time*"; "*it's a good thing but I don't always have the time*"; "*it's unnecessary so I don't bother.*" The data collected here would be the spoken word of the physiotherapist. This

could then be followed up by using observation where the researchers could see whether what the physiotherapists said was the same as what they did.

Qualitative research is useful to provide depth to our understanding. For example, a quantitative study might demonstrate that, over time, an increasing number of patients do not attend physiotherapy appointments, but it does not explain the reason or reasons why this might be happening. A qualitative study might recruit those patients who did not attend and interview them to ask why.

### Mixed methods research

Over recent years the use of mixed methods research has become more common. Mixed methods research has been defined as the integration of qualitative and quantitative research methods within a single study (Creswell and Plano Clark 2011). The example of non-attendance could be an example of a mixed methods study where the quantitative research highlights the problem and the qualitative study investigates the reasons underpinning this problem. Another common use of mixed methods research is where quantitative research is used to evaluate the effectiveness of a new treatment or intervention and qualitative research is used to understand how the treatment was delivered in practice, whether barriers were faced and, if so, how these were overcome.

The next section will focus upon some common sub-classifications of quantitative research because this is where most confusion seems to arise.

## Quantitative; observational or interventional?

So, you have identified that numerical data has been collected in the research you are studying or that collection of numerical data is appropriate to answer the research question you have formulated. At this stage the next question is to ask whether the study is or will be observational or interventional/ experimental. Observational research describes a situation where the research participants *are not* exposed to treatment or intervention as part of the research. Interventional/experimental research describes a situation where the research participants *are* exposed to treatment or intervention as part of the research (Dawson and Trapp 2001). An example of observational research would be where researchers are interested to know whether people who attend pulmonary rehabilitation classes experience further functional improvement following discharge from the class. At the point of discharge a measure of function could be taken, for

example the six-minute walk test, and this could be repeated at time intervals for as long as is required. During this follow-up period when the six-minute walk test is repeated, further medical treatment or rehabilitation might be accessed and received by the patient but this is independent of the research and not delivered as part of the study. Although this is a common source of confusion, this study is still observational in nature.

An example of interventional/ experimental research would be where researchers are interested to know whether people who attend additional pulmonary rehabilitation classes beyond those conventionally prescribed experience further functional improvement. At the point of completion of the standard number of classes and prior to beginning the additional classes, a measure of function could be taken, for example the 6-minute walk test. The research participants would then attend the additional classes as part of the research before another 6-minute walk test is repeated to determine whether further progress has been made. The key aspect here is that the additional rehabilitation would not have been received if the research had not been undertaken and so the research participants are exposed to treatment as part of the research and not as a part of usual care.

## Classification of observational studies

### *Case-study/ Case series*

A case-study is a report or a description of some or all aspects of a patient encounter. Usually this report will describe an uncommon clinical presentation (Chance-Larsen and Littlewood 2010), a novel approach to diagnosis or a treatment that would not typically be administered (Littlewood and May 2007). The role of a case-study is to introduce or highlight the rare case or novel approach for the interest of the wider clinical or research community. For some, a case-study would not be regarded as research but we include it here because these studies are frequently published and have a useful role in introducing rare conditions or novel approaches and as a basis upon which to begin to plan future research.

A case-series is basically an extension of the case-study. The case-series consists of a report or a description of some or all aspects of a number of patient encounters. The role of the case-series is also similar to that of a case study but the meaning or implication arising from a case-series is greater due to the greater number of patients that are included.

### *Case-control study*

The case-control study is designed to investigate factors that might contribute to or protect from the development of a disease or condition. This design is not to be confused with the case-study or case series; they are distinct research designs with very different roles. The case-control study recruits a group of cases, meaning people with a condition of interest or diagnosis, and a group of controls, meaning people similar to those with the condition or diagnosis but without the specific condition. For example, a group of people with osteoarthritis of the knee could be recruited as cases along with a group of people without osteoarthritis of the knee but similar to the cases in terms of age, gender and socioeconomic status. The history of the cases and controls would then be examined to determine similarities and differences in terms of potential risk factors, meaning factors that might contribute to the development of the condition (Dawson and Trapp 2001). Using the example of osteoarthritis of the knee, factors including family history of osteoarthritis, diet and previous levels of sporting activity might be investigated retrospectively (looking backwards) through clinical records, interviews or questionnaires. If one factor, for example a family history of osteoarthritis, is more commonly reported in the group of cases then a conclusion suggesting an association between this factor and the development of osteoarthritis of the knee could be drawn. If one factor, for example a history of a Mediterranean-based diet, is more commonly reported in the group of controls then a conclusion suggesting an association between this factor and protection against osteoarthritis of the knee could be drawn. At this stage a word of caution; association does not mean causation and a case-control study is not the design to establish causality. So, a Mediterranean-based diet might be associated with less osteoarthritis of the knee but this does not mean that if people adopt such a diet that they will not develop the condition. Other factors, for example obesity, might be the true source of the problem. The issue of establishing causation will be discussed more in relation to the randomised controlled trial.

### *Cohort study*

The cohort study refers to a process of data collection from people with shared characteristics, for example the same diagnosis (Herbert et al 2005). So, for example, a cohort study might recruit a group of people who consult their general practitioner complaining of low back pain. This cohort would be followed to see, for example, how the associated pain and

disability change over time and how long it takes to recover. Such a cohort study has the potential to offer useful information relating to the natural history of low back pain which enables an understanding of the course of the condition and prognosis.

### *Cross-sectional study*

In contrast to the cohort study which is regarded as longitudinal because it collects data over time, the cross-sectional study describes collection of data at one point in time (Herbert et al 2005). Most commonly a cross-sectional study would be used to describe current approaches to treatment of a clinical condition or would be used to investigate how common a clinical condition is or would be used to evaluate the diagnostic accuracy of a test or procedure. For example, a researcher might be interested to know how physiotherapists currently treat a clinical condition in order to plan an experimental study comparing a new treatment to an existing treatment. A cross-sectional study might also be used to investigate whether practice has changed from one time point to another, maybe in relation to a policy change or in response to publication of new guidance.

## Classification of interventional studies

### *Randomised controlled trial*

The randomised controlled trial is regarded by many as the most appropriate research design to evaluate the effectiveness of an intervention (Littlewood 2011). There are three key components to a randomised controlled trial and the clue is in the name. Firstly, the research participants are allocated to two or more groups *randomly*, meaning by chance. Secondly, in its most basic form, research participants are allocated to the intervention or *control* group. Thirdly, the intervention group is compared to the control group in order to evaluate whether one group has performed better than the other and hence whether one treatment is more effective than another (Torgerson and Torgerson 2008). Figure 2.2 offers a schematic representation of the randomised controlled trial.