The role of psychological variables in the assessment and physiotherapeutic management of musculoskeletal disorders.

Klaber Moffett, Jennifer

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THE ROLE OF PSYCHOLOGICAL VARIABLES IN THE ASSESSMENT AND PHYSIOTHERAPEUTIC MANAGEMENT OF MUSCULOSKELETAL DISORDERS

Jennifer A. Klaber Moffett

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ABSTRACT

Physiotherapy is a health care profession that emphasises the use of physical approaches in the prevention and treatment of disease, pain and disability. Much of physiotherapy practice is based on untested methods, involving processes which are poorly understood. Most previous research has failed to take into account psychological processes when assessing the outcome of treatment, and little can be concluded from the results due to the shortcomings in design, such as the lack of adequate control groups and blind assessors. The aim of the present thesis is to apply scientific methods, using rigorously designed studies, 1) to test the efficacy of physiotherapy techniques aimed at pain relief in musculoskeletal disorders, and 2) to explore the role of psychological variables, in the development of musculoskeletal disorders and their treatment.

The relevant literature across several disciplines, which includes physiotherapeutic, medical and psychological research, is surveyed and reviewed, and underlines the paucity of well-constructed outcome studies.

The role of psychological variables in the development of musculoskeletal disorders and in the perception of physical symptoms such as pain is reviewed. Cognitive, behavioural and affective processes are considered in relationship to chronic pain, and the pain literature on anxiety, depression, helplessness, attitudes to health and locus of control is reviewed. The effects of the therapist-patient relationship are considered and the literature on the placebo response is overviewed, with special reference to physiotherapy practice and pain relief in musculoskeletal disorders.

Studies:
Firstly, the incidence of low back pain in student nurses was investigated in a longitudinal prospective study. Physical and psychological factors which may contribute to the reporting of low back pain in student nurses were studied and significant predictors were identified.

Secondly, a randomised controlled trial of mechanical cervical traction for patients with neck and arm pain, comparing it with a placebo control treatment mimicking traction, was carried out. Outcome of treatment was assessed by measures of pain, psychological functioning, functional ability, and range of motion, in a single blind study. Neither the assessor nor the patient was aware of the treatment allocation. Both the placebo and the weighted traction improved significantly following treatment on measures of self-reported pain and other related symptoms. But the differences
between the two groups did not reach statistical significance. In addition surface electromyography was used to investigate the effects of cervical traction on the neck muscles, and provided no support for the theory that cervical traction can be useful for facilitating relaxation of tense neck muscles.

Finally, a randomised double blind placebo controlled trial was conducted in two stages, to evaluate the effectiveness of pulsed short wave for pain relief in osteoarthritic hips and knees. In Phase I, a pilot study was carried out comparing three slightly different methods of application, prior to the main part of the study. Phase II then used these results to compare 1) active treatment with, 2) dummy treatment and 3) no-treatment. Outcome of treatment was assessed by means of pain reports including pain diaries, psychological functioning, functional ability, and range of motion. The results of this study provided no support for the use of pulsed short wave therapy for pain relief where patients are expecting surgery. Subjects who were not awaiting surgery regardless of whether they received placebo or active treatment reported significant improvements in pain scores.

The results of these studies are used to discuss the importance of psychological processes in physiotherapy and musculoskeletal disorders.
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DEDICATION

To Jonathan:

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CHAPTER ONE: INTRODUCTION

This thesis is concerned with investigating the role of psychological variables and their relationship to physical variables in musculoskeletal disorders, physiotherapy practice and clinical research. It concentrates on quantitative research, particularly the use of randomised controlled trials to study specific treatment effects and distinguish them from placebo effects.

Physiotherapy may be seen as a profession, in its adolescence. It is asserting itself and striving for autonomy. It is currently in the process of establishing a firm knowledge base. Since the readership of this thesis is expected to cross multidisciplinary boundaries, an attempt is made to provide background information and where appropriate a historical perspective aiming to put the research into context.

1.1 MOTIVATION AND BACKGROUND TO THE THESIS

Physiotherapy is a health care profession which emphasises the use of physical approaches in the prevention and treatment of disease and disability [76]. However, in this era of high technology treatments, it is important to take into consideration behavioural events which may promote ill health and undermine the effectiveness of treatment [287]. It is now recognised in allied professions, such as the medical and nursing professions, that any treatment outcome may be influenced by psychological factors [314]. In a recent report [76], the Chartered Society of Physiotherapy (CSP) further defines the physiotherapist's role:

"The analysis by Chartered Physiotherapists of their patients' physical problems takes account of the patient's current psychological, cultural and social factors, and is based on an assessment of movement and function. The aim is to identify and diagnose the specific components of movement or function responsible for the patients' physical problems. The skills and knowledge required to make such a diagnosis draw on the general corpus of knowledge and skills within the health professions, with a special emphasis on an understanding of the physical structure and function of the human body. Chartered physiotherapists use both specific treatments and prophylactic methods. The therapeutic modalities used by physiotherapists include movement, massage, and manipulation techniques, together with the application of electro-physical modalities. Physiotherapists must be skilled in the use of these, and in related educational and self-care approaches to prevent, cure or alleviate physical manifestations of somatic and psychological disease" (italics added).
Chapter One

Although in this statement the patient's psychological status is acknowledged, the wider influence of psychological processes such as the therapists' beliefs, attitudes, expectations and behaviour, and also the now well-documented potential influence of the therapist-patient relationship over a treatment outcome [247], [112], are not referred to. The CSP curriculum does not emphasise the need to consider the interaction of psychological processes with physical processes [424], [314], although they should be considered as an integral component in the successful rehabilitation of all patients. In a recent revision of the International Classification of Diseases of Mental and Behavioural Disorders [439] - page 5, the categories "Psychogenic" and "Psychosomatic" have both been omitted because of the different interpretations of the words in different languages and different psychiatric traditions. Also the use of the term "Psychosomatic" as a category would imply that "psychological factors play no role in the occurrence, course and outcome of other diseases not so described".

In musculoskeletal disorders, one of the commonest presenting symptoms is pain, and the individual's perception of this may be influenced by concomitant psychosocial and environmental processes. The pain experience is multidimensional e.g. [261], [394] and apart from the sensory components also has affective, behavioural and cognitive aspects, which need to be taken into account by any health professional assessing or treating a patient. Research, reported mainly in the psychological literature, has demonstrated that the development of pain and the individual's perception of it may be influenced by many different although often inter-related psychological variables. These include for example, anxiety [406], [357], [84], depression [373], [152], [236], expectations [209], [85], perceived control [315], [91], and self-efficacy [16], [303].

All these variables may be seen, not only as influences on the development of a painful condition, but also as potential mediators of the patient's response to treatment. If the psychological variables are seen to be effective in improving a patient's level of reported pain they are referred to as placebo effects.

An understanding of these factors is relevant both to the clinical physiotherapist and to research. It may be that an application of this knowledge can be used to increase the effectiveness of physiotherapy treatment, including the administration of physical modalities such as electrotherapy or traction. When clinical trials are set up these factors need to be taken into consideration, as discussed in reference to the clinical trials reported in chapters Six through to Nine of this thesis.
Introduction

1.2 AIMS

The aim of this thesis is to investigate the importance of psychological processes in physiotherapy management of patients with musculoskeletal disorders. Two approaches are used in this attempt. Firstly, relevant literature from medicine and psychology is surveyed and related to physiotherapy practice, to provide evidence of the likely interaction of physical and psychological processes. Secondly, randomised controlled trials of physiotherapy techniques and a longitudinal study of back pain in nurses, carried out by the author, demonstrate the need to pay attention to psychological variables. Without this very rigorous research methodology, incorrect conclusions could be drawn from the observation of patients, and their response to treatment.

1.3 OUTLINE OF THE THESIS

Having discussed the background and motivation of this thesis, the contents of the remaining chapters are outlined as follows:

Chapter Two discusses the development of the physiotherapy profession, and introduces reasons for consideration, of not only physical processes, but also the importance of the role of psychological processes. Physiotherapy practice and its general principles, as related to musculoskeletal disorders (MSD), are briefly discussed. A broad overview of progress in physiotherapy research in the evaluation of treatment is then provided, with particular regard to the methodology.

Chapter Three describes MSD in the context of physiotherapy and recent related quantitative research in physical therapy modalities. Studies of physiotherapeutic methods aimed at pain relief comprised of mechanical methods such as traction and electrotherapy which are considered relevant to this thesis, are reviewed.

Chapter Four then considers how psychological variables and the perception of pain and physical symptoms may be associated with the development of MSD. The literature on chronic pain and its relationship to anxiety, depression, helplessness, attitudes to health, and locus of control are reviewed. The physiotherapist's influence on the behavioural response of the patient and the importance of the therapist-patient relationship are reviewed from the scientific literature. Psychological responses to physical treatment, such as an improvement in reported levels of well-being, are discussed. The relevant pain relief and placebo literature is then briefly reviewed.
Chapter One

Chapter Five reports a longitudinal prospective study of low back pain in student nurses looking at physical and psychological factors which may contribute to the reporting of back pain. The results of this study have previously been published in [231].

Chapter Six reviews important considerations in designing a randomised controlled trial that will stand up to scientific scrutiny. This is in part based on a paper by the author [226].

Chapter Seven reports a randomised controlled trial of mechanical cervical traction, for patients with neck and arm pain, comparing it with a quasi-placebo control treatment mimicking traction. Outcome measures including subjective pain reports, measurement of Range of Motion of the neck, state and trait Anxiety Inventory scores and the General Health Questionnaire are used to evaluate the clinical effectiveness of cervical traction. This study has previously been reported in [229].

Chapter Eight reports a study carried out on a sub-sample of patients with neck pain to evaluate the effects of cervical traction on the neck musculature. The activity in these muscles is assessed using surface electromyography (EMG) recordings. Regression analysis is used to investigate the relationship between this physiological measure and the psychological measures referred to above in the summary of Chapter Five. The results of this study have been reported in [230].

Chapter Nine presents the overall rationale for a randomised controlled trial to evaluate the effectiveness of pulsed short wave in pain relief for patients with osteoarthritic hips. A double blind design is possible since during active treatment the patient does not feel any sensation such as heat. It is therefore possible for the assessor to be blind to the treatment allocation. This chapter describes the methodology and findings of Phase I of the study. This preliminary trial was necessary to determine which application to use in the main study. It also serves as a pilot study, prior to commencing Phase II.

Chapter Ten reports the results of the main part (i.e. Phase II) of the placebo-controlled randomised controlled trial of pulsed short wave aimed at pain relief for patients with osteoarthritic hips or knees. The results are discussed and interpretations are provided which may further our understanding of the link between physical and psychological processes in physiotherapy.
Chapter Eleven summarises the results of the previously reported studies taken as a whole and discusses these findings in the light of current research. Implications for further research are reported.
CHAPTER TWO: OVERVIEW OF CURRENT PHYSIOTHERAPY PRACTICE AND RESEARCH

2.1 THE DEVELOPMENT OF PHYSIOTHERAPY AS A PROFESSION IN THE UK

In order to appreciate the current position of physiotherapy in the health care professions in the UK, the development of the profession will be traced from its origins, and then physiotherapy education will be discussed, before going on to consider a scientific basis for the profession.

2.1.1 Origin of the Profession

Historically, physiotherapy in the UK is derived from remedial massage. The Chartered Society of Physiotherapy was founded in 1884 by four nurses who were keen to restore the reputation of massage as an "honourable profession" [74]. Highly colourful accounts of massage parlours appeared in the newspapers causing them to fall into disrepute. Today there are about 25,000 chartered physiotherapists, 12,000 of which are currently employed in the National Health Service hospitals [334]. Physiotherapists also work in Health Centres with General Practitioners, in schools, in the community, in industry, in private practice, or in sport. Most work closely with other members of the medical team and specialise in orthopaedics, rheumatology, neurology, cardiac rehabilitation, paediatrics, respiratory problems and many other areas. Mainly due to historical precedent, the majority of the profession is female, and it is possible that its development has been handicapped by the common occurrence of members leaving the profession soon after qualification to start a family.

2.1.2 Physiotherapy Education

In Britain physiotherapy education has since 1988 progressively moved from hospital-based training, to the more academic environment of universities and polytechnics, and by 1992 all pre-registration education in physiotherapy was degree-based. A recent report on physiotherapy education [75] stated that: "This very rapid development-only five degree courses existed three years ago-has often been achieved in the face of opposition from Regional Health Authorities, but it now appears to be widely accepted that physiotherapists should and must receive degree based education if they are to adapt successfully to the changing health care environment". Physiotherapy education has therefore changed from Diploma courses to Bachelor of Science degree courses and to problem-based learning which is more likely to encourage a critical approach. The requirement of the BSc course includes a small-scale research project and the
present curriculum aims to encourage a critical and evaluative approach to physiotherapy practice.

2.1.3 A Scientific Basis For Physiotherapy

The CSP Curriculum of Study [76] sets out a list of subjects to be studied under the heading "Scientific Basis of Physiotherapy" which are anatomy, physiology, general pathology, human growth and development, behavioural sciences and scientific principles underlying the uses of physiotherapy modalities. Under the heading "Behavioural Sciences" (p.20) the study of relevant psycho-social theories of health and behaviour and the causation of ill-health is referred to. Knowledge of learning processes, skill acquisition, motivation, self-image, body image, cultural differences and communication skills are all acknowledged as important for the physiotherapist to exert a positive influence on the rehabilitation process. A further ten points under "Indicative Content - Behavioural Sciences" are included [76].

Physiotherapists are currently developing their profession and striving for autonomy. It is however recognised that this process of evolution depends on the profession defining a body of knowledge to establish physiotherapy as a unique clinical science [24], [97], [291]. The importance of research has been acknowledged by the Chartered Society of Physiotherapy for some time. A 1976 editorial in the Physiotherapy Journal [319] made the statement that "No discipline today can hope to defend itself effectively against scepticism unless its treatments are based on scientific proof established by experimental research". However, nearly twenty years on, quantitative assessment in physiotherapy is still in an early stage of development.

The Chartered Society of Physiotherapy has demonstrated its positive attitude to research, by the establishment of a Physiotherapy Research Foundation in 1989, aiming to encourage research. A recent report states that "Critical appraisal and objective analysis of outcomes are now accepted as fundamental and necessary to practice" [77]. Attempts are being made to evaluate all aspects of the clinical field so that physiotherapy methods may be based on research instead of anecdote and received wisdom of traditional methods. Many analogue studies have been carried out by undergraduate physical therapists, as part of their qualification for a BSc degree (vide 2.3.2). This type of study design in lieu of patients, uses normal subjects, often fellow students, on whom different methods of treatment are experimentally tested. The findings from a such a study cannot be directly generalised to the therapeutic situation, although it may provide some information about responses to particular treatment modalities.
Clinical research is needed to provide a sound scientific basis for physiotherapy practice [15], and also to ascertain which are the most efficient and cost-effective methods of achieving our goals. The government White Paper on the NHS reforms, makes this particularly pertinent at this time. [100]. A more recent Department of Health sponsored paper concludes that "for the NHS, the ethical imperative is to encourage the research necessary to know how to use its limited resources to the best advantage of all in its care" [5].

2.2 PHYSIOLOGICAL AND PSYCHOLOGICAL PROCESSES IN PHYSIOTHERAPY

The overall aim of physiotherapy is to obtain or maintain maximal physical function and relieve pain. Physiotherapy methods are based on movement, manual therapy and physical agencies [74].

Owing to its close links with the medical profession, physiotherapy has until recently adopted a strictly biomedical model. This is based on the principle that disease and disability arise from deviations in normal physiology and does not take into account psychology and human behaviour. It is associated with the dualist theory described by Descartes in the seventeenth century. This philosophy until quite recently was adopted in medicine and encouraged Western Society to think of Mind and Body as two separate entities [14]. This principle was encouraged by ever increasing specialisation in the sciences. Although the importance of psychological processes in medicine is usually not denied, their relevance is not always considered.

There is still a tendency amongst many practitioners and researchers to categorise patients into those whose problem stems from the mind and those whose problem arises from the body. Particularly in back pain, many attempts have been made to label patients as "organic" or "functional", depending on whether or not a physical foundation for the problem can be found. However, this dichotomy appears to be neither conceptually valid nor of practical value [346], [293], [424] and it has been suggested that this distinction should be discarded in favour of an approach which also assesses current emotional stressors and available coping mechanisms.

The more recent biopsychosocial model of medicine puts equal emphasis on biological, psychological and environmental factors in the interpretation of illness and pain [354], [134], [410]. The persistence and or severity of pain reported by a patient may be difficult to understand in terms of its aetiology and natural history alone. Psychological processes such as symptom perception, behavioural change, and attitudes and beliefs about health and health care need to be taken into account in all patients [372], [346].
In the presence of powerful reinforcers in the patient's environment, such as for example an over-solicitous partner, pain complaints may persist long after the healing time of the tissues. The alteration of social contingencies plays a primary role in successful treatment [139], a point which will be taken up again in sections 4.3. and 4.4.

Many experienced clinicians agree that physiotherapy, although primarily based on physical processes, is influenced by psychological processes. However, a brief search by the author, for physiotherapy textbooks housed in the library of a London teaching hospital, revealed a very limited mention of "Psychology", "Behavioural Sciences", or "Cognitive Factors". Ten textbooks from before 1980 were searched for these words or other closely related words (e.g. "Emotional", "Placebo") in the indices where they only appeared a total of 17 times, in the bodies of the books where they appeared on a total of 19 pages. Ten post-1980 textbooks included six mentions of the relevant words in the index and they appeared on 88 pages, 81 pages appearing in just two of these books. Four of these recent books did not mention any of the relevant words. A standard textbook entitled "Psychology for Physiotherapists" [117] fails to point out the influence of psychological variables on physical symptoms. It also omits to discuss the influence of psychological factors in response to forms of physical treatment. The word "placebo" does not appear in the index.

By contrast, in a standard textbook used by medical students "Psychology Applied to Medicine", pain is used as a model to illustrate the importance of considering both physiological and psychological processes in health and disease [424]. If the role of psychological variables is not taken into account in evaluating the outcome of treatment, such as pain relief or increased functional ability, causal effects may be misinterpreted [336], [226]. For example, if the potency of the placebo effect is not taken into account false conclusions may be reached about the process of a particular form of physiotherapy, as discussed in section 4.5.

2.3 CURRENT STATE OF PHYSIOTHERAPY RESEARCH IN TREATMENT EVALUATION

2.3.1 Research Methodology

Many different types of research strategies may be appropriate to evaluate physiotherapy treatment, depending on the research question. Physiotherapy may be considered as both an art and a science and its evaluation may therefore require a multidimensional approach. This thesis is concerned primarily with quantitative research, but acknowledges that both qualitative and quantitative methods may add to
Chapter Two

the body of knowledge. Probably a combination of the two will provide the greatest progress [362].

2.3.1.1 Qualitative Research Methods

The purpose of qualitative research is to explore a process or a concept, and it may be a useful and necessary tool to use prior to quantitative analysis. One example of qualitative enquiry ethnography, which was originally developed in the field of social anthropology, and has also been used extensively in educational and nursing research [37], [385]. It is claimed to be useful in studying human behaviour from the perspective of those persons being studied [6]. It could therefore be applicable to the study of processes in physiotherapy where human behaviour and relationships are of paramount importance [352].

Qualitative methods have the advantages of being more flexible and allowing more for the complexities of real life situations compared with quantitative research methods. Proponents claim that far "richer" information may be gained through this more natural method with the observer acting as the research instrument and constantly "reflecting" on the process [204]. However, because of its flexibility, the validity and reliability of the method may be questionable. Threats to validity such as observer effect and observer bias are dealt with, it is claimed by thorough data-collection processing, spending sufficient time in the field, establishing trust with the individuals observed, use of multiple data sources and the collection of confirming and disconfirming evidence. However, it seems likely that prolonged and intense involvement in the clinical setting would increase the observer bias but not systematically, so that it would make it impossible to make appropriate allowances or in some instances even to recognise it. The researcher in qualitative research is the instrument and constantly tries to interpret the data. The validity of the work depends on their identifying the potential sources of bias due to the inherent subjectivity of the process but this in turn requires considerable insight on the part of the researcher. External validity may be threatened as it may be difficult to generalise the findings to any other situation than that which is described. Qualitative research may be thought of as inductive research and exploration and may be used as a preliminary to the deductive approach of quantitative research.

2.3.1.2 Quantitative Methods

Quantitative research employs the more traditional scientific approach of testing a hypothesis based on a given theory. It encompasses many different methodologies. The research design may be descriptive or manipulative, retrospective or prospective,
cross-sectional or longitudinal. An example of a longitudinal, prospective study can be found in Chapter Five: "A study of back pain in student nurses". This is a correlational study aiming to find out which physical and psychological characteristics are associated with back pain reports.

Most of the other studies reported in this thesis (Chapters Seven through to Ten) are randomised controlled trials (RCTs), a design which provides a rigorous model for clinical trials. They use the classical experimental paradigm where the effects of different interventions on the same population are compared, under controlled conditions. Using the null hypothesis, the aim of such a study is to see whether any statistically significant difference in outcome between the two or more groups can be found. Even with the most rigorous use of scientific inquiry it is not possible to actually prove any form of treatment is effective. It is only possible to demonstrate that there is a high probability that it is effective. Objectivity can be maximised in a randomised clinical trial by making sure wherever possible that the observer or assessor is "blind" to which treatment group the patient attended. The strengths and weaknesses of the RCT in the evaluation of rehabilitation are discussed in a series of invited papers forming part of a symposium on research methodology [226], [155], [12]. These papers aim to complement standard textbooks on clinical trials [278], [323], which are mainly aimed at drug trials, to which the design readily lends itself. In the field of physical therapy where "hands-on-treatment" is often guided on a completely individual basis according to the therapist's assessment for the patient's needs at that moment, it is more difficult to apply this model. However, there are some aspects of physiotherapy where the treatment is more clearly defined and the treatment is administered via a mechanical device that can be quantified. Chapters Seven through to Ten report studies to evaluate mechanical traction and an electro-magnetic field aimed at pain relief, both of which are well-suited to the model of a RCT.

Quantitative research in the clinical setting has the disadvantage of being much more restrictive than qualitative research. Once the population and all the relevant variables are defined they cannot in any way be changed even if a very good reason for doing so becomes apparent half way through the study. The protocol has to be strictly adhered to, and both the validity and reliability would be threatened if this was not the case. Many decisions about how the treatment is to be given have to be laid down before starting the data collection. Flexibility is then sacrificed in order to control as many variables as possible. In quantitative research the diversity of human behaviour and interaction is usually considered as a confounding variable that needs to be controlled as efficiently as possible.
Chapter Two

This thesis is concerned with quantitative methods of research which can be used to measure the effectiveness of different methods of treatment used in physiotherapy. Based on numerous well-designed experimental studies it should be possible to build up a body of knowledge based on firm and objective evidence. The requirements of a rigorously designed RCT to evaluate physiotherapeutic outcome are discussed in Chapter Five.

2.3.2 Progress in Quantitative Physiotherapy Research

As an attempt to assess broadly the progress in quantity and quality of physiotherapy research carried out in the last decade, the author carried out a brief review of three of the core journals comparing 1978 and 1979 with 1988 and 1989. The journals reviewed were Physiotherapy, the British journal published by the CSP, Physiotherapy Canada, and Physical Therapy, the journal of the USA. They were selected as they are three of the most widely available journals which existed prior to 1980.

Papers were surveyed if they were considered "Quantitative research related to treatment" and were analysed more closely if they were "Clinical trials". The following operational definitions were used:

1) "Quantitative research related to treatment": Research aiming to investigate the effects of different methods of physiotherapy management. This included all studies where research questions were addressed concerning the effects or processes in clinical outcome of treatment such as analogue studies, reliability studies, descriptive studies of the process of the tissue response to trauma or disease or treatment, surveys, correlational studies, single case studies, and clinical trials.

2) "Clinical trials": As above using a clearly defined population to study effects of treatment.

The results of this survey are tabulated below in tables 2.1 and 2.2 and show an increase in the output and the quality of the research in the last decade.

The large proportion of recent analogue studies mostly using students as subjects rather than patients, reflects both the requirements and the constraints of physical therapists in carrying out small research projects as part fulfilment of an MSc or BSc course. The lack of randomised controlled trials is at least in part due to the fact that most physiotherapy research, especially in the USA, has been carried out in colleges and schools of physiotherapy where the researcher was actually employed as a lecturer. In this capacity the individual was encouraged to conduct research. However there
Table 2.1 Quantitative research reports related to therapy, comparing 1978/79 with 1988/1989 in 3 core physiotherapy journals

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<td>Physiotherapy</td>
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<td>Physiotherapy Canada</td>
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<td>25</td>
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<td>Physical Therapy</td>
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<td>126</td>
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Table 2.2 Clinical trials related to physiotherapy reported in 3 core physiotherapy journals, comparing 1978/79 with 1988/1989

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<tr>
<td>Physiotherapy</td>
<td>2 (not controlled)</td>
<td>4, (1 controlled, 1 within subjects design)</td>
</tr>
<tr>
<td>Physiotherapy Canada</td>
<td>2 (not controlled)</td>
<td>6, (5 controlled)</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>11, (4 included a control group, 3 attempted to match groups, 3 within subjects design)</td>
<td>10 clinical trials with control groups, (7 with random allocation but none mention &quot;blind&quot; assessment), 18 analogue studies using &quot;normals&quot; or animals, (5 within subjects design).</td>
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were practical constraints. Apart from time constraints, being university-based and not hospital-based they may not have had ready access to patient populations that are necessary for the setting up and running of a randomised controlled trial.

All these factors which in the past were associated with the limitations of research in the USA, are now relevant to physiotherapy research in the UK, since all the courses here are now university-based. In this country however there is one possible advantage; historically most schools of physiotherapy have direct or close geographical links with hospitals. In fact many schools still function primarily within the hospital site, having established the necessary academic links with a university to provide the designated input for a BSc degree course.

The next chapter is concerned with a broad overview of the musculo-skeletal conditions commonly treated by physiotherapists for pain relief. The literature relating to pain relief in these conditions using ultrasound, transcutaneous electrical nerve stimulation (TNS) and Low Intensity Laser Therapy (LILT) is then critically reviewed.
3.1 CATEGORIES OF MUSCULOSKELETAL DISORDERS TO BE STUDIED

Musculoskeletal disorders (MSD) include a wide-ranging number of different conditions. According to the International Classification of Diseases (ICD-9) [438], MSD includes conditions ranging from relatively minor localised disorders such as Achilles tendinitis to systemic joint diseases such as rheumatoid arthritis. Recent trauma and congenital problems are not included under this classification, whereas mechanical problems associated with repeated minor trauma and/or an inflammatory process are included. The latter may be manifested as a primary process e.g., rheumatoid arthritis or a secondary process in degenerative conditions e.g., osteoarthritis [368], [329]. MSD affect all age groups, causing a great deal of suffering particularly as a result of loss of mobility [216]. They cause more sickness absence than any other physical condition, including hypertension, heart, gastrointestinal, kidney and pulmonary problems [349]. MSD probably form the majority of the work load in most out-patient physiotherapy departments and fifteen percent of all GP consultations [174]. The total cost of these conditions in the working population in the UK has been calculated at £25 billion per annum [209], [190].

This thesis is limited to the scientific assessment and physiotherapeutic management of MSD. In order to put the research reviewed into context for a multidisciplinary readership, MSD will be considered under the headings of soft tissue damage and repetitive strain, osteoarthritis, rheumatoid arthritis, low back pain, and neck pain. A brief overview of the aetiology and epidemiology of each group of these conditions will be included. This is then followed by a review of recent clinical trials investigating the use of different electrotherapy modalities for pain relief in MSD, in the second part of this chapter (section 3.2).

3.1.1 Soft Tissue Damage and Repetitive Strain

Soft tissue damage and repetitive strain include any MSD affecting the capsule of the joint, muscle, musculotendinous junction, fascia or ligaments. The problem may arise from overuse of tendons, for example in the wrist and forearm, often associated with keyboard operators and assembly line workers [318]. Pain and dysfunction may be severe due to inflammation of the tendon sheath, but is eased by resting that particular structure. Continued use of these tissues may lead to thickening of the tendon sheath.
and a chronic, persistent problem. It may also affect other parts of the body such as tendons associated with the shoulder and the knee, conditions which are the subject of some of the clinical trials evaluating different methods of pain relief discussed below.

MSD of the soft tissues are not only associated with repetitive strain but also degeneration, as with some common conditions of the shoulder for example. The aetiology of shoulder conditions such as frozen shoulder and rotator cuff syndromes is poorly understood, although they are clinically well known to cause considerable pain and disability. "Frozen shoulder" which is characterised by a painful restriction of both passive and active movement in all directions has a characteristic self-limiting natural history. This can be divided into three phases: 1) painful, 2) adhesive, 3) resolution [298]. The mean age of onset of this condition is 60 and it is rarely seen in people younger than 40, implying an association with the ageing process and degeneration. Rotator cuff disorders of the shoulder are somewhat better understood and more localised. Cadaveric studies in conjunction with biomechanical studies have provided evidence of its aetiology. It is probably associated with degenerative changes on the underside of the acromion and reactive inflammatory bursa resulting in impingement of the rotator cuff muscles during elevation of the arm [42]. Chronic irritation is exacerbated by the poor blood supply of the tendons, particularly the supraspinatous and bicipital tendons, which become inflamed, and gradually attrition, bursal thickening and fibrosis occur [52]. It is sometimes associated with injury in younger people, otherwise wear and attrition do not normally cause a full-thickness tear of the rotator cuff muscles until the age of 50 or 60. The soft tissues which maintain the integrity of the shoulder joint appear to be particularly vulnerable at this age. It is also worth noting that it is the only joint in the body from which is suspended a dependent weighty structure.

3.1.2 Low Back Pain

Back pain is a very common problem which by the age of 65 has probably affected 90% of the population at some stage in their lives [242]. By this age it seems that the prevalence, at least in men, decreases [242] and it appears to peak between the age of 45 to 55 years [223], [192].

Back pain is a symptom and not a disease. It is often defined as pain which a patient reports as emanating from an area between the gluteal folds below, and the vertebrae prominens above, [9]. But this includes upper back pain and may also include "neck pain". Low back pain is more often separated out as being limited above, by the lower border of the rib cage [341], [343], [421].
Chapter Three

Classification and diagnosis of the problem are a major stumbling block for the researcher, the clinician and the patient [289]. Epidemiologists and clinicians use different methods of classification. It seems to be widely accepted that only around 5-15% of back pain cases can be reliably diagnosed in a clinical setting [295], [107], [289]. So it is generally very difficult for the clinician to assign precise and appropriate methods of treatment. A variety of different methods of treatment may be tried, which is costly and may not influence the natural history at all [428], [289].

It has been estimated that patients presenting to a GP with clear cut signs of a prolapsed intervertebral disc (PID) represent only 5% of all back pain patients [343]. This is the condition which is generally thought to be very common and is often referred to as a "slipped disc", a term which leads to many misconceptions. The disc itself does not get displaced; rather, some of its contents may break through the tough annular wall of the disc if this is fissured. If the nerve root is embarrassed, pain and other unpleasant sensations may be felt in the leg, and sensory and/or muscle power may be reduced in the related dermatome. It is less common after the age of 40, probably because of the loss of turgor and elasticity in the discs with increasing age [216], [196].

Another cause of back and leg pain, accompanied by narrowing of a disc space as seen on pain radiographs, is disc degeneration. This is present in 90% of the population at least to some extent by the age of 40 [401]. This is termed lumbar spondylosis and is common in middle years, being associated with degenerative changes of the intervertebral disc at multiple levels of the spine. It is part of the ageing process which begins before the second decade. At a later stage osteoarthritis of the facet joints occurs, but it does not invariably give rise to pain [242], [326].

The natural history of mechanical low back pain is self-limiting, with only 10% of cases not having resolved within one month [113]. After 6 months only 7% still have back pain, but it is these remaining people with back pain who account for the very high cost of the problem, both in terms of personal suffering and economic loss to the country as a whole [216]. Much research on back pain has been carried out, but both its development and its effective management are not well understood [409], [289].

The prevalence of back pain peaks in middle age, in worker's most productive period, and it accounts for more sickness absence than any other physical condition. During the second half of the 1980s, the number of certified days of incapacity due to back
pain in the UK rose by 69%. By the end of the decade, back pain accounted for 13% of all certified days of incapacity [103].

It is noteworthy that a number of studies have shown that psychosocial factors may be more predictive of disability associated with back pain than physical or biomechanical factors [263], [166], [413]. An acute onset of back pain or sciatica may cause severe pain making any movement of trunk difficult and frightening. Fear of causing further damage may produce long lasting repercussive effects, contributing to the pathogenesis of a chronic back pain problem [225]. Fear and pain are physiologically linked as shown by the classical experiments with Pavlov's dogs and the importance of the learning process in the development and perception of pain [137] will be discussed further in the next chapter.

3.1.3 Neck Pain

Neck pain which emanates from the cervical spine is almost as common as back pain [318], and forms a large part of a physiotherapist's work load. It is often considered by clinicians to be associated with tension, stress and anxiety, but research on neck pain is sparse [325]. According to a study carried out in Sweden, 50% of the general population may suffer from neck pain at some stage in their life time [196], but industrial and forest workers reported a much higher prevalence rate of 80% [197].

Workers who habitually adopt a static sedentary posture where the eyes are fixed in one position whilst performing a task with the hands also placed in a single fixed position, are notably much more at risk of developing neck pain [168]. People who have plenty of opportunity of moving around and also are able to socialise with other people are less at risk [318].

The neck is comprised of cervical vertebrae which are much smaller than the lumbar vertebrae and are vulnerable to mechanical strain. It is an unusually mobile structure and supports the head which weighs about 5-6 kilograms. Problems in the neck most commonly arise at its base where it joins the relatively rigid structure of the thoracic spine and rib cage.

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1Source note: A 1% Department of Social Security sample of claims to sickness and /or invalidity benefit which excludes days of incapacity where Statutory Sick Pay is claimed from the employer and most short spells of incapacity covered by self-certification.
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Cervical spondylosis is one of the commonest causes of neck pain in patients attending a physiotherapy department [229] and its aetiology is similar to lumbar spondylosis in the back. It is due to wear and tear which is accelerated by instability, repetitive loading or injury to the intervertebral segment [66]; Although X-rays showing signs of degeneration in cervical vertebra are not likely to improve over time, it has been found that patients' symptoms, even if they are of many years duration commonly do improve with time regardless of what treatment is given [56]. Further evidence for this view is provided by a study reported in Chapter Seven. The nerve root may be embarrassed as it emerges between the vertebrae, resulting in pain and/or loss of power in the muscles supplied by the effected nerve. This condition is referred to as a cervical radiculopathy and patients with this often very painful condition may seek pain relief from a physiotherapy department, cervical traction being one of the most likely forms of treatment to be offered, as described further in Chapter Seven. If the spinal cord is embarrassed by impingement of bony or soft tissue in the spinal canal, the resulting condition is likely to be more serious and is outside the scope of physiotherapy. This is referred to as cervical myelopathy and a patient with this condition needs to be very carefully observed and investigated by medical specialists to limit its progression.

3.1.4 Osteoarthritis

One of the most ubiquitous conditions under the heading of musculoskeletal disorders is osteoarthritis (OA), also known as osteoarthrosis. It is usually referred to as osteoarthritis although in fact this term does not describe the condition as accurately. Unlike rheumatoid arthritis discussed below (vide 3.1.5), it is not primarily a disease of inflammation, although low grade inflammation is associated with the process of joint degeneration [387], [368]. It is a condition affecting synovial joints, involving remodelling of the bone and degeneration of articular cartilage as a response to wear and tear. The process starts in the second decade and by the age of 40 according to autopsy studies is evident in weight-bearing joints in 90% of the population. It is associated with pain emanating from the joint which is often referred into distal muscles, deformity of the affected joint and progressive loss of function. Early changes in the articular cartilage cannot be detected on X-ray [387]. Later stages of the condition involve increased density of the bone and remodelling of the bone as a response to a change in joint biomechanics. Soft tissues are also affected at this stage. The tissue of the synovial membrane and capsule of the joint becomes vascular and thickened, which may give rise to deformity. The associated muscle atrophy is due at least in part to disuse, but may also be a specific effect of OA [387]. Immobilisation of a joint results in loss of Type I muscle fibres, whereas in OA muscle weakness is
associated with a loss of Type II muscle fibres [238]. There is no known neurogenic component of the muscle wasting. Pain may arise from stimulation of the nociceptors within the capsule, ligaments, periosteum, fascia, and blood vessels as a result of distension and secondary inflammation.

Only 30% of people with radiographic evidence of degenerative joint changes complain of concomitant pain [397], [277], [43]. This poor correlation between X-ray changes and pain reports complicates the diagnosis and management of these patients [145]. It has also hindered the progress that can be made in medical research.

Mechanical factors such as wear and tear, previous inflammatory joint conditions, injury to the joint, prolonged pressure, prolonged immobility, and ligamentous laxity may all contribute to the development of osteoarthritic joints [277]. In the hip joint for example, the childhood conditions of slipped upper femoral epiphysis, Perthes disease, and congenital dislocation of the hip (CDH) may give rise to osteoarthritis of this joint [216].

Epidemiological studies provide some evidence of the association of specific occupations with prevalence of one particular set of joints affected. Different repetitive tasks and their association with specific joints affected have been investigated. Hadler [175] in a study of workers in a textile factory found that task-related impairments were consistently associated with a repetitive stereotyped usage of the hand, which was more evident in the right hand. Miners have been found to have a high prevalence of OA of the elbow and knees [240], and cotton pickers a high prevalence of OA of the fingers [241]. Jurmain [213] carried out a large anthropological survey, comparing remnants of ancient populations' skeletons and lifestyles with recent ones and found a link, between the physical strains their bodies had to withstand and the prevalence of OA.

A number of studies provide evidence of degenerative joint changes associated with excessive or competitive use in sport. For example, Lee et al [243] reported associations of OA of the ankles, foot and knees in soccer players, OA of the shoulders and elbows in baseball pitchers, OA of the patellofemoral joints in cyclists, and OA of the hands in boxers.

However, other studies have provided contrary evidence and concluded that regular competitive sporting activities are not necessarily associated with an increased prevalence of OA [440], [148]. According to Medsger & Masi [277], who used loss of joint space as the criterion for the presence of OA, there is little evidence of the deleterious effect of exercise. Professional runners for example do not have a high
prevalence of OA hip [328]. It seems likely that the risk is increased where the joint surface is disrupted, for example following meniscectomy [294] or disruption of the articular cartilage itself.

3.1.5 Rheumatoid Arthritis

Rheumatoid arthritis (RA) unlike OA is a systemic condition involving an inflammatory process [368]. It mainly affects connective tissue, particularly the synovial membrane associated with the joints. It has a variable course and may start typically with the small joints of the hand and feet and progress on to affect the joints of the elbow, knee, shoulder and hips, usually in a symmetrical pattern [216]. Unlike osteoarthritis it is a generalised condition which may also be associated with loss of appetite and weight, malaise and depression. Pain and limitation of movement may give rise to severe disability, although the course of the disease is quite variable. In rheumatoid arthritis patients seen at hospital and followed up for six years only 24% were able to carry on with normal activities, 40% were moderately incapacitated, 26% became more severely crippled and 10% had become dependent on others [118]. In studies of rheumatoid arthritis in a general population the progression of the condition did not appear to be so relentless although this discrepancy is partly due to limitations in definite diagnoses of the condition [7].

There is a higher prevalence among women, as confirmed by a large scale survey carried out in the USA [299], of 4.6% compared to 1.7% in men. In spite of a great deal of research in the area, the aetiology of rheumatoid arthritis is not well understood. It is thought that there is a hereditary link and also that the auto-immune response may be a significant factor in its development [216].

Also psychological factors have been suggested to play a role in the development of the condition as discussed by Anderson in a review article [10]. More recently it has been demonstrated that a cognitive-behavioural treatment programme can influence the disease symptoms in rheumatoid arthritis [304].

Rheumatoid arthritis is a condition which physiotherapists often treat, and painful joints caused by RA have been the subject of a number of clinical trials discussed below in section 3.2.

3.2 Methods of Pain Relief for MSD in Physiotherapy

Although movement, exercise and patient education are major components of a physiotherapist's toolbox and are used in a large variety of different ways for the treatment of MSD as well as many other neurological and systemic disorders, they are
outside the remit of this thesis. In this present work we are concerned with the
evaluation of methods of pain relief used by physiotherapists for patients with MSD,
through the administration of various physical modalities. Various forms of
electrotherapy are included in these categories, and so for example is mechanical
traction for spinal pain. Studies of cervical traction will be discussed further in Chapter
Seven.

A variety of different forms of electrotherapy are used, aiming to provide pain relief
either directly or indirectly, by reducing swelling and inflammation. Electrotherapy by
definition, implies the use of electronic equipment usually with a complex system of
dials and switches and may therefore be associated in the patient's mind with "hi-tech"
wizardry. The placebo effects associated with the use of these machines for pain relief
are likely to be an important factor. One might expect that work in this field, which is
associated with electronic engineers and physicists, would have been subjected to
rigorous scientific scrutiny and evaluation. Chapters Nine and Ten describe a study to
evaluate one such mode of treatment, pulsed short wave (PSW). Other forms of
electrotherapy used for pain relief in MSD are discussed below, in an overview of the
research literature under the headings, ultrasound, transcutaneous electrical nerve
stimulation (TNS), and laser therapy.

3.2.1 Ultrasound

This method of treatment, which is claimed to have a healing effect on the tissues and
provide pain relief, is widely used by physiotherapists. The equipment consists of a
treatment head or applicator which is applied to the skin either with a coupling agent
or in water. The treatment head consists of a transducer which causes a small ceramic
crystal to vibrate and produce ultrasonic waves. Animal studies have provided
evidence of a healing effect, which may be related to the thermal effects, but also
physiological non-thermal effects have been demonstrated on animals [119]. In a
recent review article on therapeutic ultrasound, Kitchen & Partridge [221] cite no less
than 113 papers on the use of therapeutic ultrasound. However they are nearly all
either descriptive studies, or animal studies investigating the physiological effects on
the tissues of rabbits, or rats. Only seven are controlled clinical trials. In one of these
[434] the dosage used in the treatment of ankle sprains is not detailed, and therefore
could not be replicated. Three studies carried out to study the effects of tissue healing
vary in the rigorousness of the research design [339], [273], [65]. Roche and West
[339] carried out a small randomised study (n=26) of patients with venous ulcers and
claimed that the healing was statistically significant at the end of the 14 days of
treatment in patients who had received the active treatment, but not in patients who
Chapter Three

received the sham application. However, they do not report differences between the groups. Also the study was flawed by the lack of blinding, neither the therapist nor the assessor being blind to the treatment allocation. Callam [65] in a similar group of patients with leg ulceration (n=56), failed to blind the therapist and assessor, and also failed to provide a placebo control group. He reported significant differences between the groups, but because of the defects in the study design the results need to be interpreted with caution. In a rather more rigorous double blind placebo controlled study, McDiarmid [273] had previously reported the effects of ultrasound on patients with pressure sores (n=40). They found small differences in favour of the active treatment which did not reach statistical significance.

Holmes [195] in a critical review of clinical trials of ultrasound (US) for soft tissue injury, cited 55 papers but of those which used US without combining it with other treatments he found only 3 studies without major flaws. Two double blind randomised controlled trials carried out on tennis elbow investigating the effects of pulsed US on grip strength, weight tests, pain were reported, with contradictory findings [47], [176] Binder and colleagues [47] found that the treatment group did significantly better compared to the placebo control group (n=38) on these outcome measures, whereas Haker & Lundeberg [176] in their study (n=43) did not obtain positive findings in favour of the active treatment. Neither did Lundeberg et al [255] using the same outcome measures to investigate the effectiveness of continuous US for pain relief for tennis elbow. These last two rigorously controlled studies carried out on patients with tennis elbow failed to provide evidence for the usefulness of US for the relief of pain in tennis elbow.

Closer scrutiny of Binder's reported findings [48] suggests that although they are published in a prestigious and widely read journal they should be interpreted with caution. Baseline data are not provided, so it is not possible to check that the two groups were comparable and in addition the randomisation procedure is not properly described, and this may have provided a source of bias in favour of the treatment group. There may have been other potential sources of bias. It is not certain that the treating physiotherapist was unaware of the treatment modality, as a special switch had to be manipulated by a therapist depending on whether the active or sham mode was being administered. Also, it would have been reassuring to know that the testing of the machine for output which was repeatedly carried out, was never done in the presence of the patient or the treating physiotherapist. Under such conditions it could be difficult for them both to remain blind to the treatment allocation.

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From this review of the literature, it appears that the most rigorously controlled trials of US for tissue healing and pain relief, failed to provide differences in treatment outcome comparing active and dummy applications of treatment. Evidence of the effectiveness of US for pain relief in MSD therefore remains doubtful.

3.2.2 Low Intensity Laser Therapy

Therapeutic "Low Intensity Laser Therapy" (LILT) is a popular form of electrotherapy with physiotherapists who have found it to be an effective method of pain relief [31]. As with other equipment for administering electrotherapy this has fuelled extravagant claims by the manufacturers. In contrast to surgical lasers LILT does not normally raise the body tissues by more than 1°C [203]. The photobiological effects are not well understood but animal studies have provided some evidence for a role in accelerating wound healing and in pain relief [180].

A quantity of research papers on the topic abound but they are mainly published in specialised laser journals, and are often only available in abstract format or in a foreign language [31]. Very few controlled trials of laser therapy for pain relief exist. A number of different methods of application are used. Popular methods include Helium-Neon (He-Ne), Gallium-Arsenide (Ga-As) and also infrared. Dosages used also vary and the combination of these all these different parameters make comparison of research results very difficult.

Early studies by Walker et al [414], [415] in the USA, and [122] in the UK reported encouraging results. Also a large number of studies with positive findings were reported in languages such as Chinese, and Russian but unfortunately cannot be assessed satisfactorily from the abstract alone. England et al 1989 [122], reported a controlled study of LILT on 30 patients with bicipital or supraspinatous tendinitis of the shoulder. The patients were randomly allocated to active or dummy treatments and both the patient and the assessor were unaware as to whether they had received dummy or placebo treatment. A statistically significant difference was reported in outcome measures of range of motion, reported pain and function, in favour of the treatment group.

Walker et al [414] in a single blind study investigated the effects of He-Ne LILT on neurogenic and arthrogenic pain. They irradiated skin overlying the site of pain and the appropriate nerve, but in the control group they irradiated the skin which was not overlying these sites. In the experimental group 72% of patients experienced an 82% reduction in pain compared with only 10% in the control group reporting relief. It
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seems possible that this methodology might have biased the results in favour of the experimental group because of the relatively greater credibility, suggestion and resulting expectations of efficacy, due to the chosen areas of irradiation. Later single blind studies by Walker also produced encouraging results apparently providing evidence of pain relief superior to placebo applications in patients with rheumatoid arthritis (e.g. [416]).

Hansen & Thoroe [180] in Denmark attempted to repeat Walker’s findings on a group of patients with oro-facial pain, using an infrared diode laser. They used a double blind rigorously controlled design (n=40), taking trouble to blind the patient and therapist from knowledge as to whether active or sham applications were being given. They used a modified cross-over technique, in which non-responders were changed to the other group in the middle of the study without their knowledge. They argued that this method of investigation, which was only suitable where an immediate response to treatment could be expected, has at least two advantages. Firstly, it was possible to follow through the natural course of the responders as their treatment allocation remains the same throughout. Secondly the lack of response in non-responders immediately after their change in treatment allocation provides further evidence of a placebo response. The use of cross-over designs in RCTs is discussed in Chapter Six.

Palmgren et al [306] also in Denmark using a double blind design (n=35) investigated the effect of LILT on painful small joints of the hand in patients with rheumatoid arthritis. They reported a significant difference between the active and placebo groups, in terms of improvements in subjective pain reports, grip strength, swelling, range of motion ROM, and early morning stiffness. They also reported that the erythro-sedimentation rate (an index of the inflammatory status) was reduced only in the active group from 28 mmh to 19 mmh after 12 treatments. They postulated that stimulation of macrophages in the blood circulation, together with laser induced excitation of synovial cells within the painful joints, might effect the body’s immune system.

However, Hall et al [179] in the UK in a similar double blind study, of patients with painful rheumatoid hands (n=40), found that LILT was no more effective than the placebo application, in terms of disease activity, swelling, hand strength, range of movement and pain measured during gripping. Subjective pain measures and the Health Assessment Questionnaire, an arthritis specific scale were recorded, prior to the treatment, immediately after the 12 treatment sessions, at one month and at 3 months after the treatment had ended. But these researchers found no significant differences in outcome between the dummy and active modes. Since some evidence for its effectiveness at least in animal studies exists [31], Hall and colleagues [179] concluded
that it would be worth carrying out further research attempting to match the wavelengths and applications used in these studies.

Other rigorously designed placebo controlled double blind studies of laser therapy were carried out by the Swedish research group previously referred to in section 3.2.1 on clinical trials of ultrasound for pain relief. But these also failed to produce positive results. The efficacy of LILT for pain relief in tennis elbow was studied by Lundeberg and colleagues [254] in a double blind study comparing 1) He-Ne, 2) Ga-As laser therapy with 3) placebo laser therapy. Acupuncture points were irradiated but no significant differences in pain measures were found. Since these workers believed one reason for these negative results may have been too low a dosage to be effective they repeated the investigation using a higher dosage [177], but still obtained negative results. According to Baxter [311] the dosage that they used in this study was still lower than commonly used in clinical practice, and also he questions the appropriateness of using acupuncture points for irradiation sites.

However, Gam et al [150] carried out a meta-analysis of placebo-controlled trials of LILT. They concluded that from the combined analysis of 9 double blind studies of LILT and 4 single blind studies, active LILT was no more effective than sham LILT for pain relief in musculoskeletal disorders.

It seems that the use of this modality is founded mainly on anecdotal evidence of its usefulness in providing pain relief.

3.2.3 Transcutaneous Electrical Nerve Stimulation (TNS)

TNS has major practical advantages over other forms of electrotherapy, being portable, relatively cheap and simple enough to allow self-administration. It is also non-toxic and non-invasive, (which is true to a lesser extent with Ultrasound and Pulsed Short Wave) and may reduce the in-take of analgesics [340]. It is advocated by many to be especially useful for pain relief.

It is commonly used in Pain Clinics [108], [210], by different members of the clinical team, including nurses, doctors, physiotherapists and psychologists. Perhaps for this reason, its use for pain relief has been more widely researched as evidenced by the number of randomised controlled trials, some of which are well-designed, compared with other forms of electrotherapy referred to in this chapter. Johnson and colleagues [210] reported the results of a retrospective study on the use of TNS. On the basis of issuing 1582 patients with machines over a period of 10 years at the Newcastle Pain Clinic, which have been returned by only 655 patients over this period, they concluded
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that the rest of the patients (57%) were still using the machines at 10 years follow-up. It seems that there could be a number of reasons for patients not returning the machines, including inertia, forgetfulness, or thinking that they might be useful one day. In many cases since it is a small piece of equipment, it could easily have been either stored in their home out of sight, perhaps never or rarely used, or possibly lost.

TNS is a form of electrical stimulation that produces a perceptible tingling sensation underneath the electrodes which are fixed to the skin. It's use has been based on the rationale as postulated in the "Gate Control Theory of Pain" [281]; high frequency non-painful stimulation of the large diameter fibres of the central nervous system can inhibit the passage of nociceptive impulses in smaller diameter nerve fibres. In addition, it has been shown that low frequency TNS, also referred to as "acupuncture-like" stimulation, can raise the levels of endorphins in the spinal fluid [365].

Roche & Wright [340] reviewed 9 randomised controlled trials for arthritic pain, and concluded that overall the trials provided evidence for its usefulness. They discussed the placebo effect but did not thoroughly address the methodological problems related to this and the evaluation of TNS in these studies. They did not consider two important issues relevant to the interpretation of these studies; 1) the credibility of the placebo, and 2) the problem of a cross-over design in RCTs. Both of these are related to the difficulty of providing for sufficient "blinding" of the patient as to which study group they have been allocated to [109].

In early studies the double blind design was adopted using sham TNS which provided no sensation, and for example Thorsteinsson et al [386] using this model in a cross-over trial to evaluate the effects of TNS on chronic pain concluded that the patients who had the active treatment did better than the sham group. Another study comparing active TNS versus sham TNS was carried out by Abelson and colleagues [1], for patients requiring pain relief for rheumatoid arthritis of the wrist. These workers also found that the active treatment was more effective than the placebo/sham group. In fact they reported a 5% reduction in pain when resting and when gripping for the placebo group compared to a 45% reduction in the active treatment group, which was statistically significant at the 1% level. Subsequently these workers headed by Langley [239] repeated this study avoiding a cross-over trial. They pointed out this design was inappropriate, because the patient was no longer blinded when they perceived a sensation with one application of the treatment, and not with the other. In addition they also considered the importance of using treatment and placebo groups that are equally credible to the patient, and to this end use an ingenious design to increase the suggestion associated with TNS. Patients in this study all had electrodes
attached to their skin, and were apparently wired up to a TNS machine, but it was rendered inactive if they were in the placebo group and therefore received no stimulation from the machine. However, the machine which they were connected to was also linked up to an oscilloscope from which the patient could observe a pattern of pulsed waves implying that the machine was producing the effect and that it was providing them with a subliminal effect too. This study was carried out as an experiment on one occasion only and demonstrated that by increasing the suggestion in the placebo group and providing distraction, the active treatment group did no better in terms of pain relief than the sham group. The importance of cognitive factors such as suggestion, distraction and expectations are seminal issues in this thesis and will be discussed further in the next chapter and also in Chapters Ten and Eleven.

Deyo et al [108] carried a very carefully designed and well-controlled study of TNS for back pain patients. The purpose of the study was to compare the use of TNS on its own and in combination with a set of documented and popular set of stretching exercises. Four treatment groups were used comparing 1) TNS (n=36), 2) sham TNS (n=36), 3) TNS plus the exercise programme (n=37), and 4) sham TNS plus the exercise programme (n=36). At one month the researchers found no significant difference between the TNS and the sham TNS on any of the nine outcome measures of functional status, pain measures or spinal range of motion; 47% of the TNS group showed some overall improvement in pain indicators compared with 42% in the sham group. There was no interaction effect between the exercise and TNS groups, but there was a significant effect in the exercise group compared to the TNS group. They concluded that exercise on its own is as useful as in combination with TNS.

However, in spite of these somewhat negative results, a case for its use is still arguable and this will be discussed further in Chapter Eleven. TNS is accompanied by low risk, has a good placebo effect which may provide pain relief at least in the short term for approximately 30% [125], [386] to 42% of cases with chronic or intractable pain [108]. Also it can conveniently be used as an adjunct to other forms of pain management [340], and more specifically can be used to encourage increased activity in painful chronic disorders such as back pain.

The first section of this chapter (3.1) has attempted to provide a brief overview of the aetiology and epidemiology of common musculoskeletal disorders, only referring in passing to possible psychological factors which may be involved. The next chapter reviews the literature on the possible influence of social learning, and social modelling on the perception of pain. The role of psychological variables such as anxiety and depression and the locus of health control on the development and maintenance of
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MSD are also discussed. Possible mechanisms for the maintenance of chronic pain, for example the medical model, and secondary gain provided by the clinical setting as well as by an over-solicitous partner are then considered. Psychological responses to treatment by a physiotherapist and doctor are also reviewed.
CHAPTER FOUR: PSYCHOLOGICAL VARIABLES IN PAIN AND MUSCULOSKELETAL DISORDERS

4.1 CLINICAL PRESENTATION OF PAIN AS A SYMPTOM OF MSD

Pain is probably the commonest symptom in patients presenting with MSD disorders in a physiotherapy department. Low back pain is very common as previously discussed (3.1.2), with between 50% and 80% of the population suffering from it at some stage in their lives. However, the vast majority of these patients cannot be reliably diagnosed and their problems are therefore classified as non-specific mechanical low back pain [141]. It is often very difficult for the clinician and therapist to pin-point the precise cause of their patient's pain. Commonly the underlying mechanical, biological and psychological factors are difficult to separate (vide 2.2.2). But in order to know where to aim their treatment the physiotherapist takes the patient's history and carries out an examination in order to elicit signs and symptoms which may aid a diagnosis. As with doctors, the physiotherapist is trained and experienced in pattern recognition [237]. Through complex information-processing the clinician attempts to find a clinical explanation of the pain to accommodate these signs and symptoms. Additional information such as X-rays may be available but can be misleading, because in arthritis and in back pain there is a very poor correlation between X-ray findings and pain, particularly in the complex area of the lumbar spine [326], [141]. A patient's reluctance to move a joint is very frequently caused by pain or fear of it. Spinal range of motion which is often used as an objective measure of pain and considered by some to be more reliable than the measurement of pain, depends in part on psychological factors in back pain patients [147]. It may be thought of as a form of pain behaviour [137].

Although there is no universally accepted definition of pain, that devised by the Subcommittee on Taxonomy of the International Association for the Study of Pain, [200] is commonly cited. They define pain as "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". In any case pain is a complex, multidimensional phenomenon which needs to be considered in terms of affective, cognitive and behavioural elements as well as it's sensory component. Both introspection and experimental data have demonstrated that individuals can discriminate between the sensory and affective components of pain [88], [344]. Also recently many researchers have emphasised the importance of cognitions in the perception and reporting of pain. Even in the laboratory setting nociceptive input and reported pain do not have a linear relationship...
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[134]. Pain is modulated on a number of different levels, for example by attention and perception of control [396], [88]. These factors will be discussed below under the following headings: the assessment of pain, the development and perception of pain in MSD, the maintenance of pain and disability and the response to treatment.

4.2 THE ASSESSMENT OF PAIN

Pain is an individual and highly personal experience. It is therefore not possible for an observer to measure the pain experience directly. Alternative means of assessing pain have therefore been developed.

In an attempt to further their understanding of the pain phenomenon scientists have carried out a great deal of research in the laboratory using both humans and animals. In clinical practice the patients' pain stimulus is not quantifiable, and in any case is probably not a good indicator of the pain experienced by a patient. So another indirect measure of pain has to be utilised. Methods commonly used include behavioural measures, self-reported behaviours and, most frequently, subjective pain reports which take many different forms. One method of pain assessment which has been quite widely used in the USA and falls outside these categories, as it involves matching induced pain with clinical pain, is the submaximal effort tourniquet test (SETT) [372], [222], [261]. This is an example of an analogue approach, requiring the patient to match the induced pain to his clinical pain. The clinical pain is then described in terms of the stimulus, and probably mainly in terms of the sensory component of pain.

In the clinical setting it is important to bear in mind that pain is a multidimensional experience and therefore when assessments of pain are made, different components such as the affective component should be taken into consideration [209], [71], [282]. This can quite readily be assessed by the use of similar scales aiming to find out how distressing the pain is.

Physiotherapists in clinical practice tend to assess pain by means of simple verbal reports and observation of the patient's behaviour, in particular the way they move and respond to an examination (vide 2.3). Pain can be measured more reliably using Verbal Rating Scales (VRS), Visual Analogue Scales (VAS), Numerical Rating Scales (NRS), pain drawings, or by means of a standardised, validated questionnaire such as the McGill Pain Questionnaire (MPQ), all of which rely on patients' self-reports.

Verbal rating scales are frequently used with words such as "none, slight, moderate, and agony". But the different ways in which individuals use words, especially across different cultures. Also, such categorical scales represent problems in terms of
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analysis. The size of the categories is not known and nor is it known whether the spacing between them is equal [191].

Visual Analogue Scales (VAS) are very commonly used for both clinical and research purposes [355], [198], [335]. They traditionally consist of a line usually 10 cm long, with an anchor at each ends, which might be no pain at one end, and pain as strong as it could be at the other end. The patient is asked to mark on this scale the point which represents their pain level. Validation of this method was demonstrated by Price et al [327], as a ratio scale for chronic pain as well as laboratory pain.

All these methods of subjective pain measurement have been evaluated and found to be similar in terms of construct validity and incorrect responding, but the NRS scale (0-100) was judged to be more suitable for older people to use [205]. For this reason it was the method of collecting pain reports chosen in the pulsed short wave studies, described in Chapters Nine and Ten. This method has the advantage of not relying on a common language culture. The patient is asked to rate his pain on a scale usually of either 0-10 or 0-100. This method assumes an ability to think of numbers and therefore requires some degree of numeracy.

Any subjective method of pain measurement will tend to be subject to response bias and may be unreliable if it relies on recall. There is evidence that pain recalled is likely to depend on the level of present pain. If pain levels are lower, then the pain recalled will also be at a lower level than it actually was [123]. This problem can to some extent be overcome by getting patients to record their pain at regular intervals over a period of time, avoiding dependence on retrospective data and the attendant problems of recall. The use of pain diaries allows pain reports to be assessed over days and over weeks [314], [261]. They allow diurnal fluctuations in pain to be assessed and for activities and potential stressors to be recorded and related to the onset of pain. They may be based on simple measurement scales such as VAS or NRS, and patients are asked to fill in their pain diaries either hourly or four times a day at mealtimes. In the study of pulsed short wave for pain relief in patients with osteoarthritic hips and knees reported in Chapters Nine and Ten, the NRS was incorporated into pain diaries.

The McGill Pain Questionnaire (MPQ) is a widely used method of evaluating pain which was developed by Melzack & Torgeson over a number of years [279]. It was designed to allow both quantitative and qualitative components of pain to be considered. Melzack & Torgeson [280] produced a list of 102 words that patients used to describe their pain and asked physicians and other university graduates to classify these words into different groups. Using these data they categorised them under three main headings: sensory, affective and evaluative. These were further
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subdivided into groups such as temporal course of the pain (flickering, quivering, pulsing, throbbing, beating, pounding), spatial (jumping, flashing, shooting) and traction or pressure (tugging, pulling, wrenching). The words in each group were assigned a rank order to give each word an equivalent numerical value, representing the intensity of the pain, within each class.

In this pencil and paper questionnaire, patients are asked to select words which most accurately describe their pain. Ten of the groups of words are designed to represent sensory qualities, five affective, and only one evaluative, whilst four more are classed as "miscellaneous". The MPQ offers three separate indices, 1) The Pain Rating Index (PRI) is based on the rank order of the words chosen by the patient, from each class of words, 2) The number of words chosen, 3) The Present Pain Intensity (PPI), which is a combined six point numerical and verbal rating scale, 0-5.

The MPQ has been very widely used in many different areas of pain research and in clinical trials. Evidence for its validity has been provided through laboratory research using the cold pressor test [115]. Much research has been carried out to evaluate the MPQ and most has been supportive of its factor structure (for example [62], [395]) and its reliability [162].

However, the MPQ has been criticised for weighting sensory aspects of pain more than other components of pain, such as affective elements; offering patients twice as many categories of sensory descriptors compared with the affective descriptors [72]. For this reason it may not satisfactorily represent chronic pain. Other disadvantages of the MPQ are that some patients may have difficulty with the complexity of the vocabulary and also comparisons across cultural groups may be a problem as people use words in different ways. It is less suitable for frequent repeated administration and would therefore not be suited to studying fluctuations of pain over time.

Another method of assessing pain which takes into account the multidimensional aspects of pain and in particular its affective component, utilises pain drawings. This method has been advocated by Margoles [265] for orthopaedic patients, and by Ransford et al [331] for back pain patients. Patients are presented with a body chart which they are required to fill in to show the location of their pain and its quality. The method has the attraction of being visually simple for the clinician to use as part of a repeated assessment procedure. It has advantages over other subjective measures in that it does not make great demands on a patient's vocabulary, use of language or numeracy. Scoring systems have been developed which claim to quantify the emotional components of the pain complaint based on the percentage of body area on which the patient charts pain [265], [8]. In spite of earlier criticisms of the pain
drawing test, when it was found not to correlate with the Minnesota Multiphasic Pain Inventory (MMPI) [405] it has now been revised and seems to be a potentially useful tool if used in conjunction with other methods of pain assessment.

Intervention studies for pain relief usually use at least one of these methods of assessment. Regardless of which method is used, the reliability of the reports will depend on whether the same aspect of pain is being measured in successive assessments [314].

4.3 THE DEVELOPMENT AND PERCEPTION OF PAIN IN MSD

4.3.1 Cognitive Processes

An individual is, during his waking hours, constantly assailed with information which has to be processed to decide which of the information needs to be attended to. This process which controls the perception of external stimuli, is referred to as selective attention [391], [215]. There is much evidence to show that the same processes control the perception of internal stimuli, i.e. physical symptoms such as pain [71], [315], [424]. The nervous system is constantly being bombarded with a barrage of sensory signals. These multiple messages are integrated at a higher level of the nervous system to provide the individual with an organised meaningful message [71]. The perception of pain depends on selective attention and the filtering of relevant messages. According to Chapman [71], the probability of noticing internal bodily cues can be expressed as a function of the ratio of the strength or salience of internal information over external stimuli. If a patient is asked to concentrate on and report any pain experienced whilst a physiotherapist is examining and handling anatomical structures such as muscles and joints, an exaggerated pain response may result. By contrast, the same individual may be able to reduce pain by means of distraction, if they are absorbed in some demanding or enjoyable activity [23].

Melzack's widely documented gate theory of pain [281], although not totally substantiated, is conceptually useful in explaining the complexity of this process. It has generated an enormous quantity of research and they more recently restated the theory [282] to include more up to date neurophysiological findings. It provides a basis for understanding that pain experienced is not directly related to tissue damage. Nociceptive input is modulated by means of a gating mechanism situated in the dorsal horn cells of the spinal cord. Messages pass along two different types of nerve fibre. The first is the small diameter, unmyelinated (A-delta and C) nerve fibres along which impulses pass facilitating the opening of the gating system, allowing synaptic transmission to T-cells. The other type of nerve fibre is the large diameter (A-alpha
and A-beta) nerve fibres which carry impulses which tend to close the gate and prevent nociceptive impulses passing up towards the spinal cord to the brain to be processed as pain. The theory is especially useful in explaining the role of central modulating mechanisms such as affective and cognitive processes which influence the perception of pain.

According to Pennebaker [315] who carried out a large number of controlled experiments mainly on normal subjects, studying physical symptoms and pain reports, the awareness of an internal sensation depends on:

1) The magnitude of the internal receptor stimulus;
2) The amount of available information;
3) The individual's beliefs that may cause him to selectively attend to internal states, in the context of the pain.
4) A tendency to attend to internal sensations.

Mackworth [256] has pointed out that sometimes perceivers are very ready to respond to weak and infrequent sensory signals. Vigilance plays an important role in the perception of pain. Attention to self increases the likelihood of psychological and physiological symptoms and negative evaluation [276], [22].

Pennebaker [315]) reported an experiment carried out by the biologist Adams (1980) which demonstrated that sensations are constantly being processed by an individual although they do not necessarily reach conscious levels of awareness. The experiment showed how through learning and attention these processes could be perceived. A small rubber balloon on the end of a tube was inserted into the small intestine of an experimental subject, a common procedure for examination of the jejunum or duodenum. While it was inflated and deflated electroencephalogram (EEG) readings were taken. These showed that the activity had registered in the brain but the subject himself had no awareness of the activity. In the second part of the experiment he was trained by means of feedback to become aware of a sensation in his intestine when the balloon was being deflated and inflated. He had learnt to be aware of a sensation which he had previously been oblivious to. Attentional processes operate in conjunction with the memory system [424]. It seems that learning and the filtering of relevant messages can play an important role in the perception of physical symptoms especially pain [137].

There is some evidence that selective attention and vigilance are influenced by beliefs, attitudes and expectations [315]. Selective monitoring of physical symptoms not only
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affects the quality and severity of perceived pain, but these are also dependent on the subject's cognitive schema and experience. The pain experienced may be influenced by polarisation of attitudes, for example in the clinical setting suggestion of benefit of treatment. In an experiment where half the subjects ran on the spot for two minutes and other half walked on the spot for 2 minutes, Pennebaker [315] found that those who had had their attention drawn to flu bugs at that time of the year were significantly more likely to report flu symptoms, whereas the control group described any sensation in terms of arousal related to the activity.

According to Skelton & Pennebaker, once an individual is aware of a bodily sensation, selective monitoring occurs, and he will adopt an explanatory hypothesis that is based on their past experience or knowledge [366]. It seems that the individual then searches for verification of the process. It may be possible for a therapist to modify the patient's interpretation of their pain, by providing appropriate information. However, an established set or cognitive schema may be difficult to alter. [134]. The individual needs to not only alter their hypothesis, but also actively encode the new information within the restructured hypothesis [267].

However, there is evidence that suggestion and faith can play an important role in pain relief [321], [239]. They can provide a powerful tool in the clinical setting encouraging the patient to expect a positive outcome of the treatment they are undergoing. This practical application of a psychological process is intuitively used by physiotherapists and other health professionals, and will be discussed further (vide 4.4 and 4.5).

4.3.2 Social Influences

Early childhood socialisation and learning determines how an individual, in adult life, perceives painful stimuli and responds to physical symptoms [87], [315], [137]. This occurs mainly as a result of two closely interlinked processes—social modelling and social learning. These are primarily responsible for cultural differences as well as individual differences.

4.3.2.1 Social Modelling

Observational learning is one of the main modes of acquisition of new patterns of behaviour [17], and is also relevant to pain. According to the theory of social modelling, if an individual is exposed to someone else displaying intense and prolonged pain complaints they may develop anomalous patterns of pain behaviour [87]. Craig demonstrated experimentally, using shock-induced pain that observation of a tolerant
model can increase an individual's tolerance levels considerably [89]. In this study, exposure to a tolerant model resulted in toleration of nearly twice as strong an electric shock, compared with the effect of exposure to an intolerant model (9.93 mA compared with 5.43 mA). Both the sensory and affective components of pain reported could be influenced in this way. The theory of social modelling may also usefully be applied to preparing patients for surgery or other painful procedures, especially for children. Many studies have documented the advantages of using a tolerant model to prepare the individual for surgery, but it is also important that the model's response should be realistic or at least credible [400]. Physiotherapists working on surgical wards provide pre-operative advice and may have an opportunity of inviting the patient who is expecting surgery to talk to another patient who has undergone similar surgery and rehabilitation without experiencing untoward effects. This could be especially relevant for a therapist working on a paediatric unit. Conversely, it would probably not be helpful to meet another patient who expressed the experience in dramatic or excessively negative terms.

According to the theory of social modelling, early learning experiences also influence an adult's response to pain. A parent's response to their child's pain, whether it was calm, stoical or emotional will be noted by the child during the many inevitable minor traumas of childhood [424]. Also, the parent's expectations of its behaviour will act as a model for the child's own future response to pain [88]. Craig's experimental work [88] on the influences of social modelling on pain perception was carried out across unselected personality types and he reported that social modelling was more likely to modify pain reports and pain behaviour than individual differences. But the literature in social learning fields shows that an interaction between personality and social modelling has the greatest influence on the matching behaviour [87].

4.3.2.2 Social Learning

From early childhood experience a person may learn that complaining of pain results in attention and sympathy [137]. In this way a stimulus may be conditioned so that the person always expects to attract someone else's attention and sympathy by demonstrating the pain they are suffering. Others, whose parents reacted less to their children's pains and illnesses, may have learnt to be less demonstrative in displaying their pain. They expect no reward for complaining of pain. Different patients' responses to pain can be better understood by health professionals when these developmental factors are taken into account.

Both social modelling and social learning go a long way towards explaining both individual differences and cultural differences. Craig [87] has noted that it may be
useful for a clinician when taking a history from a chronic pain patient, to routinely obtain information about their past history of pain, including also family history of pain problems, and this advice will be considered further below (4.5.1.1).

4.3.3 Affective States

Affective states are closely interlinked with the pain experience. According to the International Association for the Study of Pain, the widely accepted definition of pain is: "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of damage" [200]. Whilst the two components sensory and affective components are linked, evidence from the laboratory and the clinical setting has shown that they can be measured separately [116], [88], [327]. With this in mind sensory and affective components pain are assessed separately in the studies of pain relief reported in Chapters Nine and Ten of this thesis. The experience of pain and the resulting pain response are closely interlinked with affective states such as anxiety, depression, helplessness, and lack of control.

4.3.3.1 Anxiety and Pain

Anxiety, depression, anger and other emotions may be associated with pain via a common psychophysiological pathway, that is the autonomic nervous system (ANS) [88]. A raised ANS response gives rise to increased activity in the viscera and in the skeletal muscles. This increase in tension may be an important factor in perpetuating a vicious cycle of pain - anxiety - muscle tension - pain, for example in patients with intractable neck pain or back pain. According to Flor & Birbaumer chronic pain patients may interpret increased muscle tension as painful stimuli, although there is evidence to show that they cannot distinguish between levels of muscle tension as well as non-pain patients [133]. These researchers postulated that chronic pain patients may become preoccupied with physical symptoms, and that somatic concern and anxiety are probably related. This confirmed work carried out by McCreary & Turner [272], which showed that these were the most important predictors of chronicity. Also, studies of EMG on chronic back pain patients [135] provided evidence for a relationship between anxiety (as measured by the state form of the State-trait Anxiety Inventory [371]), reported pain and spinal immobility.

Gilchrist [153], in a study of 1499 patients in general practice over a period of 6 years, found that patients with back pain were more likely to have a diagnosis of anxiety attached to them than non-back pain patients. The present author [222] previously carried out an experimental study using the Sub-maximal Effort Tourniquet Technique (SETT) to induce pain, and compared the pain response and its relationship to anxiety...
in chronic back pain patients and non-back pain patients. She used the Spielberger's State-trait Anxiety Inventory [371], and a pain visual analogue scale as dependent variable. She found that patients with chronic back pain (n=30) had significantly higher scores on the Trait-anxiety scales, compared with matched controls. The two groups did not however differ in their pain response, or in State-anxiety scores. Flor & Birbaumer [133] also found that patients with chronic pain reported higher levels of anxiety in a stressful laboratory situation, but they in addition also reported more physical symptoms.

The relationship between pain and anxiety is complex and uncertain. In the presence of a threat or anxiety the "flight or fight" mechanism of the autonomic response may take precedence over the pain response, so that the pain experienced is diminished or even absent. The processing of information relevant to the painful situation (vide 4.3.1) can play an important role in the perception of pain [51]. It was proposed by Weisenberg et al [426] in their attribution theory that anxiety which is relevant to the painful situation may increase it, whereas anxiety which is not relevant would decrease the pain experienced. [84] in an experimental study used finger pressure to induce pain in their subjects, compared three different conditions, provoking 1) relevant anxiety, 2) irrelevant anxiety about a stressful interview that would take place afterwards, and 3) a neutral condition. They concluded that the results of their experiment did not support Weisenberg's attribution theory, but rather could be explained by a theory of perpetual disruption. The implication of this alternative theory was that any coexisting anxiety is likely to exacerbate pain.

However, Absi & Rokke [2] carried out a study with a slightly different design to test Weisenberg's theory of relevant versus irrelevant anxiety on pain. In a more complex experimental procedure which included five different conditions they administered cold pressors, and manipulated the level and type of anxiety. Two groups were provided with relevant information about the effects of the cold pressor, designed to provoke either a high or a low level of anxiety. Two other groups were provided with two levels of anxiety provoking information about a possible (fictitious) electric shock and their likely reaction. The fifth group was a neutral group without any manipulation of anxiety levels. The results of their study provided evidence that anxiety is associated with increased pain only when it is relevant to the pain. Flor et al [135] demonstrated a correlation between state anxiety and spinal immobility in patients with chronic back pain when they were tested in a demanding experimental situation. Also, Flor & Birbaumer [133] reported increased levels of state anxiety in chronic pain patients compared with normals when they anticipated the performance of a potentially pain-eliciting task.
Outside the laboratory, pain may be associated with a whole constellation of psychological variables, especially when it becomes chronic. Weiser and Cedraschi [427] concluded from their review of the cumulative literature on psychosocial issues in the prevention of chronic low back pain, that those who are preoccupied with their symptoms, depressed and anxious, are likely to have a poor outcome. Anxiety is often associated with depression [232].

4.3.3.2 Depression and Pain

Many studies of chronic pain patients have provided evidence of a link between pain reports, pain behaviour and depression (e.g., [236], [257], [151]). However, they are mostly correlational studies and therefore provide no information as to whether the depression was causal or attributable to the chronic pain experience. Mostly, it is agreed in the literature that depression in chronic pain patients arises as a result of unremitting pain, but there may be some cases when depression itself gives rise to pain syndromes. Ten of the seventy-one patients with constant daily chronic back pain lasting at least 6 months, studied by Krishnan and colleagues [236], retrospectively reported a major depression prior to the onset of back pain.

Some researchers hypothesise that not infrequently patients may avoid major depressive symptoms by somatisation. The reporting of physical symptoms is probably more acceptable in our society, rather than mental illness. Attention and sympathy can be more readily obtained in this way. The resulting condition is sometimes referred to as "masked depression" [258], [50]. The patients' mood will not appear to be severely depressed and they may deny any emotional problems. Other researchers using the MMPI have shown that some chronic pain patient may demonstrate a distinctive "Conversion V" configuration, the depression scale being less markedly raised, compared with the Hystera and Hypochondriasis scales [193], [372]. However, they explain the less severe degree of depression in these patients by the length of history, and adaptive changes they made in their lives.

From the operant point of view, Fordyce [137] has considered depression as a state of deprivation, that is an absence of a positive reinforcer. He believed that the clinical manifestations of loss of appetite, sleep disturbance, or retarded performance were all incidental. He maintained that in most cases of chronic pain, patients became depressed because they were not able to carry out their normal activities, but he named two exceptions. One of these was people who gave up activities because they were not rewarded for them, and the other was people who found an alternative activity for which they were rewarded.
Parker & Tupling [307] in a study of patients treated by a chiropractor found that General Health Questionnaire (GHQ) scores, which if raised demonstrate a degree of psychological dysfunction, were initially raised in this group of patients, but following treatment when they reported reduced pain levels the scores returned to "normal" levels. Romano & Turner [345] reviewed the literature and reported that a relationship exists between chronic pain and depression. But a lack of controlled studies comparing depression in chronic pain patients with other chronic medical conditions as well as healthy controls makes it impossible to reach any firm conclusions about the direction of the relationship. Similarly, Turk and Rudy [393] investigated the relationship between chronic pain and depression using a cognitive-behavioural transaction model. On the basis of their findings they argued that the link between chronic pain and depression is weak, and could better be explained by a number of mediating factors, including a perception of reduced life satisfaction since the onset of pain, interference with various activities, and lowered perception of self-efficacy and control.

According to Beck [32] depression is the result of cognitive schema leading to a negative view of the self, the world, and the future. The Beck Depression Inventory (BDI) is one of the most commonly used measures of depression. It was developed because other widely used scales such as the MMPI were not specifically designed to assess depression or were based on old psychiatric nomenclature [55]. The BDI is only a measure of severity once a diagnosis of depression has been made. Recent research in the field of chronic pain has demonstrated that the BDI confuses the somatic effects of pain with the somatic effects of depression [433].

Depression has sometimes been considered in terms of a learned helplessness model e.g. [358].

4.3.3.3 Perceived Control versus Helplessness and Pain

From the standpoint of the health professional in the clinical setting, patients' sense of control over a pain problem, as opposed to a sense of helplessness, is vital in enabling them to cope [223]. Perceived control of physiotherapy patients over recovery from their disability was shown by Partridge & Johnston [311] to be predictive of recovery. Subsequently they demonstrated that it was possible to increase perception of control of recovery simply by the addition of a few paragraphs to the routine letter confirming a patient's appointment [212]. Elsewhere, it has been shown that patients who attribute their improvements to their own efforts are less likely to relapse [114].
The construct of Locus of Control (LOC) was put forward nearly 40 years ago and was based on social learning theory [348]. Lefcourt [244] in a review article on internal and external control of reinforcement pointed out that the theory referred to an individual's expectancy of a particular behaviour in a given situation being reinforced. He went on to point out it was therefore unclear as to how these expectancies could be generalised across different situations. The scale has been used in many different areas of psychological research and has been developed for use in health settings by Wallston and Wallston [418], [417]. It refers to the extent to which people believe their behaviour is likely to have an influence on their health. Those at one end of the scale have an internal locus of control, as opposed to those at the other end of the scale who believe that they have no control over their health, referred to as an external locus of control.

Locus of control has been seen as a moderator of stressful life events by a number of researchers including Parkes [310]. In her studies on stress in nurses, she found that "internals" and "externals" had different ways of coping with life stressors which depended on how they appraised the life stressors. The "internals" used adaptive coping strategies in dealing with life stressors more than the "externals", which was in line with the view that locus of control may be linked with physical and mental health in this way. The health LOC was used as a predictor of back pain in the longitudinal study of back pain described in Chapter Five of this thesis. Patients who have tried out many different forms of treatment without success are unlikely to believe they can control their pain and therefore can be expected to have an external LOC [396].

Helplessness is a concept which, at least in lay terms one would consider to be related to the external locus of control. However, Lefcourt [244] has argued that helplessness is a motivational variable, whereas locus of control is based on general expectancies.

Many recent studies point to a combination of these psychological variables playing an important role in the development and maintenance of chronic pain. A heightened awareness of somatic functioning has repeatedly been cited as an important predictor of chronicity [272], [152]. Conversely it has been shown that self-efficacy may be an important common factor in successful amelioration of painful MSD [303]. More recently it has been shown that at least in back pain patients, with a history of only two months, using a combination of Zung's Depression and Helplessness Scales, and the Modified Somatic Perception Questionnaire (MSPQ), it is possible to predict chronicity [263], [166]. These theories will be discussed at greater length in Chapter Eleven.
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4.4 MAINTENANCE OF PAIN AND DISABILITY

Acute pain usually has a well-defined cause of tissue damage and also a characteristic time course, the pain disappearing when healing has taken place [282]. The initial rapid onset of pain is referred to as the phasic component; it is typically a sharp bright pain which signals that tissue damage has occurred and evasive action is required. After a short delay the pain changes in quality, generally to a dull nagging sensation which is the tonic component. This is thought to function as a reminder to the brain of the state of the tissue damage. It is a means of fostering rest, care and protection to the damaged area whilst healing is taking place.

The tonic component of pain may continue long after healing has taken place; low levels of abnormal input of self-sustaining neural activity continue to produce pain. It has been proposed that many different factors may contribute to the maintenance of pain and disability, including both behavioural and cognitive variables. According to many researchers (e.g. [396] and [333]), problems of life and an individual's interpretation of them are all important in chronic pain. They are relevant to the development and perception of pain, as well as to the maintenance of pain (vide 4.3.1 and 4.3.2). In addition, operants such as secondary gain may play an important role in the maintenance of pain and disability.

4.4.1 Secondary Gain

The only way in which the pain experience may be observed is indirectly through pain behaviour. Initially, acute pain through nociception is likely to produce pain behaviour which may be verbal complaints, grimacing or protecting the injured part. If this pain behaviour is consequently rewarded the effects are likely to persist [139]. For example if a person with back ache is praised and given attention every time they talk about their pain or rest, they are provided with positive reinforcement for this type of behaviour and it will tend to increase the rate of its future occurrence. The hospital setting, with its emphasis on the somatic problem, may itself act as a reinforcer. Indirect reinforcement can also be a powerful shaper of pain behaviour leading to the avoidance of an unpleasant consequence [138], sometimes referred to as negative reinforcement, or avoidance learning. It can have a particularly persistent effect and may be an important factor in the development and maintenance of chronic pain problems. The person in pain who fears that movement and activity will make their pain worse, learns to avoid any physical activity in case it might produce pain [245]. This psychological barrier to exercise is likely to interact with physical barriers over a period of time, as the muscles, joints and cardiovascular system lose their physiological
condition, making even gentle exercise more demanding as the individual becomes both physically and psychologically deconditioned [134], [268]. A recognition of psychological processes, such as expectancies and self-efficacy that could influence the outcome of treatment is important in the acute stage of treatment as well as at the chronic stage in order to avoid the development of chronic disability [85].

It has been proposed that secondary gains for the invalid role, such as social benefits both emotional and financial, may contribute to the attenuation of chronic pain [137], [410]. Pain behaviour can often unwittingly be encouraged by an over-solicitous spouse, family or friends [49], through sympathy and attention and by discouraging the individual from taking an active role in domestic and social activities. There is some evidence that job satisfaction, and especially the worker's relationship with their supervisor is linked with back pain reporting [46]. Some researchers have claimed that the great increase in claims for sickness and invalidity benefits for back pain over the past decade [102] is due to both the traditional medical approach to the problem, which has been to encourage rest [343], [144], and also due to the state benefit system.[410]. Some investigators have found that compensation claims reduce the chances of symptomatic recovery with conservative or surgical treatment, e.g. [422], but others have found conflicting evidence [284]. In benefit systems where adversarial evidence has to be provided by the claimant of their back pain being related to work the outcome is less likely to be good [149], [165]. However, rehabilitation programmes for back pain within an integrated approach to the problem specifically designed to return the worker to the workplace, in spite of compensation claims, have been reported to be very effective [269], [430]. In particular there is evidence that preventative programmes, which include involvement of the management and especially the worker's supervisor are more likely to be successful [28], [106], [437]. These researchers have noted that an important component of the programme, and returning the individual back to the workplace appears to be the supervisor telling the worker that he is appreciated. There is empirical evidence for this form of positive reinforcement being the one most important single factor in return to work in this type of programme. It appears to be powerful enough to overcome other concomitant variables which may be providing secondary gain.

4.4.2 The Influence of the Therapist-Patient Relationship on Reporting Pain

Pain reinforcers are likely to be present in hospital settings; medication, rest, social (staff) attention may all reward pain behaviour [93]. The physiotherapist in her daily clinical practice has the opportunity unwittingly to reward and reinforce pain behaviour [143]. Unfortunately, she is not necessarily aware of the principles of operant
conditioning of pain. She may see the patient repeatedly for a course of treatment sessions. On each occasion, because physiotherapists are taught to assess and reassess the problem they are treating, she may feel the need to ask about the pain. Also, traditionally it has been considered good practice to tell the patient "don't do it if it hurts". The patient has been encouraged to equate hurt with harm, and if the patient continues to take this advice literally to its conclusion, he will become progressively less active, and ultimately disabled [70]. There is however evidence that pain behaviour and disability can be reduced by setting exercise quotas [114], [248]. Many pain management programmes on this basis encourage patients to work through pain or discomfort and gradually increase their exercise quota. In this way chronic debilitated patients can gradually be restored to maximal functional levels. It has also been found that patients who attribute their improvement to their own efforts are less likely to relapse [114].

It has been proposed that the doctor-patient relationship plays a very important role in a patient's recovery [424], [112]. Ley [247] in his definitive work in communicating with patients cites a large number of studies supporting this theory. He reports evidence of substantial numbers of patients who are dissatisfied with communications aspects of the doctor-patient relationship. This, at least in part, is probably due to the very brief few minutes allocated to each patient in general practice [342]. These researchers found that if doctors allocated more time for each patient, better communication occurred. A physiotherapist has a notable advantage over a doctor in this respect, often allowing 30 minutes per patient, and in many cases seeing them several times over a period of time. If good rapport is established there is an opportunity to influence the patient's behaviour, promote adaptive coping strategies and influence health attitudes and behaviour [388]. A recent hospital survey showed that 71% of patients said that "physiotherapists always made special efforts to explain things" [302]. However, good quality of communication is not always provided by physiotherapists and other health professionals. Communication skills, counselling and the importance of psychosocial processes in the patient-therapist relationship are not explicitly included in the undergraduate curriculum.

There is much evidence to support the role of ineffective coping strategies in the maintenance of chronic pain problems, especially in the presence of medically incongruent pain signs [333]. Of particular relevance to the physiotherapist is the notion that poor coping strategies are often associated with avoiding activity. Avoidance of activity which might cause pain is very relevant to the back pain problem [245], and may in the longer term, lead to chronic disability. If individuals believe that an activity is going to hurt, they may avoid it because pain is usually equated in the
patient's mind with harm. The back pain sufferer does not want to risk making it worse. This attitude is encouraged by Western medicine and society which encourages rest as the mainstay of the traditional management of back pain [144], [392], [413], [143]. Waddell and colleagues [409], [410], [412] suggest that an important factor in the escalation of disability caused by back pain in Western countries is due to inappropriate management of the problem. A recent survey of GPs in one Regional Health Authority showed that the majority consider rest to be the first choice of treatment for patients complaining of back pain [144].

Unclear diagnosis, too many investigations, medication, advice to rest and/or take time off work may all be iatrogenic [320], [250]. Doctors and therapists who concentrate on pain symptoms and tell back pain patients not to do anything if it hurts may also reinforce the problem [143]. If patients are encouraged to equate pain with harm, the tendency to avoid physical activities may increase. They are more likely to become depressed and focus on pain problems. In addition, lack of exercise increases the chances of becoming debilitated [270], [134].

Early intervention that is combined with handing responsibility over to the individual sufferer is desirable [141]. Encouragement needs to be provided to be active as possible and take control of the problem [224]. Research has shown that self-efficacy, i.e. the belief that you have the ability to cope with your health problem, is associated with a good outcome [85], [303]. On the other hand "catastrophising" is directly related to a poor outcome [347].

It has been shown that a physician can influence his patients to take up more exercise, but apparently many do not attempt to influence their patients as they believe it would not be effective [246] and the same may also be true of some physiotherapists. The therapist has an important role which may be underestimated, in encouraging patients to use active coping strategies, especially physical activities. Research has provided evidence for the advantages of goal-oriented strategies [252], [363] which have been negotiated with the patient. Therapists could probably improve patient participation and compliance with active exercise and patient education programmes, using these strategies, encouraging patients to increase their activities gradually, and get involved in activities they enjoy. A physiotherapist through repeated sessions with a patient has an ideal opportunity to build up rapport and introduce active coping strategies.

The therapist-patient relationship assumes an especially important role in treatment programmes requiring the patient to assume an active role in the management of their problem. According to Feinberg [128] who reviewed the literature on the effect of the patient-practitioner interaction on compliance amongst rheumatoid patients, at least
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50% are non-compliant irrespective of the therapy. A number of different factors need to be addressed in order to maximise compliance with a health programme [33]. These include the Health Beliefs Model which has been shown to be predictive of future compliance [202], and also the Health Locus of Control [417].

The provision of relevant information backed up with carefully produced written information is more likely to result in compliance with a particular programme. However, the quality of the written information is very important and considerable effort needs to invested in any leaflets or booklets for patients, to make sure that they are readable by the majority of patients [247]. The results of a recent survey of the readability, legibility and accessibility of patient information showed that the majority of it was aimed at white, well-educated members of society and targeted at a reading age over 13 years old [173]. However, if such information is aimed at a lower level of reading ability, i.e. the level of the Sun newspaper, and attention is given to the lay-out and general presentation, it may provide very beneficial outcomes [247], [343]. King [219] has emphasised the need to take patients' attitudes and health beliefs into account when trying to influence their behaviour. DiMatteo & DiNicola [112] defined attitude as an affective response to a person, object or concept. They pointed out that attitude may correlate with behaviour but other factors such as social norms enter into the equation to produce the intention to perform a behaviour. Although much of the literature on compliance is related to medication and its use, it is also especially relevant to physiotherapy practice [271] which often requires the patient to carry out exercises which may be painful and/or inconvenient, or alternatively the physiotherapist may expect patients to change their behaviour in some other respect which may be at least as demanding. Compliance is therefore a subject which is extremely important to the clinical physiotherapist who wishes her patient to participate in a treatment programme [224].

4.5 THE RESPONSE TO TREATMENT

The individual's response to treatment may depend to a considerable extent on a combination of the factors discussed in sections 4.1. to 4.4. But in addition another concept, related mainly to the treatment process, needs to be addressed. This is the placebo response to treatment which plays an important role in all forms of pain relief and may be very relevant to the practice of physiotherapy. It needs to be taken into account first for its clinical value and secondly for its effect on research to evaluate the response to treatment.
4.5.1 Placebo Effects

It became common practice in the 1950s to test all new drugs by comparing them with a pharmacologically inert placebo, and according to Critelli [92] in this way the term "placebo" incurred a negative connotation in medical practice. It was generally considered to be a nuisance variable. The placebo subsequently has generated much philosophical discussion and is considered a subject which in its own right is worthy of further scientific enquiry.

Richardson [336], in his critical review of the placebo literature, summarised current knowledge of the extent and range of placebos. He discussed the influence of the characteristics of the patient, the therapist and the treatment itself, and presented examples from the research literature aimed at testing a number of different theories of the placebo mechanism. The way in which a treatment is administered and the patient's perception of it are, he concluded, more important than its inherent characteristics.

The effectiveness of a placebo in a clinical trial, can be expected to be directly proportional to the effectiveness of the active analgesia with which it is being compared [425]. It is usually more effective in relieving severe pain. When it is administered as a placebo drug such as an analgesic its effect tends to mimic those of the drug with which it is being compared to. In addition, associated side effects are not uncommonly reported, both subjective ones such as drowsiness, nausea, and lack of concentration, and more objective ones such as sweating, vomiting and skin rashes [336].

There has been much discussion over the terminology of placebo effects and placebo response. Shapiro [359] defined a placebo as "any therapy...that is deliberately used for its non-specific, psychological, or psychophysiological effect, or that is used for its presumed specific effect on a patient, symptom, or illness, but which unknown to patient or therapist, is without specific activity for the condition treated".

This led to much discussion in the literature, attempting to improve on this definition of the placebo phenomenon. Grunbaum [172] provided a detailed critique of Shapiro's definition. He also criticised Beecher [35] for using the terms "non-specific" and "specific" to distinguish placebos from other forms of treatment. He posited that any given treatment for a particular condition consisted of two factors: 1) a characteristic factor, (e.g. for the prevention of recurrent Cerebro-Vascular Accidents (CVA), a drug which acts on the blood pressure reducing hypertension), and 2) incidental factors or side effects which may be wanted or unwanted, (e.g. the effect of that drug for
hypertension may also be to reduce the patient's levels of anxiety). Grunbaum also distinguished between two types of treatment effects: 1) a direct effect on the condition, and 2) an effect on other systems associated with the patient's health and life generally. He emphasised that treatment should only be considered as a placebo with respect to the particular condition at which it is targeted. He argued strongly against the use of the term placebo as a generic term for a treatment. Brody [58] in a paper examining Grunbaum's definition, also agreed that the term "non-specific" had been used inappropriately by medical writers. Brody pointed out that describing a placebo as "a non-specific response" when the response was quite specific was patently incorrect. He proposed it should instead be referred to a "as response to a so called non-specific therapy".

According to Shapiro and Morris [360], the history of medicine, that is both physiological and psychological treatment, has been the history of the placebo effect. Patients recovered in spite of the treatment rather than because of it, so that even treatments which were deleterious to health, as long as they were socially acceptable, apparently were invested with therapeutic power [92]. Totman [389] has proposed that the theory of cognitive dissonance may account for placebo effects even or especially when unpleasantness or inconvenience is associated with the treatment. According to this theory [130], when a person holds two or more beliefs which appear to be inconsistent, the individual is motivated through this state of "dissonance" which is uncomfortable, to reduce the inconsistency. If the person has undergone an unpleasant, demanding or inconvenient treatment of some kind, they are likely to justify the cost in terms of the benefits gained, in order to eliminate or reduce dissonance. That is, they are likely to report benefits in terms of, for example pain relief from the therapy. This could also be the case if the doctor has told them that the treatment would work, or that it helped someone else. Totman carried out a number of experiments to test this hypothesis. In one study, he experimentally induced pain, and administered an injection of sterile water as a placebo, the effects of which he studied in different conditions. He told the subjects that the injection was a new experimental painkilling drug, and presented it in a manner to arouse anxiety. To one group of subjects the potential benefits to science were emphasised and also they were paid. The other group did not have either of these justifications for taking part in the experiment. But nevertheless, as hypothesised by Totman, they reported greater benefits of the placebo injection. According to the cognitive dissonance theory these subjects needed to have this justification for having taken the risk of undergoing a potentially unpleasant or possibly dangerous experience.
However, there are other interpretations of these experimental findings. Another possibility is that this group of subjects were not comparable with the other group because they believed in the efficacy of the placebo analgesia, and were in fact self-selected. Perhaps patients who did not have faith in it may not have agreed to participate. Belief in a therapy is an essential factor in predicting whether a treatment will provide pain relief [321]. Yet another explanation of Totman's experimental results is that the offer of high payment may have increased anxiety levels and for this reason reduced the placebo effect in this group.

Other researchers have attempted to explain the placebo mechanism through a conditioned response model. Wickramasekera [429] pointed out that although there is evidence for a substantial placebo response in at least 35% of patients with severe pain in the clinical setting, the placebo response in the experimental setting is poorer. This difference could be due to the conditioning effect of the hospital setting which promotes the placebo effect. Further evidence to support this model of a conditioned response is a common empirical example of the immediate relief that may be obtained by taking a tablet known to contain aspirin. He argued that it must be due to the conditioning effect, as the latency was too short to be attributed to the pharmaceutical properties of the medication. Voudouris et al [407] provided some experimental support for this model. They carried out an experiment where subjects were conditioned to one type of placebo analgesic, by pairing the administration of the "analgesic" surreptitiously with an increase in painful stimuli in one half of the subjects and with a decrease in the other half. A second experiment was then carried out using different pain stimuli but the "same" placebo analgesic. The results showed that subjects who previously thought the drug was effective had more pain relief than those who had found it less helpful. More recently Voudouris et al [408] experimentally manipulated and compared conditioning and expectancy effects. They found that conditioning produced much stronger placebo effects than verbal expectancy.

These studies are open to different interpretation. The positive effects of the placebo could have been due to a reduction in levels of anxiety, since those who expected that the experimental pain would be bad were probably more anxious than those who had previously experienced little pain with the same analgesic. Anxiety reduction has been proposed by some researchers to be the mechanism of the placebo effect [35], [125], and Beecher found that the greater the anxiety the greater the relief obtained through placebo medication. There is however a lack of clear evidence to support this theory and the relationship between pain reports and anxiety are complex, as already
discussed (vide 4.3.3). Anxiety may act indirectly through the conditioning process [429], or through cognitive processes of perception.

Skelton & Pennebaker [366] posited that the placebo effect is a function of selective monitoring of bodily symptoms following treatment. If the patient expectancy for improvement has been raised by the health professional, then unless there is a particularly negative effect he will focus on a reduction in bodily sensation. There is much evidence to show that suggestion, credibility and expectancy all play an important role in the placebo response, as well as in a positive outcome to treatment generally [131], [317], [16]. It has been shown that at both cortical and sub-cortical levels suggestion can play an important role in the experience of pain and disability [10], [171], [124].

"Expectancy effects" are difficult to separate from "placebo effects", and the expressions are sometimes used synonymously [336]. Expectancy has direct effects on cognitions and indirect effects on behaviour [53]. The strength of the placebo is closely related to the strength of both the patient's and the health professional's expectations and enthusiasm for the treatment concerned [321]. The doctor or therapist's faith in the treatment, it has been proposed could be a critical factor [425], as this could influence the patient's attitude and behaviour. Placebo responders, according to O'Leary [303], may feel encouraged to have confidence in their ability to cope with the pain, with the help of the treatment. Perceived self-efficacy may be a mediator of the placebo process. Plotkin [321] emphasises the importance of the power of self-healing and its wider implications, a point which will be discussed further under 4.5.1.1.

Plotkin [321] conceptualised the placebo effect as "a special case of an intransitive phenomenon that I call self-healing". The fundamental issue he emphasised was that an individual must have complete faith in a treatment. Providing the person has no doubt, and is certain that he is going to be "cured", the placebo process can occur. The patient will then either; 1) actively engage in activities that they understand are part of the therapeutic procedure and will have complete faith in the healing powers of that behaviour; or 2) if the treatment is a passive form of therapy where the active role is only played by the therapist, the patient will begin to behave as someone who has been cured.

The biology of placebo analgesia has provided an exciting area of research, for both laboratory and clinical investigations. Results of both anatomical and physiological studies have shown that the brain possesses an intrinsic system for the control of pain [131]. Electrical stimulation of discrete sites in the brainstem can suppress pain.
response in animals and in man. Peptides pharmacologically identical to narcotic analgesic drugs have been found in the central nervous system. However, according to Rees [332] evidence to show that placebo analgesia is mediated by opioid peptides is not conclusive.

4.5.1.1 Practical Implications of the Placebo for the Physiotherapist in the Clinical Setting

From the practical point of view, placebo effects depend primarily on the individual's perception of the treatment, rather than any characteristic of the patient, the treatment or the therapist. However, there is much evidence to show that the style of administering a treatment is important [337], and the doctor's (or therapist's) personal beliefs and expectations may be quite subtly conveyed to the patient. The credibility of the treatment is all-important and needs to be taken into account when randomised controlled trials are designed [317]. Langley et al [239], in a study to evaluate the analgesic effects of TNS (vide 3.2.3), showed how it was possible to enhance a placebo effect by increasing suggestion, and its credibility by the use of distraction. These processes could be usefully exploited in physiotherapy practice to maximise the analgesic effect of treatment administered.

Plotkin [321] discussed the potentially enormous benefits of self-healing and stresses the need to make people aware of the power to control their health that they have within themselves. He notes that it would have the following benefits: 1) our dependency on the health care system would be reduced: 2) dependency on drugs and medication would be reduced, 3) self-healing, unlike medication, would could be used for different problems without the problem of tolerance; and 4) a population that is aware of its own potential for self-healing could be expected to stay healthier as they would be able to counter disease before it developed into an irreversible condition.

From Voudouris's work [407], [408] the message is that it is important to take a history of the patient's history to include their perception of their response to any previous treatment they may have had. If they previously found one form of treatment helped then, according to the conditioning theory it is likely that it will help them again.

4.5.2 Evaluation of Response to Treatment

In order to evaluate the effectiveness of any form of therapy, it is important to compare the method under investigation with a suitable placebo. Firstly, it should be a form of treatment that does not have any of the characteristic factors of the treatment
be as closely matched as possible in the two groups. For example, the use of untuned short wave diathermy as a control for a back school [38] fulfils the first criterion but not the second. It does not have similar characteristics in terms of contact time and attention provided by the therapist. Compared with the backschool it does however have different and probably not comparable incidental characteristics, such as it may have impressed the patient in terms of its apparent scientific "high tech" capacity to provide a cure.

All these aspects of placebo efficacy need to be taken into account when evaluating the effectiveness of a particular treatment for pain relief. This is especially important in the case of a new form of treatment which due to the enthusiasm of the doctor or therapist administering it, is likely to have especially potent placebo effects.

In addition the presence of a placebo response is only inferred by an improvement in a patient who has been administered a treatment without any known active ingredient [131]. It is possible that the individual's condition would have improved in any case without any intervention. In order to verify that the improvement was due to a placebo effect it is necessary to study the natural history of the condition and compare the placebo treatment group with a no-treatment control group. A rigorously designed RCT should take all these factors into account. An example of such a study is given in Chapter Ten.

Before considering the role of psychological variables in the outcome of treatment, it is important to consider their influence in the development and aetiology of pain. The next chapter reports the results of a prospective longitudinal study of back pain in student nurses. It is concerned with the physical and psychological variables which influence the perception and reporting of back pain.
CHAPTER FIVE: A LONGITUDINAL STUDY OF LOW BACK PAIN IN STUDENT NURSES

5.1 INTRODUCTION AND BACKGROUND TO THE STUDY

Concern is expressed in the literature at the recent escalation in disability owing to back pain which results in time off work [409], [296]. In the second half of the 1980s, the number of certified days of incapacity due to back pain in the UK rose by 69% and by the end of the decade back pain accounted for 13% of all certified days of all certified days of incapacity (DSS figures 1986-1990. 1 see source note, in section 3.1.2). Its prevalence in the nursing profession is second only to heavy industry [259]. This can be attributed to a combination of factors, including:

1) The considerable amount of lifting and manual handling that is regularly involved in the job [217], [260];

2) The mainly female membership of the profession and the fact that the lifting strength of women as a group is less than that of men [190];

3) The observation that on the wards at least 22% of a nurse's time is spent stooping, which may often be combined with twisting [61], [30], [11];

4) The psychologically stressful nature of the job which may often involve teenage female nurses in dealing with severe trauma, illness and death [308], [310].

In nursing, three quarters of a million working days are lost annually owing to back pain, 1 in 6 of these being attributed to patient handling incidents [379]. 43% suffer from back pain at least once during the course of a year. The problem of back pain in nurses has been brought to the forefront by cases of litigation by nurses claiming negligence on the part of the Health Authority.

A vast amount of research has been carried out on both causative and preventative factors associated with back pain. Much of this has been related to the nursing profession. There is little evidence to suggest that the incidence is reduced by traditional methods of training in lifting and handling [378], [154], [403]. It appears to be more prevalent on specific types of ward, such as geriatric and medical wards [94], [380], and is highest in student nurses and auxiliaries [251], [402].

Many personal characteristics, both physical and psychological, have been linked with back pain. These can be considered under the following headings:

1) Anthropometric measures and physical ability;
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2) Lifestyle and work;
3) Psycho-social factors.

There is some evidence that anthropometric measures such as height and weight or a ratio between these, related to obesity, may be linked to back pain [383], [285], [178]. Also the strength and endurance of the oblique abdominals, spinal extensors [167], [3], [41], [275] and quadriceps muscles may all play a role in the prevention of back strain. The ability to maintain a particular posture, over a period of time is likely to be more dependent upon maintaining an isometric contraction of relevant muscles over time, than a one-off maximal voluntary contraction. Sufficient muscle endurance is needed to maintain an erect spine with bent knees, if potentially hazardous or strenuous nursing manoeuvres are to be carried out in the recommended safe manner. Chaffin and co-workers [68], in a pre-employment testing study carried out over 18 months, found that the likelihood of back injury was increased when the job lifting requirements approached the maximum strength capability of an individual. The length of the hamstring muscles also may predispose an individual to back pain [374]. If they are short the pelvis will be rotated sooner in sitting or stooping, and flexion at the lumbo-sacral and lumbar intervertebral segments is therefore increased.

The lifestyle of the individual may affect the likelihood of back pain reported. There is some evidence that it is increased by smoking [146], [105] and decreased by regular exercise for fitness [63], [86]. Psychological factors such as anxiety, depression and a person's attitude towards their health are also likely to be associated with reports of back pain (vide section 4.3.3) [93]. In particular it can be hypothesised that people who believe that they have no control over their health and consider that whether or not they get back pain is purely a matter of chance are more likely to report back pain, because they may not attempt to take care of their backs. This is based on the concept of "health locus of control" described by Wallston et al [418] who also developed scales of measurement. However it is not known to what extent these physical and psychological characteristics contribute to the incidence and prevalence of back pain.

Student nurses present an ideal population for a longitudinal study of back pain. In this group, consisting mainly of women who are too young to have degenerative disc disease, the incidence of mechanical back strain is high. But it is possible to screen them before they are subjected to the stresses of ward work when the problem tends to arise. They can then be followed up at regular intervals during their 3 year training, and the attrition rate is likely to be relatively low.
This longitudinal study presented below, appears to be the first of its kind reported in the literature on student nurses. Its purpose was:

1) To report on the incidence of back pain and related sick-leave in student nurses over an 18 to 30 month period;
2) To examine the relationship between the incidence of back pain, the nurses' training, work and lifestyle;
3) To investigate whether individual differences (anthropometric measures and physical ability, lifestyle and work, psycho-social factors) or combinations of them predict a greater likelihood of back strain in an individual.

5.2 METHOD

5.2.1 Design

A prospective longitudinal study was carried out on student nurses over a period of 30 months. They were screened for physical and psychological factors prior to going on to the wards, and then followed up at intervals of approximately three months in the classroom setting, to collect completed diaries and questionnaires.

Prior to setting up the study ethical approval was sought and obtained from the Central Oxford Ethics Committee.

5.2.2 Subjects

All female student nurses from September 1985 to July 1987 were recruited on entry to their two schools of nursing at:

- The John Radcliffe Hospital in Oxford or,
- The Middlesex Hospital (which subsequently combined with University College Hospital in London).

They were given a brief verbal and written explanation of the study which was presented as a "Health and Fitness" project, to try to avoid biasing reports of back pain incidence. At the end of the study, on debriefing, only 10% recognised it as a study of back pain. Emphasis was placed on the anonymity and confidentiality of information gained from any individual.

A total of 374 student nurses were included in the study, 196 from Oxford and 178 from London. Thirty-five nurses dropped out of the study and 41 left the course during the study period. Reasons varied from having chosen the wrong career to
moving away and getting married, or in some cases prolonged sickness including back pain; but it was not possible to verify with any certainty the real reason in several cases. Seven students went down one set or more due to prolonged sick-leave.

It was possible to follow up a sub-sample of 199 student nurses for 20 months during their training. The remaining 175 were followed up for varying lengths of time depending on the stage at which they started their training and were included in the study. All figures reported in this chapter refer to the sub-sample of 199 nurses. 89% of the nurses were aged between 18 and 21 (range 18-44 years). 93% lived in the Nurses Home and therefore may have shared a similar domestic if not social lifestyle.

5.2.3 Procedure

5.2.3.1 Initial Screening

a) Questionnaires

At the outset of the study student nurses were asked to fill in a brief questionnaire to obtain demographic information including a history of back pain, and whether they smoked or took regular exercise.

A battery of four psychological questionnaires was administered in the classroom as part of the screening procedure:

1) Eysenck Personality Inventory, [127];

2) State-Trait Anxiety Inventory, [370];

3) Health Locus of Control [418];

4) General Health Questionnaire: 12-item version [18].

All these questionnaires previously have been used either in studies of back pain e.g. [153], [222], [307], [182] and/or in studies of nurses [309], [310] which was an important consideration in their favour.

The Eysenck Personality Inventory (EPI) was developed from the Maudsley Personality Inventory and sets out to measure two dimensions of personality, neuroticism and extraversion-introversion [127]. Eysenck and Eysenk [127] considered these personality traits to be correlates of biological factors, for example neuroticism being closely related to an inherited lability of the autonomic nervous system. They reported studies demonstrating high reliability and validity of the instrument when it was developed and it has been used in a great number of studies in the intervening years, in many different areas. Studies in the health care field have
Low Back Pain in Student Nurses

included research into the relationship between personality and drug tolerance [78] as well as personality and pain perception [183], [161]. Gordon [161] found that individuals who scored high on the neuroticism scale reported more pain than low scorers. Harkins et al [183] found that neuroticism was not related to the sensory component of either experimental or clinical pain, but that it greatly increased the level of affective disturbance and illness behaviour.

The EPI was used in the present study as a measure of neuroticism because there is some evidence of an association between neuroticism and back pain [21], [283]. Also it has previously been used in a nursing population [309] which showed that there were a higher proportion of stable extroverts in this population than expected.

The State-Trait Anxiety Inventory (STAI) was used to measure trait anxiety since it is considered to be a relatively stable personality variable, which should predict the response to potentially anxiety-provoking situations in the future [370]. Trait anxiety implies differences between people in the tendency to respond to stressful situations with varying amounts of state anxiety. But as Spielberger pointed out, previous experience is also an important factor as it will influence the extent to which an individual perceives a given situation as psychologically dangerous or threatening. People with a high trait anxiety are likely to more frequently have an elevated state anxiety, as they tend to interpret a broader range of situations as stressful.

The STAI was originally developed as an objective self-report research tool to assess state and trait anxiety in college students over a period extending from 1964 to 1970, and then revised again later in the following decade [370]. Its validity and reliability have been substantiated in a number of studies [266], [286], [300], [330]. It has more recently been used in a wide range of research areas including medical research. Previous studies have used the STAI to provide evidence of an association between back pain and anxiety [153], [222].

The General Health Questionnaire (GHQ) is a self-administered instrument originally designed for use in a general practice population in Britain to detect current, minor psychiatric disorders. [158]. An original 60-item check list has been the source of derivation for other shorter forms, including the GHQ-30, GHQ-20 and GHQ-12. More recently Goldberg [160] has reported it to be the most commonly used screening test and that over 50 well-constructed validity studies have been carried out (for example [384], [364]). It identifies two main classes of problem: "inability to carry out one's normal 'healthy' functions, and the appearance of new phenomena of a distressing nature".
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It purports to measure short-term breaks in normal psychological functioning \[159\] rather than more stable life-time traits. Goldberg \[159\] has emphasised that it measures a quality in individuals that is likely to be variable over time and was not intended to provide information which would be stable over time. It has been found that individuals complaining of back pain have higher GHQ scores but that these scores return to normal levels following treatment \[307\] at regular intervals. Parkes in a series of studies on occupational stress used the GHQ to assess the current level of psychological distress and found that nurses did not have unusually high scores compared with a community sample \[308\].

Goldberg \[159\] in the Manual of the GHQ addressed the methodological problems of designing reliability studies on an instrument that is designed to measure a variable that is likely in most individuals to vary over time. He reported a high reliability coefficient \((0.90)\) on test-retest in psychiatric patients who were assessed in a standardised interview to have a condition that had remained unchanged. He also carried out a split-half reliability study using 853 completed questionnaires and found it to be \(0.95\) \[159\].

The GHQ was designed to measure four elements of distress: depression, anxiety, social impairment, and hypochondriasis \[158\]. It was not however intended to be used for psychiatric diagnosis, but is considered suitable for use in surveys and in an occupational setting \[18\]. The short form of the GHQ, the GHQ-12 was chosen for use in this study partly because of a time premium, and because it had to be administered repeatedly during the follow-up phase, to monitor stress levels in nurses during their training.

The Health Locus of Control (HLC) was developed for use in health settings by Wallston & Wallston \[418\] as a unidimensional measure of people's beliefs that their health is or is not determined by their behaviour. As discussed in section 4.3.3.3, the scale was developed from Rotter's \[348\] and Lefcourt's research \[244\] into the internal-external control dimensions as derived from social learning theory.

It is designed to assess the extent to which people believe their behaviour is likely to have an influence on their health. Those with low scores have an internal locus of control, as opposed to those with high scores who believe that they have no control over their health, a characteristic referred to as external locus of control.
The HLC scale has 11 items, and those individuals with high scores are considered to have an external health locus of control (vide 4.3.3.3). They are presumed to have generalised expectancies that the factors which determine whether they have good or bad health are factors such as luck, fate, chance, powerful others and any other factors over which they have no control [418]. It has often been used in the health care setting in studies of pain perception and rehabilitation (e.g. [60], [182]).

It has been shown in previous research that locus of control may act as a mediator between life stressors and physical and mental well being [310], [99]. According to Parkes [310] the literature suggests that "internals" cope better with stressful situations because they use strategies which focus on altering them. Nurses are provided with some instruction on how to lift and handle patients and protect their own backs from injury, but the training is not always translated into practice in the ward situation [154]. Locus of control was used in this present study as potential predictor of back pain, by changing the word "illness" or "sick" to "back pain". It was thought to be an especially appropriate variable in a study investigating environmental factors and individual differences in relationship to the development of back pain reports in nurses.

b) Physical Screening

Student nurses underwent standardised physical tests, on an individual basis. These included measurements of weight, and standing height, from which the Quetelet obesity index could be calculated [218]. Sitting height was also measured [285].
Hamstring length was measured according to the method described by Biering-Sorensen \[41\] with modifications.

**Testing of Strength Endurance of the Muscles.** Each individual was tested on her ability to hold a specified position for each muscle group.

- **Oblique abdominal muscles** (Figure 5.1)

The subject lay with hips and knees bent, feet flat on the bed and hands clasped behind her head. She was instructed to lift her head and both shoulders off the bed bending in the middle and twisting her trunk, so that her right elbow touched a marked position to her left. This target was a bar level with the umbilicus and on a line extending from the axilla. This was then repeated to the opposite side. The position maximises contraction of the oblique abdominals \[120\].

- **Back extensors** (Figure 5.2)

The subject was lying face down with her hips (anterior superior iliac spines) at the edge of the bed, with belt fixation over the calf muscles and pelvis, and hands clasped behind her head. She was asked to raise her trunk to the horizontal in line with the legs. The positioning used was the same as Biering-Sorenson \[41\].

- **Quadriceps** (Figure 5.3)

The subject was positioned with her back up against a wall, feet 12" apart and asked to assume a position of 90 degrees at the hips and knees, keeping the back straight and arms relaxed by the side.
For each muscle group the length of time that the subject managed to maintain the defined position without deviating was timed on a stop-watch. As with any physical test of this kind the results depended on the determination and motivation of the individual subject as well as the physical strength endurance of the muscles. Six nurses did not attend for physical screening tests, and two who attended declined to attempt the strength endurance testing of the muscles, so that eight sets of data were incomplete for these physical variables.

5.2.3.2 Follow up Data Collection

This was carried out in a classroom setting each time the students returned from the wards to school. Immediately prior to starting work on the wards the nurses were asked to provide daily recordings of any pain, health problems and sick leave, on specially prepared "diary" sheets. These contained body charts for the nurses to shade in any aches or pains and Visual Analogue Scales, labelled 0 for "No pain" at one end and "Pain so bad I had to take sick leave" at the other end. No special reference to back pain was made to avoid focusing their attention on this. But our definition of
back pain was any pain below T12 according to the body chart provided, i.e. emanating from the lumbar region.

At approximately 3-monthly intervals, these diaries were collected, and new diaries were issued to be completed while they were working on their next ward. On the same occasion, they completed a questionnaire about the type of ward they had worked on. This included the ward name, and also they were asked to judge on a 6-point scale how heavy the work on that ward had been. They also were asked to report any changes in their exercise habits, and any emotional or physical strain over the period for which they had completed their last diaries.

In addition, the GHQ-12 was administered each time to monitor any variations in emotional disturbance.

5.3 RESULTS

5.3.1 Epidemiology

It was possible to follow up 199 nurses for 20 months during their training. The results reported here refer to this group of nurses for this specified time period.

One hundred and twenty-seven nurses of the 199 (64%) reported low back pain (LBP), lasting one day or more at some stage during the 20 months; 72 did not. Of those suffering low back pain, the total number of back pain days experienced ranged
from 1 to 223 days (median: 7 days). Back pain accounted overall for 50% of all types of pain reports, and over time consistently represented a large proportion of pain reports (vide Figure 5.4). It can be seen that the pattern of back pain reported over time contrasts with that of other pain reports.

The prevalence of back pain (that is the proportion of nurses reporting it in any one diary) peaks between 9 and 12 months into training and then drops off substantially (Figure 5.5).

The incidence (that is, the total number of episodes reported) follows a similar pattern. 103 nurses of the 127 (81%) reported their first episode in the initial 12 months (Figure 5.6).

74 (37%) nurses reported at least one episode of a minimum of three consecutive days within the same 12 month period. 58% of all back pain reports (minimum three consecutive days) occurred in the first 12 months.

Of 1913 reported sick days during the 20 months follow-up, 45 nurses reported a total of 118 days (6.2%) due to back pain. 37 of these nurses (82%) attributed at least one episode to heavy lifting or strain at work on the wards.

Four of the wards were rated by 98% of the nurses as largely heavy physical work, involving a lot of bending and lifting and these wards on decoding were found to be geriatric wards at two hospitals in Oxford and one in London. Fourteen new incidents of LBP lasting at least three days were linked with these wards. The greatest rate of first incidence coincided with working on two geriatric wards, one in Oxford and one
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Figure 5.6. First incidence of LBP reported by student nurses

in London. In comparison, only six new incidents were reported in association with ear nose and throat (ENT), psychiatric, gynaecological, and obstetric wards which 99% agreed were not heavy wards. These results are in line with a previous study which showed that geriatric wards are associated the greatest number of first attacks of low back pain, and account for 20% of all first-time incidence [94].

5.3.2 Factors Contributing to the Reporting of Back Pain

In an attempt to identify those nurses with a back pain problem significant enough to possibly affect their well-being and ability to function effectively, student nurses complaining of back pain were categorised according to the following criteria:

1) "CASES A": Those reporting a minimum of three consecutive days of LBP (n=85), and

2) "CASES B": Those reporting a total of 21 days LBP or more, and/or one day off sick with back pain (n=43). This group was considered more likely to include more serious cases of back pain.

5.3.2 Inferential Statistical Analysis

The SPSSX statistical software package was used to screen and analyse the data. Eight nurses who scored over five on the Lie scale of the EPI were excluded from the analysis. The lie scale has been shown to be valid, reliable and useful to detect individuals "faking good", and it is suggested that data from individuals scoring five or over may be unreliable [127].
With one exception, all students qualifying for "Cases B" also qualified for "Cases A". On closer examination, this individual reported at least one day off sick with back pain, but was unable to remember if she had experienced 3 consecutive days LBP. As her incomplete data failed to categorise her as a "Case A" as well as a "Case B", it was decided to exclude her from the analysis. One other nurse's data set was excluded as she was found to be a bivariate outlier scoring very low on the Trait anxiety scale but high on the neuroticism scale of the EPI, which is a dubious combination. She would have been classified as a non-case.

After these ten subjects were excluded, in addition to the eight who did not have complete sets of data from the physical tests, 181 nurses were finally included in the inferential statistical analysis.

5.3.2.1 "Cases A" (Minimum 3 consecutive days of LBP)

Student's t-tests were carried out to compare baseline data of "Cases A" with non-cases, on the variables listed in Table 5.1., using a total of 181 cases as discussed above. The data were not normally distributed on the following variables: the three strength endurance muscle tests, body weight, the Quetelet Index derived from weight and height, the GHQ and the extraversion scale of the EPI. Appropriate transformations were applied to normalise these sets of data, prior to analysis. The untransformed means and standard deviations are displayed in Table 5.1. and show that all three measures of muscle strength endurance, that is the duration of time for which an individual could maintain a position as indicated in Figures 5.1. to 5.3. were greater for the non-cases group, but there was considerable variation in the groups between individuals, as shown by the high standard deviations. The results of t-tests revealed no significant differences, except for the HLC which was significantly higher (that is more external) in the LBP group (t=-2.00, df=179, p<0.05).

Remaining baseline data which did not fulfil the assumptions required for t-tests, were analysed by non-parametric statistics: Mann-Whitney test for the regularity and amount of exercise the nurses reported they carried out prior to the study; and chi-squared for the "amount smoked" and for "any history of back pain". The results of all these non-parametric tests for lifestyle and situational variables comparing "Cases A" with non-cases were all non-significant, with one exception; "Cases A" nurses more frequently reported giving up regular sporting activities compared with non-cases (z=-2.3633, df=179, p<0.02).
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Table 5.1. Untransformed means and standard deviations of baseline data comparing "Cases A" with non-cases

<table>
<thead>
<tr>
<th>Baseline Data</th>
<th>Cases (n = 83)</th>
<th>Non-cases (n = 98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting height (cm)</td>
<td>123.42 (2.87)</td>
<td>123.49 (2.73)</td>
</tr>
<tr>
<td>Standing height (cm)</td>
<td>166.22 (5.43)</td>
<td>165.51 (5.75)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>59.64 (8.16)</td>
<td>59.47 (7.74)</td>
</tr>
<tr>
<td>Obesity (Quetelet Index)</td>
<td>0.22 (0.03)</td>
<td>0.22 (0.02)</td>
</tr>
<tr>
<td>Hamstring length (degrees, max 180°)</td>
<td>158.63 (11.53)</td>
<td>159.89 (10.68)</td>
</tr>
<tr>
<td>Strength endurance (secs):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oblique abdominal muscles</td>
<td>27.94 (25.08)</td>
<td>33.18 (37.44)</td>
</tr>
<tr>
<td>Spinal extensor muscles</td>
<td>104.69 (39.09)</td>
<td>106.80 (41.78)</td>
</tr>
<tr>
<td>Quadriceps muscles</td>
<td>70.29 (43.39)</td>
<td>79.05 (48.07)</td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extroversion</td>
<td>13.74 (4.06)</td>
<td>13.30 (3.81)</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>10.86 (4.49)</td>
<td>9.98 (4.52)</td>
</tr>
<tr>
<td>Lie</td>
<td>2.64 (1.33)</td>
<td>2.74 (1.50)</td>
</tr>
<tr>
<td>Trait-anxiety</td>
<td>37.52 (7.85)</td>
<td>38.84 (7.16)</td>
</tr>
<tr>
<td>Health Locus of Control</td>
<td>34.36 (6.01)</td>
<td>32.67 (5.36)</td>
</tr>
<tr>
<td>General Health Questionnaire</td>
<td>10.29 (4.76)</td>
<td>9.52 (4.21)</td>
</tr>
</tbody>
</table>

In order to test whether group membership could reliably be predicted using the foregoing baseline data [382], stepwise discriminant functional analysis was performed including all variables shown in Table 5.1. This selects for inclusion in analysis that variable which produces the greatest increase in separation between the centroids of the two groups subject to it having an F-value of at least one to enter the analysis.

Inspection of Table 5.2. shows group membership is best described by a list of seven variables in combination: HLC, low Trait anxiety, neuroticism, GHQ scores, standing height, sitting height and quadriceps muscle strength endurance. In combination, these variables provide a 66% correct prediction of 55 out 83 actual cases, also correctly predicting 62 out of 98 non-cases. This is significantly better than chance (p<0.001).
Table 5.2. Variables selected by discriminant analysis of nurses (n=181) with a minimum of 3 days back pain: "Cases A"

<table>
<thead>
<tr>
<th>Step</th>
<th>Variable entered</th>
<th>Wilks Lambda</th>
<th>Min D Squared</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HLC</td>
<td>0.97821</td>
<td>0.08872</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>Trait anxiety</td>
<td>0.96976</td>
<td>0.12420</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Neuroticism</td>
<td>0.91959</td>
<td>0.34829</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>GHQ</td>
<td>0.91164</td>
<td>0.38606</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>Standing height</td>
<td>0.90524</td>
<td>0.41694</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>Sitting height</td>
<td>0.89820</td>
<td>0.45146</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Quadriceps</td>
<td>0.89283</td>
<td>0.47810</td>
<td>+</td>
</tr>
</tbody>
</table>

5.3.2.2 "Cases B" (Total of 21 days or more LBP / one day or more off sick with LBP)

Inspection of Table 5.3 displaying the untransformed means and standard deviations, reveals that as for the previous analysis of "Cases A", a similar pattern for the three measures of muscle strength endurance. That is the duration of time for which an individual could maintain a position as indicated in Figures 5.1 to 5.3 tended to be greater for the non-cases, but there was considerable variation in the groups between individuals, as shown by the high standard deviations. "Cases B" show bigger discrepancies compared with "Non-Cases B" than "Cases A" show with all non-cases. However results of Student's t-tests revealed no significant differences between the two groups on these variables or any other of the interval level data.

But non-parametric tests using the Mann-Whitney test revealed a statistically significant difference between the two groups on two other variables. The total number of reports of physical exertion (apart from ward work or sport) over the 20 months of follow up was slightly greater in "Cases B", as was the number of episodes of emotional distress reported by an individual, respectively \( t = -2.27, df = 179, p < 0.05 \), \( t = -2.09, df = 179, p < 0.05 \)

A second discriminant analysis was carried out on this group, categorised as "Cases B", including only parametric data and this time four variables in total are selected (vide Table 5.4).
Table 5.3. Untransformed means and standard deviations of baseline data comparing "Cases B" with "Non-cases B"

<table>
<thead>
<tr>
<th>Baseline Data</th>
<th>Cases (n = 38)</th>
<th>Non-cases (n = 143)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting height</td>
<td>123.11 (2.61)</td>
<td>123.55 (2.83)</td>
</tr>
<tr>
<td>Standing height</td>
<td>166.03 (5.55)</td>
<td>165.78 (5.63)</td>
</tr>
<tr>
<td>Weight</td>
<td>59.05 (8.26)</td>
<td>59.68 (7.84)</td>
</tr>
<tr>
<td>Obesity (Quetelet Index)</td>
<td>0.21 (0.03)</td>
<td>0.22 (0.0.3)</td>
</tr>
<tr>
<td>Hamstring length (max 180)</td>
<td>159.51 (112.15)</td>
<td>159.26 (10.81)</td>
</tr>
<tr>
<td>Strength endurance (secs):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oblique abdominal muscles</td>
<td>24.84 (17.81)</td>
<td>32.36 (35.14)</td>
</tr>
<tr>
<td>Spinal extensor muscles</td>
<td>98.68 (39.45)</td>
<td>107.73 (40.67)</td>
</tr>
<tr>
<td>Quadriceps muscles</td>
<td>67.05 (36.71)</td>
<td>77.15 (48.13)</td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extroversion</td>
<td>13.55 (3.49)</td>
<td>13.48 (4.04)</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>11.13 (4.21)</td>
<td>10.18 (4.58)</td>
</tr>
<tr>
<td>Lie</td>
<td>2.68 (1.30)</td>
<td>2.69 (1.46)</td>
</tr>
<tr>
<td>Trait-anxiety</td>
<td>36.16 (7.17)</td>
<td>38.78 (7.50)</td>
</tr>
<tr>
<td>Health Locus of Control</td>
<td>34.05 (6.77)</td>
<td>33.29 (5.42)</td>
</tr>
<tr>
<td>General Health Questionnaire</td>
<td>10.13 (4.22)</td>
<td>9.80 (4.55)</td>
</tr>
</tbody>
</table>

Table 5.4. Variables selected by discriminant analysis of nurses (n=181) with a minimum of 21 days back pain, or at least 1 day off sick with back pain: "Cases B"

<table>
<thead>
<tr>
<th>Step</th>
<th>Variable entered</th>
<th>Wilks Lambda</th>
<th>Min D Squared</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Trait anxiety</td>
<td>0.97951</td>
<td>0.12475</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Neuroticism</td>
<td>0.90368</td>
<td>0.63547</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>GHQ</td>
<td>0.89397</td>
<td>0.70714</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>Quadriceps</td>
<td>0.89283</td>
<td>0.75320</td>
<td>-</td>
</tr>
</tbody>
</table>
In combination, Trait anxiety, neuroticism, GHQ scores, and quadriceps muscle strength endurance provided a 74% correct prediction (28 out of 38 actual cases), and also correctly predicted 94 out of 143 non-cases. This is significantly better than chance (p<0.001).

The length of time for which the nurses were able to maintain a particular posture (as shown on the figures 5.1 to 5.3), demonstrated systematic differences in the expected direction, although they were not statistically significant. Nurses defined as "Cases A", that is at least 3 consecutive days of back pain, as a group always showed less ability to maintain the positions which were used as measures of strength endurance, and "Cases B", those who were more serious cases of back pain, showed a further decrease in strength endurance (vide table 5.5).

### Table 5.5 Strength endurance expressed as percentage of the Non-Case values
(time in seconds subjects were able to maintain position)

<table>
<thead>
<tr>
<th>Muscle Groups tested</th>
<th>&quot;Cases A&quot;</th>
<th>&quot;Cases B&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oblique abdominals</td>
<td>84%</td>
<td>76%</td>
</tr>
<tr>
<td>Spinal extensors</td>
<td>98%</td>
<td>92%</td>
</tr>
<tr>
<td>Quadriceps</td>
<td>89%</td>
<td>87%</td>
</tr>
</tbody>
</table>

5.4 Discussion

Direct comparison of data in epidemiological studies is difficult. The methodology, retrospective collection of data, response rate, definition of the population sample and definition of low back pain all contribute to the complexity of the problem [376].

This study has attempted to minimise the dependency on memory for recall of events, and an individual's response to these (vide 4.2.3). Subjects were asked to record any ache or pain which lasted for the greater part of a day, including back pain (although this was not specifically alluded to) as it occurred. It appears to have been the first prospective and longitudinal study of low back pain to have been carried out on a largely homogeneous group like student nurses. Inclusion was necessarily sequential over the two and a half year period available, which meant that just over half of those included had complete data over a maximum period of 20 months. 90% of all student nurses entering their training were recruited to the study, although inevitably a few left the course or dropped out from the study. Coincidentally, both schools of nursing
underwent upheavals during the course of the study due to the Middlesex Hospital amalgamating with University College Hospital; and in Oxford due to preparations for transfer to the Polytechnic.

5.4.1 Work Related LBP

In this study we found a high frequency of low back pain reports in female student nurses aged 18 to 44 years (89% of them under 22). In response to an open question regarding any known cause of back pain, the majority attributed it to "Lifting at work". Evidence from this study also suggests that there was a higher rate of back pain on those wards described by nurses as involving heavy physical work, a lot of bending, and a lot of lifting, compared with those wards with little of the afore-mentioned. Other studies report a prevalence of back pain in younger age groups (<30 years) and suggest that in this group back pain is associated with heavy physical work and lifting [40], [260]. This is reported in 20-24 year old females by Videman et al [402], [251] and Skovron et al [367] and in nurses particularly related to their work [379], [181], [399]. The wards which the nurses consistently reported as heavy physical work etc., were all geriatric wards in Oxford and in London, confirming previous work [94], [380]. However, medical wards were not consistently rated as heavy, which probably could be explained by the varied occupancy, and resultant variability in functional dependence of the patients on these wards.

5.4.2 Peaking of Incidence

The results of our study showed a consistent and marked peaking of incidence of back pain between nine and twelve months into training suggesting that student nurses are specifically at risk at this time. Changes in the present schedule of training in lifting and handling need to be considered. We suggest that a greater emphasis on this aspect of training should be instituted between 6 and 9 months into training, to try to reduce the peaking of back pain incidence. Much of the literature on the subject emphasises the need for training based on sound ergonomic principles, applied in the workplace rather than the classroom [377], [154].

The precise details of content and quantity provided at the schools under investigation was not available, but approximately ten hours of training in lifting and handling mostly over the first few months appeared to be the norm but was apt to vary depending on the tutor in charge. Our findings suggest a need to consolidate early training given in the classroom, to make sure as far as possible that safe methods of lifting and handling are put into practice on the wards.
Low Back Pain in Student Nurses

The peaking of back pain incidence and prevalence between nine and twelve months into training contrasts with the pattern of pain reports due to other causes (Figure 5.4). The majority population age range of 18 to 22 is young to attribute LBP to disc degeneration. Few nurses report clinical signs commensurate with prolapsed intervertebral disc, most of them complaining of back pain without leg pain or sciatica. The back pain may emanate from cartilage end plates which distribute the compressive loads to the vertebral bodies. Microfractures may occur in a weakened spine under stress; this may affect fluid transfer and metabolism of the disc. Later on it may contribute to disc degeneration and prolapsed intervertebral disc [69], [57]. This could explain the double peaking of incidence with age, reported elsewhere [94], [353], [402]. The cause cannot be attributed to one isolated incident but must be considered as cumulative, with fatigue also playing an important role.

5.4.3 Improved Recording of LBP

In contrast to the frequent reports of LBP lasting for a minimum of three consecutive days, relatively little sick-leave was taken because of back pain. Nurses continued to work despite pain which must ultimately effect their general well-being and their effectiveness at work. Sick-leave reflects only the tip of the iceberg, so that the employing Health Authority is unlikely to be aware of the size of the problem. The DHSS-commissioned report produced by the Robens Institute on back pain in nurses [377] recommended that a standardised national reporting system should be set up, this being essential to ensure a reliable estimate of the size and nature of the problem. However, this was rejected by the DHSS in favour of local action [110]. It is imperative that the method of reporting within the profession be improved at a local level and standardised nationally. The development of information systems as recommended by the RCN advisory panel [377] is of fundamental importance, for the following reasons:

1) The present method of self-certification masks any problem of repeated minor episodes which may predispose to a more serious back pain problem;

2) Effective action can only be taken in response to detailed and reliable information; and

3) In view of the large number of litigation cases emerging, documentation of the onset of the problem and its course is essential.
Chapter Five

5.4.4 Physical Tests, Anthropometry, and Age

The results of this study did not support some previous reports of association of back pain with anthropometric measures [383], [285], [178]. They indicated that a combination of physical factors may play a role in LBP. In both "Cases A" and "Cases B", the strength endurance of the quadriceps muscles as tested in this study was one of the variables selected by the discriminant analysis (see tables 5.2 & 5.4). Lifting and handling effectively with knees bent as recommended requires good quadriceps control. It has been observed in a small biomechanical study that when quadriceps muscles are fatigued an individual is more likely to revert from a "squat lift" to a "stoop lift" in order to reduce the demands put on these muscles [390]. The test used in this present study in nurses was specifically related to the demand on the muscles in the working situation and is therefore more likely to be a valid and relevant test, compared with the tests for the oblique abdominals and spinal extensors. However, all three tests of strength endurance (quadriceps, spinal extensors and oblique abdominal muscles) produced lower mean values for the back pain cases, and "Cases B" showed a greater deficit compared with "Cases A", although the last two tests did not produce great enough differences to be selected by the discriminant analysis. This may have been due to the very large variations in the student nurses' physical capability.

One interpretation of these results is that these tests had little predictive value for LBP, perhaps because they were not specifically enough related to the task [350]. Also the tests were not evaluated for reliability and validity. The method of testing was very simple and required a minimum of basic and portable equipment. However, it can be seen on table 5.5 that the results of these tests varied across the groups in a manner consistent with the hypothesis that reduced strength and endurance of these muscles may be a risk for back pain. Some evidence for their validity and reliability is therefore provided.

All the measures were recorded at the beginning of the study prior to the onset of back pain, so that this trend of progressively reduced strength endurance in back pain cases could be viewed with caution to represent some evidence in favour of their contribution (together with other variables) to the development of back pain. The results of the t-tests however were not statistically significant due to the large standard deviations.

For "Cases A", both standing height and sitting height were selected by discriminant analysis. Mean measurements of sitting height was marginally lower in the cases (123.42 cm [sd 2.87]), compared with (123.49 cm [sd 2.73]) for the non-cases, whilst
standing height was slightly greater (166.21 cm [sd 5.443]), compared with (165.51 cm [sd 5.75]) the height of the non-cases. T-tests on all of these physical variables showed no significant differences between the cases and non-cases. This is in line with previous studies on standing and sitting height which overall have not provided conclusive evidence of a link between these anthropometric measures and back pain [324].

The distribution of age in this sample population of student nurses was very skewed with a range of 18 to 44 years, although 89% were under 22. For this reason age could not be included in the discriminant analysis.

5.4.5 Lifestyle and Situational Variables

"Cases A" reported significantly more often than non-cases that they had given up sporting activities that they had previously enjoyed "regularly". It is possible that this may have rendered them more physically unfit, but it may simply reflect other mediating factors, such as the lack of a stable lifestyle. This variable was no longer relevant in nurses who were categorised as "Cases B", and other factors may have predominated in the more serious cases. These nurses recorded more situations outside the workplace which they perceived as physically stressful and also more emotionally stressful situations. These factors, however, cannot be considered as predictors as they were recorded repeatedly over time and may have partly been the result of back pain which was already present, rather than a contributory cause. Psychological traits may play a mediating role in the way in which different individuals cope with different stressful situations [59], [310].

5.4.6 Psychological Factors

Rather than physical variables, a combination of variables from all the psychological questionnaires completed by the nurses at the beginning of the study played a more important role in predicting back pain. The results of this study are in line with two other studies, one of which was carried out in the USA [44] and the other in Norway [59]. In another much larger prospective study of back pain in the workplace 3,000 aircraft workers at the Boeing factory in Seattle were followed up for four years, and 279 reported back pain [29], [46], [44], [28]. The relationship between back pain reported in this industrial setting and physical, psychological and workplace factors was investigated. Bigos and colleagues concluded that, apart from recent back problems, non-physical factors were the best predictors of back pain reports, especially job stress and dissatisfaction with the work environment [46], [45]. In addition they
found that reporting of back pain was associated with raised MMPI scores on the Hy (hysteria) scale.

5.4.6.1 Health Locus of Control

In this present study, there was support for the hypothesis that nurses who have a highly external health locus of control are more likely to complain of back pain, although it played no role in predicting slightly more serious cases of back pain. This is consistent with the concept that "externals" would be less likely to take care of their backs, than "internals", for example by avoiding stooping as much as possible, and therefore be more at risk. HLC was not one of the predictors of the slightly more serious back pain ("Cases B"), possibly because "internals" found that taking care of their backs did not protect them from back pain as other factors were more influential at this stage. It has been noted that patients who have tried many treatments without success, may over time become less confident of their control over a pain problem [182], [396].

One of the variables included in the Boeing study was the HLC, but they did not find it had any predictive value in reporting acute back pain at work [46]. Harkapaa et al also used the HLC in their study of Finnish blue collar workers, comparing in-patient, and out-patient rehabilitation programmes for back pain patients with a control group [182], and found that together with psychological distress as measured by the GHQ, it was predictive of successful outcome of rehabilitation. In this present study it seems that having an internal HLC did not protect a nurse from more persistent back pain. Parkes [310], in her study of stress in nurses, investigated the relationship between locus of control, cognitive appraisal and coping in stressful episodes. She found that "internals" were more likely to appraise a situation, and if it was judged by them to be amenable to change, they used direct coping, but otherwise they used suppression. Parkes argued that if some control of the situation was possible direct coping would be more effective than suppression. This analysis can be used to explain in the present study why "externals" were more likely than "internals" to report mild back pain problems; but this was not the case for more serious back pain problems. Perhaps "internals" used direct coping to combat mild back pain problems, but with more serious back pain problems (possibly associated with medical consultations), control over the problem was seen to be unrealistic.

An alternative interpretation, unrelated to coping behaviour, is that the HLC was not sensitive or specific enough to be a reliable predictor. The Multidimensional Health Locus of Control was subsequently developed and the unidimensional scale of external / internal was replaced with three separate scales, "Chance", "Powerful Other" and
"Internal" [420]. Main & Waddell [262] more recently carried out a study to investigate the psychometric properties and clinical usefulness of a number of cognitive measures for assessing back pain patients. They found that in comparison with a more specifically targeted questionnaire (the Pain Locus of Control) and other cognitive measures of coping and control, the reliability of the MHLC was lower and its original published description could not be replicated with principal components analysis. Therefore no evidence for its reliability and validity was found.

More recently Wallston has critically reviewed his and other workers' experience with the HLC and MHLC [419]. He reported a series of studies in which the internal HLC explained only a very small part of the variance, and noted the failure of the measure as predictor of health in a series of studies. Wallston concluded that health values probably play a more important role than locus of control. Based on Bandura's work (e.g. [16], [17]) he also argued that perceived control may be a more useful concept than locus of control. In the field of rehabilitation, Partridge & Johnston [311] developed a measure of the "perceived control of recovery". This instrument was found to be highly predictive of recovery in stroke patients and in patients with fractured wrist bones, patients with greater perceived control recovering more quickly [212]. Health Locus of Control, however, may play only a limited role in predicting pain reports, which could explain why it was not more closely correlated with nurses reporting back pain.

5.4.6.2 Trait Anxiety

Trait anxiety, which could be expected to be positively associated with the incidence of back pain, was negatively correlated with it. This was an unexpected finding and is in contrast with previous research [153], [222]. In an earlier study of the pain response in chronic back pain patients, the present author used the SETT to induce experimental pain and investigate pain responses [222]. She found that these patients did not differ in their pain response or state anxiety scores compared with non-back pain patients. But she did find that the back pain patients had significantly higher trait anxiety scores. This association with back pain does not however provide evidence of a causal link, and raised trait anxiety scores could have been the result of unremitting pain. In another more recent study, of the determinants of the pain experience, Moosberger & Schermelleh-Engel found that patients with high Trait anxiety scores had relatively low scores on the affective measures of pain, provided their perceived levels of competence were high [290]. In the present study, the trait anxiety and other questionnaires were completed by the student nurses at the screening stage of the study prior to the onset of back pain. Rather than being a predictor of back pain, trait anxiety appeared to
provide some protection from back pain. Possibly, those who had very low scores were less cautious in their lifting and handling techniques, and therefore were more at risk. Trait anxiety and neuroticism were, however, as expected positively correlated ($r=0.73$).

5.4.6.3 Neuroticism

Those scoring higher on neuroticism were more likely to report back pain. This was in line with the findings of Bru et al [59], who in a correlational study of 586 female staff members (mainly nurses) in a Norwegian hospital, investigated the relationship between a number personality traits and reports of musculoskeletal pain, categorised as neck, shoulder and low back pain. These researchers reported neuroticism as one of the mediators of back pain reports [59], and also trait anxiety although the relationship was weaker. Neuroticism and trait anxiety were correlated in this study too although in both the present study and in Bru's the overlap of variance for which they both account is only 50%. On examination of the items in the two questionnaires it is apparent that the Eysenck scales include more than just a measure of anxiety. The neuroticism scales include items related to somatic perceptions such as "Do you get palpitations or thumping in your heart?", "Are you troubled by aches and pains?", "Do you worry about your health?". Previous research has suggested that individuals who are concerned with their bodily functions and tend to focus on physical sensations, are more likely to report these as pain [315], [366], [276] (vide 4.3.1). Somatic concern has also been shown to play an important role as a predictor of outcome of back pain and disability in the longer term [272], [263], [166] together with other cognitive variables (vide 4.4). In the Boeing study, previously discussed in 5.4.6 the most important predictor on the MMPI scales was raised $Hy$, and those in the highest quintile were twice as likely to report a back pain injury as those in the lowest quintile [46]. This additional somatic component of the EPI neuroticism scale could help to explain why this variable was selected in combination with low trait anxiety scores, as a predictor of back pain reports in the present study of student nurses.

5.4.6.4 General Health Questionnaire

The score on the GHQ was also included in the factors contributing to the incidence of back pain. Those who, according to this short 12-item version of the GHQ, reported more psychological disturbance, were more likely to report back pain. The GHQ was not originally developed as a predictive tool [159] but results of previous research have provided some evidence of its predictive validity [39]. In a study carried out by the author on chronic back patients comparing their pain response with non-back pain patients she found that GHQ-30 scores were significantly higher in the back pain group.
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[222]. The shorter 12-item version also appears in this present study to have had some weak predictive power contributing to the identification of nurses likely to report back problems. The student nurses who reported back pain had a slightly higher GHQ scores than a similar occupational group of recent school leavers [18]. Nurses who during their time on the wards more frequently reported emotional distress, were more likely to report back pain. Harkapaa et al in their study of back pain patients found that patients who had high levels of distress according the GHQ-12 scores were less likely to be accomplished at demonstrating the exercises they had been taught [182]. These authors suggested this was due to the patients' distress interfering with their ability to learn, but it could also have been due to their distress causing a lack of motivation to practice the exercises.

In both "Cases A" and "Cases B", the variables primarily, were selected by discriminant analysis to differentiate between cases of back pain and non-cases were primarily psychological. The subsequent addition of physical variables to the analysis improved the correct prediction of "Cases A" by only two percent and "Cases B" by eleven percent. These results imply that psychological variables are equally important for both categories of back pain, but physical variables may be more important in the potentially more serious cases. In the slightly more serious cases of back pain ("Cases B"), presumably biomechanical factors assumed more importance.

5.5 CONCLUSIONS

1 Since the reporting back pain peaks so markedly towards the end of the first year of training, consideration should be given to a modified programme of training in lifting and handling, particularly with regard to its timing and emphasis in the course.

2 There is no standardised method of recording back pain at work and any changes in its incidence are difficult to monitor. A policy needs to be introduced to develop an improved method of recording back injury/back pain at work and any resulting sick-leave.

3 Survival analysis to include the total number of nurses recruited to the study (n=376) could shed further light on the incidence of low back pain in student nurses.

This chapter has reported the incidence of back pain in student nurses over a period of 20 months and investigated potential factors which might contribute to nurses reporting back pain. Both physical and psychological variables have been shown to
play a role in the development of back pain in student nurses, and also situational variables such as the number of emotionally stressful episodes reported by the individual have been shown to be related to the reporting of back pain. The results have highlighted the multifactorial nature of the problem, with psychological factors playing the major role in predicting back pain reports.

The following chapter considers the methodological requirements of a randomised controlled trial, before reporting the role of psychological variables in the patients' outcome in a series of physiotherapy studies.
CHAPTER SIX: THE METHODOLOGICAL REQUIREMENTS OF A RANDOMISED CONTROLLED TRIAL

6.1 INTRODUCTION

In order to evaluate the effectiveness of physiotherapy outcomes, wherever possible randomised double blind placebo controlled trials are desirable. A number of methodological issues need to be addressed when they are designed.

The main purpose of a randomised controlled trial (RCT) is to reduce the potential influence of bias, when assessing and comparing different forms of treatment. The aim should be to minimise the chances that any change in the patient's condition could be due to anything other than the treatment under investigation [323], [322].

6.2 RANDOMISATION

A method of randomisation is needed which confers on every patient an equal chance of being allocated to either treatment group. If there are sufficient numbers in each group there is then a high chance that different characteristics amongst the study patients will be evenly distributed across the different groups, so that valid comparisons in treatment response can be made across the groups [226]. However, stratification can also be useful to allow more detailed information to be derived through sub-categories which can be analysed in separate cells of a factorial design [323].

6.3 THE SAMPLE

The sample from which the patient population is drawn needs to be clearly defined and, in the field of MSD particularly, operational definitions are essential, as diagnostic categories can often not be reliably distinguished in clinical practice, and there is a great deal of overlap in terminology. Both inclusion and exclusion criteria need to be clearly listed. There is often a fine tension between these two. If the exclusion criteria are too extensive and allow only a very specific group of patients to be included, it may be impossible to recruit a sufficient number of patients, and also the generalisability of the study will be reduced. However, if the inclusion criteria are too wide, then the internal validity of the study will also be threatened, as some patients may receive inappropriate treatment.

This is a major problem in the field of MSD. For example in trials of back pain treatment, homogeneity is considered to be a difficulty. As mentioned in 3.1.2 it is
only possible to confidently attach a precise diagnostic label to a very small percentage
of LBP patients [295], [107], [289]. The selection criteria will depend on the
treatment being investigated, and a balance needs to be found between practical
realism, statistical assumptions and ethical considerations [423]. Heterogeneity of the
sample is one of the reasons suggested by Beckerman [34] in a review 180 clinical
trials, for the frequent failure of physiotherapy studies to provide evidence of a positive
outcome of treatment [34].

6.4 CONTROL GROUPS

Much physiotherapy research has failed to include a control group (vide Chapters Two
and Three), and it has therefore been impossible to assess whether positive results
reported were due to changes in the condition related to its natural history, due to the
phenomenon of regression to the mean or due to placebo effects of treatment.

6.4.1 No-Treatment Control

A no-treatment control group is needed in order to take into account the
improvements that may have occurred due to the exacerbations and remissions which
are a common characteristic of many categories of MSD. Patients are likely to enter
the study when they are suffering an exacerbation of their condition, otherwise they
would probably not at that stage be requiring treatment. When the groups are analysed
post-treatment the means of the outcome variables are likely to have regressed closer
to a zero or neutral point, regardless of any treatment provided. It may be difficult in
practical terms to include a no-treatment control group in the design, but this may be
possible in some circumstances, where for example the treatment under investigation is
not routinely available (vide Chapter Ten).

In other circumstances however, it may be quite practical, and accommodate ethical
considerations to have a waiting-list control group where patients are randomly
allocated to a treatment group immediately or treatment is delayed for a period e.g. 3
months. It appears that a patient who has been referred to physiotherapy through a
hospital out-patient system can expect to wait rather longer than that before being
given a physiotherapy appointment in current routine clinical practice [174].

6.4.2 Placebo Control

The potency of the placebo is widely documented [336], [321] and therefore if the
"active" components of a particular form of treatment are to be scrutinised, then it is
essential that these effects are compared with a suitable placebo. It is important that
the placebo is credible to the patient and is administered with the same degree of
enthusiasm and suggestion as the treatment under investigation [239]. In this way the patient's expectations of the treatment which are also known to be influential will be raised equally in either case. The placebo should mimic the "active" treatment as far as possible, so that the patient cannot tell the difference between the two.

The attention provided to the patient by the therapist has a major healing effect, and needs to be taken into account, as it is also likely to influence treatment outcomes [104], [226]. Similarly the therapist-patient relationship as discussed in 4.4.2 needs to be considered. As far as possible all these factors need to be controlled and standardised.

6.5 CROSS-OVER DESIGNS

It has been pointed out that cross-over designs are not appropriate in rehabilitation research. It is unlikely that the patient would be blind to the treatment allocation if given both forms of treatment [239], [109]. A sham application of treatment is not likely to be credible to a patient who has experienced the active application.

Another reason for avoiding a cross-over design is because of possible carry-over effects, which could be physiological, such as muscle strengthening, or psychological, such as learning effects [423], [408].

The use of a modified cross-over design, where patients who are not responding to treatment are changed in the middle of their treatment without their knowledge to the other group has some advantages [180]. A non-response at the cross-over point can provide further evidence of a placebo effect.

6.6 INDEPENDENT ASSESSOR

It is essential, in order to reduce bias, that the assessor in a clinical trial should be blind to the treatment group to which the patient has been allocated [109], [226]. In practical terms in a small department it may pose a problem that can only be solved in terms of practicalities such as staff allocation, and is primarily a problem of where and when the treatment and assessment are carried out. The essential factor is that assessor remains unaware of the type of treatment provided to the patient. In order to avoid the patient disclosing the information to the assessor, it may also be important to explain this to the patient. In practice it is usually possible for the assessor to ask the patient not to discuss their treatment, until some later point, for example when they have completed the assessment. If attention is not given to these practical details the internal validity of the investigation can be seriously threatened.
If possible the therapist providing the treatment should also be blind to treatment allocation, and this has been the case in the later studies reported in Chapters Nine and Ten. The term double blind which was originally used for drug trials where the doctor who both provided the drug, and also assessed the outcome of treatment, was unaware during the trial as to which patients were provided with the active or the placebo drug. In this thesis double blind is reserved for studies where the patient, the therapist and the assessor were blind to the treatment allocation. Studies in which the patient and the assessor are blind to the treatment allocation (vide Chapters Seven and Eight), but the therapist providing the treatment is not, are referred to as single blind, in this thesis even though the patient was also unaware the treatment allocation. This point will be taken up again and discussed in more detail in the final chapter.

6.7 Outcome Measures

Since pain and other physical symptoms of MSD are multidimensional the outcome measures need to reflect this and should measure more than one aspect of the problem. They also need to be reliable, valid, appropriate and sensitive enough to measure differences, which may not be very great. Wherever possible outcome measures which have been shown to have these qualities should be chosen. However, it is also important that they are relevant and it is not always easy to find appropriate measurement tools.

The most important measures are those which can be equated with the patient's perception of their problem [235], and therefore are subjective. Objective measures may have little inherent value to the patient and do not necessarily correlate well with subjective measures such as pain [104]. For these reasons Deyo [104]. argues that it is better not to use objective measures as a proxy for subjective measures. However, objective measures are less valuable but are useful for secondary analysis and to improve our understanding of the condition [423], and its natural history and aetiology, in the context of behavioural and environment factors.

6.8 Statistical Analysis

Appropriate methods of analysis need to be applied, depending on the qualities of the data. Non-parametric analysis should be used if the data do not meet the required assumptions. As far as possible Type I errors where the null hypothesis is incorrectly rejected may be avoided by applying rigorously controlled and standardised procedures and increasing the internal validity of a study. Type II errors where the null hypothesis is erroneously accepted may occur where the sample size is insufficient [220], [233].
Requirements of a Randomised Controlled Trial

This is a common problem in clinical research which reduces the power of the statistical analysis and is discussed later in more detail in 7.4.3.

6.9 OTHER COMMON DEFICIENCIES

There are a number of other deficiencies commonly to be found in rehabilitation and pain relief research. Frequently a description of baseline variables with appropriate tables is missing, so that it is not possible for the reader to assess whether there is an even distribution in patient characteristics across the groups [104], nor to compare differences across the groups in the effects of treatment. Also the design should include an adequate description of drop-outs [234]. The length of follow-up also needs to be considered. Although the primary concern may be to know if a particular treatment can in the short term influence the natural history of a condition, it is also of interest to study the longer term effects. This may be especially important if carry-over effects are expected, or if the natural history of the condition is variable characterised by exacerbations and remissions. Weber [423] has suggested that if the immediate effects of treatment are of interest rather than the natural history of the condition, then assessments should be made at 1-2 days, 2 weeks, 4 weeks and 3 months. Practical limitations such as availability of resources often are the decisive factors in deciding on the follow-up period.

Koes and colleagues in the Netherlands have carried out critical reviews of the literature on both exercise [234], and spinal manipulation [233] for back pain. They devised a method of scoring a RCT on its methodology and describe their system which has been subsequently used by Shekelle [361] in a further analysis of the spinal manipulation literature. Koes et al [233] found 35 randomised controlled trials on spinal manipulation reported in the literature, but very few of these were not seriously flawed. Two independent reviewers read these papers and scored them with a system which allocated a maximum of 100 for a paper which according to their listed criteria included all the methodological points for a perfect study. They found only 4 papers scored 50 or more, and the papers with the less highly rated designs more often reported positive results.

It is notable that studies which are of a higher methodological standard tend to be less likely to report a positive outcome (vide 3.2). Few studies into the effectiveness of physiotherapy practice have taken into account even the most basic points such as an independent assessor and are therefore seriously flawed. The following four chapters describe RCTs which to have attempted progressively to address these methodological issues. Chapter Six investigates the clinical effectiveness of mechanical cervical
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traction aimed at relieving neck and arm pain, and Chapter 7 reports its effects on the neck musculature.
CHAPTER SEVEN: AN INVESTIGATION INTO THE CLINICAL EFFECTS OF CERVICAL TRACTION

7.1 INTRODUCTION

The previous chapter provided some evidence for a significant although small contribution of neuroticism (vide 5.4.5) as a predictor of back pain reports in student nurses. But a recent study of hospital workers also mainly nurses but of an older age group (mean age 38 years), found that neuroticism was more closely associated with reports of neck pain [59]. Neck pain as previously noted is a common problem (vide 3.1.3) for which a variety of different forms of physical treatment are available although the literature does not provide any convincing evidence to support any of the methods. There is a paucity of studies related to neck pain in the literature and an almost complete absence of controlled clinical trials investigating the effects of physiotherapy for the relief of neck pain.

Cervical traction as an out-patient form of physiotherapy has been widely recommended for the relief of neck and arm pain [264], [169], [64]. Many different methods of application have been described, including forms of mechanical and manual traction, both of which can be intermittent or sustained [79], and the choice of technique seems to be directed by individual preference and clinical experience in this area. Grieve [169] for example, advocates the use of the minimum poundage and duration necessary to achieve the desired result, whilst Cyriax [95] refers to the need for an estimated manual pull of up to 300 pounds for reducing a cervical disc. Some practitioners use an electrically operated traction bed whilst others use simple mechanical traction, that is a weight and pulley system providing a pull on the neck via a head halter.

The effects of traction on the joints and soft tissue are poorly understood, but it has been postulated that pain relief may be achieved by reducing the pressure on the nerve root by enlargement of the intervertebral foramen, separation of facet joints and stretching of soft tissues, [64], [201]. Several studies have attempted to substantiate this theory, by manipulating variables such as the angle of pull, and poundage applied to compare the amount of joint separation obtained, [79], [80], [81], [398]. Another theory is that cervical traction relieves pain by facilitating relaxation of the neck musculature, and several mechanisms for this effect have been postulated [170], [184], [375], [351]. There is some evidence of a link between relaxation and pain relief [249]
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and relaxation training is often used in cognitive behavioural programmes for chronic pain patients.

The previous chapter provided some evidence for a significant although small contribution of neuroticism (vide 5.4.5) as a predictor of back pain reports in student nurses. But a recent study of hospital workers mainly nurses but of an older age group (mean age 38 years), neuroticism was more closely associated with reports of neck pain [59]. Flor and colleagues [134] have postulated that chronic pain patients become preoccupied with their pain symptoms and tend to interpret increased muscle tension as pain.

The only other previous attempt to evaluate the clinical effectiveness of traction was a complex nine-centre trial conducted by the British Association of Physical Medicine in 1966 [56]. This concluded that cervical traction was indicated only when severe symptoms could not be relieved in a simpler way. This was an interesting and valuable study of traction and other physiotherapy techniques but the conclusions that can be drawn are limited as it was a pragmatic study in that the procedures were carried out were not standardised.

A small informal survey was conducted amongst twelve recently qualified physiotherapists, each representing a different school of physiotherapy in Britain, and this suggested that most physiotherapists were taught to apply a relatively small poundage of 6-12 pounds, and very occasionally as much as 15 pounds. They were generally very uncertain as to the indications and the specific purpose of the treatment apart from pain relief.

It is widely accepted by the clinician, although research evidence is minimal, that psychological factors such as stress, anxiety, and neuroticism play an important role in complaints of neck and arm pain [59]. In the previous chapter neuroticism, GHQ scores, HLC and low trait anxiety were contributory predictors of back pain reports in nurses. According to Flor [134] Anxiety may determine the response to treatment whether it is a placebo or active form of treatment (vide 4.5.1).

The study described below focuses on the commonest method of applying cervical traction, (according to clinical and teaching experience as well as the survey) and aimed to establish whether:

1) Traction is more effective than placebo traction in relieving pain in the neck and arm.

2) Anxiety affects the outcome of treatment.
7.2 METHOD

Ethical approval to carry out this study was sought and obtained from the Central Oxford Research Ethics Committee, prior to setting up the study.

7.2.1 Design

This was a randomised, single-blind controlled trial, and neither the assessor nor the patient was aware of the treatment allocation for the duration of the study. 100 patients were randomly allocated to weighted traction (group I) or placebo traction (group II). All patients attended 12 sessions over a four-week period, attending regularly on a Monday, Wednesday and Friday, unless they were symptom-free sooner. During this period they also attended a 'neck school' (one session of one hour) to receive neck-care education. Measures of pain, mobility and psychological function were administered before, after and at a three month follow up session. The use of a collar, which is common practice in the management of neck pain, and drug in-take were not modified if already prescribed but were carefully monitored for subsequent analysis if appropriate.

Ethical approval to carry out this study was sought and obtained from the Central Oxford Research Ethics Committee, prior to setting up the study.

7.2.2 Patients

100 patients with neck and arm pain, primarily cervical spondylosis (vide 3.1.3) referred from out-patient clinics at the Nuffield Orthopaedic Centre, were included in the study. Six patients either failed to complete the course of treatment, or did not attend for either of the second or third assessments. Data were analysed on the remaining 94 patients, (36 men, and 58 women) and this sample had a mean age of 49.3 years, (SD 10.2 years). Ten of these did not have complete data for all three assessments.

7.2.2.1 Exclusion Criteria

Patients who had any of the following were not considered eligible and were excluded from the study:

1) A history of neck and arm pain of less than 3 months;

2) Shoulder movement limited by 25% or more on the affected side (which might require additional physiotherapy);
3) Received physiotherapy in the last 6 months;
4) Had unsuccessful cervical traction previously;
5) A systemic or other condition for which traction would normally be contra-indicated, e.g. vertebral artery insufficiency, severe spinal osteoporosis, etc.

Consent to take part in the study was obtained from patients prior to examining and assessing them.

7.2.3 Instrumentation and Questionnaires

1) A simple inclinometer was used to measure neck movements. In an earlier study the author demonstrated that this method of measurement was shown to be relatively objective and accurate compared with visual estimations traditionally used in the clinical setting [228]. It has the advantage of being simple and easy to use in the clinical setting. Flexion, extension, left and right side flexion were measured with the patient sitting upright facing a mirror to facilitate monitoring of a standardised position by both the patient and the therapist who stood behind the patient. The inclinometer was strapped to the head and positioned directly above the tragus of the ear to enable the degrees of inclination of the neck into flexion and extension to be recorded by the assessor. It was then positioned posteriorly directly above the seventh cervical vertebra to measure the degrees of inclination to record left and right sideflexion. Rotation to both sides was measured with the patient lying supine on a couch, with the inclinometer secured to the top of the head. The movements were carried out by the patient under a standardised instruction from the assessor asking him to move his head "as far as possible" in the given direction.

2) Self-report Visual Analogue Scales using a 10 cm long line were used to rate (i) pain intensity, (ii) sleep disturbance, (iii) social dysfunction, and (iv) one individually chosen activity of daily living (ADL). The latter was included because previous research has shown that if patients are allowed to choose a function that was a particular problem with more severe initial impairment, it allowed for the possibility of greater change over time and provided a more sensitive measure of functional disability [356]. In each case patients were asked to provide an estimate averaged over the past 2-3 days.

3) The General Health Questionnaire GHQ [158], as discussed in the previous chapter (vide 5.2.3.1), where it was used to monitor nurses' emotional status. For clinical utility the short version, the GHQ-12 was used.
4) The State-Trait Anxiety Inventory STAI [370] of which both the state and trait measures were used (vide 5.2.3.1).

In addition, all patients were given a routine physical examination and assessment, from which further demographic and medical information was obtained. This included testing of the upper limb muscle power and biceps/triceps reflexes which could be compromised by pressure on a nerve root in the cervical region. These were recorded and checked against available records from the referring orthopaedic surgeon or rheumatologist. They were not found to be sufficiently reliable to be included in the analysis, partly perhaps because they were recorded at different time points, so that natural fluctuations in the natural history of the condition may have explained some of the differences in evaluation of the patient's neurological status.

7.2.4 Assessments

The measurements and examination described above were carried out pre- and post-treatment, that is four weeks after the first assessment, and at 3 months follow-up.

7.2.5 Procedure

Randomisation

Patients were randomly allocated to Group I or II, by drawing numbers out of an envelope and assigning them to the predetermined group indicated by the number.

7.2.5.1 Group I: Traction

Sustained cervical traction was applied by means of a halter, aiming to give equal pull on the chin and the occiput using a simple rope and pulley system to which weights could be added. The patient's head was placed in slight flexion on two pillows (approximately 25 degrees angle of pull) but if this was uncomfortable an alternative position was found. Patients were told that they would feel a gentle pull on their head and neck when the traction was applied, and that it was important that they should try and relax as much as possible. They were asked if they felt an equal pull on the occiput and chin, and also if they were comfortable or had any pain. In two cases only patients chose to alter the position slightly. A weight of between 6 and 15 pounds was applied, based on the individual patient's body weight in stones. This figure minus one was used to determine the poundage. Thus a 10-stone patient would receive a definitive pull of 9 pounds by the second visit, having only received seven pounds on the first occasion to allow the neck to get used to the pull. The purpose of this crude formula, which some physiotherapists have been taught to use during their training,
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was to provide an appropriate pull on a larger individual's neck, aimed at producing a similar effect to a lesser weight on a smaller person. On monitoring the symptoms it was found that two larger people (who according to this formula should ultimately have had 15 pounds applied), did not tolerate this weight, and complained of a subsequent headache, and the weight was therefore reduced.

7.2.5.2 Group II: Placebo Traction

Exactly the same procedure applied to Group II as Group I, except that only 2 pounds were applied to the rope and pulley system to take up the slack of the rope and mimic traction. With all the forces taken into account no more than one pound was acting on the neck.

It was previously ascertained that it is difficult for people to estimate whether they have 2 or 8 pounds applied to the head if the weight is gently and progressively applied. Patients in this study could not see how many weights were applied, they were not told how many weights were being applied and therefore it is likely in both groups were not aware of the poundage being applied, and.

7.3 RESULTS

Table 7.1 displays the means and standard deviations of the baseline data on entry to the study. The data were examined for normality and missing data, and were not transformed. Independent t-tests showed no significant difference between the two groups on any of the variables, except the length of past history. In spite of random allocation to the two groups, the weighted traction group had a significantly longer mean duration of symptoms of 5.7 years, compared to the placebo group with 2.9 years (t=2.73, df=64.3, p< 0.01).

Of the 94 patients who completed the course of treatment represented in Table 7.1., 10 patients failed to attend either the second or the third assessment and could not therefore be included in further analysis. Of the 84 remaining patients, failure to complete two further assessment scales on each of the three assessment points resulted in missing data for 2 cases for social dysfunction and 7 more for ADL.
Table 7.1 Comparison between the two groups on baseline data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Weighted Traction</th>
<th>Placebo Traction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean (sd)</td>
</tr>
<tr>
<td>Age</td>
<td>44</td>
<td>49.32 (10.23)</td>
</tr>
<tr>
<td>Duration of symptoms (weeks)</td>
<td>44</td>
<td>33.98 (27.64)</td>
</tr>
<tr>
<td>Chronicity (years)</td>
<td>43</td>
<td>5.67 (5.89)</td>
</tr>
<tr>
<td>State anxiety (20-80)</td>
<td>44</td>
<td>35.61 (10.33)</td>
</tr>
<tr>
<td>Trait anxiety (20-80)</td>
<td>44</td>
<td>39.95 (11.52)</td>
</tr>
<tr>
<td>GHQ (0-36)</td>
<td>43</td>
<td>13.72 (4.55)</td>
</tr>
</tbody>
</table>

Table 7.2 Comparison between the two groups on mean reported pain, sleep disturbance, social dysfunction and functional activities on Visual Analogue Scales (0-10).

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Group</th>
<th>N</th>
<th>Before Mean (SD)</th>
<th>After Mean (SD)</th>
<th>Follow-up Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Scores</td>
<td>Treatment</td>
<td>41</td>
<td>5.10 (2.32)</td>
<td>3.17 (2.44)</td>
<td>2.78 (2.34)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>43</td>
<td>4.60 (2.06)</td>
<td>3.67 (2.65)</td>
<td>3.19 (2.77)</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>Treatment</td>
<td>41</td>
<td>3.68 (2.60)</td>
<td>1.70 (2.10)</td>
<td>2.10 (2.49)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>43</td>
<td>3.77 (2.91)</td>
<td>2.44 (2.63)</td>
<td>1.86 (2.51)</td>
</tr>
<tr>
<td>Social Dysfunction</td>
<td>Treatment</td>
<td>41</td>
<td>4.42 (3.09)</td>
<td>2.73 (2.90)</td>
<td>2.34 (2.75)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>41</td>
<td>4.27 (2.78)</td>
<td>3.24 (2.95)</td>
<td>1.93 (2.25)</td>
</tr>
<tr>
<td>Functional activities</td>
<td>Treatment</td>
<td>35</td>
<td>5.86 (2.25)</td>
<td>3.09 (2.65)</td>
<td>2.80 (2.72)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>42</td>
<td>5.74 (2.54)</td>
<td>3.60 (2.54)</td>
<td>3.93 (2.98)</td>
</tr>
</tbody>
</table>

Table 7.2 shows the untransformed means (and standard deviations) for reported pain, sleep disturbance, social dysfunction, and functional activity scores for the two groups, all of which appear to improve slightly over time. This impression was confirmed by the analysis of variance with repeated measures over time which was used to compare improvements in scores (Visual Analogue Scales) before, after, and at follow-up three months later for reports of pain ($F=21.19$, df=2,164, $p<0.01$), sleep disturbance ($F=23.58$, df=2,160, $p<0.01$), social dysfunction ($F=20.73$, df=2,160, $p<0.01$), ADL.
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(F=42.62, df=2,150, p <0.01). None of the between-groups main effects yielded significant F ratios, on any of these variables. Inspection of Table 7.2 also shows that reduction in clinical symptoms was generally slightly greater in the traction group. However, none of the Group x Time interaction effects approached statistical significance.

Pearson's correlation was carried out to see if there was a statistically significant correlation between any of the outcomes with the demographic data, individual differences and the remaining baseline data. The results are shown in Table 7.3., displaying a correlation matrix for the demographic data and individual differences. Inspection of this table shows that there are weak negative correlations between State, and trait anxiety and changes in reports of pain and sleep disturbance, but these are only significant at the 5% level of significance. In order to take into account the possibility of chance significant findings where a number of variables have been analysed, a conservative interpretation of the results is assumed in this thesis, and alpha is only considered to be significant where it reaches the 1% level of significance. Using this adjusted alpha level, the only significant correlations were between Age and ADL (functional activity) as shown on Table 7.3.; By the follow-up assessment at 12 weeks there was a significant negative correlation between the two (r=-0.3022, p<0.01).

State and trait anxiety were however weakly correlated with changes in pain (see table 7.3) and since these measures were slightly higher in the placebo group, a 2-way analysis of covariance was carried out using, pain, sleep, social dysfunction and ADL as dependent variables and state and trait anxiety as covariates. The results of these analyses did not however change the pattern of the results reported for analysis of variance using the same the variable without these covariates.

Inspection of Table 7.4 displaying the untransformed means (and SD) of the recorded range of neck movement in all patients with complete data for this variable (n=80) before, and after at follow up shows that the movements tended to increase slightly over time and in most cases more in the traction group than the placebo group. The results of an analysis of variance with repeated measures over time for these cervical movements are shown in Table 7.5. It can be seen that flexion and sideflexion to the right yielded a statistically significant F value for the Group x Time interaction, in favour of the traction group.
Table 7.3 Correlation matrix displaying results of Pearson's product moment of correlation for baseline data and changes in VAS reports of pain (Pain12, Sleep12, Social12) and functional disability (ADL12) at 4 weeks and 12 weeks after the first treatment (Pain13, Sleep13, Social13, ADL13)

<table>
<thead>
<tr>
<th>Baseline variables</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pain12</td>
</tr>
<tr>
<td>Group</td>
<td>-0.1680</td>
</tr>
<tr>
<td>Age</td>
<td>-0.1142</td>
</tr>
<tr>
<td>Chronicity</td>
<td>-0.029</td>
</tr>
<tr>
<td>GHQ</td>
<td>-0.0053</td>
</tr>
<tr>
<td>State anxiety</td>
<td>-0.1800*</td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>-0.1772*</td>
</tr>
</tbody>
</table>

*p<0.05, ** Considered statistically significant (p<0.01)

Table 7.4 Comparison between the two groups on means (& standard deviations) of range of motion of the cervical spine measured in degrees

<table>
<thead>
<tr>
<th>Movement</th>
<th>Group</th>
<th>n</th>
<th>Before Means (SD)</th>
<th>After Means (SD)</th>
<th>Follow-up Means (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weighted</td>
<td>42</td>
<td>44.73 (12.96)</td>
<td>48.17 (12.57)</td>
<td>47.83 (14.13)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>38</td>
<td>49.11 (13.02)</td>
<td>47.03 (10.07)</td>
<td>46.21 (12.76)</td>
</tr>
<tr>
<td>Flexion</td>
<td>Weighted</td>
<td>42</td>
<td>52.05 (14.21)</td>
<td>53.86 (11.54)</td>
<td>54.87 (13.56)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>38</td>
<td>48.53 (14.00)</td>
<td>50.74 (13.25)</td>
<td>50.97 (14.99)</td>
</tr>
<tr>
<td>Extension</td>
<td>Weighted</td>
<td>42</td>
<td>33.76 (7.88)</td>
<td>36.71 (11.42)</td>
<td>37.10 (11.93)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>38</td>
<td>32.79 (8.88)</td>
<td>33.63 (10.79)</td>
<td>32.61 (10.67)</td>
</tr>
<tr>
<td>Left-side</td>
<td>Weighted</td>
<td>42</td>
<td>34.52 (9.21)</td>
<td>36.76 (12.67)</td>
<td>36.24 (12.62)</td>
</tr>
<tr>
<td>flexion</td>
<td>Placebo</td>
<td>38</td>
<td>37.61 (9.09)</td>
<td>36.89 (9.12)</td>
<td>33.55 (10.66)</td>
</tr>
<tr>
<td>Right-side</td>
<td>Weighted</td>
<td>42</td>
<td>58.52 (12.88)</td>
<td>60.79 (11.20)</td>
<td>61.83 (11.49)</td>
</tr>
<tr>
<td>flexion</td>
<td>Placebo</td>
<td>38</td>
<td>57.39 (11.70)</td>
<td>58.40 (13.16)</td>
<td>58.79 (14.48)</td>
</tr>
<tr>
<td>Left rotation</td>
<td>Weighted</td>
<td>42</td>
<td>56.14 (12.46)</td>
<td>59.50 (15.97)</td>
<td>60.79 (14.75)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>38</td>
<td>59.89 (13.04)</td>
<td>60.29 (12.74)</td>
<td>60.08 (15.44)</td>
</tr>
</tbody>
</table>
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Table 7.5 Results of analysis of variance with repeated measures over time of cervical range of motion comparing the two groups pre- and post-treatment and at follow-up

<table>
<thead>
<tr>
<th>Movement (degrees)</th>
<th>Main effects</th>
<th>F</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>Group</td>
<td>0.05</td>
<td>1.78</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>0.19</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>3.94</td>
<td>2.16</td>
<td>0.02</td>
</tr>
<tr>
<td>Extension</td>
<td>Group</td>
<td>1.74</td>
<td>1.78</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>1.80</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>0.02</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td>Left side-flexion</td>
<td>Group</td>
<td>1.96</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>2.21</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>1.68</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td>Right side-flexion</td>
<td>Group</td>
<td>0.01</td>
<td>1.78</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>2.02</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>4.48</td>
<td>2.16</td>
<td>0.01</td>
</tr>
<tr>
<td>Left rotation</td>
<td>Group</td>
<td>0.59</td>
<td>1.78</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>2.79</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>0.14</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td>Right rotation</td>
<td>Group</td>
<td>0.21</td>
<td>1.78</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>1.97</td>
<td>2.16</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Group x Time</td>
<td>1.58</td>
<td>2.16</td>
<td>NS</td>
</tr>
</tbody>
</table>

Stepwise multiple regression was also carried out to see if any of the demographic or baseline variables such as age, use of a collar, or the response to the psychological questionnaires were associated with any of the clinical outcome measures specifically or in combination. The results are shown on Table 7.6. Only state anxiety scores were selected as a predictor of pain reduction, but this accounted for just 6.5% of the variance. Trait anxiety was selected by the regression analysis as a predictor of reduction in sleep disturbance (6.8% of the variance). Age was selected as an explanatory variable for a reduction in social dysfunction (6.0% of the variance), and trait anxiety was again selected for its association with a reduction in functional disability (5.8% of the variance). All these variables were negatively correlated with an improvement in clinical outcome measures, but they only accounted for a very small amount of the variance.
Table 7.6 Results of multiple regression analysis of baseline variables associated with changes in reports of subjective pain, sleep disturbance, social function and ADL measured before and after cervical traction

<table>
<thead>
<tr>
<th>Dependent variable (Reduction in)</th>
<th>Explanatory variable</th>
<th>Coefficient B (se)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (Pain12)</td>
<td>State anxiety</td>
<td>-0.6654 (0.28984)</td>
<td>0.0242</td>
</tr>
<tr>
<td></td>
<td>(constant)</td>
<td>3.755948 (1.125743)</td>
<td>0.0013</td>
</tr>
<tr>
<td>Sleep disturbance (Sleep12)</td>
<td>Trait anxiety</td>
<td>-0.07627 (-0.32384)</td>
<td>0.0211</td>
</tr>
<tr>
<td></td>
<td>(constant)</td>
<td>4.608788 (1.335469)</td>
<td>0.0009</td>
</tr>
<tr>
<td>Social dysfunction (Social12)</td>
<td>Age</td>
<td>-0.092568 (0.038856)</td>
<td>0.0197</td>
</tr>
<tr>
<td></td>
<td>Constant</td>
<td>5.686130 (1.912225)</td>
<td>0.0039</td>
</tr>
<tr>
<td>Functional disability (ADL12)</td>
<td>Trait</td>
<td>-0.077501 (0.036663)</td>
<td>0.0379</td>
</tr>
<tr>
<td></td>
<td>Constant</td>
<td>5.555353 (1.502891)</td>
<td>0.0004</td>
</tr>
</tbody>
</table>

7.4 DISCUSSION

Cervical Traction is still frequently used by physiotherapists and recommended by orthopaedic surgeons and rheumatologists, despite the questions raised 20 years ago in the multicentre study conducted by Brewerton et al for the British Association of Physical Medicine [56]. The present smaller controlled study looked at the effects of simple mechanical traction on clinical symptoms and muscle tension.

The findings of this present study are consistent with those of Brewerton [56] who found that 75% of patients with neck and arm pain improved after treatment at 4 weeks whether they received traction, were positioned comfortably, given a collar, had heat or took aspirin. Patients in the present study also got better regardless of whether they had the active or placebo treatment.

7.4.1 Psychological Variables

Patients randomly allocated to the placebo traction group had by chance slightly higher STAI and GHQ scores at baseline (Table 7.1). The only predictor of outcome selected by multiple regression was state anxiety. This is in line with previous research that showed that both anxiety and neuroticism were associated with neck pain in hospital workers [59], although the strength of the relationship varied in different sub-samples.
of their population reflecting, they argued, the influence of the different situational
demands on the different groups of workers. Mitchell et al, in a study of chronic neck
pain and back pain patients, found that neck pain patients were significantly more likely
to deny having any other problems apart from their pain [288]. However, neither
group of patients demonstrated high levels of emotional disturbance, in terms of
anxiety and depression. In this present study, state anxiety was found to be weakly
and negatively correlated with a good outcome. According to the results of the
multiple regression, it seems that patients who were less anxious were more likely to
benefit from the treatment whether it was the weighted traction or the placebo traction.
Possibly if they were more anxious they would have had increased tension in their neck
muscles and the traction was for this reason less effective. However, according to the
results of analyses of covariance, baseline state and trait measures of anxiety did not
appear to be important factors in patients' differential response to weighted and
placebo traction. Flor & Birbaumer have shown that pain patients report more daily
hassles, more marital and work related stress, less perceived support and less problem-
solving abilities than healthy normals [133]. They demonstrated that patients with
chronic pain are more likely to label muscle tension as pain. Muscle tension and
anxiety and their relationship with treatment outcome are investigated in the study,
reported in the following chapter, in which surface EMG recordings were used to
assess tension in the neck musculature before and after traction in the upright position
and in the supine position.

For practical and clinical reasons the shortest form of the GHQ was used in this study.
According to the results of multiple regression GHQ-12 was not a predictor of
outcome in patients with neck pain. In the study of student nurses reported in Chapter
Five, it was associated with a greater risk of reporting back pain, but only in
combination with trait anxiety, neuroticism and HLC (vide 5.3.2). In two separate
analyses the GHQ only entered the equation after trait anxiety, and neuroticism had
been selected by the regression analysis. Possibly, in this present study a longer
version of the GHQ might have been more sensitive and therefore been a better
predictor of outcome in neck pain patients. The internal consistency of a shorter
version (GHQ-12) would not be expected to be so high, although Banks in a study of
mental health across three occupational groups found that its internal consistency was
acceptably high, varying between 0.82 and 0.90 [18]. In Chapter Ten the GHQ-30 is
used as one of the outcome variables in the study to evaluate pulsed short wave for
pain relief in patients with arthritic hip and knee joints.
7.4.2 Measurement of Range of Motion of the Neck

According to the results of the study, weighted traction tended to produce a greater range of cervical motion compared with the placebo. Possibly it had the effect of stretching out soft tissue contractures and allow a little more movement to take place. While statistically significant differences were found it is questionable whether they were of clinical significance. In a previous study by the author of the intra-rater reliability of the method of measurement using a simple inclinometer, previously carried out by the author, a series of normal subjects (n=12) without neck pain were tested [228]. 216 movements of the neck were carried out and it was concluded that using this method of measurement less than 10 or 15 degrees of movement should not be taken as a measure of progress in an individual. It could be argued that more of the same treatment, for example for longer, perhaps 40 minutes, and/or more frequently spread out over a longer period, might produce a bigger difference in range of movement. Traditionally, mechanical cervical traction is applied for about twenty minutes, either two or three times a week or sometimes on daily basis, but this is probably mainly for convenience rather than on any theoretical basis. If the main aim of the treatment was to increase range of motion by stretching out soft tissue, that is the ligaments and muscles perhaps traction would be more effective if it were applied for longer.

7.4.3 Chronicity and Improvement in Pain

In spite of the chronicity of the problem patients in both the treatment groups reported significant clinical improvements on all measures at three months. Post-treatment scores for the clinical symptoms appeared to be slightly lower for the weighted traction than for the placebo traction. However, there was no statistically significant difference between the groups, except on the range of motion. It was considered that the failure of weighted traction to produce a significantly better effect than placebo traction could be due to the greater chronicity of the former group. But this interpretation was considered unlikely as chronicity was poorly correlated with changes in pain and was not a predictor of outcome according to the results of the multiple regression analysis. For this reason chronicity was not used as a covariate in the analyses of covariance.

7.4.4 Sample Size

In considering possible reasons for the differences in outcomes not reaching statistical significance, the sample size needs to be taken into account. It was calculated retrospectively from the pain reports that for the study to have a power of 80% with a
5% significance level, 90 patients would have been needed in each group [220]. Therefore, a type II error may have been committed resulting in the null hypothesis being incorrectly accepted. The power of this present study was only 50-60%, with 40-50 patients in each group, and it took about two years to recruit even these numbers to the study.

7.4.5 Follow-up Assessments

The follow-up assessments showed that the small trend of improvement in symptoms immediately after treatment at 4 weeks was in general maintained at 3 months follow-up. It would have been interesting to follow the patients up for a longer period, to monitor their progress over a longer period of time, but available resources and time constraints would not have allowed this. An extra years funding was needed to complete the study, without extending the 3 months follow-up period. It might have been possible to justify 2 years extra funding if there had been a notable difference between the active and placebo treatments.

In clinical practice, physiotherapists usually provide neck pain patients with information and advice related to taking care of their neck. In order to try to control this extra potentially important variable, all patients in both groups attended a standard neck school. This consisted of a one-hour session of neck care education, and may have been an additional factor in increasing the rate of recovery. It was based on similar principles to the back school [223], [301] and aimed to give patients a greater feeling of control over their problem. Further research is needed to evaluate its clinical role. It may have had a significant influence on patients' symptoms in this study.

7.4.6 Conclusions

Conclusions that can be drawn from the results of this study are limited due to the lack of a no-treatment control. When this study was set up it was not considered possible on ethical or practical grounds to include a third group of patients to whom no treatment is given during the observation period of the study. The natural history of cervical spondylosis which comprised the majority of the patient population in this study is characterised by periods of exacerbation and remission. Therefore due to the natural history of the condition and regression to the mean, patients who presented with higher levels of pain initially are likely to be in a recovery phase by the time they are reassessed, regardless of any treatment (vide 6.4). Other factors may have contributed to an improvement in patients' symptoms, including their regular attendance at a physiotherapy department with the concomitant social support gained [226]. This effect could be especially important in some groups of people, for example
older patients who live on their own. Other methodological issues are discussed in section 8.4.4.

This chapter has reported the results of a study to evaluate the effects of cervical traction on neck pain patients' reports of pain and disability. The next chapter reports the results of a study to investigate its effects on the neck musculature [230]. It was carried out on a sub-sample of patients included in the study described in this chapter,
CHAPTER EIGHT: AN INVESTIGATION OF THE EFFECTS OF CERVICAL TRACTION ON THE NECK MUSCULATURE

8.1 INTRODUCTION

Neck pain and cervical spondylosis are often associated with a painful muscular response secondary to joint and neural involvement [25], [292]. Prolonged muscular contractions result in pain, firstly owing to an accumulation of metabolites and secondly owing to the constriction of the blood supply to the muscle. In clinical practice it is often assumed that cervical traction relieves pain by facilitating relaxation of the neck musculature, and several mechanisms for this effect have been postulated [169], [201], [375], [351]. The results of three separate studies [208], [98], [292] using EMG recordings of the upper trapezius muscle during intermittent traction suggest that this form of traction does not reduce muscle tension. However, to date no EMG studies have been carried out on sustained cervical traction. The study described below focuses on one of the commonest methods of applying mechanical cervical traction, and aims to establish whether:

1) Neck muscle tension as measured by EMG activity is reduced by weighted or placebo traction.

2) Neck muscle tension is associated with age or duration of symptoms, state and trait anxiety at baseline, or a reduction in reported pain, sleep disturbance, social dysfunction, or functional disability.

8.2 METHOD

8.2.1 Design

As part of the larger clinical study [229] reported in Chapter seven, patients were randomly allocated to weighted traction or placebo traction. On a subset of the first 52 patients from both groups, surface EMG recordings were made during one treatment session, over the upper trapezius muscle (on the painful side) prior to the application of traction, during traction and after it.

8.2.3 Instrumentation and Questionnaires

1) A Medilec MS 91 Spinal Monitor and three silver-silver chloride surface electrodes were used to obtain surface EMG recordings as tracings, from the upper trapezius muscle. Not only is this a convenient muscle to test because it is superficial but also previous researchers confirmed our view that this is the most representative muscle of
The Effects of Cervical Traction on Neck Musculature

the neck musculature, extending as it does from the occiput to the lowest cervical vertebra [208], [351], [98]. A linear relationship between integrated EMG readings and muscle tension has previously been demonstrated [96]. An integrator was not available for use in this study but it has been shown that the procedure used as a proxy provided a reliable estimate of IEMG recordings [227].

2) A simple inclinometer was used to measure neck movements [228]. Flexion, extension, left and right side flexion were measured with the patient sitting upright, and left and right rotation in the supine position.

3) Self-report pain scales (0-10) were used to rate (i) pain intensity, (ii) sleep disturbance, (iii) social dysfunction, and (iv) one individually chosen activity of daily living (ADL). In each case patients were asked to provide an estimate averaged over the past 2-3 days.

4) The General Health Questionnaire GHQ-12 [158], as used in the study of back pain in nurses (vide 5.2.3.1).

5) The State-Trait Anxiety Inventory STAI [370] which was previously used in the nurses study (vide 5.2.3.1)

8.2.2 Procedure

Once the definitive weight (2 lbs for the placebo control group and 6-12 lbs depending on body weight for the other group) was reached, an assessment of EMG activity in the neck musculature was carried out on the first 52 (placebo and weighted traction) patients. For each patient, on one occasion at the second or third treatment session, surface EMG recordings were made by placing two electrodes 3 cm apart along the length of the upper trapezius fibres, the lower electrode being level with the spinous process of the seventh cervical vertebra (C7). The ground electrode was placed over the deltoid muscle on the ipsilateral side, as shown on Figure 8.1.

Readings were obtained, pre- and post-traction, with the patient instructed to relax as much as possible, in each of the following positions:

1) Standing with feet apart, looking ahead;
2) Lying down comfortably positioned with two pillows and the head flexed to about 25 degrees.
3) Lying down with traction just applied;
4) Lying down with traction applied for 20 minutes;
5) Lying down after removing traction;
6) Standing, as before traction.

For each patient recording 1) could then be compared with recording 6), 2) with 5) and 3) with 4). To assist in clarity, data analysis of 3) and 4) are not reported on here as they are very similar to 2) and 5) which we consider to be more relevant.

Quantitative analysis of the EMG readings was made by a manual counting procedure since an integrator was not available. This consisted of counting the amplitude of the peaks of the tracings at millisecond intervals on the graph paper which produced a working unit of microvolts per millisecond, useful for comparative purposes. This method was laborious but was demonstrated in another study to provide a reliable estimate of the total area under the curve, known as Integrated EMG [227].

8.3 RESULTS

Eight out of 52 EMG readings were not included in the analysis, since the validity of the recordings was questionable, either because of interference from unidentifiable outside sources, or in two cases patients complained of dizziness. EMG readings nevertheless had a large variance which was not surprising since a couple of the patients were particularly tense. Because the data were skewed, square root or log transformations were carried out, to restore normality prior to analysis. Inspection of Table 8.1 displaying the untransformed means and standard deviations of the EMG readings of the two groups in the upright position and in supine before and after
The Effects of Cervical Traction on Neck Musculature

traction, shows that the EMG tends to decrease following traction. This was confirmed by the results of Analysis of Variance with Repeated Measures which demonstrated a statistically significant difference for the main effect of time in the supine position (F=5.81, df=1.42, p<0.02). The variance amongst patients was much greater in the upright position and the F-value did not reach statistical significance (F=2.89, df=1.42, p>0.05). There was no significant difference in EMG recordings between the two groups in the supine or upright position before and after traction or any significant interaction effects between the groups by time (F<1, df=1.42, NS).

Table 8.1 Untransformed means & standard deviations of EMG readings for weighted and traction groups measured before and after traction in the upright and supine positions

<table>
<thead>
<tr>
<th>Position for EMG recording</th>
<th>Treatment</th>
<th>n</th>
<th>Mean (SD)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upright</td>
<td>Weighted</td>
<td>43</td>
<td>176.78 (72.97)</td>
<td>170.17 (64.12)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>44</td>
<td>174.10 (74.79)</td>
<td>157.24 (65.22)</td>
</tr>
<tr>
<td>Supine</td>
<td>Weighted</td>
<td>43</td>
<td>59.04 (17.51)</td>
<td>55.52 (15.65)</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>44</td>
<td>62.43 (21.59)</td>
<td>53.76 (14.30)</td>
</tr>
</tbody>
</table>

Table 8.2 Correlation Matrix (Pearson's moment) to show strength of association between Age, Chronicity (duration of history), Psychological status, PAIN1 (initial pain report), PAIN12 (Pain reduction following treatment) and EMG recordings in the upright & supine positions, including changes in EMG readings following traction

<table>
<thead>
<tr>
<th>Log EMG readings</th>
<th>Age</th>
<th>Chronicity</th>
<th>State</th>
<th>Trait</th>
<th>GHQ</th>
<th>PAIN1</th>
<th>PAIN12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upright position</td>
<td>-0.1623</td>
<td>-0.0804</td>
<td>0.3204*</td>
<td>0.2519</td>
<td>0.1353</td>
<td>-0.1028</td>
<td>0.0373</td>
</tr>
<tr>
<td>Supine position</td>
<td>0.2126</td>
<td>-0.1471</td>
<td>0.0062</td>
<td>-0.0027</td>
<td>-0.1149</td>
<td>-0.2300</td>
<td>-0.2123</td>
</tr>
<tr>
<td>Changes in EMG Upright after traction</td>
<td>-0.680</td>
<td>-0.2689</td>
<td>0.0947</td>
<td>0.0315</td>
<td>-0.0333</td>
<td>0.0969</td>
<td>0.0758</td>
</tr>
<tr>
<td>Changes in EMG Supine after traction</td>
<td>0.2567</td>
<td>-0.0310</td>
<td>0.1539</td>
<td>0.1223</td>
<td>0.1470</td>
<td>0.0021</td>
<td>-0.1785</td>
</tr>
</tbody>
</table>

*p<0.018
Chapter Eight

Table 8.3 Correlation Matrix (Pearsons product moment) to show strength of association between changes in cervical ROM and EMG recordings in the upright & supine positions, including changes in EMG readings following traction

<table>
<thead>
<tr>
<th>Log EMG readings</th>
<th>Flexion 12</th>
<th>Extension12</th>
<th>LSideflex12</th>
<th>RSideflex12</th>
<th>LRotation12</th>
<th>RRotation12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upright position</td>
<td>-0.1023</td>
<td>-0.2526*</td>
<td>-0.2648*</td>
<td>-0.3546*</td>
<td>-0.1653</td>
<td>-0.0308</td>
</tr>
<tr>
<td>Supine position</td>
<td>-0.0660</td>
<td>-0.1835</td>
<td>-0.1761</td>
<td>-0.0422</td>
<td>-0.2385</td>
<td>-0.2019</td>
</tr>
<tr>
<td>Changes in EMG Upright after traction</td>
<td>0.0033</td>
<td>-0.2774*</td>
<td>-0.0903</td>
<td>-0.1491</td>
<td>-0.1907</td>
<td>-0.0732</td>
</tr>
<tr>
<td>Changes in EMG Supine after traction</td>
<td>0.0133</td>
<td>-0.2602*</td>
<td>-0.0666</td>
<td>-0.1152</td>
<td>-0.2033</td>
<td>-0.3263*</td>
</tr>
</tbody>
</table>

*Statistically significant at p<0.05

Table 8.2 shows the relationship of EMG readings with age, chronicity, psychological states (STAI state & trait anxiety scores and GHQ scores), PAIN1 (initial pain report), PAIN12 (pain reduction following treatment). Only state anxiety was weakly correlated with EMG readings in the upright position prior to traction at a marginally significant level (p<0.02).

The strength of association between clinical measures such as pain (PAIN1) and pain reduction (PAIN12) and EMG readings, recorded on one occasion, with the patient upright and supine was very low.

Pearson's product moment correlations were also computed on changes of measured range of neck motion and EMG readings and the results are displayed in Table 8.3. They show that extension, left and right side flexion and right rotation had some weak relationship with EMG readings taken in the upright position. Possibly according to these results, patients with more tension in their neck muscles would have been less likely to gain more movement in the neck following traction. Since the results were only significant at the 5% level and there were a number of correlations, they were not considered statistically significant.

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8.4 DISCUSSION

This study explored the effects of sustained traction on EMG activity of the neck musculature, (mainly the upper trapezius) comparing weighted with placebo traction.

8.4.1 Muscle Tension and EMG Recordings

A significant reduction in EMG activity in the upper trapezius muscle over the 20 minutes duration of traction was produced in both groups when supine but when the patient returned to the upright position the effect was no longer significant. However, comparison of the mean changes in EMG activity as shown in Table 8.1 imply that little or no weight seems more likely to induce relaxation than applying heavier weights. Response of patients to weighted traction was very variable and some patients showed an increase in muscle tension. This was in line with previous studies which have used EMG to investigate the effects of intermittent traction on the neck musculature [292], [208], [98].

Jette [208] recorded electrical silence in the upper trapezius when subjects were recumbent. In the author's experience, although EMG activity was considerably reduced in lying, some electrical activity was present, possibly because our patients were in slightly more neck flexion (that is two pillows instead of one) causing stretching of the upper trapezius. Weighted traction could be expected to increase muscle activity, to counter opposing force applied. This would be consistent with Delacerda's finding of increased EMG activity during the pull phase of intermittent traction [98]. However, we do not know what effect a period of longer than 20 minutes, say one hour's sustained traction would have on the EMG activity.

In this present study a link between high levels of anxiety and a poorer outcome was found. Also patients who were more anxious as expected had greater tension in their neck muscles as measured by EMG. However EMG recordings were not related to reported pain levels. Since patients showed a more marked reduction in muscle tension in the placebo traction group, it can be concluded that mechanical cervical traction given in the way described in 7.2.5 does not facilitate relaxation.

8.4.2 Psychological Variables

8.4.2.1 State Anxiety

Patients who were more anxious, as measured by the State-Anxiety Inventory, tended to have higher EMG recordings in the standing position, prior to lying down and
applying traction. The previous study provided some slight evidence for a negative association between anxiety and reduction in pain and sleep disturbance. The implication of this is that patients who have lower levels of anxiety also have less muscular tension in their neck muscles and are more likely to improve than those who are very anxious. This was the case regardless of whether the traction applied to the neck was weighted or placebo. However, there was a poor correlation between EMG reduction and pain reduction.

8.4.2.2 Surface EMG and Pain Reports

The lack of association between EMG readings and pain reduction found in this study is in line with previous work on tension headaches carried out by Pearce & Morley which demonstrated a poor correlation between reported pain and surface EMG recordings [313]. From the results of this study they concluded that the main cause of headaches was not muscle tension. Cognitive and behavioural processes could however be mediators of tension and pain. In line with the findings of this present study, Flor et al [135] in a study of chronic back pain patients found that EMG reactivity in the paraspinal muscles was related to psychological variables including depression and state anxiety scores. In particular they found evidence to support their hypotheses firstly that muscular hyperactivity as measured by EMG is related to personally relevant stressors and secondly that the return to baseline values following stressful situations was not immediate.

8.4.2.3 GHQ Scores

Baseline GHQ scores in this study were not related to outcome or muscle tension. Possibly the short GHQ-12 was not sensitive enough to detect differences amongst the neck pain patients. One of the longer versions, such as the GHQ-30 which is used in the study reported in Chapter Ten, might have been predictive of outcome, although in the study of back pain in nurses the GHQ-12 was one of the predictors of back pain reports. It may be that this short form which has been used in community and occupational settings [18], [160], is not so appropriate for a chronic pain population.

8.4.3 Clinical Implications

Further research is needed to ascertain whether simply lying down in a comfortable position, (that is without the placebo effect of traction) can effectively reduce muscle tension in the patients with pain in the neck. Linton in a review of the literature on behavioural remediation of chronic pain reviewed five different controlled studies of relaxation training for chronic pain patients and there appears to be good evidence that
The Effects of Cervical Traction on Neck Musculature

it can effectively reduce pain [249]. However, he noted that in four out of these five studies, the training was explicitly linked with the use of relaxation as a coping strategy and cognitive aspects may therefore play an important role in the training.

Manual cervical traction is a technique commonly used by physiotherapists and other manual therapists, which may be effective in reducing pain. It is however applied in many different ways and is much more difficult than mechanical traction to standardise and quantify. In clinical practice it is commonly combined with other techniques, such as joint manipulation. Studies comparing simple manual traction with these combined techniques might be useful. The hands-on effect might have a powerful additional placebo effect which would need to be taken into consideration [104].

8.4.4 Conclusions

The overall findings of Chapters Seven and Eight have indicated that patients with neck and arm pain tend to report less pain over a period of three months whether they have had weighted or placebo traction. There was no significant difference between the groups over time. Regardless of group membership, patients who were more anxious had more muscle tension in their neck as measured by surface EMG. They also obtained less pain relief if they scored high on the State Anxiety Inventory. Muscle tension in the supine position was poorly and negatively correlated with pain reports and pain relief.

For a number of methodological reasons the findings of these studies should be interpreted with caution. Because of the considerable variation in individuals' responses to treatment a much larger sample size would have been required to increase the power of the statistical analysis. The negative findings may possibly be attributed to the small numbers included in the study. The main outcome variable used in the studies of cervical traction was one-off reports of pain, which are associated with problems of recall and the need to average pain estimates over a period time, whereas pain usually fluctuates in intensity and quality over time. In the next two chapters which report studies to investigate the effectiveness of Pulsed Short Wave Therapy for relieving pain in patients with osteoarthritic hips or knees, pain diaries are used which have many advantages in terms of reliability and validity [206]. Also, the lack of a no-treatment control group in the cervical traction study did not allow the natural history of the condition and the phenomenon of regression to the mean to be taken into account. In the succeeding study described in Chapter Ten, a no-treatment control group was included, since it was considered to be ethically and practically reasonable, being a treatment that would not be routinely offered to these patients.

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The studies reported in the next two chapters overcome a number of the methodological issues (see Chapter Six) which have been problematic in this study.
CHAPTER NINE:  
A RANDOMISED CONTROLLED TRIAL OF PULSED SHORT WAVE THERAPY (PSW) FOR PAIN RELIEF IN PATIENTS WITH OSTEOARTHRITIC HIPS: PHASE I: A PILOT STUDY

9.1 INTRODUCTION
The application of Pulsed Short Wave (PSW) is a method of treatment used by physiotherapists primarily for pain relief, although it is claimed also to reduce inflammation and swelling. It was introduced from the USA about 30 years ago, and has over the past 10 years gained considerable popularity in this country [157]. It is used for the treatment of soft tissue injuries and also for more chronic conditions including osteoarthritic hip pain [164]. It is suggested in the literature that the high frequency electromagnetic field may act at a cellular level [126]. Clinical advocates conjecture that it may have the ability to restore the membrane potential of a damaged cell [253], [189] and may also influence the healing process by helping to re-establish the sodium and potassium ionic balance.

9.1.1 The Type of Current
Therapeutic usage of radio-frequency energy dates back to early experiments with spark-gap oscillators in the late nineteenth century [111]. Short wave diathermy, which is radio-frequency electromagnetic energy of sufficient intensity to produce a biological thermal effect, has been used therapeutically since 1928 [156]. The internationally agreed waveband for its operation is 27.12 MHz as for most other medical equipment. Figure 9.1 shows its relationship with the usage of other wavebands on the electromagnetic frequency spectrum.

![Waveband Usage](image.jpg)

Figure 9.1 Electromagnetic Waveband Usage

Short wave diathermy produces both an electrostatic and an electromagnetic field, and the result is a deep heating effect in the tissues [156]. In some cases a thermal effect may not be desirable [136], for example, where pain is caused by an inflammatory
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reaction, or where there is an artificial joint implant which being metal would concentrate the heat and result in a deep burn.

Pulsed short wave (PSW) consists of bursts of this same alternating high frequency (HF) current, interspersed with a cut-off phase, during which time heat formed in the tissues can be dissipated [157]. One complete HF cycle lasts for approximately 36 nanoseconds [305]. The number of these cycles depends on the pulse width which, depending on the machine used, may be set at 65 microseconds (Megapulse machine) or 400 microseconds (Curapuls/Ultramed). These pulse widths contain respectively 1,800 and 10,800 complete HF cycles [305]. The length of the rest period between the pulses will depend on the pulse repetitions per second, which on most machines can be varied. It is in any case always much longer than the burst, and allows relatively high levels of electromagnetic energy to be transmitted to the body tissues without producing any marked heating in the tissues [305]. The mean wattage or energy supplied to the tissues determines whether there are any apparent heating effects. To avoid thermal effects it is recommended by the electromedical suppliers to use less than 25 mean watts (Bosch 1987). No heat is discernible below this level, although it is likely that some very minimal thermal effect occurs deeper in the tissues.

A pulsed electromagnetic field (PEMF) has been used in the treatment of un-united bone fractures with apparent success in several different trials e.g., [27]. These workers however used a lower frequency PEMF of about 15 Hz, which according to Bassett [26] has a specific effect on the cell. Charman [73] states that this form of treatment should not be confused with the much higher frequency (27 MHz) used by physiotherapists and some orthopaedic surgeons. However, this is still controversial and other specialists in medical electronic engineering believe that the specificity of the frequency may not be important [82]. Possibly pulse width and amplitude may be more important for PEMF's influence on the tissues. Pething [316] discusses the frequency dependency of the permittivity of several different tissues of high water content and reports that permittivity is very high at around 27.12 MHz as shown below.

9.1.2 The Effect of Pulsed Short Wave on Tissues at a Cellular Level

Many different hypotheses have been put forward to explain the apparent effect of PEMF on tissue healing at a cellular level. When tissue damage occurs some cells will die and it is possible that PEMF could assist in the process of phagocytosis [126]. Phagocytes using their pseudopodia absorb the dead (deoxygenated) cells, a process which has been shown to be more effective when the tissue fluid is agitated. Adey [4]
suggested that PEMF could influence the mobility of intramembranous particles, thus assisting in the healing process.

During tissue damage, many surviving cells suffer a reduction in their cell membrane potential. Ionic imbalance then results in oedema of the tissues. Bentall [36] suggested that a PEMF may repolarise a partially depolarised cell. He further hypothesised that this could be linked with the action of the sodium pump.

Collis and Segal [83] carried out a series of well-designed in vitro experiments, which provide evidence of a specific effect of PEMF on the cell membrane, using the same field type as was used for the healing of un-united fractures. They applied a PEMF across the epithelium of a rabbit's colon and studied the effect on the sodium flux through the membrane. They found that when the field was applied at right angles to the epithelium, an increase in sodium flux was produced in one direction accompanied by a reduction in the other direction. This effect was reversed when the tissue was rotated through 180 degrees. Collis & Segal concluded that PEMF can have a direct effect on ions moving across a tissue by altering the surface charge of the epithelial wall and perhaps also by stimulating transport processes.

A number of animal studies have provided some evidence in favour of the effectiveness of PSW (27 MHz) in accelerating healing or regeneration of living tissue. Nadasdi [297] induced experimental arthritis in rats which he then claimed to have significantly reduced by means of PSW. Fenn [129] treated experimentally induced haematomas in rabbits' ears with PSW, and found that the haematomas were significantly more rapidly absorbed in the treatment group compared with the control group. The effect of PSW on the regeneration of nerve tissue in rats has also been studied. Nerve conduction studies, histology and nerve fibre counts apparently all indicated an acceleration in regeneration in the treated animals compared to the control group [436].

9.1.3 Clinical Trials

A number of clinical trials of PSW used in the management of musculo-skeletal problems are reported in the literature, with variously significant findings. Wilson [435] claimed superior results of PSW used for treating sprained ankles compared with the better known continuous short wave diathermy. Statistically significant improvements were found in favour of the PSW therapy for pain relief, disability and swelling of the ankles. Pasila [312] carried out a trial on a similar patient group but did not find that pain or disability were significantly effected by PSW compared to a placebo. They did report a significant difference between the groups for swelling and walking ability. Barclay [19], in a series of 230 patients with hand injuries, found that
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the treatment group compared to the control group did significantly better as far as pain, swelling and functional disability were concerned. More recently, Foley-Nolan [136] reported a "double blind" study using PSW in the form of a collar to treat neck pain. He claimed that it was more effective than a dummy placebo application. But it is not clear from the short report whether the procedure ensured that the patients were unaware as to whether they were receiving dummy or active treatment. None of these studies, even though some were described as "double blind" mentioned any attempt to blind the therapist to the treatment or at least a blind and independent assessor.

Two other studies refer explicitly to an independent assessor blind to the treatment provided. However, differences in the parameters used in the application of the PEMF make it difficult to compare the results of these studies directly with the above trial results. Binder [47] obtained significantly good results, as measured by pain reports and range of motion, in patients with chronic and recalcitrant rotator cuff tendinitis using a lower frequency (75Hz) PEMF which was applied for 5-9 hours daily. But Barker [20], who like Wilson [435] and Pasila [312] treated sprained ankles, found no significant difference between the treatment and control groups, possibly due to the application of a lower intensity dosage. This last study appears to be the only one to date that used a truly double blind design, where the therapist is also blind to the treatment. In other trials where this is not the case the results of the study are open to interpretation [360], [336]. The bias due to the enthusiasm and expectations of the therapist is likely to influence the patient's response to treatment.

9.1.4 Rationale of the Study

There are no randomised controlled studies to date on the use of PSW for the relief of pain in osteoarthritis of the hip, although it is one of clinicians' most favoured methods of treatment [164].

Although total joint arthroplasties provide excellent pain relief [188], [404], [211], [431], patients often have to wait for many months or years for the surgery. A Department of Health document [101] shows that the average waiting time to come in for elective surgery to their hip joint was 213 days. The range is not reported but the upper limit is likely to stretch into years. Wilkund & Romanus [431] in Sweden, who carried out a study of patients on a waiting list for surgery comparing the quality of life before and after hip arthroplasty reported that the main indication for surgery was the need for pain relief. Results of this prospective longitudinal study, carried out from 1985 to 1988, showed excellent improvements in quality of life for those who had surgery, but 15 of the 56 patients followed up had for various reasons three years later still not had surgery. In Britain where health resources are likely to be more limited
Trial of PSW for Osteoarthritic Hips: Phase One

the situation appears to be similar. Delays in some cases are due to the length of the waiting list and in other cases because the patient is not considered suitable for surgery. Owing to other complications some patients may not be able to have surgery at all [431], even though they are in considerable pain.

Night pain is a common problem associated with arthritic hips [431]. Also walking and general mobility are usually restricted by pain which ultimately may make the patient house-bound. Negotiating steps, getting in and out of a car, and doing up shoes are particularly awkward and painful manoeuvres for these people [214], [188]. Any means of effectively providing pain relief for this group of patients would be welcome. Pulsed short wave is thought to be a useful method of reducing inflammation and pain in arthritis but has yet to be tested in a randomised controlled trial. In this type of treatment using modern equipment that may be associated in the patient's mind with advanced technology, the placebo factor is especially potent [239]. The credibility of the treatment and the expectations will be further increased by the enthusiasm of the therapist as referred to in section 6.4.2 [336]. Previous studies, with the exception of Barker [20] who evaluated low power PEMF, even though they may use the term "double blind" do not take these factors into account. Since this form of treatment is not accompanied by any sensation, patients are unable to distinguish between active and dummy mode and it lends itself well to the rigorous design of a truly double blind study, where the patient, the therapist providing the treatment and the assessor are all blind to the treatment allocation.

Since there are no guidelines based on any systematic investigation to demonstrate the most effective method of application, a small national survey of "experts" and users was therefore carried out, prior to setting up Phase I. However, the responses were quite varied and in any case based on anecdotal evidence or clinical speculation. The results of this questionnaire on their own were therefore not considered specific enough to base the decision as to which method of application should be used in a trial of PSW therapy for pain relief in osteoarthritic hip patients. A preliminary study, referred to as "Phase I" was therefore necessary to decide on the method of application for the main part of study, "Phase II", the results of which are described in the following chapter.

9.1.5 The Overall Aim of the Investigation

The overall aim of the investigation, which is in two parts (Phases I and II) was to study the effectiveness of PSW in reducing clinical symptoms and signs, in patients suffering from painful osteoarthritic hip joints.
Chapter Nine

9.1.5.1 The Aims of Phase I

1) To compare the effectiveness of three different "sub-thermal" applications/dosages of PSW (same mean wattage of approximately 23 watts) for pain relief in osteoarthritic hips.

2) To find evidence of a physiological effect on the tissues, distinguishable from any thermal effect. If there were any statistically significant difference in outcome between groups of patients who had been administered the same level of wattage or energy, it would suggest the possibility of the difference being due to a specific electrophysiological effect produced by a particular application. If no difference between the groups could be discerned, it could be argued that any physiological effect was probably due to a common energy output, that is a very low heating effect inside the tissues which in all cases was approximately the same.

9.1.5.2 The Aims of Phase II

1) To investigate whether there is any significant difference between active and dummy PSW in its effectiveness in reducing pain and functional disability in patients with osteoarthritic hips. In order to control for a number of factors associated with the placebo effect discussed in section 9.1.4 comparison of the clinical effects of active PSW were made with a placebo control group, identical in every respect to the active group except for the dummy mode of application.

2) To investigate whether patients attending the physiotherapy department three times a week for three weeks to receive either active or dummy PSW gain statistically significantly more reduction in pain and functional disability, compared to patients in the control group who do not attend for treatment. This comparison takes into account changes that may be expected to occur in a condition such as osteoarthritis, a condition that is likely to gradually progress although its time course is very variable. It is characterised by exacerbations and remissions which is another reason why a no-treatment control group needs to be included in any objective evaluation of the effectiveness of a treatment programme. Phase II is reported in Chapter 10, and the remainder of this present chapter is devoted to describing Phase I and reporting its results.
9.2 **METHOD**

9.2.1 **Design**

Both Phase I and Phase II were double blind randomised controlled trials. Figure 9.2 shows the overall plan of the investigation.

![Flowchart to show overall plan of investigation](image)

Figure 9.2 Flowchart to show overall plan of investigation

9.2.2 **Population**

Patients referred from the out-patient clinics of the Nuffield Orthopaedic Centre with osteoarthritis of the hip were invited to take part in the study if they appeared to meet all the inclusion criteria. Initially, it was hoped that the population could be drawn entirely from these orthopaedic and rheumatology clinics, since they were held five days of the week and patients with OA hips formed a sizeable although variable proportion of the referrals. We estimated that of 5 patients apparently suitable for inclusion, who might be referred to us, at least 1 or 2 would fit the criteria and be prepared to take part in the study. However, recruitment for the study was very slow for a number of reasons. Not being able to include patients who had multiple joint or other medical problems, was probably the main factor in reducing the available population, but this was considered necessary to protect the internal validity of the
population, but this was considered necessary to protect the internal validity of the study, even though it could be argued that to some extent this was at the expense of its external validity. It would have been difficult to relate any changes in pain and disability scales to the joint being investigated, if multiple joints were involved. Ethically, in the clinical situation it would also have been difficult for the therapist not to have offered some form of treatment and advice regarding the other problems, which might well also effect the joint under investigation. However, patients with unilateral, single joint involvement, OA may not be typical of the population of OA sufferers, and therefore the results of the study possibly do not hold for patients with more generalised forms of arthritis.

In order to gain sufficient patient numbers it was decided to recruit patients who were on a waiting list for total hip arthroplasty. This list was accessed with permission from all the relevant orthopaedic surgeons, and any patients on this waiting list who fitted our criteria for inclusion, provided that they were not expecting surgery for at least 6 months, were invited to take part in the study. If the patient had not got a date for surgery, the records were consulted to confirm that no date had been allocated in the register. It was considered important that the patient should not be expecting surgery imminently, and be focused into this major event in their lives. If this was the case their commitment and enthusiasm for conservative treatment, involving regular visits to the physiotherapy department, might be considerably reduced.

9.2.2.1 Inclusion Criteria
1) Radiological changes in the hip reported as degenerative or osteoarthritic;
2) Pain predominantly emanating from one hip joint;
3) Ability to walk 50 metres.

9.2.2.2 Exclusion Criteria:
1) Previous arthroplasty on joint to be treated;
2) Recent surgery to this joint in past 6 months;
3) Physiotherapy for this joint over the past 6 months;
4) Documented contra-indications to PSW, e.g. pacemaker, pregnancy;
5) Serious obesity as defined by Quetelet's Index [218].

Patients who met the criteria were given an explanation of the study, and if they consented to take part were included in the study.
9.2.3 Equipment

A pulsed short wave machine Ultramed 11S 601 (supplied by medical students' charitable funds) with a drum applicator called a "Circuplode" containing a coil, provides the PEMF. It was placed almost in contact with the patient, directly over the centre of the joint being treated. The machine was modified (by Central Medical Equipment in conjunction with Bosch) for Phase II of the study, to enable a physiotherapist to apply the treatment without knowing whether it was in active or dummy mode, so that the study could be truly double blind. The modification provided the therapist with ten different points on a dial, which were used in rotation. Patients were sequentially allocated to a number on this dial. When the machine was switched on, half of the points on the dial provide active, and half provide dummy applications. The code for these points was in a sealed envelope and remained unknown to the researchers until all the data had been collected.

9.2.4 Outcome Measures

9.2.4.1 Pain Diaries

In the studies reported in the previous chapters (vide 7.2.3), one-off subjective estimates of pain reported by the patient were used as the main outcome measure. But it has recently been demonstrated that the reliability and validity of subjective pain reports can be greatly increased by obtaining a series of pain reports over a period of time [206]. In this present study pain diaries in the form of a small booklet made up of index cards were used as the main outcome measure. They allowed pain reports to be assessed over days and over weeks [314], [261].

Patients were asked to complete them four times daily, at "breakfast time", "lunch time", "tea time" and "last thing at night" using a numerical rating scale (0-100), where 0 represented no pain and 100 represented pain as strong as it could be. This method of scoring was chosen as it was considered more appropriate than visual analogue scales for our population which consisted largely of older people [205]. Patients were urged to keep their pain diaries somewhere to hand all day, for example on their table next to the salt and pepper, to help remind themselves to complete them throughout the day, rather than filling them in retrospectively at the end of the day or, even worse at the end of the week. Patients were asked to report separately how "strong" the pain was (sensory component) and how "distressing" (affective component) the pain was. Since pain is a multidimensional phenomenon and the affective component is likely to be influenced by factors such as mood, expectations and anxiety [209], [71], [282], it
was considered necessary to assess sensory and affective components separately. Each pain diary contained a week's data and was collected regularly by the researcher when it had been completed.

9.2.4.2 Subjective Pain Reports Obtained at Assessment

Patients were asked by the therapist at each assessment, how bad their hip pain had been over the past few days, using the same scale as was used for the pain diaries, that is a numerical rating scale "0-100". They were also asked to rate the level of any referred pain experienced in their low back, thigh, knee and below the knee, using the same rating system and they were also asked whether the pain had been constant or intermittent. One purpose of this was to try and obtain a picture of the typical patterns of referred pain.

9.2.4.3 Sleep Disturbance/Night Pain

Patients were asked if they had any pain at night that was bad enough to keep them awake. If the answer was "no", this was recorded as "0", if they said "yes", they were asked to quantify the sleep disturbance by considering to what extent they were kept awake by the pain, on a scale of "0-100". If any patient claimed that they had been awake all night because of the pain they would have been allocated a score of "100".

9.2.4.4 General Health Questionnaire

Several different self-administered psychological questionnaires were considered and tried out for suitability on a few patients, during Phase I of the study, including the Profile of Mood States POMS [274], the GHQ-28, and the GHQ-30 [159]. It was decided that the most suitable questionnaire was the General Health Questionnaire. This instrument had an additional advantage of having been developed in Britain. As discussed previously (vide 5.2.3.1) it has been validated for screening minor psychiatric disorders in use in various medical settings in at least seven separate studies [160]. The GHQ-12 was used in the studies reported in Chapters 5, 7 and 8. Although emotional status as measured by this short version of the GHQ played a role in predicting reports of back pain in student nurses (5.4.6.4), it did not appear to contribute to explaining variations in outcome for neck pain patients undergoing cervical traction (8.4.2.3).

GHQ scores have been shown to decrease in a chiropractic sample of New Zealand patients, where the physical symptoms have improved following treatment [307]. Therefore following treatment of painful arthritic joints it seemed likely that we could expect to see a reduction in GHQ scores. The GHQ-28 has four separate sub-scales
for somatic symptoms, anxiety and insomnia, social dysfunction, and depression [159] and therefore appeared to be more specific and possibly yield more information. However, in practical terms a few patients found some of the questions distressing and perhaps inappropriate.

It was therefore decided to use the GHQ-30 which focuses on psychological components of ill-health [160], as an outcome measure in Phase II of this study. Most patients managed to fill it in with minimal assistance, although in several cases we had to read the whole list of 30 items out loud, because "they had forgotten their reading glasses". The majority of our patients found it acceptable and completed it in 5-10 minutes. The simple Likert method of scoring as referred to in the Manual of the GHQ was used [159] which produces scores ranging from 0-90.

9.2.4.5 Functional Disability and Activities of Daily Living

Initially, when setting up the study, the literature was searched for suitable measures of functional outcome but none were found that appeared to be well-constructed, appropriate and reported in the literature as being reliable and valid. A range of different activities of daily living were chosen which from clinical experience were known to be commonly affected in patients with osteoarthritis of the hip, and which also tend to be referred to in the literature [185], [188], [214]. Functional disability was scored by asking patients to assess on a scale marked 0-10, how much of a problem particular activities had given them over the past 2-3 days. This was repeated for the following activities:

1) Getting in and out the bath;
2) Putting socks, stockings on;
3) Getting on and off the toilet;
4) Going up and down stairs;
5) Getting in and out of a car;
6) Carrying out one individually chosen activity.

(see Appendix Two, for a complete copy of this measuring tool)

The last question was included as according to Scott [356] allowing patients to choose a function which was a particular problem to them was especially useful in assessing the results of treatment. By providing higher starting points, the problem of baseline floor effects is reduced.
9.2.4.6 Measurement of Active Range of Hip Motion

Movements at the hip joint are especially difficult to measure reliably in a clinical setting because of the tendency for the pelvis to take part in any movement unless great care is taken to stabilise the pelvis. Accurate placement of a measuring tool on the axis of rotation, over the centre of the hip joint was a problem which was further increased by the need to align it with the whole of the leg. Special large scale measuring instruments were developed at the Rehabilitation Engineering Department at Mary Marlborough Lodge, Oxford, and a small study was carried out to test the reliability of the method.

Reliability Study

A small reliability study was conducted on the same population of patients with osteoarthritic hips, and demonstrated that the use of this simple equipment improved the reliability of measuring range of motion at the hip joint, compared with visual estimations which are routinely used in clinical practice. For hip abduction the reliability for intra-tester readings as measured by Pearson's product moment correlation coefficient was $r=0.933$, compared with $r=0.871$ for visual estimation. The reliability for intra-tester readings as measured by Pearson's correlation coefficient in a small reliability study with the same population of patients with OA hip pain, was for internal rotation $r=0.902$, compared with $r=0.863$ for visual estimation, for external rotation $r=0.902$, compared with visual estimation $r=0.790$.

Hip abduction

Hip abduction was measured using a specially designed large scale goniometer measuring the active range of motion at the hip joint. The patients were measured in the supine position with a smooth board under their leg so that when they were asked to abduct their leg ("slide your leg as far out to the side as you can"), they did not have to support the weight of their leg or overcome any excess friction. The contralateral leg was bent at the knee and the foot was over the edge of the bed resting on a low support, in order to stabilise and fix the pelvis, as much as possible. This was essential if the movement was to be localised to the hip joint. The board itself was marked off in degrees and acted as a goniometer from which the measurements were made. For accurate measurements to be made it was necessary to have perfect alignment of the goniometer/board in relationship to the hip joint. This was facilitated by means of a pointer which could be placed over the centre of the hip joint and provided a guide against which the board could be placed.
Internal and external rotation

Active internal and external rotation of the hip was measured with the patient seated on a hinged board with the thigh located in a metal trough. This position had several advantages and was chosen for the following reasons. Firstly the pelvis is at least partly stabilised in the seated position; secondly since the ilio-femoral and pubo-femoral ligaments are relaxed when the hip is flexed [121], therefore allowing a greater range of both internal and external rotation at the hip to take place; thirdly, the seated position, with the patient's lower leg hanging down directly over the large scale goniometer/board provided a convenient and well controlled position from which a measurement could be taken. The therapist used a hand at the ankle to guide the movement of the foot along the board which was marked off in degrees, and encouraged the patient to keep both buttocks down on the board.

These measurements which were part of the pre-, post and follow-up assessments were carried out by the same therapist on each patient each time.

9.2.5 Procedure

Ethical approval to carry out this study was sought and obtained from the Central Oxford Research Ethics Committee, prior to setting up the study.

9.2.5.1 Baseline Stabilisation

At the initial contact with the patient, the drug regime was discussed in some detail with the patient. Those who considered their current drug regime unsatisfactory, for example due to side effects, were encouraged to discuss this with their GP so that changes in drug regime could be made if necessary immediately. Drug therapy was stabilised as far as possible during a two week baseline period, prior to entry into the study. Every attempt was made to ensure that they had at least been on the same non-steroidal anti-inflammatory drugs (NSAID) and/or analgesics for 2 weeks prior to their first assessment. All drug intake was recorded daily in the patient's pain diary, as described above. This baseline stabilisation procedure was important, in order to reduce the possibility of any change in the patients' reported condition being due to a change in their drug in-take.

The patient's gait was also checked at the initial contact and, if appropriate, a walking aid was supplied and the patient was taught how to use it correctly. Weight and diet were also discussed where this was deemed important, using the Quetelet Index as a
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guide [218]. No other advice or treatment was provided, apart from PSW therapy, until the trial was completed.

9.2.5.2 Randomisation

Initially in Phase I, random allocation was carried out by drawing numbers out of an envelope to allot patients to one of the three different treatment groups. In Phase II patients were allocated to their treatment groups using a more sophisticated method of called "Minimisation", as described by Pocock [323]. This method of randomisation which uses a simple computer software program is especially suitable for smaller trials. It allows stratification to take place at the same time as randomisation. Variables which might influence the outcome of treatment can be programmed into it at the outset of the study and prior to beginning the allocation process. In this way an even distribution of patient characteristics which on theoretical grounds could be confounding factors and influence the outcome of treatment can be allocated across the treatment groups. In this study, variations in patient's age, duration of history and whether or not they were on a waiting list for surgery, could be evenly distributed across the treatment groups.

9.2.5.3 Treatment

PSW was administered three times a week for 15 minutes, over a period of three weeks. The patient was positioned comfortably supported with pillows in the supine position and the circuplode was positioned directly over the centre of the hip joint, not quite touching the skin.

No other concurrent form of physiotherapy treatment was given.

The method of application and dosages used in Phase I of this study were chosen as a result of discussions with clinicians who frequently use PSW, and took into account the results of the survey of users (vide 9.1.4). The following three variations of application/dosage were compared, each providing a mean wattage of 23 watts which was considered to be subthermal for practical purposes:

"Dose" A = 200 pulses/sec x 3
"Dose" B = 110 pulses/sec x 5
"Dose" C = 82 pulses/sec x 7

The last figures (3,5,7) refer to the intensity of the current designated by the manufacturer but related to the amplitude of the pulses. If a significant difference in clinical effects had been found between the applications it would have provided some
support for the existence of a specific effect over and above documented thermal effects.

The possibility of having the machine further adapted by electronic engineers to allow the therapist to be blind to the treatment variations without the introduction of another therapist was explored but regrettably proved not to be practical. Therefore, a second physiotherapist set up the dials according to the application that the patient had been randomly allocated to, so that the therapist who was responsible for looking after the patient and providing their treatment did not know which dosage was being used.

9.2.5.4 Assessments

These were carried out by the same research physiotherapist prior to the course of treatment and immediately after it. In Phase II, it was repeated a third time 3 months after the first assessment, always by the same therapist. The assessor was not aware whether the patient had received dummy or active treatment.

9.3 RESULTS OF PHASE I

Prior to data analysis, all the data sets were screened for accuracy of data entry and variables were transformed as appropriate, to normalise the data distribution for parametric statistical analysis, as recommended by Tabachnick [382], pages 58-122.

9.3.1 Demographic Findings at Baseline

Of the 45 subjects included in the study, 21 were male and 24 female with ages ranging from 36 to 86 years old. 37% were under 60 years old, 14% were aged between 60 and 70, and 48% over 70. 73% reported a history of pain in the joint under investigation of over one year, and 18% had a history of over 5 years. 31% of hip patients claimed to have constant pain. At baseline, 50% of all the patients suffered from disturbed nights due to pain. 49% reported taking analgesics for their pain, and 49% non-steroidal anti-inflammatory drugs.

9.3.2 Comparison of Baseline Data across the Three Treatment Groups

To test whether any pre-treatment differences existed at baseline between the three treatment groups in spite of random allocation, the data were compared using one-way analysis of variance. The means and standard deviations of the untransformed variables at baseline are displayed on Table 9.1 and there were no statistically significant differences between any of them, AGE, DURATION OF HISTORY,
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HIPSEVA, NPSEVA, FLOOA, FCARA, FSPECA: F<1, df 2,42, NS, and FBATHA and FSOCKA: F<2, df=2,39, NS, and FSTAIRA: F=3.01, df=2,41, p<0.07 (see Table 9.1).

9.3.3 Comparing Treatment Effects across Three Groups over Time

Analysis of Variance with Repeated Measures over time was used to analyse all parametric data generated from the outcome measures from each patient pre- and post-treatment. This procedure allowed the effect of interaction of the different treatments with the time factor to be studied. The untransformed means and standard deviations shown on Table 9.1. demonstrate some changes over time and in most variables there was some reduction in reported pain or disability following treatment. The F ratios for some variables did reach a significant value for the main effects GROUP or TIME, but there was no GROUP X TIME effect for any of them.
TABLE 9.1 Untransformed means, standard deviations of control, three groups (DoseA, DoseB, DoseC) of patients with OA hip pain (n = 45) for age & duration of history measurements of pain & functional disability at the first & second assessment points. Phase I

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Time</th>
<th>Dose A</th>
<th>Dose B</th>
<th>Dose C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>AGE (years)</td>
<td></td>
<td>64.93</td>
<td>10.83</td>
<td>67.27</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64.00</td>
<td>12.36</td>
<td></td>
</tr>
<tr>
<td>DURATION OF HISTORY (months)</td>
<td></td>
<td>45.33</td>
<td>54.91</td>
<td>53.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>33.87</td>
<td>29.73</td>
<td></td>
</tr>
<tr>
<td>HIP PAIN (NRS 0-100)</td>
<td></td>
<td>35.15</td>
<td>19.05</td>
<td>37.31</td>
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<td></td>
<td></td>
<td>35.42</td>
<td>18.15</td>
<td></td>
</tr>
<tr>
<td>HIPSEVA</td>
<td>1</td>
<td>37.31</td>
<td>21.18</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>29.08</td>
<td>21.39</td>
<td>26.25</td>
</tr>
<tr>
<td>HIPSEVB</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIGHT PAIN (NRS 0-100)</td>
<td></td>
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<td></td>
<td></td>
<td>20.38</td>
<td>26.65</td>
<td></td>
</tr>
<tr>
<td>NPSEVA</td>
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<td>27.33</td>
<td>30.81</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPSEVB</td>
<td>1</td>
<td>21.00</td>
<td>26.54</td>
<td>16.15</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY</td>
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<tr>
<td>(Combined VRS &amp; NRS 0-10)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting in &amp; out of bath</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATHA</td>
<td>1</td>
<td>2.86</td>
<td>2.68</td>
<td>4.38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.25</td>
<td>2.01</td>
<td></td>
</tr>
<tr>
<td>FBATHB</td>
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<td>2.29</td>
<td>2.46</td>
<td>4.62</td>
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<tr>
<td></td>
<td></td>
<td>1.83</td>
<td>2.48</td>
<td></td>
</tr>
<tr>
<td>Putting on tights/socks</td>
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<td>3.29</td>
<td>2.58</td>
<td>5.40</td>
</tr>
<tr>
<td>FSOCKA</td>
<td>1</td>
<td>5.40</td>
<td>2.77</td>
<td>3.92</td>
</tr>
<tr>
<td>FSOCB</td>
<td>2</td>
<td>5.40</td>
<td>2.32</td>
<td>4.15</td>
</tr>
<tr>
<td>Getting on and off toilet</td>
<td></td>
<td>0.73</td>
<td>1.53</td>
<td>1.60</td>
</tr>
<tr>
<td>FLOOA</td>
<td>1</td>
<td>1.60</td>
<td>2.35</td>
<td>0.46</td>
</tr>
<tr>
<td>FLOOB</td>
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<td>0.67</td>
<td>1.59</td>
<td>1.67</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.07</td>
<td>2.06</td>
<td></td>
</tr>
<tr>
<td>Going up &amp; down stairs</td>
<td></td>
<td>2.93</td>
<td>2.02</td>
<td>3.73</td>
</tr>
<tr>
<td>FSTAIRA</td>
<td>1</td>
<td>4.47</td>
<td>2.83</td>
<td>2.33</td>
</tr>
<tr>
<td>FSTAIRB</td>
<td>2</td>
<td>3.73</td>
<td>2.69</td>
<td>1.67</td>
</tr>
<tr>
<td>Getting in &amp; out of a car</td>
<td></td>
<td>4.08</td>
<td>2.53</td>
<td>3.69</td>
</tr>
<tr>
<td>FCARA</td>
<td>1</td>
<td>3.69</td>
<td>2.93</td>
<td>4.00</td>
</tr>
<tr>
<td>FCARB</td>
<td>2</td>
<td>4.00</td>
<td>2.16</td>
<td>3.11</td>
</tr>
<tr>
<td>Individual ADL problem</td>
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<td>5.69</td>
<td>2.43</td>
<td>6.38</td>
</tr>
<tr>
<td>FSPECA</td>
<td>1</td>
<td>6.38</td>
<td>2.26</td>
<td>6.27</td>
</tr>
<tr>
<td>FSPECB</td>
<td>2</td>
<td>5.92</td>
<td>2.40</td>
<td>5.09</td>
</tr>
</tbody>
</table>

Trial of PSW for Osteoarthritic Hips: Phase One
Table 9.2 Untransformed means & standard deviations of pain reports (sensory & affective components [0-100] averaged over the weeks from patients with OA hip (N=45) PHASE I

<table>
<thead>
<tr>
<th>SENSORY</th>
<th>TIME</th>
<th>Dose A</th>
<th>Dose B</th>
<th>Dose C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Means (SD)</td>
<td>Means SD</td>
<td>Means (SD)</td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>Baseline</td>
<td>52.01 (18.85)</td>
<td>58.55 (16.71)</td>
<td>49.14 (24.38)</td>
</tr>
<tr>
<td>During treatment</td>
<td>Wk 1</td>
<td>48.93 (20.83)</td>
<td>58.27 (19.66)</td>
<td>47.03 (26.42)</td>
</tr>
<tr>
<td></td>
<td>Wk 2</td>
<td>48.04 (19.89)</td>
<td>54.74 (19.40)</td>
<td>41.65 (23.84)</td>
</tr>
<tr>
<td></td>
<td>Wk 3</td>
<td>48.54 (18.54)</td>
<td>55.37 (21.71)</td>
<td>39.02 (21.79)</td>
</tr>
<tr>
<td>End of treatment</td>
<td>Wk 4</td>
<td>47.71 (16.68)</td>
<td>53.88 (20.12)</td>
<td>37.88 (24.18)</td>
</tr>
<tr>
<td>AFFECTIVE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>Baseline</td>
<td>41.49 (21.14)</td>
<td>42.95 (23.42)</td>
<td>36.45 (24.63)</td>
</tr>
<tr>
<td>During treatment</td>
<td>Wk 1</td>
<td>36.53 (23.70)</td>
<td>42.48 (25.67)</td>
<td>36.92 (24.97)</td>
</tr>
<tr>
<td></td>
<td>Wk 2</td>
<td>36.93 (24.01)</td>
<td>40.14 (24.91)</td>
<td>29.53 (22.70)</td>
</tr>
<tr>
<td></td>
<td>Wk 3</td>
<td>37.20 (23.08)</td>
<td>42.36 (21.31)</td>
<td>27.77 (23.73)</td>
</tr>
<tr>
<td>End of treatment</td>
<td>Wk 4</td>
<td>35.57 (22.33)</td>
<td>39.92 (21.88)</td>
<td>27.70 (22.15)</td>
</tr>
</tbody>
</table>

9.3.3.1 Comparison of Reports from Pain Diaries

Pain reported 4 times daily was averaged out over the day and then over the weeks, keeping the sensory and affective components separate. Inspection of Table 9.2 displaying the untransformed means and standard deviations of the patients' pain reports over a five week period shows a reduction in pain levels. Analysis of variance with repeated measures over time showed no significant difference between the groups, for the sensory or affective components of the pain reports (respectively: F<2, and F<1, df=2,31, NS) but the F-values for TIME were highly significant in both cases (respectively F=7.42, df=4,124, p<0.001 and F=4.81, df=4,124, p<0.002). There was however no interaction effect for GROUP X TIME (F<2, df=8,124, NS).
9.3.3.2 Comparison of Subjective Pain Reports Provided at the Time of Assessment

The results of analysis of variance were as follows for subjective pain reports communicated directly to the therapist at each assessment point referring to any pain in the hip over the last few days HIPSEV, and night pain/sleep disturbance NPSEV reported by the patient: HIPSEV, GROUP and GROUP X TIME : F<1, df 2,35, NS, TIME: F=6.94, df=1,35, p<0.02, NPSEV, GROUP, GROUP X TIME and TIME: F<2, df=2,39, NS.

9.3.3.3 Subjective Report of Functional Disability

The functional activities of daily living were each scored separately, as it was not considered legitimate to combine them into a single score. There was no significant difference between the groups over time for any of the functional disability reports. The results of analysis of variance with repeated measures over time are shown on Table 9.3.

Table 9.3 Results of analysis of variance with repeated measures over time for measurements of functional disability pre-, and post- treatment on osteoarthritic hip patients (n=45)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10: )</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>Main effects</td>
<td>Group</td>
<td>3.97</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>1.10</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;1</td>
</tr>
<tr>
<td>FSOCK</td>
<td>Main effects</td>
<td>Group</td>
<td>3.33</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;2</td>
</tr>
<tr>
<td>FLOO</td>
<td>Main effects</td>
<td>Group</td>
<td>&lt;2</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>&lt;2</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;1</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>Main effects</td>
<td>Group</td>
<td>3.51</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>&lt;2</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;2</td>
</tr>
<tr>
<td>FCAR</td>
<td>Main effects</td>
<td>Group</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;1</td>
</tr>
<tr>
<td>FSPEC</td>
<td>Main effects</td>
<td>Group</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Time</td>
<td>&lt;3.78</td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group x time</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
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Table 9.3 Untransformed means, standard deviations of Dose A, Dose B, Dose C groups for hip patients (n=45) of measurements of hip range of motion at the first & second assessment points.

<table>
<thead>
<tr>
<th>Movement (degrees)</th>
<th>Time point</th>
<th>Dose A</th>
<th>Dose B</th>
<th>Dose C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Hip Abduction</td>
<td>1</td>
<td>19.27</td>
<td>5.90</td>
<td>16.54</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>18.73</td>
<td>4.86</td>
<td>15.31</td>
</tr>
<tr>
<td>Hip Internal Rotation</td>
<td>1</td>
<td>13.21</td>
<td>10.35</td>
<td>9.86</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>14.93</td>
<td>8.73</td>
<td>13.71</td>
</tr>
<tr>
<td>Hip External Rotation</td>
<td>1</td>
<td>15.62</td>
<td>8.09</td>
<td>20.93</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>16.46</td>
<td>7.41</td>
<td>24.07</td>
</tr>
</tbody>
</table>

9.3.3.4 Range of Motion

Hip Abduction, internal and external rotation were measured at the first and second assessment points using especially designed large scale goniometers. Although inspection of Table 9.3 displaying the untransformed means and standard deviations reveals some differences in the mean values at baseline, one-way analysis of these variables did not yield statistically significant F-values, \( F=1.60, \, df=2,40, \, NS \).

Also the results of one-way analysis of variance for the baseline data of medial and lateral rotation were not statistically significant, respectively: \( F<2, \, df=2,39, \, NS \), and \( F<2, \, df=2,38, \, NS \).

It can be seen on Table 9.3 that for hip abduction over time there was a slight reduction in range of motion, but the results of analysis of variance with repeated measures demonstrated that this did not reach statistical significance, \( F=2.48, \, df=2,37, \, NS \) and there was also no significant differences for GROUP X TIME, \( F<1, \, df=2,37, \, NS \). The GROUP effect however was significant, \( F=4.82, \, df=2,37, \, p<0.02 \).

According to the mean values both internal and lateral rotation tended to increase slightly over time and for the former the differences over time were statistically significant, (respectively \( F=9.61, \, df=1,37, \, p<0.004 \) and \( F<2, \, df=1,36, \, NS \)), but of doubtful clinical significance. F-values for GROUP differences were not significant, respectively for internal and lateral rotation, \( F=2.20, \, df=2,37, \, NS \) and \( F=2.65, \, NS \).
df=1,36, NS, and nor were interaction effects GROUP X TIME, F<1, df=2,37, NS, and F=2.10, df=2,36, NS.

9.4 DISCUSSION

There was an improvement over time in all the means of variables representing pain reports, and the differences over time were highly statistically significant for both the sensory and affective components of pain diary data, as well as the one-off subjective pain reports obtained at the assessment points. However, the functional disability reports did not appear to change very much over time, and none of them were significantly different over time. The range of motion was not surprisingly little changed over time. Pulsed short wave therapy was aimed at pain relief primarily. If this aim was achieved possibly freer joint movement might result. However, this assumes that a limitation in movement is due to pain rather than shortened or fibrosed tissue. Since osteoarthritic changes affect not only the joint surface but also the joint capsule and other surrounding soft tissue (vide 3.4.1), restriction in joint motion is likely to be primarily mechanical in nature and therefore unlikely to be altered by the application of PSW. Following total hip arthroplasty pain which is the major indication for surgery is usually markedly reduced [431] but joint mobility is not necessarily improved.

Since there were no significant differences between the treatment groups over time for pain reports, functional disability or range of movement, the dosage and application of treatment for Phase II was decided on, by analysing the best mean improvement in pain reports. The main outcome measure, that is the sensory component of the pain reported in the daily diaries (averaged out over the weeks), improved by 8% for Dose A and Dose B, whereas Dose C showed an improvement in 23% over a five week period. On this basis it was decided to use Dose C for Phase II.

Even if there had been no statistically significant improvement over time according to these results, it would still have been necessary to proceed to phase II to compare the active treatment with the placebo and a no treatment control group. It was possible, since these patients were suffering from a chronic condition and most of them were on the waiting list for total hip surgery, that without any treatment, they would have got worse. Any treatment effect could only be ascertained by comparison with a no-treatment control group. Phase II of the study was therefore carried out, using Dose C in its active mode, comparing it with the dummy application and a control group who did not attend the hospital. Since recruitment of patients with OA hip pain, who fitted the criteria was so slow and it took 2 years to complete Phase I of the study, after careful consideration, it was decided in the main part of the study, Phase II, to include
patients with knee pain too. This part of the investigation is described in the following chapter.
CHAPTER TEN:
A RANDOMISED CONTROLLED TRIAL OF PSW FOR PAIN
RELIEF IN PATIENTS WITH OSTEOARTHRITIC HIPS &
KNEES.
PHASE II: COMPARING AN ACTIVE AND A DUMMY
APPLICATION WITH A NO-TREATMENT CONTROL GROUP

10.1 INTRODUCTION

The previous chapter reported the results of a study (Phase I) to compare three
different dosages/modes of applications of PSW to find out which was the most
effective in relieving pain in patients with OA hips. Although there was no statistically
significant difference between the groups over time, one method appeared to be more
effective according to the mean changes in the main outcome measure. The pain
reports averaged out from the daily diary data over the weeks showed an improvement
of 23% for this method compared with only 8% for each other method of application.

Treatment using modern equipment that may be associated in the patient's mind with
advanced technology, may provide an especially potent placebo response. The
therapist's enthusiasm will also increase the credibility of the treatment and the patient's
expectations, as previously discussed in section 6.4.2., and also 9.1.3 and 9.1.4 [336].
Previous studies, with the exception of Barker [20] who evaluated low power PEMF,
even though they may have used the term "double blind", did not appear to take these
factors into account. In these studies the therapist as well as the patient was probably
not blind to the treatment allocation, and an independent assessor who was also
unaware of the treatment allocation was not explicitly referred to.

For reasons discussed in the previous chapter under section 9.4 and in 10.2.2 patients
with OA knee pain as well as patients with OA hip pain were included in Phase II of
the study.

The purpose of Phase II was to evaluate the effectiveness of PSW in the relief of pain
in osteoarthritis of the hip and knee, distinguishing between placebo effects and any
specific physiological effects, and to answer the following questions:

a) Does active PSW reduce pain, functional disability and range of motion
significantly more than dummy PSW in patients with OA hip and knee pain?
Chapter Ten

b) Does attending the physiotherapy department three times a week for three weeks to receive active or dummy PSW significantly relieve pain, compared to patients in the control group who do not attend for treatment?

10.2 METHOD

10.2.1 Design

Both Phase I and Phase II are double blind randomised controlled trials. For the overall plan see Figure 9.2.

10.2.2 Population

This was the same as described for Phase I of the study in the previous chapter in section 9.2.2., but with one notable addition. Since the numbers of patients fulfilling our criteria proved in Phase I to be smaller than expected, it was decided to include patients with OA knee pain as well as OA hip pain patients. Patients with OA of the knee and hip were included in two separate allocation systems so that the findings from each group could be initially analysed on its own allowing data to be compared across the two groups before carrying out a combined data analysis (see section 10.3).

For Phase II it was decided that the demands that the treatment programme and study protocol put on patients in particular travelling to and from the hospital for regular treatment together with the need to complete regular pain diary reports, made it inappropriate to include very elderly or frail people. An arbitrary inclusion limit was set at 80 years old.

Patients who met the criteria were given an explanation of the study (see Appendix One), were invited to take part in the study, and if they consented were included in the study.

10.2.3 Equipment

A pulsed short wave machine Ultramed as described in 7.2.3 was modified by the suppliers to enable a physiotherapist to apply the treatment without knowing whether it was in active or dummy mode, so that the study could be truly double blind. The machine was modified by the provision of ten different points on a dial, which were used in rotation. Patients were sequentially allocated to a number on this dial. When the machine was switched on, half of the points on the dial provided active, and half provide dummy applications. The code for these points remained in a sealed envelope and was unknown to the researchers until all the data had been collected.
The patients were unable to distinguish between active and dummy mode, since the radiation was an electromagnetic field and no detectable heating was produced. An explanation of the treatment had forewarned them that they should not expect to feel any sensation.

10.2.4 Outcome Measures

Outcome measures that were piloted in Phase I, were used in Phase II as well, and described in 9.2.5.1. The main outcome measure was subjective pain reports: 1) recorded daily in "pain diaries" and averaged out over the weeks; 2) obtained by the therapist at each assessment point. Both of these were scored on a numerical rating scale (0-100), and also the patient's estimate of how much "benefit" they had derived from the treatment, also on a scale of 0-100. Functional disability in terms of subjective problems with daily living activities was assessed, the GHQ-30 was used as a simple self-administered questionnaire to assess any minor psychiatric problems, and range of motion of the hip joint was measured using a special large scale goniometer. Apart from range of motion measurements all these outcome measures were considered to be equally suitable for patients with knee pain as for the patients with hip pain.

10.2.4.1 Measurement of Active Range of Knee Motion

A standard goniometer was used to measure the active range of flexion and extension at the knee joint. It had long arms and was made of translucent plastic which facilitated accurate placement of it over anatomical surface markings of the knee joint. The measurement was carried out with the patient in the semi-recumbent position, on a treatment couch, with a smooth board placed under the leg. This enabled the patient to bend their knee by sliding their foot towards their hip, with minimal friction. The patient was asked to bend the knee as high as possible without raising their heel from the board, and then to straighten the leg as far as possible. Measurements were taken at the end points of the range of available movement with the goniometer aligned along the lateral aspect of the femur and tibia with the axis of rotation of the measuring device placed over the centre of rotation of the knee joint.

Three measurements were taken for both flexion and extension and the average reading was used in the analysis.
10.2.5 Procedure

10.2.5.1 Baseline Stabilisation

This was in principle the same as described in section 9.2.5.1 for Phase I of the study. Drug therapy was stabilised as far as possible during a two week baseline period, prior to entry into the study. Patients were asked to record any drug intake daily in the pain diary.

The patient's gait was also checked at the initial contact and, if appropriate, a walking aid was supplied and the patient was taught how to use it correctly. Weight and diet were also discussed, if the patient was overweight. In Phase I, no other advice or treatment was provided, apart from PSW therapy, until the trial was completed. In Phase II, because we included patients with OA knee problems, who would routinely be taught simple quadriceps exercises when they were seen by a physiotherapist, we changed the baseline procedure to include a simple exercise routine for both hip and knee patients, described further in Appendix Two. This procedure took about 10 minutes to teach the patient at the first encounter, and the patient was then advised to carry these out daily themselves at home. If the patient requested further exercises or advice they were told that the therapist wanted to see how they got on with the PSW for 3 months and would reassess their needs again at that point. In fact following the third and final assessment, they were then routinely given further advice and exercises as considered appropriate by the therapist.

10.2.5.2 Randomisation

In Phase II patients were allocated to their treatment groups using the method of randomisation "Minimisation" (vide 9.2.5.2). Patients with OA knee problems were allocated separately from patients with hip problems so that each patient group could initially be analysed separately.

10.2.5.3 Treatment

PSW was administered three times a week for 15 minutes, over a period of three weeks, as described in the previous chapter, in section 9.2.5.3. No other form of physiotherapy treatment was given, whilst they were in the study. Patients did not expect to feel anything, and so had no way of knowing what type of treatment they were receiving. The attention placebo factor, including the amount of time spent with the patient, was carefully controlled and standardised, so that these factors could be taken into account. At each patient's visit the therapist spent no more than a total of
about five minutes with them while setting up and removing the equipment. Trouble was taken with each patient to make sure that they were comfortable and the therapist expressed concern over their welfare, and attempted to build up some rapport with the patient, as would occur in good clinical practice. However, conversation was limited to general topics, and detailed discussions related to their particular condition or the treatment being provided were avoided.

PSW was administered to patients with OA knee pain in the semi-recumbent position with sufficient pillows placed under the knee joint to support it in mid flexion, in a comfortable relaxed position, with the patella not overlying the knee joint. The circuplode emitting the PEME was placed directly over the knee joint.

10.2.5.4 Assessments:

In Phase II a third assessment point was included, the patient being followed up for three months. Each assessment was carried out by the same research physiotherapist on three occasions: before treatment, immediately after the course of treatment i.e. at one month and at 3 months. The assessor was not aware whether the patient has received dummy or active treatment.

10.3 ANALYSIS AND RESULTS OF PHASE II

Ninety-two patients with pain predominantly in one joint due to OA, 46 with OA hip pain and 46 with OA knee pain were included in the study and largely complete data sets were available for analysis of all these patients on all baseline measurements. None of the patients receiving treatment (dummy or active) dropped out or failed to attend the hospital for their course of treatment. However, 4 patients (3 with hip pain, 1 with knee pain) did not attend for their third assessment as they had their date for surgery to the joint brought forward. One other patient with OA knee pain was admitted to hospital with other medical problems and therefore only received 6 treatments instead of 9, and did not attend for her second or third assessments. The total number of drop-outs by the third assessment were 5; of these were in the control group, 2 in the dummy group and 1 in the active treatment group. One patient with OA hip found it difficult when filling the pain diaries to distinguish between the arthritic pain and the burning sensation which he believed he was getting from a recently diagnosed inguinal hernia in the ipsilateral hip. Since he felt his diary reports were unreliable it was decided to omit them from the analysis.
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10.3.1 Demographic Findings at Baseline

Of the 92 subjects included in the study, 34 were male and 58 female with ages ranging from 35 to 80 years old. 33% were under 60 years old, 37% were aged between 60 and 70. Patients were included on the basis of a predominantly unilateral single joint complaint of osteoarthritis in the hip or knee, but 40% admitted to at least one other joint problem which did not interfere with their daily living activities, and 40% reported a concurrent medical condition such as hypertension. 80% had a history of pain in the joint under investigation of over one year, and 34% had a history of over 5 years. 12% of hip patients claimed to have constant pain, whereas 17% of knee patients reported constant pain. At baseline, 50% of all the patients suffered from disturbed nights due to pain, and 12% claimed to be kept awake for half the night or more. 46% reported taking analgesics for their pain, and 55% non-steroidal anti-inflammatory drugs.

10.3.2 Combining Pain Reports for Hip and Knee Pain Patients

For patients included because of their knee pain, one-off subjective pain reports associated with the skin overlying this joint was called their main pain and for patients included because of their hip pain, any report of pain in this anatomical region was also referred to as their main pain. This variable is from now on referred to as $MAINPAIN$. A copy of the form used to record these one-off pain reports is provided in Appendix Two.

10.3.3 Screening of Data and its Distribution

Prior to data analysis, all the data sets were screened for accuracy of data entry and variables were transformed as appropriate, to normalise the data distribution for parametric statistical analysis as recommended by Tabachnick & Fidell [382] pages 58-122. For certain variables, large numbers of patients reported zero scores so that the distribution of the data was so skewed that it was not possible to normalise it with any transformation. These variables were night pain reports ($NPSEV$) and all the referred pain reports collected at the same time as $MAINPAIN$ (vide 9.2.4.2). Since these data sets did not fulfil the assumptions of parametric data analysis, they were treated as ordinal data and analysed using non-parametric data analysis (vide 10.3.8).

10.3.3 Comparing the hip and knee patient groups

T-tests were carried out to compare the data sets for the two groups of patients, i.e. those with OA hip pain and those with OA knee pain on demographic variables,
Table 10.1 Untransformed means, standard deviations & ranges on demographic data & measurements of pain, GHQ & functional disability of hip patients (n=46) & knee patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>HIPS</th>
<th>KNEES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63.35</td>
<td>9.91</td>
</tr>
<tr>
<td>Duration of history (months)</td>
<td>58.71</td>
<td>55.98</td>
</tr>
<tr>
<td>Main Pain (NRS 0-100)</td>
<td>39.85</td>
<td>22.31</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>30.54</td>
<td>13.04</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Combined VRS &amp; NRS 0-10:)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>3.76</td>
<td>2.82</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>4.17</td>
<td>2.68</td>
</tr>
<tr>
<td>FLOO</td>
<td>2.00</td>
<td>2.45</td>
</tr>
<tr>
<td>FSOCK</td>
<td>4.33</td>
<td>2.97</td>
</tr>
<tr>
<td>FCAR</td>
<td>4.41</td>
<td>2.64</td>
</tr>
<tr>
<td>FSPEC</td>
<td>5.50</td>
<td>2.71</td>
</tr>
</tbody>
</table>

measurements of pain, GHQ and subjective measures of functional ability. Table 10.1 shows the untransformed means and standard deviations of the separate baseline data for hip and knee patients.

The results of t-tests comparing the data sets for hip and knee problems (Table 10.1a in Appendix Three) demonstrated no statistically significant differences on any of the following variables analysed: AGE (t=0.11, df 90, NS), DURATION OF HISTORY (t=1.50, df 80.5, NS), MAINPAIN [severity of main pain reported either in hip or knee] (t=1.34, df 90, NS), and GHQ (t=1.49, df 90, NS). Also, no statistically significant differences were found at baseline comparing functional ability scores on a numerical rating scale for: FBATH [getting in and out of a bath], (t=1.58, df 77, NS), FSTAIR [going up and down stairs] (t=1.44, df 90, NS). It was therefore considered legitimate to combine these data sets for patients with pain due to OA of the hip or knee for further analysis on all these variables. However, results of t-tests for other functional disability scores demonstrated statistically significant differences between
the two patient groups for the following variables: *FLOO* [getting on and off the toilet] \((t=-2.34, df=87.7, p<0.03)\), *FSOCK* [putting on socks or tights] \((t=4.78, df=90, p<0.001)\), *FCAR* [getting in and out of a car] \((t=3.54, df=79, p<0.001)\) and for *FSPEC* [one specially chosen problem activity] \((t=2.38, df=87, p<0.02)\). Data sets from these particular variables were therefore not used in the analysis of combined data sets, but were analysed separately. For clarity these results are reported elsewhere in Appendix Four.

### 10.3.4 Comparing Baseline Data Sets

To test whether any pre-treatment differences existed at baseline between the control, dummy and active treatment groups in spite of random allocation, the data were compared using one-way analysis of variance.

Data from the hips and knees were analysed together, except for the variables listed above *(vide 10.3.3)* that had shown significant differences for the hip and knee data at baseline. Table 10.2, displays the untransformed means and standard deviations of variables for the three different groups at baseline showing that all have similar values across the three groups with the exception of *DURATION OF HISTORY*. Results of one-way analysis of variance (Table 10.2a in Appendix Three) carried out on these variables demonstrate that none yield significant F-values: *AGE* \((F<1, df=2,89, NS)\), *DURATION OF HISTORY* \((F=2.63, df=2,87, NS)\), *W0PS* and *W0AS* (Baseline data for sensory and affective components of pain diaries - *(vide section 10.3.7)*), *MAINPAJN* \((F<2, df=2,89, NS)\), *GHQ* \((F<2, df=2,89, NS)\), *FBATH* \((F<2, df=2,77, NS)\), *FSTAIR* \((F<2, df=2,90, NS)\).

Data collected from measurements of range of motion at the hip and knee joints were analysed separately (see Appendix Four).

### 10.3.5 Comparing Treatment Effects across Three Groups over Time

Analysis of Variance with Repeated Measures over time was used to analyse all the combined data sets first, as discussed in 10.3.4 comparing the three treatment groups at intervals of one month and three months after the first assessment.
Table 10.2 Untransformed means, standard deviations of control, dummy & active groups at baseline on combined data for hip patients (n=46) & knee patients (n=46) on various demographic variables & measurements of pain & functional disability

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>CONTROL</th>
<th>DUMMY</th>
<th>ACTIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MEAN</td>
<td>SD</td>
<td>MEAN</td>
</tr>
<tr>
<td>AGE (years)</td>
<td>64.42</td>
<td>10.32</td>
<td>63.48</td>
</tr>
<tr>
<td>DURATION OF HISTORY (months)</td>
<td>111.23</td>
<td>151.30</td>
<td>103.07</td>
</tr>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td>33.84</td>
<td>24.76</td>
<td>38.39</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>28.13</td>
<td>10.40</td>
<td>27.26</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>3.56</td>
<td>3.18</td>
<td>2.86</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>3.90</td>
<td>2.57</td>
<td>3.52</td>
</tr>
</tbody>
</table>

10.3.5.1 Comparison between the Three Groups on Reports from Pain Diaries

Data from the pain diaries were analysed keeping the sensory and affective reports separate. The pain reports recorded at breakfast time, lunch time, tea time and at bed time were averaged out first over the days, and then over the weeks for each patient. One week of baseline data, comprised of both sensory \( W0PS \) and affective components \( W0PA \) was then compared with a total of 6 weeks of data. That was comprised of i) four weeks \( W1PS, W2PS, W3PS, W4PS \), and \( W1PA, W2PA, W3PA, W4PA \) spanning the duration of time between the first and second assessment points and including the three weeks of treatment, and, ii) two weeks of pain diary data \( W5PS, W6PS \) and \( W5PA, W6PA \) collected prior to the third assessment point, three months after the first assessment point. Table 10.3 shows the untransformed means and standard deviations of the weekly sensory and affective pain reports (averaged over the days), for the combined data sets, which are graphically displayed on Figures 10.1 and 10.2. It can be seen from these that the sensory and affective reports followed a very similar pattern; both the dummy and the active treatment groups improved slightly during treatment but reported more pain when treatment was withdrawn, although the affective component was consistently at a slightly lower level than the sensory
component of the pain reports, and the control group even at baseline reporting higher pain levels than the treatment groups. However, one-way analysis of variance carried out at baseline, immediately following treatment, and at follow-up on both the sensory and affective components of pain showed that none of the differences between the groups approached statistical significance, in each case F<2, df 2,88, NS. Two-way analysis of variance however was statistically significant for TIME for the sensory component of pain: F=9.76, and for the affective component: F=11.05, in both cases df 6, 72, p<0.0001. But neither GROUP, nor GROUP X TIME were statistically significant (see Table 10.3a in Appendix Three).

Figure 10.1 Mean Sensory Pain Diary Reports of all Patients Averaged out over Days, and Weeks comparing Control, Dummy and Active Groups

Figure 10.2 Mean Affective Pain Diary Reports Averaged out over weeks for Control, Dummy and Active Groups
Table 10.3 Untransformed means & standard deviations of pain reports (sensory & affective components) averaged out over the weeks for combined data sets from patients with OA hip (N=46) & patients with OA knee (N=46)

<table>
<thead>
<tr>
<th>SENSORY</th>
<th>Control Means (SD)</th>
<th>Dummy Means (SD)</th>
<th>Active Means (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIME</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>Baseline</td>
<td>WOPS 34.69 (22.010)</td>
<td>28.40 (18.60)</td>
</tr>
<tr>
<td>During treatment</td>
<td>Wk 1</td>
<td>WIPS 35.79 (23.19)</td>
<td>24.97 (16.76)</td>
</tr>
<tr>
<td></td>
<td>Wk 2</td>
<td>W2PS 36.19 (24.41)</td>
<td>23.10 (16.74)</td>
</tr>
<tr>
<td></td>
<td>Wk 3</td>
<td>W3PS 36.00 (23.58)</td>
<td>22.49 (15.97)</td>
</tr>
<tr>
<td>End of treatment</td>
<td>Wk 4</td>
<td>W4PS 34.56 (23.20)</td>
<td>24.04 (18.56)</td>
</tr>
<tr>
<td>Follow up</td>
<td>Wk 11</td>
<td>W5PS 39.27 (27.52)</td>
<td>30.40 (24.33)</td>
</tr>
<tr>
<td></td>
<td>Wk 12</td>
<td>W6PS 39.87 (27.36)</td>
<td>30.87 (24.68)</td>
</tr>
<tr>
<td>AFFECTIVE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>Baseline</td>
<td>WOPA 33.10 (21.83)</td>
<td>26.86 (18.91)</td>
</tr>
<tr>
<td>During</td>
<td>Wk 1</td>
<td>W1PA 34.04 (22.60)</td>
<td>23.36 (17.20)</td>
</tr>
<tr>
<td></td>
<td>Wk 2</td>
<td>W2PA 34.61 (24.14)</td>
<td>21.25 (16.55)</td>
</tr>
<tr>
<td></td>
<td>Wk 3</td>
<td>W3PA 34.25 (23.35)</td>
<td>20.94 (15.71)</td>
</tr>
<tr>
<td>End of treatment</td>
<td>Wk 4</td>
<td>W4PA 32.73 (22.96)</td>
<td>22.58 (18.39)</td>
</tr>
<tr>
<td>Follow up</td>
<td>Wk 11</td>
<td>W5PA 37.95 (27.76)</td>
<td>29.32 (24.41)</td>
</tr>
<tr>
<td></td>
<td>Wk 12</td>
<td>W6PA 38.65 (27.56)</td>
<td>29.80 (24.99)</td>
</tr>
</tbody>
</table>

10.3.5.2 Comparison between the Three Groups over Time on Main Pain, Reported Benefit, and Functional Disability

Table 10.4 displays the untransformed means and standard deviations for these combined data sets and shows some variation between the groups over time, the trend being for the control group to steadily get worse over time whilst the dummy and active groups improved slightly. The results of Analysis of Variance with Repeated Measures over time confirm an interaction effect for GROUP by TIME (F=3.17, df 4,168, p<0.02) for MAINPAIN which is graphically displayed on Figure 10.3.
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However, one-way analysis of variance and Bonferroni t-tests, which were carried out to test whether the group differences between the three groups for MAINPAIN2 and MAINPAIN3 at the second or third assessment points were statistically significant, did not yield significant F-ratios: F<2, df 2,88, NS and F=2.03, df 2,84, NS. Inspection of Table 10.4 indicates that patients in the dummy group tended to report a greater BENEFIT than the active group, and the results of analysis of variance for repeated measures over time demonstrated a marginally significant difference between the groups (F=3.9, df 1,45, p<0.06). None of the measures of functional disability displayed on Table 10.4 yielded statistically significant F values for the GROUPS X TIME, and the full results of the analyses are shown on Table 10.4a in Appendix Three.

![Figure 10.3 Mean Pain Reports (MAINPAIN) for all Patients (N=92)](image)

**Figure 10.3** Mean Pain Reports (MAINPAIN) for all Patients (N=92)

10.3.5.3 Comparison between the Three Treatment Groups over Time on GHQ-30 Scores

Inspection of Table 10.4 shows that levels of distress as measured by the GHQ-30 scores tended to improve slightly with treatment over time but reverted by the third assessment after treatment had been withdrawn. Analysis of variance with repeated measures over time showed that TIME was a significant factor, F=6.6, df=2,168, p<0.02, but GROUP and GROUP X TIME did not yield significant F values (see Table 10.4a in Appendix Three).
Table 10.4 Untransformed means & standard deviations comparing control, dummy & active groups on measurements of pain, subjective benefit, GHQ, functional disability pre-, post-treatment & at follow up for combined data from hip patients (n=46) & knee patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Time points</th>
<th>Control</th>
<th>Dummy</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Means (sd)</td>
<td>Means (sd)</td>
<td>Means (sd)</td>
</tr>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td>1</td>
<td>33.07 (24.54)</td>
<td>36.55 (20.04)</td>
<td>37.52 (20.22)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>38.21 (27.29)</td>
<td>26.90 (21.40)</td>
<td>35.00 (23.98)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>44.00 (31.22)</td>
<td>29.83 (26.54)</td>
<td>33.45 (25.32)</td>
</tr>
<tr>
<td>REPORTED BENEFIT (NRS 0-100)</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(NRS 0-100)</td>
<td>2</td>
<td>-</td>
<td>50.45 (31.01)</td>
<td>40.12 (24.95)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>-</td>
<td>53.86 (29.36)</td>
<td>35.92 (32.84)</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>1</td>
<td>28.24 (10.75)</td>
<td>25.72 (9.38)</td>
<td>29.34 (12.78)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28.10 (12.13)</td>
<td>22.31 (11.97)</td>
<td>27.93 (14.20)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>32.00 (14.18)</td>
<td>26.79 (13.58)</td>
<td>30.27 (15.80)</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>1</td>
<td>3.70 (3.20)</td>
<td>2.71 (2.29)</td>
<td>3.30 (2.38)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>3.61 (2.62)</td>
<td>3.08 (2.38)</td>
<td>3.13 (2.70)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4.04 (3.15)</td>
<td>3.17 (2.71)</td>
<td>3.70 (2.82)</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>1</td>
<td>3.93 (2.57)</td>
<td>3.32 (2.54)</td>
<td>3.75 (2.29)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4.18 (2.70)</td>
<td>3.00 (2.54)</td>
<td>3.75 (2.25)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4.79 (2.74)</td>
<td>3.14 (2.62)</td>
<td>3.86 (2.76)</td>
</tr>
</tbody>
</table>

10.3.5.4 Separate Analysis of Patients with OA Hip Pain and OA Knee Pain

When the baseline data was compared significant differences between the patients with and knee arthritis were found on some of the variables measuring subjective reports of functional disability (vide 10.3.3) and these data sets therefore had to be analysed separately. The results of these further analyses are reported in Appendix Four.
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10.3.6 Comparison of Patients on Waiting List for Joint Replacement Surgery with those not on Waiting List

All the analyses described above were then repeated including only patients who were not on the waiting list joint replacement surgery, (NON-WL group, n=40). Inspection of Table 10.5, displaying the untransformed means and standard deviations of MAINPAIN reports, subjective BENEFIT, GHQ, and various measures of functional disability of this sub-sample, reveals that all the scores tended to represent less reported pain and more benefit across all three groups at all three assessment points compared with the previously described combined data sets (n=92) shown on Table 10.4. WL patients in the active treatment group reported less than half as much benefit from the treatment at follow-up assessment compared with the NON-WL group. Analysis of variance with repeated measures over time yielded no significant differences for the NON-WL group on the main and interaction effects, but in the same analysis of the WL group a significant difference was found demonstrating that in this case that patients who received the dummy treatment reported greater benefit than the active treatment group.

Comparison of Figures 10.4 and 10.5 graphically displaying the MAINPAIN reports over time for respectively the NON-WL and WL groups, show two different interaction effects. Differences between the groups comparing the WL patients with NON-WL patients at baseline on the MAINPAIN scores were confirmed by t-tests (t=-2.03, df=90, p<0.05). However, this difference appeared to be due to the wide gap observed between the mean scores of the control group patients as shown on Tables 10.5 and 10.6. Patients expecting surgery scored on average 42 on MAINPAIN, whilst patients not on the waiting list scored 21. When the control groups were omitted from the analysis, t-tests showed no statistically significant differences between the WL and NON-WL patients at baseline (t=0.83, df=59, NS).
Analysis of Covariance was therefore carried out with WL and GROUP as grouping factors, and MAINPAIN2, MAINPAIN3 as dependent variables and MAINPAIN1 as the covariate, excluding patients in the control group. GROUP membership was not a significant factor (F<2, df=1,53, NS), but inspection of Table 10.9 displaying the means and standard deviations of MAINPAIN1, MAINPAIN2 and MAINPAIN3 shows that patients who were on a waiting list for surgery had higher scores especially at the third time point of assessment. Even when the baseline scores were taken into consideration, WL was a significant factor (F=5.39, df=1,53, p<0.03). All patients reported slightly less pain immediately following treatment, but the dummy group appeared to improve most at this time point. Inspection of Tables 10.5 and 10.6 shows that WL patients reported increased pain at three months when the treatment had been withdrawn, while NON-WL reported decreased pain levels. Results of Analysis of Covariance yielded a significant F-value for the interaction effect of WL X TIME (F=15.06, df=1,54, p<0.04)
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Table 10.5 Untransformed means & standard deviations comparing control, dummy & active groups on measurements of pain, benefit, GHQ & functional disability, pre-, post- treatment & at follow up for combined data from hip patients & knee patients who were not on a waiting list for joint replacement surgery (N=40)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Time points</th>
<th>Control</th>
<th>Dummy</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Means (sd)</td>
<td>Means (sd)</td>
<td>Means (sd)</td>
</tr>
<tr>
<td><strong>MAIN PAIN (NRS 0-100)</strong></td>
<td>1</td>
<td>20.75 (16.56)</td>
<td>36.36 (26.84)</td>
<td>33.75 (18.21)</td>
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<td></td>
<td>2</td>
<td>22.75 (21.84)</td>
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<td>25.00 (25.79)</td>
<td>19.38 (19.05)</td>
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<tr>
<td><strong>Reported Benefit</strong></td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>-</td>
<td>54.00 (31.25)</td>
<td>50.00 (26.22)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>-</td>
<td>59.50 (33.12)</td>
<td>47.92 (33.87)</td>
</tr>
<tr>
<td><strong>GHQ (scores 0-90)</strong></td>
<td>1</td>
<td>25.42 (9.42)</td>
<td>24.18 (7.34)</td>
<td>27.81 (8.75)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>23.17 (8.23)</td>
<td>19.55 (8.75)</td>
<td>24.38 (10.14)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>25.08 (8.76)</td>
<td>25.18 (11.22)</td>
<td>24.56 (8.87)</td>
</tr>
<tr>
<td><strong>FUNCTIONAL DISABILITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>FBATH</strong></td>
<td><strong>FBATH</strong></td>
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<tr>
<td></td>
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<td><strong>FSTAIR</strong></td>
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</tr>
<tr>
<td></td>
<td></td>
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<td>3</td>
<td>3.50 (2.88)</td>
<td>2.64 (3.11)</td>
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Table 10.6 Untransformed means & standard deviations comparing control, dummy & active groups on measurements of pain, benefit, GHQ, & functional disability, pre-, post- treatment & at follow up for combined data from hip patients & knee patients who were on a waiting list for joint replacement surgery (N=52)

<table>
<thead>
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<th>VARIABLES</th>
<th>Time points</th>
<th>Control</th>
<th>Dummy</th>
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</thead>
<tbody>
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<td></td>
<td>Means (sd)</td>
<td>Means (sd)</td>
<td>Means (sd)</td>
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<tr>
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<td>42.15 (22.29)</td>
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<td>58.41 (26.71)</td>
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<td></td>
</tr>
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<td></td>
<td>2</td>
<td>47.50 (31.87)</td>
<td>29.42 (19.20)</td>
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</tr>
<tr>
<td></td>
<td>3</td>
<td>49.17 (26.36)</td>
<td>22.92 (27.34)</td>
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<td>GHQ (scores 0-90)</td>
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<td>26.67 (10.52)</td>
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<td>3</td>
<td>36.88 (15.44)</td>
<td>27.78 (15.06)</td>
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<td></td>
</tr>
<tr>
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<td>3.00 (2.04)</td>
<td>4.08 (2.40)</td>
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<td>2</td>
<td>4.25 (2.42)</td>
<td>3.40 (2.03)</td>
<td>4.31 (2.50)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>5.58 (2.87)</td>
<td>3.40 (2.56)</td>
<td>4.69 (2.87)</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>1</td>
<td>4.75 (2.43)</td>
<td>3.59 (2.52)</td>
<td>4.67 (2.35)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4.75 (2.50)</td>
<td>3.47 (2.45)</td>
<td>4.83 (2.48)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>5.75 (2.27)</td>
<td>3.47 (2.29)</td>
<td>5.00 (2.50)</td>
</tr>
</tbody>
</table>
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When the control groups were omitted from the analysis, t-tests carried out on \( W0PS \) and \( W0PA \) (at baseline) showed no significant differences between the \( WL \) and \( NON-WL \) patient groups (\( t=-0.89, \text{df}=59, \text{NS} \)).

Two-way analysis of variance with repeated measures over time was therefore carried out with \( WL \) and \( GROUP \) (Treatment group) as grouping factors, and \( W0PS, W1PS, W2PS, W3PS, W4PS, W5PS, W6PS \) as dependent variables, excluding patients in the control group. The differential effect of time over the four groups is graphically displayed on Figure 10.6, and shows that pain scores of patients on the \( WL \) regardless of whether they had dummy or active treatment hardly changed at all during treatment, and when it was withdrawn, tended to get worse. In contrast, \( NON-WL \) patients improved by about 50%, whilst receiving dummy or active treatment and reverted slightly when it was withdrawn. GROUP membership was not statistically significant (\( F<1, \text{df}=1.44, \text{NS} \)), but \( WL \) and TIME did yield statistically significant F-values (respectively \( F=8.75, \text{df}=1.44, p<0.006 \) and \( F=5.14, \text{df}=6.264, p<0.001 \)). The interaction effect of \( WL \) and TIME was also highly significant (\( F=3.90, \text{df}=6.264, p<0.002 \)).

### Sensory Pain Diary Reports Comparing Waiting-list (WL) with non-WL Patients in Active & Dummy Groups

![Sensory Pain Diary Reports](image)

**Figure 10.6 Sensory Pain Diary Reports comparing Waiting-list (WL) with non-WL Patients in Active & Dummy Groups**

The same analysis for \( W0PA, W1PA, W2PA, W3PA, W4PA, W5PA, W6PA \) was carried out with similar results. GROUP membership was not significant (\( F<1, \text{df}=1.44, \text{NS} \)), but again \( WL \) and TIME yielded statistically significant F values (respectively \( F=9.29, \text{df}=6.264, p<0.001 \)).
df=1.44, p<0.004 and F=4.37, df=6,264, p<0.001). Also the interaction effect of WL and TIME was again highly significant (F=3.30, df=6,264, p<0.004).

Patients in the WL group were mainly suffering from OA hip pain. This uneven distribution of membership in treatment groups occurred in spite of the use of the Minimisation method for random allocation, because only 10 of the 46 hips were not expecting surgery. In order to check whether it was the difference between the response of patients with hip or knee problems, rather than WL versus NON-WL patients that was important, a 2-way analysis of variance with GROUP and HORK (hip or knee pain) as factors was carried out, to separate out the hip patients from the knee patients. The results of this analysis did not yield significant F-values for GROUP or HORK, respectively F<2, df=2,68, NS and F=3.02, df=1,68, NS. It seemed therefore that whether or not a patient was suffering from OA of the knee or the hip was not an important factor affecting pain reports, whereas whether or not a patient was in the WL group, expecting surgery was.

10.3.7 Comparison of MAINPAIN Pain Reports with Pain Diary Reports

In order to compare the two methods of measuring pain reports, Pearson correlations of product moment were carried out to test the strength of association between 1) MAINPAIN1 and W0PS, 2) MAINPAIN2 and W4PS, 3) MAINPAIN3 and W6PS. These were all highly significantly correlated, respectively: r=0.6651, 0.8106, 0.8367, p<0.01.

This procedure was repeated comparing 1) MAINPAIN1 and W0PA, 2) MAINPAIN2 and W4PA, 3) MAINPAIN3 and W6PA. These were all highly significantly correlated, respectively: r=0.6540, 0.8110, 0.8285, p<0.01.

It can be seen on the correlation matrices in Table 10.7(i) and (ii) that the correlations between the W0PS, W4PS and W6PS, as well as between W0PA, W4PA and W6PA were all markedly higher when compared to correlations between MAINPAIN1, MAINPAIN2, and MAINPAIN3.
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Table 10.7 Correlation matrix (Pearson product moment) to show strength of association between pain reported at assessments and pain reports from pain diaries averaged out over weeks.

(i) Correlations between sensory component of pain diary reports and pain reported at assessments

<table>
<thead>
<tr>
<th></th>
<th>W0PS</th>
<th>W4PS</th>
<th>W6PS</th>
<th>MAINPAI N1</th>
<th>MAINPAI N2</th>
<th>MAINPAI N3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W0PS</td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>W4PS</td>
<td>0.8175</td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>W6PS</td>
<td>0.7618</td>
<td>0.8049</td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAINPAI N1</td>
<td>0.6615</td>
<td>0.5521</td>
<td>0.5332</td>
<td>1.0000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAINPAI N2</td>
<td>0.6076</td>
<td>0.8104</td>
<td>0.6223</td>
<td>0.5153</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>MAINPAI N3</td>
<td>0.6466</td>
<td>0.7779</td>
<td>0.8367</td>
<td>0.4873</td>
<td>0.6646</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

(ii) Correlations between affective component of pain diary reports and pain reported at assessments

<table>
<thead>
<tr>
<th></th>
<th>W0PA</th>
<th>W4PA</th>
<th>W6PA</th>
<th>MAINPAI N1</th>
<th>MAINPAI N2</th>
<th>MAINPAI N3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W0PA</td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>W4PA</td>
<td>0.8200</td>
<td>1.0000</td>
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<td></td>
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<tr>
<td>W6PA</td>
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<td>0.8039</td>
<td>1.0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAINPAI N1</td>
<td>0.6540</td>
<td>0.5596</td>
<td>0.5386</td>
<td>1.0000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAINPAI N2</td>
<td>0.6084</td>
<td>0.8110</td>
<td>0.6207</td>
<td>0.5153</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>MAINPAI N3</td>
<td>0.6299</td>
<td>0.7648</td>
<td>0.8285</td>
<td>0.4873</td>
<td>0.6646</td>
<td>1.0000</td>
</tr>
</tbody>
</table>
10.3.8 Analysis of Non-Parametric Data

Non-parametric data analysis was carried out on remaining data that did not meet the assumptions required for parametric statistics. The distribution of data for referred pain and for night pain was extremely skewed and could not be normalised. For the purpose of analysis these were therefore treated as dichotomous data. In order to study the effect of treatment on referred pain, each area of pain scored by a patient as greater than zero was given a score of one. Any change on subsequent assessments were calculated and categorised as the "same", "better", or "worse". Results of data analysis using Pearson chi-square test of association were not significant on these variables, either for patients with hip or knee pain. No significant changes were found for patients with hip pain, between the first and second assessment assessments (chi-square=2.58, df=4, NS, or the first and third assessments (chi-square=7.199, df=4, NS). Nor were they found for patients with knee pain at either assessment point (chi-square<2, df=4, NS and chi-square=3.013, df=4, NS). Reported night pain was also treated as categorical data and combined data sets (n=92) were analysed using Pearson chi-square test of association but no statistically significant differences were found at either assessment point (chi-square=5.303, df=4, NS, and chi-square<2, df=4, NS).

10.3.9 Summary of Results

Patients included in this study were found to have a history of pain in the joint which was being investigated, for at least one year in 80% of cases, and 34% had a 5 year history of pain.

The main outcome measure pain diary reports of both sensory (W0PS, W1PS, W2PS, W3PS, W4PS, W5PS, W6PS) and affective (W0PA, W1PA, W2PA, W3PA, W4PA, W5PA, W6PA) components of pain were averaged over days and over seven weeks for each patient. These pain diary reports, like the one-off pain reports MAINPAIN, improved slightly over time, for both the dummy and active groups, while the control group tended to get worse. However, the control group patients reported steadily increasing levels of pain for MAINPAIN when communicating directly to the therapist, which was not so apparent from the pain diary reports (compare Figures 10.1 and 10.3). The results of two-way analysis of variance confirmed an interaction effect for MAINPAIN but the results of Bonferroni tests showed no significant differences between the three groups at the second and third assessment points. Two-way analysis of variance of the pain diary data did not yield any significant interaction effects, only a significant TIME effect.
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There were no significant interactions for any of the functional ability or ROM variables. For some data sets, patients with OA knee and hip had to be analysed separately as their data was not comparable at baseline, but these analyses did not yield any results that were of statistical or clinical significance.

Analysis of covariance comparing patients on the waiting list (WL) with those not expecting joint replacement surgery (NON-WL) revealed significant main effects for WL and also for WL X TIME, using WL and GROUP as grouping factors and the baseline MAINPAIN as a covariate (see Figures 10.2 and 10.3). Only the treatment groups were compared as the WL and NON-WL groups were only comparable when the control group was omitted. NON-WL patients reported significantly less pain to the therapist than the WL patients and the response to withdrawal of treatment was different with the WL patients reporting more pain at this stage. The analysis revealed no significant difference for GROUP. A similar result was obtained when the pain diary reports were analysed in the same way, but in this case the F values were highly statistically significant for WL, TIME and WL X TIME as reported in section 10.3.6 (see also Figures 10.4 to 10.6).

GHQ scores tended to improve slightly with treatment but became raised again when it had been withdrawn at three months follow-up. Patients in WL group tended to have slightly higher GHQ scores especially in the control group, than the NON-WL group. Patients in the WL group reported significantly more BENEFIT from treatment if they had received dummy treatment rather than active treatment.

Comparison of pain diary data sets and MAINPAIN data sets showed that correlations between the pain diary data were notably higher than correlations between MAINPAIN, as shown on Tables 10.7 (i) and (ii).

10.4 Discussion

All 92 patients included in this study were complaining of pain predominantly in their hip or their knee joint, the cause of which had been diagnosed as osteoarthrosis/osteoarthritis (OA), and degenerative changes were detectable on a plain radiograph. Fifty-two of these were awaiting joint replacement surgery, for which the primary indication is pain relief. Patients who were expecting to have surgery within six months were excluded from the study, as it was felt that they would be too focused on the forthcoming procedure to make conservative treatment, entailing three visits per week for three weeks to the physiotherapy department, a worthwhile proposition.
Most patients who were on the waiting list for surgery did not know when they would have surgery. This depended partly on the pressure of limited hospital resources, but also on the state of the individual themselves. In some cases their general medical health rendered them temporarily unfit to undergo general anaesthesia and major surgery; in other cases the joint in question was not considered to be sufficiently troublesome to warrant surgery at that time point. In several cases the patient had been put on a waiting list, in the early stages of osteoarthrosis in the expectation that they would come to the top of the waiting list by the time they really needed the operation. Many were not expecting to have surgery for at least eighteen months or longer.

Patients were initially randomly allocated either to a no treatment control group, or to a treatment group when they were invited to attend for a course of pulsed short wave therapy. If they were in the treatment group they had an equal chance of being allocated to either a dummy or active application of PSW, according to the sequential dial settings of the machine, half of which were set to administer the active PSW output, whilst the other settings although providing an apparently identical application were actually a dummy application.

The results of this study suggested that without any treatment patients with painful arthritic hips and knees tended to get worse over the three month period during which they were monitored, on average reporting 33% more pain to the physiotherapist (see Table 10.4). Patients who attended the hospital, that is both the active and placebo group, according to the on-off pain reports did better than patients who were in the no-treatment control group and did not receive treatment. However, the F-ratios yielded by the post-hoc Bonferroni test did not yield significant values. The pain diary reports did not yield any interaction effect to demonstrate a difference between the groups over time. It is possible that with larger numbers these would have been significant, providing stronger evidence for the placebo benefits of attending the hospital as an out-patient.

However, the results of this study do not provide evidence for the effectiveness of pulsed short wave, as used in this study, to treat painful arthritic hips and knees. Moreover, there was a tendency for the dummy group to report less pain and more subjective benefit from the treatment than the active treatment group.
10.4.1 Osteoarthritis, Surgery and the Problems of Pain Assessment

There is a poor correlation between severity of pain reported and degree of degenerative changes in osteoarthrosis [397], [277], [43]. It is therefore not possible for the surgeon to make an objective assessment of the need for surgical replacement based purely on arthritic changes seen on X-ray. Over the age of 75 years, 80% of the population have radiographic signs of degeneration, but only 50% report symptoms [369]. Cognitive and behavioural factors influence the reporting of signs and symptoms [333]. Exaggerated pain reports associated with the expectation of surgery are discussed in the literature [199] particularly in relationship to chronic back pain. But the principle is also relevant to chronic pain due to arthritis of the hip or knee, where objective signs such as X-rays cannot on their own be relied upon to assess the need for surgery. Theoretically, medical treatment or surgery is prescribed for physical indications but according to Waddell et al even surgery is actually determined to a large extent by the patient's distress and pain behaviour [411]. Possibly patients who were on the waiting list for surgery therefore represented a more distressed group, and a poorer outcome of treatment in this group would be in line with previous research [409], [263].

10.4.2 Perceived Control and Expectations

Control group patients who were not on the surgical waiting list also reported a small increase in pain but of only 14% on average (see Table 10.5). Whereas, control group patients on the waiting list reported 40% more pain by the end of the three month period (see Table 10.6). These differing figures may simply be an indication of the natural course of the condition, and the different response may be the result of the two groups simply being derived from two distinct populations. However, another explanation may be that the patients' response is influenced by the expectations of the benefits of surgery. Artificial hip and more recently also artificial knee joint surgery are generally considered to be highly successful in relieving pain [211], [431]. But a patient may be aware that when and whether the surgeon offers them surgery depends largely on the severity of pain communicated. A need to report high levels of pain to a clinician could be seen as a coping strategy which is maladaptive for pain relief, and not available to the patients who had similar joint problems but were not waiting for surgery. Patients who were not on the waiting list reported less pain and, it seemed, used coping strategies which were more effective. It could be speculated that they might have had a more internal Locus of Control depending more on their own ability to help themselves rather than relying on external (e.g. surgical) help, although the results of this study cannot provide any support for this supposition, as the Health
Locus of Control [417] was not considered a useful measure for this group of patients. More recently it has been postulated that perceived control may be a more useful concept in predicting outcome of treatment [419]. Perceived control of recovery has been shown to be a predictor of outcome following active rehabilitation for patients recovering from a stroke or wrist fracture [311]. Although PSW is a passive form of treatment and the patient does not play an active role in the treatment, it is possible that patients on a waiting list gave up trying to help themselves whereas the other group used a more effective coping strategy and continued to carry out their normal activities as far as possible. According to Plotkin’s hypothesis on placebogenesis patients who have faith in a treatment will act as if they have been “cured” [321].

10.4.3 Contrasting Levels of Pain Reports in WL versus NON-WL Patient Groups

Since the different pain reports for the waiting list and non-waiting list patients at baseline was due to differentials in the control groups, these groups were omitted for the purposes of comparison, so that the levels of fluctuations over time for the two treatment groups, that is the dummy and active groups could be studied. Although the levels of pain reports for the two groups (WL and NON-WL) were similar at the outset, and also both groups showed slight improvement during treatment, there was a notable difference over the follow up period. Three months after the first assessment, the patients who were on the waiting list had raised levels of pain reports whereas the non-waiting list patients reported further reductions in pain. The most obvious interpretation is that the patients who are on a surgical waiting list differ fundamentally from patients who are not on a surgical waiting list and belong to a different population. However, since their pain reports at the outset were similar, if the assumption is made that these patients do come from a similar population, there are two other possible interpretations of the different responses to treatment. Perhaps patients who had been offered surgery did not find any credibility in the likely efficacy of PSW as an interim measure, if their joint was considered bad enough by a surgeon to require surgical replacement.

Since according to the pain reports even patients on the waiting list gained some improvement whilst they were attending for treatment, a more likely explanation is that a fear of being taken off the waiting list for surgery (or being put to the bottom of the list) if they continued to report less pain may have influenced the severity of their pain reports. The literature provides some evidence that the expectations of pain relief to be gained from surgery may influence pain reports (vide 10.4.4) [199]. But research does not appear to have focused on the effects of being on a surgical waiting list. A
comparison could be made across two similar patient groups; one of whom would be given strong assurance that they would receive surgery by a certain date, regardless of pain levels reported; while the other group (like many of the OA hip pain patients in this present study) would not be given a firm date, and would be told that the operation would depend on how bad the pain was.

10.4.4 General Health Questionnaire

The GHQ-30 was used as an outcome variable to assess changes in levels of distress between the groups over time. These scores tended to decrease slightly with treatment but revert to higher levels after treatment had been withdrawn. Patients on the waiting list tended to have somewhat higher scores than those who were not expecting surgery. The GHQ scores followed a similar pattern to the \textit{MAINPAIN} reports, with \textit{NON-WL} patients not only reporting less pain and lower levels of distress as measured by the GHQ scores, but improvement only being demonstrated on these scores in the \textit{NON-WL} groups. Overall the GHQ scores recorded at baseline in this study are comparable with those of a RCT of chronic back pain patients in which a fitness programme was evaluated [142]. However, in contrast to the present study, back pain patients attending the exercise programme as well as a back school improved significantly more on the GHQ-30 scores as well as the sensory and affective components of pain diary reports (\textit{vide} 11.1). Presumably when the patient perceives their problem has resolved they report less pain and less distress, and the GHQ-30 appears in these studies to reflect any differences.

10.4.5 The Response Bias and One-off Pain Reports

The differences between the \textit{WL} and \textit{NON-WL} are more apparent in the pain reports provided for the physiotherapist at the 3 assessment points, than collected from the pain reported 4 times daily in the written diary recordings. One explanation of this is that patients were demonstrating a response bias with the one-off pain report when face to face with their physiotherapist. Reports from diaries are possibly less susceptible to bias as they are not a vehicle for such direct communication. This is one reason why they may be more reliable than one-off reports such as represented by the variable \textit{MAINPAIN}.

All subjective reports suffer from a possibility of response bias [72], and this has already been referred to in relationship to surgery. Patient may wish to impress the clinician or therapist with their high level of pain or may wish to please, for example by demonstrating a lower level of pain after a course of treatment. Depending on the likely gain, patients will report different levels of pain intensity to different people. For
example, Ignelzi et al [199] found that 46% of chronic pain patients using the MPQ reported significantly higher levels of pain to a neurologist compared to the psychiatrist or psychologist. There was no difference in levels of pain provided for the psychiatrist and the psychologist, so it appears that the patients may have been trying to impress the neurologist with their high pain scores in the hope that he would recommend surgery. Also Block [49], in an interesting study of chronic pain patients, demonstrated response bias depending on their spouse's attitude to their pain problem. The patients were interviewed and for the first half of the interview told that a ward clerk, i.e. a neutral observer would be in an adjacent room, whilst for the second half of the interview they were told that their spouse would be there. This study showed that patients who had a solicitous partner, as established by means of a pain behaviour questionnaire, gave higher pain scores than when they believed the neutral observer was present. Those who had a partner who was not solicitous towards pain complaints provided lower pain reports when they believed their partner was present.

The very similar pattern that the sensory and affective pain followed is notable. The mean affective reports were at all times lower than the sensory, which may be a reflection of the relative emotional stability of this population compared with for example a population of back pain sufferers. Other studies have shown marked differences in sensory and affective pain reports in chronic back pain population e.g. [142]. The affective component of pain may be reduced by an intervention more markedly than the sensory component [432], [142]. In this present study there was a large variation in reporting amongst individuals for both sensory and affective pain reports.

10.4.6 Problem of Recall, and Fluctuating Pain Levels with One-off Reports

Owing to the problem of recall the data collected by means of repeated pain reports in the pain diaries is likely to be more reliable than the one-off pain reports, MAINPAIN [123], [206]. In this study of patients with OA hip and knee pain quite frequently a patient might complain of very severe pain when engaged in a particular weight bearing activity, for example part of the stance phase of walking, when the leg tended to "give way". This high level of pain may have lasted only for a few minutes or perhaps half an hour, and for the rest of the time they may have had no pain, or a low level of pain, as was shown in their pain diary. But for the one-off pain report, even assuming a high degree of numeracy, it was difficult for the patient to know how to provide an accurate report. The resulting figure did not appear to accurately reflect the fluctuation in levels of pain reported throughout the day. Pain diaries had the advantage of not relying on memory, which tends to bias pain reports. There is evidence that pain recalled is likely
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to be influenced by the level of present pain. If current pain levels are low, then the pain recalled will also be at a lower level [123].

In order to avoid patients having to rely on recall of pain, patients were urged to fill in their pain diaries throughout the day so that they could either report on pain at that moment or pain retrospectively averaged over the last few hours since the last mealtime. It seemed better to do the latter as a number of patients reported that they did not have pain unless they were weight bearing and would be putting "zero" throughout because they had no pain when they were sitting down for their meal, filling in their diary. The problem with this approach is that they have a potential problem with recall, albeit only over a period of 3-4 hours, and also may need to average their pain.

10.4.7 The Advantage of Pain Diaries over One-off Pain Reports

Correlation between pain diary reports was consistently higher than between MAINPAIN reports, which could be interpreted as evidence of greater reliability. An alternative possibility is that patients may have recalled previous numbers they had recorded and the resulting high correlation of figures was due to a response set.

The use of pain diaries allows pain reports to be assessed over days and over weeks and has several advantages [314], [261], [206]. Jensen in a recent study of chronic pain demonstrated the importance of averaging multiple pain reports in order to improve the reliability and validity of measuring average or usual pain levels [206]. The method also has the advantage of allowing diurnal fluctuations in pain to be assessed and for activities and potential stressors to be recorded and related to the onset of pain. In this study patients were asked to rate how strong their pain was (sensory component), and how distressing their pain was (affective component), four times a day: at breakfast time, lunch time, at tea time and again before going to bed at night. The reports were based on a Numerical Rating Scale, 0-100, a separate number being provided for the sensory and affective components. Patients got used to doing this and although the prospect appeared onerous to some of them when the task was first explained, they did not appear to find it a problem once they had started doing it. Only one patient out of 135 patients in the study of osteoarthritic patients was not included because she did not wish to keep pain diaries.

10.4.8 Physiological or Placebo Effects of Treatment

The results of this study showed no differences in effect between active or dummy treatment on the levels of pain reported. But patients in the dummy group reported
significantly more benefit from treatment than the active treatment group. It appears that the active PSW as administered in this study (with a circuplode at a dosage of 82 pulses per second at an intensity of 7) was not beneficial for this patient population. Although the mean wattage provided by this pulsed electromagnetic field estimated as 23 watts, was considered to be sub-thermal, it is possible that a heating effect produced in the deeper tissues. In the presence of inflammation in the soft tissues of the joint heat may increase the inflammatory reaction and cause more pain, in some patients. This could explain why the dummy group tended to report more benefit, also slightly less pain. It can be concluded that the active application of PSW as carried out in this study is unlikely to provide any beneficial physiological effects. This application and dosage however is one that is commonly used in clinical practice (vide 9.2.5.3).

Patients who were responsive to treatment, that is patients who were not on the waiting list for surgery, improved while they had treatment (either active or dummy) by about 50% on average according to the pain level reported to the therapist. This provides strong evidence of the powerful placebo effect of this method of treatment. This has been previously demonstrated to be the case with ultra-sound, in a series of studies on post-operative treatment of dental extraction [186], [187], [194] These researchers concluded that the machine producing the ultrasound has a powerful placebo effect but that the therapist applying the treatment was also an important factor. Apart from pain reports they also use physiological outcome measures. To assess the status of inflammatory process they measured serum C-reactive protein, and also used an objective method to measure swelling of the jaw. Both of these measures were significantly reduced by the dummy application of ultrasound compared to a no treatment control. These authors concluded that the placebo response consisted of reported pain relief but also anti-inflammatory effects, which may have also been produced by the dummy application of pulsed electromagnetic energy in the present study.

10.4.9 Sample Size

A much larger sample size would have been needed to yield any significant differences on pain diary reports between the groups over time. It was calculated retrospectively that for the study to have a power of 80% to demonstrate any actual differences (based on the findings of Phase I according to the differences between the groups in changes in pain diary reports) 182 patients would have been needed in each group. In this study there were only 45 patients in each group, and it took over 2 years to recruit them.
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10.4.10 Conclusions

The findings of this study can only be generalised to PSW as applied in this study for pain relief in patients with OA hip or knee pain. It is possible that a different method of application, using different machine settings, would yield different results. It is also possible that if more acute conditions, including early OA of the hip, the knee and other joints, were treated with PSW the effects might be shown to be more positive.

- Evidence was found of a significantly different pain response depending on whether or not patients were on a surgical waiting list.

- Patients who attended the hospital for PSW, that is both the active and placebo group tended to report less pain than patients who were in the no-treatment control group and did not attend hospital.

- No evidence was found to support the use of PSW for patients with OA hip or knee pain, as applied in this study.
CHAPTER ELEVEN: DISCUSSION

This thesis has been concerned with the scientific evaluation of physiotherapy practice related to musculoskeletal disorders, taking into account the role of psychological variables such as anxiety, and distress, and exploring possible of placebo responses. Musculoskeletal disorders are very common, accounting for 15% of all GP consultations, and the evidence suggests that when they are treated by physiotherapy, patients consider that their problem is well managed [174]. However, the physiological processes are poorly understood, and are not well documented.

The conclusions reached in this thesis, through critical reviews of the literature in Chapter Three and the results of RCTs reported in Chapters Seven through to Ten, failed to provide evidence for the effectiveness of certain aspects of physiotherapy practice for MSD. One of the principle aims of this thesis was to establish the extent to which methods of scientific evaluation can be applied to investigate the effectiveness of physiotherapy treatments, and this thesis has presented studies which progressively apply a more stringent methodology. In the following section, the methodology of the design of the clinical trials reported in Chapters Seven and Eight is compared and contrasted with the design of the studies reported in Chapters Nine and Ten. An overview of the findings of the clinical trials reported in this thesis is then provided (11.2). Evaluation of the relative role of physiological and psychological variables in pain reports associated with MSD are then considered, in the following section (11.3). Many psychological questionnaires have been developed and have been shown to be valid, sensitive and reliable e.g. GHQ, but there is a paucity of such measures to assess changes in physical and functional ability. Finally the limitations of the scope of this thesis will addressed (11.4), before the final conclusions are reached.

11.1 COMPARISON OF THE METHODOLOGY OF THE CLINICAL TRIALS

The later studies, reported in this thesis in Chapters Nine and Ten, use a more refined approach, than the earlier studies of cervical traction reported in Chapters Six and Seven. Methodologically the design of the PSW studies reported in Chapters Nine and Ten is much more sophisticated and represents an even more rigorous approach to the evaluation of physiotherapy practice. These studies demonstrate that it is possible, at least in some applications of physiotherapy, to apply a truly double blind methodology with an independent assessor, the therapist and the patient all being unaware of the treatment allocation. A number of other points in the design helped to strengthen and improve the methodology. These include 1) the incorporation of a no-treatment
control group, 2) the use of sensory and affective pain diary reports, 3) the use of a more sophisticated method of randomisation, and of 4) an automated method of applying a sham/dummy.

No-Treatment Control Group

An important methodological advance in the PSW study was the inclusion of a no-treatment control group which allowed the natural history of the condition to be taken into account. This demonstrated that all patients according to the pain reports, tended if treatment was absent or withdrawn to have more pain over time, which possibly could reflect a response bias - a point which will be taken up later (11.3.2). In the cervical traction study both the treatment group and the placebo group reported less pain following treatment. The condition being studied in that trial was neck pain, mainly cervical spondylosis which is characterised by exacerbations and remissions; due to the statistical phenomenon of regression of the mean, since a no-treatment group was not included, it is possible that these patients would have shown improvement without treatment. An earlier study of the management of neck pain patients had shown that regardless of whether patients are given cervical traction, given a dummy treatment at hospital, or a placebo pill at home, all patients tended to improve [56].

Subjective Pain Reports

In the PSW study a total of seven weeks of pain diary data, with separate recordings of sensory and affective components of pain, were collected and analysed separately. This provided a more reliable measure of pain than the one-off pain reports used in the cervical traction study [206]. A series of pain reports over time can take into account fluctuations in levels of pain and therefore provide more valid data than reports of current pain. Also, in acknowledgement of the multidimensional aspects of pain, it is useful to collect separate reports of sensory and affective components (4.2). In the PSW study the means of these two components of pain followed very similar fluctuations over the three months while these patients were being monitored, the sensory component being slightly higher than the affective component. In another recent study of chronic back pain patients Frost et al used separate measures of the sensory and affective components [142]. Patients were randomly allocated to an exercise programme and back school or a back school only, and patients who attended the exercise class were found to have significantly reduced affective and sensory components of pain but the affective component was reduced. Similar differential effects were found by Williams and colleagues in the evaluation of a cognitive-
behavioural programme for chronic pain patients, with greater reductions in the affective than the sensory component [432].

**Randomisation Procedure**

For random allocation to be effective in reducing bias every patient included in the study should have an equal chance of being allocated to any of the treatment groups. Instead of drawing numbers out of an envelope, which was the method of randomisation used in the cervical traction study, a more sophisticated method was used in the later PSW study. This was the Minimisation method which also stratifies patients across the groups taking account of potentially confounding factors and it is therefore especially useful in studies with a smaller sample size, since the groups become more comparable [323]. This procedure, although it can carried out manually, was facilitated by means of a simple computer program.

**Sham/Dummy Application**

Sham procedures, which are a good basis for a placebo-control group, were used in two different ways in the cervical traction study and PSW study. In the earlier trial, weighted mechanical traction (8 to 15 lbs) was compared with the application of a lighter weight (2 lbs) considered just sufficient to take up the slack of the rope and mimic traction. The investigators had previously ascertained that it is difficult for a subject to distinguish between these provided the weight is not rapidly applied, so the patient was unlikely to be able to distinguish between the treatment and the sham procedure. But the therapist applying the traction could not be blind to the treatment applied and may have therefore inadvertently influenced the outcome through biased expectations and enthusiasm. In the PSW study this was not possible as the procedure was automated and the therapist was unaware of the treatment being provided. This was made possible by the adaptation of the PSW machine with ten different dial settings on the machine. Half of these were sham and half provided active treatment. Patients were allocated sequentially to the different dial settings, each of which had a 50% chance of being active or dummy. There was no way in which the two could be distinguished by the therapist or the patient, since the treatment was an electromagnetic field which produces no noticeable heating effect and the patient was told not to expect any sensation of any kind.
Chapter Eleven

11.2 OVERVIEW OF THE FINDINGS OF THIS THESIS

Findings from the Reviews of Literature

This thesis has demonstrated that it is possible to apply the rigorous design of a double blind placebo controlled trial to some forms of physiotherapy treatment. Three separate research areas of the literature have been presented in Chapters Two through to Four. These have been used to review the research literature on 1) physiotherapy for the relief of musculoskeletal problems, 2) the development of back pain and its management, and 3) the psychology of pain. The overall findings of the reviews of clinical trials discussed in Chapter Three covering ultrasound, TNS, and low intensity laser therapy demonstrated little evidence to support the effectiveness of these forms of treatment. This was in line with the findings of Beckerman and colleagues in the Netherlands [34] who recently carried out a critical survey of the literature on physiotherapy for musculoskeletal disorders. They reported finding 400 RCTs and, using a standardised stringent assessment of the methodology, found little evidence for the efficacy of physiotherapy for MSD. But they emphasised that owing to the prevalence of methodological flaws, it could not be concluded that physiotherapy has no effect. The tendency was found, in the review of this literature reported in Chapter Three, for the studies with the most rigorous methodological designs to demonstrate negative results. But in many cases this may have at least in part been due to the sample size not being large enough.

Chapter Four used the research findings from the literature on the psychology of pain, as well as the more medically orientated literature on back pain, to discuss factors which may influence the development of pain and the outcome of treatment. The research findings from the literature on the psychology of pain and physical symptoms were discussed in terms of cognitive processes such as vigilance and somatisation, social influences, and affective states such as anxiety, depression and neuroticism. The very large literature on back pain found in medical, psychological and physiotherapy journals, is especially important in the context of this thesis because it crosses these interdisciplinary boundaries, and often acknowledges the role of psychological variables in the development and management of physical disorders. In a series of compelling papers Waddell and colleagues put forward a new approach to assessing and managing the problem, advocating a biopsychosocial model to replace the traditional model, e.g. [409], [410]. The dominant influence of psychosocial factors in the development and management of back pain has been demonstrated in a number of studies notably in the large scale study of back pain at the Boeing factory e.g. [46], [45], [45]. The findings of the longitudinal study of student nurses reported in Chapter
Discussion

Five are in line with this general finding. It demonstrated that the HLC, neuroticism (EPI), GHQ, and trait anxiety in combination may help to predict the reporting of back pain, together with two physical variables, height and quadriceps muscle strength. As in the Boeing study, psychosocial factors took precedence over biomechanical and anthropometric measures, in predicting back pain reports (11.3.1).

Cervical Traction Studies

The results of the cervical traction study reported in Chapter Seven did not support the use of this technique for routine use. Patients in both the treatment and the placebo groups tended to improve in terms of subjective pain reports and functional disability scores. The treatment group did slightly better than the placebo group but the differences did not reach statistical significance. However, in common with the findings of an earlier study [56], it was concluded that cervical traction was indicated only when severe symptoms could not be relieved in a simpler way. The study to assess the effects of cervical traction on the neck musculature reported in Chapter Eight showed that this treatment did not facilitate a reduction in muscle tone as measured by surface EMG.

Increased muscle tone was found to have some association with raised state anxiety, which was in line with the findings of Bru [59]. This is discussed further in section 11.3.1.

Pulsed Short Wave Studies

The results of the PSW study reported in Chapter Ten provided no evidence for its efficacy in relieving pain in the hip or knee due to osteoarthritis. However, individuals who were not on a waiting list for total hip arthroplasty did significantly better than patients who were expecting surgery. This result is of some interest for several reasons. Firstly, the most obvious explanation, that patients expecting surgery were a more severe group, is not supported because of the lack of difference between the two groups on pain scores at the outset. A more likely explanation is therefore that these patients were not able to benefit from any conservative treatment as their expectations for pain relief were totally focused on awaited surgery. This finding has much wider implications for all patients on waiting lists and will be discussed further in 11.3.3.

11.3 The Influence of Psychological Variables in the Physical Management of MSD

There are a number of different ways in which psychological variables may influence the development and management of MSD. This thesis has been concerned with
11.3.1 Affective Distress and Life Stressors

In this thesis the GHQ as a measure of distress and the STAI as measures of anxiety were the main psychological measures used. In the longitudinal study of back pain in student nurses, the GHQ-12 and the trait anxiety inventory were used alongside the Health Locus of Control and the neuroticism scale of the EPI. These questionnaires were all administered prior to the reporting of back pain in nurses, which was monitored over a two year period. In combination, these psychological variables were selected by the regression analysis, and took precedence over a number of physical variables which added very little to the prediction of back pain reports (vide 5.3.2.1 and 5.3.2.2). The methodology of this study was longitudinal which has an advantage over cross-sectional studies (e.g. [3811]) in which correlational results are difficult to interpret if the psychological variables are measured at the same time as physical symptoms [90]. In this present study of nurses, life events were also recorded and the results of analysis showed that the number of reports of episodes of both emotional and physical stress were significantly greater in the back pain cases. However, it was not possible for the analysis to use these factors as predictors of back pain since it was not known whether they preceded these pain reports.

In the cervical traction study reported in Chapters Seven and Eight, the GHQ-12 was used again, together with the State and Trait Anxiety Inventory, as predictors of treatment outcome. The GHQ-12 did not prove to be a predictor, and possibly a longer form of this questionnaire as used in the PSW study might have been more sensitive. Reduction in pain reports following cervical traction was weakly linked with lower state and trait anxiety scores. Weisenberg et al [426] proposed in their attribution theory, that only anxiety which is relevant to the painful situation would increase pain reports. Although some experimental studies have supported the theory [2], [13] others have not [84]. The role of mediating personality traits such as anxiety can be expected to depend on situational demands [59].

State anxiety was also significantly linked with increased tension in the neck musculature, according to surface EMG readings (8.4). Cervical traction, according to these results, did not reduce muscle tension, which was apparently influenced by other factors. Less tension in the supine position but not the upright position was weakly associated with a reduction in pain reports. Increased tension is probably not only related to personality traits such as anxiety or neuroticism but is likely to be mediated by external stressors and life events [59]. Flor et al [135], in a study of chronic back
pain patients showed that these patients demonstrated abnormal reactive muscle tension (in their spinal muscles) when exposed to personally relevant stressors.

In the PSW study the GHQ-30 was used as an outcome variable but did not vary greatly with treatment or across the groups, although it was somewhat higher in the patients expecting surgery. Also in this sub-sample of patients the distress as measured by the GHQ scores tended to increase over time whereas in patients who were not expecting surgery it tended to improve.

In the PSW study the most interesting psychological variables to consider are the cognitive and affective factors which may have influenced the pain reports and also the placebo response which resulted from the application of a dummy treatment, and the differential response to treatment of patients waiting for surgery compared with those not expecting surgery.

11.3.2 Pain Response Bias

Pain reports were apparently influenced by whether or not the patient was reporting directly to the therapist or in a pain diary (10.4.4). This difference may have been due to the problems of one-off reports discussed earlier in this chapter (11.1). Also, a response bias may have resulted from patients who were afraid that they might be removed from the surgical waiting list if they reported low pain scores (10.4.5).

11.3.3 Placebo Response

Evidence of a strong placebo response in the PSW study is provided by the significantly greater benefit of treatment perceived by patients who received the dummy application, in comparison with those who received the active treatment and those who did not attend hospital. This was especially true of the patients on the waiting list, with those who had the active application reporting about half as much benefit as the other groups. It has to be speculated that the active application may have delivered a dosage which was physiologically harmful for these patients (10.4.8).

According to the one-off pain reports patients who attended the physiotherapy department regularly for nine treatment sessions of PSW, regardless of whether it was dummy or active treatment, reported significantly less pain afterwards than the control group who only attended the physiotherapy department to be assessed.

Hashish et al [186] found that a dummy application of ultrasound following dental surgery provided effective pain relief and in addition a reduction in oedema and inflammation. They suggested that this physiological effect could be explained by the
**Chapter Eleven**

 placebo-induced endogenous opioids inhibiting the production of substance P. This has the effect of increasing the pain threshold by desensitising the nociceptors but also is known to mediate the inflammatory response by controlling vascular permeability and mast cell degranulation [140]. This provides an insight into the possibility of demonstrating in future research how psychological processes in the management of physiotherapy can be of fundamental importance, and the possibility of direct links between stress or anxiety and physiological changes in body chemistry. It also emphasises the power of the placebo not only in influencing the reporting of pain, but also on an individual's nociception at a tissue level.

Conversely, patients in the sub-sample of PSW study who were on the waiting list for joint replacement surgery appear to have been unable to respond positively to either the dummy and the active application. They may suffer from an increased sense of passive helplessness whilst waiting to have the operation performed on them. Any sense of self-efficacy and ability to cope may meanwhile be reduced. There is much evidence in the literature to show that the individual's perception of self-efficacy and ability to use effective coping strategies may be important factors in the chronic pain experience [303], [424], [338], [290], [207].

Also, an individual who is expecting surgery is less likely to have faith in a form of conservative treatment such as PSW. Plotkin [321], in his discussion of the placebo response pointed out that when a patient has faith in a treatment he will then start to act as a person who has been cured. Although the link between the autonomic and central nervous systems allows an individual to exert remarkable control and regulation over many somatic processes, his attitude and belief in the treatment are also very influential [321].

**11.4 THE LIMITATIONS OF THE SCOPE OF THIS THESIS**

The physiotherapist has a variety of highly specialised techniques available for pain relief. Many of these are hands-on techniques, where it would not be possible for the therapist to be blind to the treatment provided. This thesis has limited itself to more mechanical aspects of treatment that can be more readily described, quantified and standardised. However, this type of treatment forms only a small part of the skills of a physiotherapist, and probably could be performed by anyone with a small amount of training.

It is particularly the highly specialised hands-on skills such as manipulation and other manual techniques that may be considered to be the most powerful tools for the physiotherapist to use in combating pain. Where hands-on application of treatment is
provided the procedure becomes more difficult to describe fully and so do the patient responses. But these methods of managing pain also need to be evaluated. Double blind studies cannot be applied to all forms of physiotherapy management, although single blind studies with an independent assessor could theoretically be applied to most types of treatment using ingenuity to devise suitable sham treatment that will mimic the non-placebo treatment, so that the placebo control treatment is both credible and comparable [423], [104].

Another major disadvantage of randomised controlled trials is the rigidity of the design, which cannot entertain any changes in the procedure once the study has started. In clinical practice physiotherapists typically assess a patient, treat them, then reassess to see if any changes have occurred, reappraise the treatment and alter it if improvement does not appear to have taken place. On this basis, it is very difficult to describe a protocol which could be replicated for individual patients and that rigorously fulfils the criteria for internal and external validity. However, the lack of good outcome measures in physiotherapy practice results in an assessment of the patient's condition which may be less than reliable, and may often be biased for example by the physiotherapist's expectations.

11.5 Future Research

Cervical traction did not appear to have the desired effect of relaxing the neck muscles. Extrapolating from the findings of Flor and colleagues [135] to neck pain patients, cognitive factors such as the individual's interpretation of the life stressors and the pain experience itself may have played a more important role in muscle tension and pain reports. Flor & Birbaumer in a more recent study found that chronic pain patients may interpret muscle tension as pain, and that their ability to distinguish pain and muscle tension is reduced [133]. These would be interesting areas for further research in relationship to the physiotherapy management of back and neck pain.

The results of the study of PSW (10.3) have shown that in some cases the dummy treatment is at least as, or more effective than the active treatment. Since the supposed underlying physiological effects of physiotherapy treatment, such as PSW, are so poorly understood, it is important that more work is carried out to elucidate its effects, before further large scale clinical trials are carried out. The effects on the tissues need to be studied in humans and also in animals, to rigorously investigate any physiological changes that may take place in the tissues. Further in vitro experiments [83] to study the effect of PSW (as used in physiotherapy departments) to see if it was possible to replicate the previous study which stimulated the sodium flux with a different frequency of a PEMF, would be useful, and also the measurement of any thermal
effects in the deeper tissues of normal subjects when different dosages of PSW are applied. It is possible that a dosage such as the one used in the PSW study reported in this study may have been thermal although no heating effect was reported by the patients.

Future research needs to give attention to the choice of outcome measures. Instruments to measure psychosocial factors abound, and many have been well-developed with studies demonstrating their reliability and validity, but the same cannot be said for outcome measurement in physiotherapy. Campbell has proposed that this lack of appropriate measures is one important explanation for the paucity of good outcome research in physiotherapy [67]. Outcome measures, whether measuring physical or psychological factors, need to be appropriate to the patient's condition and the treatment being provided. Specific questionnaires may be required to target specific areas being studied. There is a need for both objective outcome measures and subjective measures to be developed, which in either case must be shown to be reliable, valid, and sensitive enough to detect small changes. Measures are needed that assess both local observable changes, such as measurement of joint motion at the spinal level being manipulated, and the effects on the individual as a whole. For this, functional activities scales and also quality of life measures may be appropriate [394]. Quality of life measures have been shown to be better predictors of long term outcomes in rheumatological conditions than traditional measures [132], and could be useful as outcome measures in future clinical trials of physiotherapy. Examples of these generic measures are the Sickness Impact Profile, developed in the USA but also used in the UK for chronic pain patients [432], and the Nottingham Health Profile which was developed in Britain and has been very widely used for a range of conditions [431]. According to Borgquist and colleagues it may pick up differences in patient outcome status which other methods fail to find [54]. It would probably be appropriate for use in further studies of pain relief for arthritic problems involving the lower limb, and also for the evaluation of treatment of neck pain, in combination with other more specific measures of psychological and physical status.

A number of psychological questionnaires which were not used in this thesis could be useful for assessing physiotherapy methods for pain relief in MSD. Questionnaires which assess perceived control or competence may be useful in predicting outcome of treatment [290], [311]. Recently a system known as the Distress and Risk Assessment method has been developed for back pain patients, which appears to be able to predict chronicity in patients with a history of only two months. It has four scales and uses a combination of Zung's Depression and Helplessness Scales, and the Modified Somatic
Discussion

Perception Questionnaire (MSPQ) [263], [166]. This could readily be incorporated into physiotherapy trials of back pain.

**Final Conclusions**

The potency of the placebo effect in physiotherapy treatment has been acknowledged and needs to be taken into consideration both in clinical practice and in research. The self-healing effect of the placebo in physiotherapy could be recognised as a valuable resource, and if the processes whereby its effects come about were more fully understood, its power could then be maximised. Even if PSW can only be shown to have placebo effects, if it provides pain relief then it may be justifiable to continue to use it as an adjunct to more active forms of treatment which encourage self-help, particularly exercise. If effective pain relief can be achieved through PSW this may enable patients to become more active and resume their normal activities. Roche [340] came to a similar conclusion in relationship to TNS for arthritic pain.

The social and financial costs of treatment need to be considered in the light of the known effectiveness of these treatment methods and this is true of physiotherapy as well as all other health care programmes. The advantages of bringing patients in to hospital several times a week are less clear where only short term placebo effects of treatment can be demonstrated. Other more efficient methods of treatment where the patient can be encouraged to take a more active role in their rehabilitation and learn affective coping strategies may be preferable. Some physiotherapy departments have recently reviewed their clinical and organisational practice and now use less electrotherapy, and emphasise self-management. The patient then is seen sooner by the physiotherapist and needs fewer interventions [163]. Further research into alternative methods of treatment for MSD is needed, for example into the development of exercise programmes taking into account cognitive behavioural principles.

With ever-increasing pressure on limited health resources, it is of great importance that physiotherapists should make sure that their methods of providing health care, including pain relief, are efficient, and that the intervention does indeed deliver the supposed benefit. More efficient and effective treatment methods taking psychological processes into account, need to be routinely used by physiotherapists for the benefit of the individual and to reduce the impact on society as a whole.
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# APPENDIX ONE: GLOSSARY OF ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADL</td>
<td>Activities of daily living</td>
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<tr>
<td>ANS</td>
<td>Autonomic nervous system</td>
</tr>
<tr>
<td>BDI</td>
<td>Beck Depression Inventory</td>
</tr>
<tr>
<td>CDH</td>
<td>Congenital dislocation of the hip</td>
</tr>
<tr>
<td>CSP</td>
<td>Chartered Society of Physiotherapy</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>ENT</td>
<td>Ear, nose and throat</td>
</tr>
<tr>
<td>EPI</td>
<td>Eysenck Personality Index</td>
</tr>
<tr>
<td>GHQ</td>
<td>General Health Questionnaire</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HLC</td>
<td>Health Locus of Control</td>
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<tr>
<td>LBP</td>
<td>Low back pain</td>
</tr>
<tr>
<td>LOC</td>
<td>Locus of Control</td>
</tr>
<tr>
<td>MHz</td>
<td>Megahertz</td>
</tr>
<tr>
<td>MMPI</td>
<td>Minnesota Multiphasic Personality Inventory</td>
</tr>
<tr>
<td>MSD</td>
<td>Musculoskeletal disorders</td>
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<tr>
<td>NRS</td>
<td>Numerical rating scale</td>
</tr>
<tr>
<td>NSAID</td>
<td>Non-steroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>OA</td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>PEMF</td>
<td>Pulsed electromagnetic field</td>
</tr>
<tr>
<td>PID</td>
<td>Prolapsed intervertebral disc</td>
</tr>
<tr>
<td>POMS</td>
<td>Profile of mood states</td>
</tr>
<tr>
<td>PPI</td>
<td>Present pain intensity</td>
</tr>
<tr>
<td>PSW</td>
<td>Pulsed short wave</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>ROM</td>
<td>Range of motion</td>
</tr>
<tr>
<td>SETT</td>
<td>Submaximal effort tourniquet test</td>
</tr>
<tr>
<td>STAI</td>
<td>State-trait anxiety inventory</td>
</tr>
<tr>
<td>TNS</td>
<td>Transcutaneous electrical nerve stimulation</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
<tr>
<td>VRS</td>
<td>Verbal rating scale</td>
</tr>
</tbody>
</table>
INTRODUCTION TO STUDENT NURSES

Nurses are subjected to many different stresses on the various wards, particularly during their training and we want to find out how individuals are affected by these factors.

In order to carry out this study we need your co-operation. This would involve you in filling in questionnaires and being screened for physical factors including measurement of specific muscle groups and other body measurements like height etc.

The next and most important part is that we would like you to fill in Diaries for us. The specific details we require will be clearly noted in the front of each Diary. It includes information related to any illness etc. We will collect and then issue Diaries at two to three month intervals. At this time we will ask you to fill in two more short questionnaires. Without your co-operation and commitment in filling in your Diaries the study would not be possible and so we depend very much on your help.

All the information will of course be completely confidential and every individual will remain anonymous. Although we have the full support of the School of Nursing, the study and results from the study are independent of the School.

Participation in the study is of course voluntary. I shall give you time to think about what I have said and shall come back in two days time with the questionnaires, for those that are interested in taking part.
Appendix Two

PAIN DIARY SHEET FOR ONE MONTH'S DATA GIVEN TO NURSES IN BACK PAIN STUDY

MONTH ... Dates ........................................

1. Note any time(s) off work due to sickness or illness. For each occasion write date of first day off and first day back at work and give reason(s), e.g. 'flu, sciatica, headache etc.

<table>
<thead>
<tr>
<th>DAYS OFF</th>
<th>REASONS</th>
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</thead>
<tbody>
<tr>
<td>From</td>
<td>To</td>
</tr>
</tbody>
</table>

? a) Give details of any aches or pains experienced during the month.

For each episode of pain enter the details briefly in the box provided below.

Specify which region has been troublesome and shade in the appropriate area on the diagram opposite.

<table>
<thead>
<tr>
<th>WHICH REGION</th>
<th>DATE OF ONSET</th>
<th>DURATION OF PAIN</th>
<th>FIRST NOTED AT WORK?</th>
<th>ANY KNOWN CAUSE</th>
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</tbody>
</table>

b) Please put a mark on the scale below to represent the severity of pain/ache.
(If more than one episode enter date by the appropriate mark)

No discomfort ———— pain so bad that you had to have time off
DATA SHEET COMPLETED BY NURSES EACH MONTH REGARDING WARD WORK AND PERCEIVED STRESSORS, BOTH PHYSICAL AND EMOTIONAL

DATA FORM 2

Student Nurse No.: 

1. Name which ward(s) you have been working on since you were last in block.

1st ward

2nd ward

2. Would you consider that the work you have had to do on this ward was particularly - (ignore 2nd placement if not applicable)

1st placement 2nd placement

YES NO YES NO

i) heavy physical work

ii) involved a lot of lifting

iii) involved a lot of bending

iv) involved a lot of standing

v) involved a lot of walking

vi) very demanding both physically and mentally

3. During the last three months have you had any episode(s) of excessive physical exertion which you are not normally subjected to, e.g. moving house, sponsored run etc?

YES NO

If YES, briefly specify what it was and the date it happened.

4. Have you had any emotional upsets or changes in your life over the last three months?

YES NO

If YES, briefly write what this was and when it happened.
Appendix Two

DATA SHEET COMPLETED BY NURSES EACH MONTH REGARDING REGULAR EXERCISE/SPORT

5. Have you taken up any new type of exercise or sporting activity during the last two or three months?

   YES □   NO □

   If YES, briefly say what and when you started it.

6. Have you, for any reason, been unable to pursue any regular exercise sessions or sporting activities over the last three months?

   YES □   NO □

   If YES, give the reason, e.g. no time, too tired etc.
CERVICAL TRACTION STUDY: SUBJECTIVE REPORTS OF FUNCTIONAL DISABILITY

15. **PAIN**

Please indicate the severity of your pain during the last 7 days by putting a mark on the scale below.

| No Pain | Worst Possible Pain |

16. **SLEEP DISTURBANCE**

To what extent does the pain disturb your sleep?

| Not at all | Unable to sleep at all |
| Able to sleep through the night |

17. **SOCIAL/LEISURE ACTIVITIES**

To what extent has your neck/arm problem affected your social/leisure activities?

| Not affected | Completely unable to pursue leisure/social activities |
| Able to pursue all leisure/social activities |

18. Can you think of any one daily activity/function which has become particularly difficult for you to do? (specifically related to your neck/arm pain)

specify: .......................................................... 

| Able to do without difficulty | Completely unable to do |
EXPLANATION OF STUDY TO OBTAIN CONSENT

1. PURPOSE
To gain a better understanding of how we can help relieve hip pain.

2. HOW?
By means of PULSED SHORT WAVE. This produces electro-magnetic energy which is thought to relieve pain and inflammation. It has been used commonly in this country for 5 - 10 years, and patients are finding it helpful.

3. WHAT DO YOU EXPECT TO FEEL?
Usually no heat or any other sensation.

4. WHAT WOULD IT INVOLVE?
   a) An initial assessment (1½ hours approximately in 2 weeks time) followed by 3 weeks of treatment 3 times a week.
   b) Follow up assessment at the end of the treatment in about 1 month's time.
   c) Keeping regular diary recordings of pain from now until the end of treatment.

5. CONSENT TO PARTICIPATE
You are under no obligation to participate, but we would be most grateful if you would like to. If you prefer not to take part your future management will not be affected. If you have a place on the waiting list for hip surgery your position will not be affected. We have the consent of your Orthopaedic Consultant if you wish to be included in the study.

6. TRAVEL EXPENSES
We may be able to give some help with this if you feel the cost of travel is prohibitive.

7. CONFIDENTIALITY
Any information that we obtain from you will, of course, be confidential.
### PULSED SHORT WAVE STUDY:

**DATA SHEETS FOR ONE-OFF SUBJECTIVE PAIN REPORTS**

<table>
<thead>
<tr>
<th>Pain distribution</th>
<th>Intermittent or constant (incl. night pain)</th>
<th>Intensity 0 - 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Back pain above P.S.I.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) Ant. groin pain/ lat. hip pain/ buttock pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3) Thigh pain (below groin and gluteal fold)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(4) Knee pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(5) Below knee pain</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Was there any apparent reason for the onset of the problem?  
   Yes  No

   If yes, what?
PULSED SHORT WAVE STUDY:

DATA SHEET FOR SUBJECTIVE FUNCTIONAL DISABILITY SCALES

CONFIDENTIAL

Sheet No. 5

PULSED SHORT-WAVE STUDY OF OSTEO-ARTHRITIC HIPS/KNEES

FUNCTIONAL ASSESSMENT

NAME: Date:

All questions refer to the last 2 - 3 days. If not applicable state N/A in box provided. Otherwise, circle most appropriate number.

1.) Is getting in/out of the bath: -

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.) Do you find putting socks/stockings on: -

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.) Is getting on/off the toilet: -

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.) Is going up/down stairs (using your walking aid if applicable): -

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.) Do you find getting in/out of a car: -

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.) Please name one activity which you would expect to do frequently if you had no hip pain (eg shopping, hoovering, ironing, foot-care, gardening). Please mark the level of difficulty.

<table>
<thead>
<tr>
<th>No problem</th>
<th>Slightly difficult</th>
<th>Moderately difficult</th>
<th>Extremely difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PULSED SHORT WAVE STUDY:

EXERCISE PROGRAMME FOR PATIENTS WITH OA HIP PAIN

Stand up straight, steadying yourself with a hand on a heavy piece of furniture with your good leg on a block the height of a telephone book, with your other leg hanging free.

Exercise one  Take this leg slowly out to the side keeping your body erect and bring it slowly in again

Exercise two  Take your leg back as far as possible keeping your body erect and slowly bring it back

These exercises should be done 10 times each every day.

EXERCISE PROGRAMME FOR PATIENTS WITH OA KNEE PAIN

Exercise One

Sit up with both your legs on a sofa, and put a firm roll or block about 4" high under your thigh close to the knee. Tighten your thigh muscle by raising your lower leg at the same time as pressing down with your thigh onto the block.

If you are doing it correctly your leg will be locked into a straight at the knee joint, and your upper leg will not have been raised.

While you are doing this rest your hand on your thigh to feel the muscle working, and count to 10 while you keep it as tight as possible, then slowly lower. Relax and repeat this 10 times. Then do this again twice more.

Exercise Two

If this is very easy, you are ready to do this same exercise with a small weight attached to your ankle, try using 2lbs. One practical way to do this at home is with a known weight such as a bag of rice in a small shopping bag hanging over your ankle.

You should try and do these exercises everyday.
Appendix Two
APPENDIX THREE:
ADDITIONAL TABLES OF RESULTS OF ANALYSES RELATED TO PHASE II OF PSW STUDY REPORTED IN CHAPTER TEN

Table 10.1a. Results of t-tests (including transformations used in analysis) comparing baseline data on demographic variables & measurements of pain, GHQ & functional disability of hip patients (n=46) & knee patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>T value</th>
<th>df</th>
<th>p value</th>
<th>Transformation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE (years)</td>
<td>0.11</td>
<td>90</td>
<td>NS</td>
<td>sqrt(81-age)</td>
</tr>
<tr>
<td>DURATION OF HISTORY (months)</td>
<td>-1.50</td>
<td>80.5</td>
<td>NS</td>
<td>log</td>
</tr>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td>1.34</td>
<td>90</td>
<td>NS</td>
<td>sqrt</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>1.49</td>
<td>90</td>
<td>NS</td>
<td>log</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>1.58</td>
<td>77</td>
<td>NS</td>
<td>sqrt</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>1.44</td>
<td>90</td>
<td>NS</td>
<td>-</td>
</tr>
<tr>
<td>FLOO</td>
<td>-2.34</td>
<td>87.7</td>
<td>&lt;0.03</td>
<td>hips sqrt, knees log</td>
</tr>
<tr>
<td>FSOCK</td>
<td>4.78</td>
<td>90</td>
<td>&lt;0.0001</td>
<td>hips —, knees sqrt</td>
</tr>
<tr>
<td>FCAR</td>
<td>3.54</td>
<td>79</td>
<td>&lt;0.0007</td>
<td>—</td>
</tr>
</tbody>
</table>

* Statistically significant results. Data from hips & knees to be measured separately for these variables.
### Table 10.2a Results of one-way analysis of variance comparing control, dummy & active groups combined baseline data for hip patients and knee patients (n=92) for demographic variables & measurements of pain, GHQ & functional disability

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Sums of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE (years)</td>
<td>1.3193</td>
<td>2,89</td>
<td>0.6596</td>
<td>0.43</td>
<td>NS</td>
</tr>
<tr>
<td>DURATION OF HISTORY (months)</td>
<td>1.4134</td>
<td>2,87</td>
<td>0.7067</td>
<td>2.63</td>
<td>&lt;0.08</td>
</tr>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td>9.5973</td>
<td>2,89</td>
<td>4.7986</td>
<td>1.09</td>
<td>NS</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>0.0195</td>
<td>2,89</td>
<td>0.0097</td>
<td>0.35</td>
<td>NS</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10)</td>
<td>0.6384</td>
<td>2,76</td>
<td>0.3192</td>
<td>0.33</td>
<td>NS</td>
</tr>
<tr>
<td>FBATH</td>
<td>4.0266</td>
<td>2,89</td>
<td>2.0133</td>
<td>0.32</td>
<td>NS</td>
</tr>
<tr>
<td>FSTAIRS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 10.3a. Results of two way analysis of variance to compare pain diary reports over time for combined data sets from patients with OA hip (N=46) & OA knee pain (N=46)

<table>
<thead>
<tr>
<th>Pain diary reports</th>
<th>Main effects</th>
<th>Group</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensory</td>
<td>Group</td>
<td>2.01</td>
<td>2,72</td>
<td>NS</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>9.76</td>
<td>6,72</td>
<td>NS</td>
<td>&lt;0.07</td>
</tr>
<tr>
<td></td>
<td>Group x time</td>
<td>0.80</td>
<td>12,432</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Affective</td>
<td>Group</td>
<td>1.99</td>
<td>2,72</td>
<td>NS</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>11.05</td>
<td>6,72</td>
<td>NS</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Group x time</td>
<td>0.78</td>
<td>12,432</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>VARIABLES</td>
<td>F value</td>
<td>df</td>
<td>p value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
<td>----</td>
<td>---------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>0.67</td>
<td>2, 84</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>2.07</td>
<td>2, 168</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>3.17</td>
<td>4, 168</td>
<td>&lt;0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REPORTED BENEFIT (NRS 0-100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>3.90</td>
<td>1, 45</td>
<td>&lt;0.06</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>0.01</td>
<td>1, 45</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>0.61</td>
<td>1, 45</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>1.89</td>
<td>2, 84</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>6.60</td>
<td>2, 168</td>
<td>&lt;0.002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>1.70</td>
<td>4, 168</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLOO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>2.70</td>
<td>2, 40</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>3.12</td>
<td>2, 80</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>3.00</td>
<td>4, 80</td>
<td>&lt;0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSOCK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>3.05</td>
<td>2, 43</td>
<td>&lt;0.06</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>0.77</td>
<td>2, 80</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>3.00</td>
<td>4, 80</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>FSPEC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td>Group</td>
<td>1.39</td>
<td>2, 39</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>3.49</td>
<td>2, 78</td>
<td>&lt;0.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group x time</td>
<td>0.78</td>
<td>4, 78</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 10.5.a Results of analysis of variance with repeated measures over time comparing control, dummy & active groups on measurements of pain, GHQ, functional disability pre-, post- treatment & at follow up for combined data from hip patients & knee patients who were not on a waiting list for joint replacement surgery (N=40)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Main effects</th>
<th>Interaction</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.39</td>
<td>2, 36</td>
</tr>
<tr>
<td>REPORTED BENEFIT (0-100)</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.59</td>
<td>1, 21</td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.41</td>
<td>2, 36</td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10:)</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.06</td>
<td>2, 27</td>
</tr>
<tr>
<td>FBATH</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.21</td>
<td>2, 36</td>
</tr>
<tr>
<td>FSTAIR</td>
<td>Group</td>
<td>Time</td>
<td>Group x time</td>
<td>0.23</td>
<td>2, 72</td>
</tr>
</tbody>
</table>

* significant at p<0.05, ** significant at p<0.01
Table 10.6.a Results of analysis of variance with repeated measures over time comparing control, dummy & active groups on measurements of pain, GHQ, functional disability pre-, post- treatment & at follow up for combined data from hip patients & knee patients on a waiting list for joint replacement surgery (N=52)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAIN PAIN (NRS 0-100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group</td>
<td>3.27</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time</td>
<td>2.53</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group x time</td>
<td>3.42</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REPORTED BENEFIT (0-100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group</td>
<td>5.80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group x time</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ (scores 0-90)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Main effects</td>
<td>Group</td>
<td>1.93</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time</td>
<td>6.97</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group x time</td>
<td>1.80</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10;)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBATH</td>
<td>Main effects</td>
<td>Group</td>
<td>1.67</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time</td>
<td>2.27</td>
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<td></td>
<td></td>
<td>Group x time</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSTAIR</td>
<td>Main effects</td>
<td>Group</td>
<td>2.30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time</td>
<td>1.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group x time</td>
<td>1.36</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* significant at p<0.05, ** significant at p<0.01
Appendix Three
APPENDIX FOUR:
SEPARATE ANALYSES OF DATA SETS FOR HIP AND KNEE PAIN PATIENTS (SEE CHAPTER TEN)

Because of significant baseline differences between patients with hip and knee pain on some of the variables, further analyses was carried out on each of these separately, and are reported here (vide.10.3.3.).

* Patients with OA hip pain

Results of one way analysis of variance (Table 4.1) comparing the control, dummy and active groups at baseline confirmed no significant differences on any of the variables: *FBATH, FLOO, FSOCK* (F<2, df 2,43, NS), except *FCAR* (F=3.32, df 2,41, p<0.05).

Further analysis on this variable for patients with hip pain was therefore not pursued.

Table 4.2 displays the untransformed means and standard deviations for patients with OA hip pain of all the other functional disability variables for the three different groups at baseline pre-, post-treatment and at follow up.

Table 4.1 Results of one-way anova comparing control, dummy & active groups at baseline on measurements of functional disability for HIP patients only

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Sums of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUNCTIONAL DISABILITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Combined NRS &amp; VRS 0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>FLOO</em></td>
<td>1.5471</td>
<td>2, 43</td>
<td>0.7735</td>
<td>0.75</td>
<td>NS</td>
</tr>
<tr>
<td><em>FSOCK</em></td>
<td>26.1379</td>
<td>2, 43</td>
<td>13.0689</td>
<td>1.52</td>
<td>NS</td>
</tr>
<tr>
<td><em>FCAR</em></td>
<td>41.6453</td>
<td>2, 41</td>
<td>20.8227</td>
<td>3.32</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><em>FSPEC</em></td>
<td>14.1958</td>
<td>2, 43</td>
<td>7.0979</td>
<td>0.96</td>
<td>NS</td>
</tr>
</tbody>
</table>

Measurements of range of motion, abduction [*ROMAB*], internal [*ROMMR*] and external [*ROMLR*] rotation of the hip (in each case, the mean of three readings as described in 9.2.4.6.) were compared at baseline across the three groups. The results of one-way analysis of variance for the *ROMAB* and *ROMLR* were not statistically significant (respectively: F<2, and F<1, df=2,43, NS). However, analysis of *ROMMR*
Appendix Four

did produce a statistically significant difference between the three groups at baseline (F=7.11, df=2.43, p<0.003), in spite of random allocation, and this variable was therefore not used for further comparisons between the groups. The untransformed means and standard deviations of ROMAB and ROMLR for hip patients pre-, post- treatment & at follow up can be seen in Table 4.2.
### Table 4.2 Untransformed Means & Standard deviations comparing control, dummy & active groups on functional disability & range of motion pre-, post-treatment & at follow up for HIP patients (N=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Time point</th>
<th>Control</th>
<th>Dummy</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>means (sd)</td>
<td>means (sd)</td>
<td>means (sd)</td>
</tr>
<tr>
<td><strong>FUNCTIONAL DISABILITY</strong> (Combined NRS &amp; VRS 0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FLOO</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.12 (1.09)</td>
<td>0.98 (0.91)</td>
<td>0.81 (1.07)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.60 (1.11)</td>
<td>0.67 (0.87)</td>
<td>0.79 (0.98)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1.86 (0.98)</td>
<td>0.87 (0.91)</td>
<td>0.98 (1.09)</td>
<td></td>
</tr>
<tr>
<td><strong>FSOCK</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5.36 (3.50)</td>
<td>3.93 (2.66)</td>
<td>3.86 (2.71)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6.00 (2.91)</td>
<td>4.07 (2.58)</td>
<td>3.50 (2.53)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6.29 (2.89)</td>
<td>4.67 (2.77)</td>
<td>3.43 (2.93)</td>
<td></td>
</tr>
<tr>
<td><strong>FSPEC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6.07 (2.53)</td>
<td>5.57 (2.44)</td>
<td>5.07 (3.02)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6.50 (2.59)</td>
<td>4.57 (2.59)</td>
<td>4.36 (2.79)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6.79 (2.29)</td>
<td>5.93 (2.53)</td>
<td>5.64 (3.69)</td>
<td></td>
</tr>
<tr>
<td><strong>RANGE OF MOTION (degrees)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip abduction <strong>ROMAB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15.86(7.17)</td>
<td>20.67(7.83)</td>
<td>20.57(8.47)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15.57(9.76)</td>
<td>21.60(8.35)</td>
<td>21.86(11.28)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>13.71(8.65)</td>
<td>19.73(9.00)</td>
<td>20.21(11.76)</td>
<td></td>
</tr>
<tr>
<td>External rotation <strong>ROMLR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>18.00(13.48)</td>
<td>14.13(5.67)</td>
<td>17.57(9.50)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15.64(9.53)</td>
<td>16.27(6.16)</td>
<td>20.29(10.03)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>13.78(13.10)</td>
<td>15.27(6.04)</td>
<td>17.14(8.17)</td>
<td></td>
</tr>
</tbody>
</table>

The results of Analysis of Variance with Repeated Measures over time for **FLOO**, **FSOCK**, and **FSPEC** demonstrated no statistically significant interaction effects for differences over time except for **FLOO**. Inspection of Table 4.2. shows that any differences in means are very small and probably not of clinical significance. The results of the anova are displayed on Table 4.3.
The range of motion measured at the hip joint was compared across the three groups using analysis of variance with repeated measures. Inspection of Table 4.2. shows that ROMAB and ROMLR measured in degrees varied very little across the groups over time, with the control group having slightly reduced mean range of movement at the second assessment point. GROUP and TIME did not yield statistically significant F values for ROMAB (F = 2.12, df = 2,40 and F = 1.90, df = 2,80, NS), and neither did GROUP for ROMLR (F < 1, df = 2,40 and 2,80, NS). The F-value of TIME for ROMLR however did marginally reach statistical significance (F = 3.10, 2,80, p < 0.06), but there was no significant interaction effect for either ROMAB or ROMLR, as shown by the results of analysis of variance with repeated measures over time (respectively: F < 1, df = 4,80, NS and F = 1.70, df = 4,80, NS).

Table 4.3 Results of anova with repeated measures over time comparing control, dummy & active groups on functional disability for HIP patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTIONAL DISABILITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Combined VRS &amp; NRS 0-10:)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLOO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>2.70</td>
<td>2,40</td>
<td>0.0794</td>
</tr>
<tr>
<td>Time</td>
<td>3.12</td>
<td>2,80</td>
<td>0.0498</td>
</tr>
<tr>
<td>Group x time</td>
<td>3.00</td>
<td>4,80</td>
<td>0.0231</td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSOCK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>3.05</td>
<td>2,43</td>
<td>0.0587</td>
</tr>
<tr>
<td>Time</td>
<td>0.77</td>
<td>2,80</td>
<td>0.4687</td>
</tr>
<tr>
<td>Group x time</td>
<td>3.00</td>
<td>4,80</td>
<td>0.4893</td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSPEC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>1.39</td>
<td>2,39</td>
<td>0.2615</td>
</tr>
<tr>
<td>Time</td>
<td>3.49</td>
<td>2,78</td>
<td>0.0354</td>
</tr>
<tr>
<td>Group x time</td>
<td>0.78</td>
<td>4,78</td>
<td>0.5422</td>
</tr>
<tr>
<td>Interaction</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Patients with OA knee pain

The results of one way analysis of variance displayed on Table 4.4. comparing the control, dummy and active groups at baseline shows that in each case there were no significant differences (F < 2, df 2,43, NS).
Table 4.4 Results of one-way anova comparing control, dummy & active groups at baseline on measurements of functional disability for KNEE patients only (N=46).

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Sums of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTIONAL DISABILITY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Combined NRS &amp; VRS 0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLOO</td>
<td>0.0629</td>
<td>2, 43</td>
<td>0.0314</td>
<td>0.35</td>
<td>NS</td>
</tr>
<tr>
<td>FSOCK</td>
<td>2.3209</td>
<td>2, 43</td>
<td>1.1604</td>
<td>1.17</td>
<td>NS</td>
</tr>
<tr>
<td>FCAR</td>
<td>5.6024</td>
<td>2, 42</td>
<td>2.8012</td>
<td>0.73</td>
<td>NS</td>
</tr>
<tr>
<td>FSPEC</td>
<td>6.1670</td>
<td>2, 43</td>
<td>3.0835</td>
<td>0.64</td>
<td>NS</td>
</tr>
</tbody>
</table>

Measurements of ROMEXT [extension] and ROMFLEX [flexion] of the knee joint were compared at baseline across the three groups, by means of one-way analysis of variance, and were found not to be significantly different, F<1, df=2,43, NS.
### Table 4.5 Untransformed means & standard deviations pre-, post- treatment & at follow up comparing control, dummy & active groups for various functional disability measures & range of motion for knee patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>Time point</th>
<th>Control</th>
<th>Dummy</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>means (sd)</td>
<td>means (sd)</td>
<td>means (sd)</td>
</tr>
<tr>
<td><strong>FUNCTIONAL DISABILITY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Combined NRS &amp; VRS 0-10).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FLOO</strong></td>
<td>1</td>
<td>1.00 (1.46)</td>
<td>0.57 (1.02)</td>
<td>0.67 (1.40)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1.33 (2.16)</td>
<td>0.36 (0.74)</td>
<td>1.00 (1.51)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1.53 (2.07)</td>
<td>1.43 (2.44)</td>
<td>1.00 (1.51)</td>
</tr>
<tr>
<td><strong>Fsock</strong></td>
<td>1</td>
<td>1.33 (2.66)</td>
<td>1.93 (2.53)</td>
<td>2.00 (2.17)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2.13 (2.92)</td>
<td>1.50 (2.59)</td>
<td>1.87 (2.13)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2.13 (2.83)</td>
<td>1.79 (2.61)</td>
<td>2.33 (2.47)</td>
</tr>
<tr>
<td><strong>FCAR</strong></td>
<td>1</td>
<td>2.36 (1.86)</td>
<td>2.63 (1.77)</td>
<td>1.92 (1.38)</td>
</tr>
<tr>
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<td>2</td>
<td>3.21 (2.36)</td>
<td>1.88 (2.36)</td>
<td>2.58 (1.31)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2.57 (2.62)</td>
<td>2.50 (3.30)</td>
<td>3.00 (2.13)</td>
</tr>
<tr>
<td><strong>Fspec</strong></td>
<td>1</td>
<td>4.21 (2.39)</td>
<td>4.38 (1.89)</td>
<td>3.71 (2.05)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4.92 (3.29)</td>
<td>3.23 (2.89)</td>
<td>2.57 (1.82)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4.64 (3.00)</td>
<td>4.38 (2.96)</td>
<td>3.71 (3.05)</td>
</tr>
<tr>
<td><strong>RANGE OF MOTION (degrees)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee flexion</td>
<td>1</td>
<td>113.36(16.93)</td>
<td>114.07(14.36)</td>
<td>114.00(16.67)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>107.93(22.97)</td>
<td>116.93(14.88)</td>
<td>114.87(15.45)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>116.71(18.04)</td>
<td>115.21(12.45)</td>
<td>114.13(14.07)</td>
</tr>
<tr>
<td>Knee extension</td>
<td>1</td>
<td>5.54(6.16)</td>
<td>5.36(5.60)</td>
<td>4.53(4.88)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5.54(6.73)</td>
<td>5.36(6.00)</td>
<td>5.87(7.30)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4.38(5.56)</td>
<td>5.79(7.90)</td>
<td>4.60(6.13)</td>
</tr>
</tbody>
</table>

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Separate Analyses for Hips & Knees

Table 4.6 shows the results of Analysis of Variance with Repeated Measures over time for the same variables listed above in Table 4.5. It can be seen that they yielded no statistically significant F-values on any of the main effects or interaction effects for knee pain, except FLOO which yielded a significant F ratio for the time effect, F=3.17, Df 2,82, P<0.05. The differences however were not of clinical significance.

The range of motion measured at the knee joint was compared across the three groups using analysis of variance with repeated measures. Inspection of Table 4.5 shows that ROMFLEX and ROMEXT measured in degrees, varied very little across the groups over time, with the control group having a slightly reduced mean range of movement at the second assessment point. GROUP, TIME and GROUP X TIME did not yield statistically significant F-values for ROMFLEX (respectively F<1, df=2,40, 2,80, NS, and F=2.24, df=4,80, NS), or ROMEXT (in each case F<1, df=2,40, 2,80, 4,80, NS).

Table 4.6 Results of anova with repeated measures over time comparing control, dummy & active groups for functional disability measures for data for KNEE patients (n=46)

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>F value</th>
<th>df</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNCTIONAL DISABILITY (Combined VRS &amp; NRS 0-10:)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLOO</td>
<td>Main effects</td>
<td>Group</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>3.17</td>
<td>2, 82</td>
</tr>
<tr>
<td></td>
<td>Group x time</td>
<td>0.89</td>
<td>4, 82</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSOCK</td>
<td>Main effects</td>
<td>Group</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>0.48</td>
<td>2, 82</td>
</tr>
<tr>
<td></td>
<td>Group x time</td>
<td>0.78</td>
<td>4, 82</td>
</tr>
<tr>
<td></td>
<td>Interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSPEC</td>
<td>Main effects</td>
<td>Group</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td>0.40</td>
<td>2, 82</td>
</tr>
<tr>
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<td>Group x time</td>
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