The Conservative Treatment of Low Back Pain

A Study of McKenzie Physiotherapy And Slow Release Ketoprofen

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DECLARATION

The work contained in this manuscript is my own with the exception of the following items:

Julia Kilby and Mark Stigant were largely responsible for construction of the diagnostic algorithm. They took part in it's assessment by examining patients whilst I acted as observer. They also helped with the reliability studies of the flexible ruler and the goniometer by performing repeat examinations for the purposes of inter observer reliability estimation. Mark Stigant developed to pain distribution scoring drawing and both Mark Stigant and Julia Kilby collected the pre and post treatment recordings which allowed the behaviour of the pain intensity and distribution to be examined.

Dr James Pearson, Department of Epidemiology, checked my calculations for the power curves for the study.

SYNOPSIS

Acute low back pain: A randomised, controlled, prospective trial of ketoprofen and McKenzie physiotherapy within three weeks of onset.

Aims:

(1) To establish whether McKenzie physiotherapy is beneficial compared with a non steroidal anti inflammatory drug in the treatment of acute low back pain.

(2) To investigate the mode of action of McKenzie lumbar spine treatment.

Method:

Patients with acute back pain of less than three weeks standing aged between 18 and 55 years were admitted to the trial. On attending clinic the patient underwent interview and examination by a doctor. Those patients without evidence of nerve root entrapment; underlying pathological lesion or psychological abnormality (illness behaviour) completed formal psychometric testing and social enquiry. The St Thomas back disability questionnaire was used throughout the study and was the principle outcome measure. Patients underwent randomisation into study and control groups. They both had information leaflets; and a supply of back disability questionnaires with stamped addressed envelopes to return to the study office at weekly intervals. Both groups were seen again on the seventh week after the onset of the back pain.

Study Group Patients were assessed by one of two research physiotherapists and underwent a treatment regimen according to the McKenzie principles. Control Group Patients were given a 28 day course of non steroidal anti inflammatory drug.

At follow up clinic repeated clinical examination and questioning recorded the following outcomes: disability; analog pain score; return to work; patient's appraisal of change in condition and personal responsibility for pain control. Further postal follow up occurred at six months and one year.

Initial psychological factors explained much of the disability seen seven weeks after the onset of back pain. An analysis of covariance employing psychological information showed that physiotherapy was significantly more effective in reducing disability at the seventh week only when the 8.5% of patients who the physiotherapists were unable to diagnose on their first assessment were excluded from analysis. The physiotherapy patients were away from work significantly longer than the patients who had drug treatment. At six months and one year a tendency to less frequent attacks in the physiotherapy group was not significant owing to the power of the study. Physiotherapy patients became significantly more responsible for their pain than the drug patients when assessed by means of a pain locus of control questionnaire. This finding persisted at a year after onset.

INTRODUCTION

Back pain and subsequent low back disability are commonly encountered problems which have a great impact on health resources. Family doctors see this condition on a daily basis .

In spite of the frequency with which this condition occurs there is no consensus as to the underlying pathology; the classification or the treatment. Over the past fifty years a large number of different treatments have been tried in an effort to alleviate discomfort and promote the rapid return of normal function.

No single treatment approach has provided the "solution" to low back pain and low back disability. The heterogeneity of the condition seems to preclude this.

This study examines one aspect of low back pain and evaluates two commonly used conservative treatments.

1. The meaning of diagnoses

The possibility of identifying divisions and structure in nature lies at the root of any attempt to sub-divide the causes of back pain into diagnostic categories. The arbitrary and rather elusive definition of what constitutes a diagnosis has been addressed by Kendell[1] who asserted that "Historically there can be little doubt that the concept of disease originated as an explanation for the onset of suffering and incapacity in the absence of obvious injury.". Philosophical considerations indicate that our current usage of diagnoses and nosologies are value laden. Social values determine what does and does not constitute a diagnosis[2]. In turn the establishment of a diagnosis places that condition within the realm of medicine - whether or not the medical profession is able to deal with that condition effectively. Examples of differences across culture and time underline our dependence on social values to demarcate normality from illness. Reznek concludes: "Whether some condition is a disease depends upon where we choose to draw the line of normality, and this is not a line that we can discover. Hence we cannot discover disease status. Rather, we invent disease status by imposing our distinction between disease and normality in the world."[2].

The most recent International Classification of Diseases Coding[3] illustrates the problem and provides a clue regarding one of the stumbling blocks which have prevented progress in the understanding of back pain. Conditions such as spinal enthesiopathy [720.1]; lumbago [724.2] and sciatica [724.3] are included as diagnoses. With a welter of possible diagnoses to apply the tendency for confusion and imprecision is irresistible. Central to this confused approach is philosophical imprecision.

2. The philosophy of diagnosis

2.1. Inductive logic for the classification of low back pain causes

The foundations of British scientific philosophical thought were laid by Francis Bacon. The scientist observes the natural world and without prior assumptions infers natural law and reason from his observations. This approach, known as inductive logic, held sway for over two hundred years. To find the diseased abdominal cavity awash with pus; a perforation of the appendix and bacteria within the wall of the appendix is sufficient to infer a bacterial infection as the cause of the condition. The scientific community was shaken in 1739 when David Hume[4] removed one of the foundation stones of inductive logic. He argued, irresistibly, that inductivists depended for their method on a basic assumption - that cause could be inferred from effect. Much thinking based on inductive logic is seen in our current classification of back pain.

2.2. Radiological classification - An example of flawed logic

To codify vertebral spondylosis [ICD 721.3] depends upon the central assumption that the appearances seen on a plain radiograph of the spine are a clear guide to the cause of the condition. In the case of vertebral spondylosis and back pain, cause is not related to effect[5,6,7]. Karl Popper[8] eventually formulated a deductive logical system to replace the weak and discredited inductive method.

2.3. Deductive logic for the classification of low back pain causes

Deductive logic is based on the principle that it is impossible to prove anything absolutely but refutation is more certain and often absolute. A thesis is proposed; the scientist then develops an anti-thesis by which the thesis is tested. Eventually a

syn-thesis is created - this representing the best available picture of causation thought responsible for the observed effects.

Back pain is a sufficiently complex problem that the deductive method of enquiry is the only suitable route to progress. The application of a deductive method to the diagnostic classification of back pain simplifies the problem.

Separate those causes of back pain which may be reliably inferred from the history, clinical examination and special investigations and approximately 80% remains without a diagnosis. This may be called, let us say, 'back ache of uncertain cause'. Such an approach has been adopted by Waddell[9], who employs the term simple mechanical back ache, and forms the method of categorisation used in this study.

3. "Is simple mechanical low back pain a medical condition?"

The answer to this question, following from the preceding discussion, must be currently - yes. However, a need to re-appraise the status of low back pain and disability from time to time is important if dangerous precedents are not to be set in the future. As Kleinman[10] states, "a small shift in the boundary between cases managed solely in the popular sector and those cared for professionally could overwhelm professional institutions". His concept of illness and disease is that disease is a condition which doctors treat well in a technological sense but that illness is a condition requiring an understanding of the patients opinions; beliefs; psyche and social circumstances. On the basis of current performance one cannot help thinking that low back pain is an illness and not a disease. Central to the question posed is the use of the classical medical model as our framework for thinking about low back disability. The Bio-Psycho-Social model, (page 16) may be used to clarify the context in which low back disability is seen.

REVIEW OF THE LITERATURE

1.Quality of the literature.

A large body of work exists concerning the treatment of mechanical low back pain. The Quebec Task Force on Activity Related Spinal Disorders[11] reviewed the scientific

literature and found that many of the published studies had serious flaws. In the decade from 1977 they identified 7,000 articles. Of these 4,000 were thought to be "of better quality". These 4,000 articles were scrutinised by means of strict criteria and 469 articles selected. Of the 469 only 201 were found to be very good or good although the exact criteria used were not stated. For reasons of diplomacy, these articles were not cited specifically but the method used in their selection was validated and found to be good[12]. The check list used in the Quebec study is a blue print for any future high quality research work in the field of low back pain. Interestingly, the Quebec criteria were similar to the standards listed by the Ontario Workers Compensation Board task force[13], although there may have been a degree of collusion in arriving at the final check list. Deyo's review of literature[14] regarding conservative treatment of low back pain presents a simplified précis of studies of various modalities of treatment. A similar good quality review was carried out by Gilbert[15]. A review of clinical trials to estimate the recovery curve for populations suffering from mechanical low back pain highlights some of the difficulties. Some papers do not mention how long the patients have been suffering from pain. With a condition which tends to improve naturally within twelve weeks this information is vital.

For most topics of interest, research starts with case reports; building up to series and finally trials of treatment. The power of trials increases as the questions asked defy solution with weak study designs. Where large effects are sought, less rigorous research is acceptable. The presence of confounding factors and complicated aetiologies also necessitates complicated study designs to allow for unwanted influences on results. The study of mechanical low back pain has now reached the point where only a prospective randomised control trial with blind assessment will suffice.

MAGNITUDE OF THE LOW BACK PROBLEM

1.Incidence of low back pain

At some stage in their lives, between eighty and one hundred percent of the population of the Western World will suffer from low back pain[16,17]. In any one year approximately 6% of the elderly[18] and more of the younger population[19] suffer from low back pain. Waddell[20] even suggests that back pain may, from one perspective, be

normal. Clearly a large proportion of the population do not share this view and see an episode of back pain as a worrying event worthy of medical attention. One survey of British medical practice[21] showed that four percent of the population sought medical advice for a new attack of back pain each year. This gives an estimated 2.2 million consultations for a new attack of back pain in 1983[22].

2.Incidence of low back disability

Similar patterns of disability arising from back pain are seen both in Europe and North America[23,24,11]. In Sweden a 290% rise in the number of disability pensioners with rheumatic diseases was seen over the three decades from 1952[25]. This was almost entirely due to low back pain and sciatica. During those same decades the number of people registered disabled through circulatory diseases rose by 33% whilst a 9% reduction occurred in respiratory diseases and a 39% reduction was seen in mental illness. Workmen's Compensation schemes in the United States and Canada make direct comparison with the British situation difficult. The advantage of such compensation boards is that they possess very detailed statistical information relating to cost and the use of medical resources which simply is not available in Britain. Eventually data collected according to the recommendations of the Korner Report[26] should become available. This may provide the basis for large scale epidemiological surveys which have hitherto been scarce and fragmentary in this country.

3.The cost of low back pain and disability

3.1 Health service and social security

A total of £150 million was thought to have been spent in the treatment of back pain by the National Health Service in 1982[22]. In addition, back pain resulted in a tenth of all certified days of sickness requiring £193 million in sickness benefit. The Department of Health and Social Security Working Group on Back Pain[27] estimated the annual loss of productivity to be equivalent to the production of a town of 120,000 people. The figures available from the United States indicate an annual cost of approximately $16Bn.[28]. Of this figure, $5Bn. was in compensation which compares with $4.6Bn six years previously[24]. Costs vary in America from state to state particularly in terms of

medical costs[29]. Whilst Britain does not operate a Workers Compensation scheme, there are comparable hidden costs in the support given by our welfare benefit system.

3.2 Industrial costs

A retrospective study[30] of 31,200 employees of the Boeing Company provided important information in connection with industrial costs. Over a fifteen month period a total of 4,645 injuries were recorded of which 900 involved the back. Whilst claims for back injury amounted to 19% of all claims they consumed 41% of the total injury costs ($1,800,000). Of all the back injury claims the most costly ten percent accounted for 79% of the total back injury costs. The authors found that a small percentage of all claims gave rise to the biggest costs. In 1982 the estimated cost of low back pain and disability to industry exceeded £1000 million[22].

Interestingly Abenhaim's work[31] suggests a very similar pattern with 75% of the expenditure in Quebec in 1981 going to the 7.4% of patients who had been off work for more than six months. The Boeing data expressed as a logarithmic relationship is shown in Figure 1.

The authors conclude that "Controlling the cost of back injury in industry depends to a large degree on controlling or preventing the small percentage of high cost back injuries." They do not specifically mention that it is medical intervention rather than the patient's back per se which accounts for medical costs (33% of all back injury expenditure).

They point out the difficulty of studying the patients who have crossed the "rubicon" into chronic back disability as regards the large number of patients who have to be studied prospectively to obtain useful information. Prospective studies from the same centre have shown that prediction of the "high cost worker" is not possible using cardiovascular fitness[32] or isometric lifting strength[33].

The factors which correlated with high cost claims, in the retrospective study, for back injury were female sex and age greater than 31 years. Also employees new to the

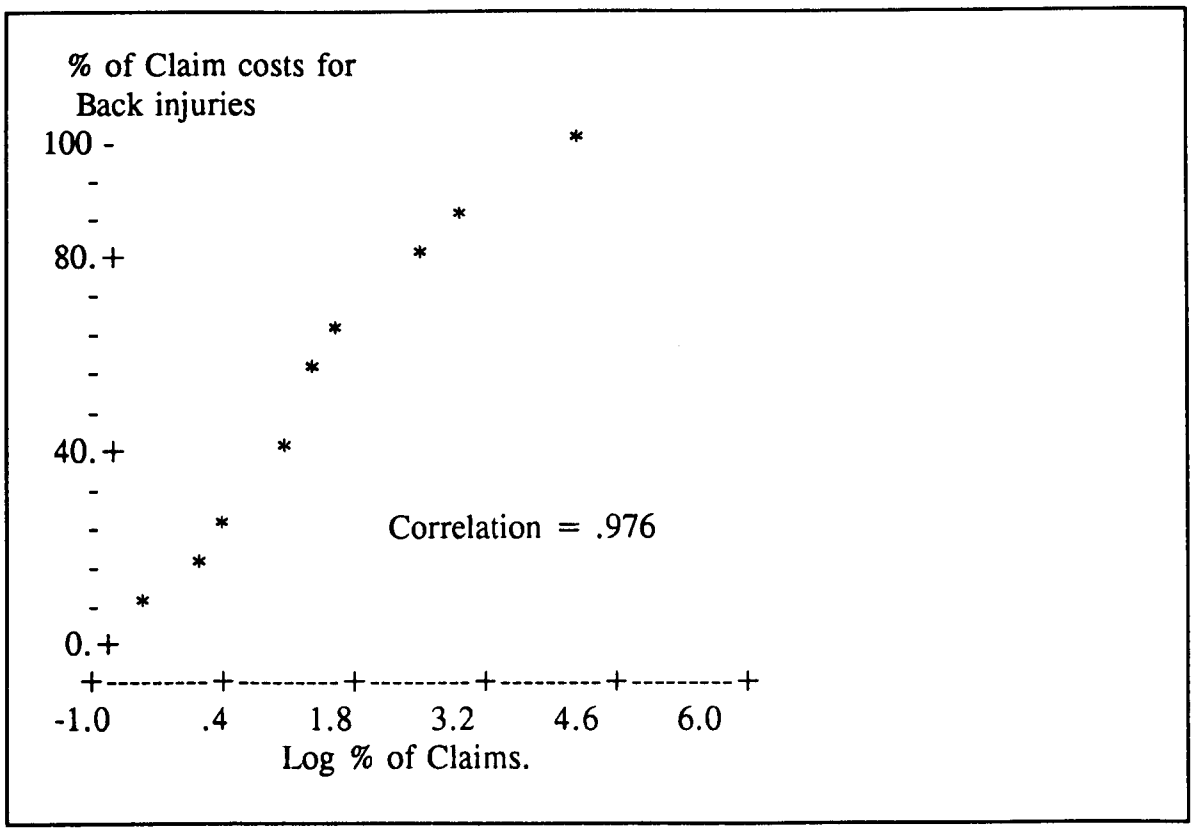


Figure 1 Boeing study data - claims and costs

company were at greater risk of sustaining a back injury. Workers under the age of 25 years had more injuries than those in older age groups but tended to have low cost claims. Women had fewer low cost claims than men.

Although there was no correlation between the job classification or the grade at which a worker was employed and the incidence of back injury a very strong correlation was found between high cost back injuries and the appraisal of the worker by their supervisor. A disproportionate number of the back injuries and particularly the high compensation cost injured belonged to the worst appraisal grade.

Social factors play a great part in influencing the likelihood of an attack of low back pain becoming an episode of prolonged disability[34]. The Boeing study[30] underlines and supports the findings of an earlier study[35] which outlines the role played by social factors. Attitudes to work and concerning the current episode of back pain also play a

major part in the risks of prolonged disability[36]. Back pain is a recognised cause of long term sickness certification[37].

THE NATURE OF LOW BACK PAIN

It must be stated quite emphatically that low back pain differs from myocardial infarction; osteoarthrosis of the hip and peptic ulceration. When a medical practitioner is confronted with an article on cough; itch or urinary frequency they would expect a broad discourse on the physiology and likely causes of these symptoms. The immediate reaction to an article on low back pain may well be an expectation of advice on treatment or on the latest theory of aetiology. All further discussion is prefaced with the fact that low back pain is a symptom like cough, itch or urinary frequency and not a distinct diagnosis like myocardial infarction, osteoarthrosis or peptic ulceration.

1. Historical context

Most standard text books of medical history do not index lumbago, back pain, or back ache with only a few detailing Domenico Cotungo's treatise on sciatica[38]. Without focused and intensive investigation, backache could be thought of as a modern condition, but this seems an unreasonable supposition. With the exception of exposure to vibratory forces[39], changes in our physical environment have not been so great as to account for the current importance of back disorders. Blundell Bankart[40] showed a very precise understanding of the various types of low back pain in his monograph on manipulative therapy.

2. Ethnic context

Our appreciation of ethnic differences in the experience of back pain have been hampered by lack of any structured data collection which inevitably marks the health-care organisations of those very cultures which we need to study. Furthermore, the semantics of pain and what constitutes a medical condition are too complicated to allow easy conclusions to be drawn from such studies[41]. Certainly there are very real differences in the way in which pain is perceived in different cultures[42]. There are few studies examining the effect of migration on low back pain[43].

3. Modern empirical classifications

3.1. Quebec classification

The Quebec Task Force on Activity Related Spinal Disorders[11] combined it's literature review with an empirical classification of activity related low back pain to form a table of treatments and indications for treatment. In recognition of the importance of duration of symptoms on the prognosis they include a three tier subgrouping based on duration of symptoms and likewise have subgroupings for those at work and idle at the time of assessment. The first four groups are the most frequently seen in the acute back clinic.

Classification	Symptoms	Work status W=Working I=Idle	Duration a=<7 days b=7-49 days c=49 days+
1	Pain without radiation		
2	Pain + radiation to extremity proximally		
3	Pain + radiation to extremity distally		
4	Pain + radiation + neurological signs		
5	Presumptive compression of a spinal nerve root on a simple X-Ray		
6	Compression of a spinal nerve root confirmed by specific imaging techniques		
7	Spinal stenosis		
8	Post surgical status, 1-6 months after intervention		
9	Post surgical status, >6 months after intervention (9.1=Asymptomatic 9.2=Symptomatic)		
10	Chronic pain syndrome		
11	Other diagnoses		

Table 1 Quebec classification of activity related spinal disorders

The Quebec classification is comprehensive and includes groupings which are more useful in a scientific rather than a clinical sense. Category 5 is of root entrapment based on plain radiological changes which is a very unreliable basis for a diagnosis of root entrapment. This they acknowledge. The merit of this group is that it allows the

reported treatment of such a group of patients to be compared with other similar patients.

3.2. A Pragmatic classification

Three broad categories of causation for back pain may be identified with an acceptable degree of precision. These conditions must be excluded before a diagnosis of simple mechanical back ache may be established.

3.2.1. Pathological causes of back pain

Pathological (tumour or local disease related) causes for back pain may lie within the spine but may also be due to abdominal or retro-peritoneal conditions. Previous neoplastic or serious infective conditions increase the chances of a pathological cause for back pain. The pain of pathological lesions is unlike that of mechanical back pain in that, independent of activity, it occurs spontaneously and often prevents or disturbs sleep. The thoracic spine is relatively untroubled by mechanical disorders and thoraco-lumbar or thoracic spinal pain is more commonly due to a pathological cause. Children and adolescents seldom suffer from mechanical back pain so that back pain presenting before the age of 18 years should be meticulously assessed. Likewise, those over the age of 55 years presenting with an attack of back pain have an increased chance of having a pathological lesion underlying their disorder.

3.2.2. Nerve root entrapment

Escaping from the confusion created by the term prolapsed intervertebral disc or sciatica, a further category of causation may be identified, termed nerve root entrapment[44]. Those instances of back pain accompanied by new neurological symptoms or signs; either at rest or after exercise; have to be dealt with in a manner which uses detailed enquiry into symptoms, physical and neurological examination - after exercise if necessary - and special investigations. The identification of an entrapment of the spinal cord; the cauda equina or a single nerve root allows directed action to release the entrapment.

3.2.3. Illness behaviour

A small portion of those patients seen with back pain express their experience of illness in a different way to the normal sufferer. This is a condition which has been termed illness behaviour[45]. The treatment of such cases depends upon an alteration of the patient's perception of their body and their pain.

3.2.4. Simple mechanical back pain

This leaves over 80% of back pain without a positive diagnosis[46]. Clearly this is an unsatisfactory situation for the medical profession. The search for reliable prognostic indicators or special investigations has not yet produced a solution. We still do not have a histochemical stain or imaging technique for pain. Mooney[47] may be correct in attributing the bulk of simple mechanical low back pain to disc disorders but there is no hard evidence to support this supposition. The adoption of imprecision and pseudo-diagnosis does not further our understanding low back pain. Because of our failure to identify those sub-groups of low back pain which respond reliably to surgical treatment it is best to study conservative approaches to treatment - at least initially.

THE NATURE OF LOW BACK DISABILITY

1. The nature of disability

1.1. The medical model

Classical medicine has developed from the work of the great European pathologists and surgeons in a way which has been called the medical model. In this paradigm of thought a disease process is one with pathological abnormalities which may be identified by means of history, examination and special investigations. A condition such as osteoarthrosis of the hip is well suited to consideration under the rules of the medical model. A characteristic history along with physical findings is supported by special investigations such as plain radiographs. Once detected the abnormality may, if possible, be corrected and a solution achieved with return of function.

1.2. The increase of low back disability

Low back *disability* has evaded a solution based on the medical model in "western" countries (Figure 2) implying a failure of the medical model in helping us to deal with

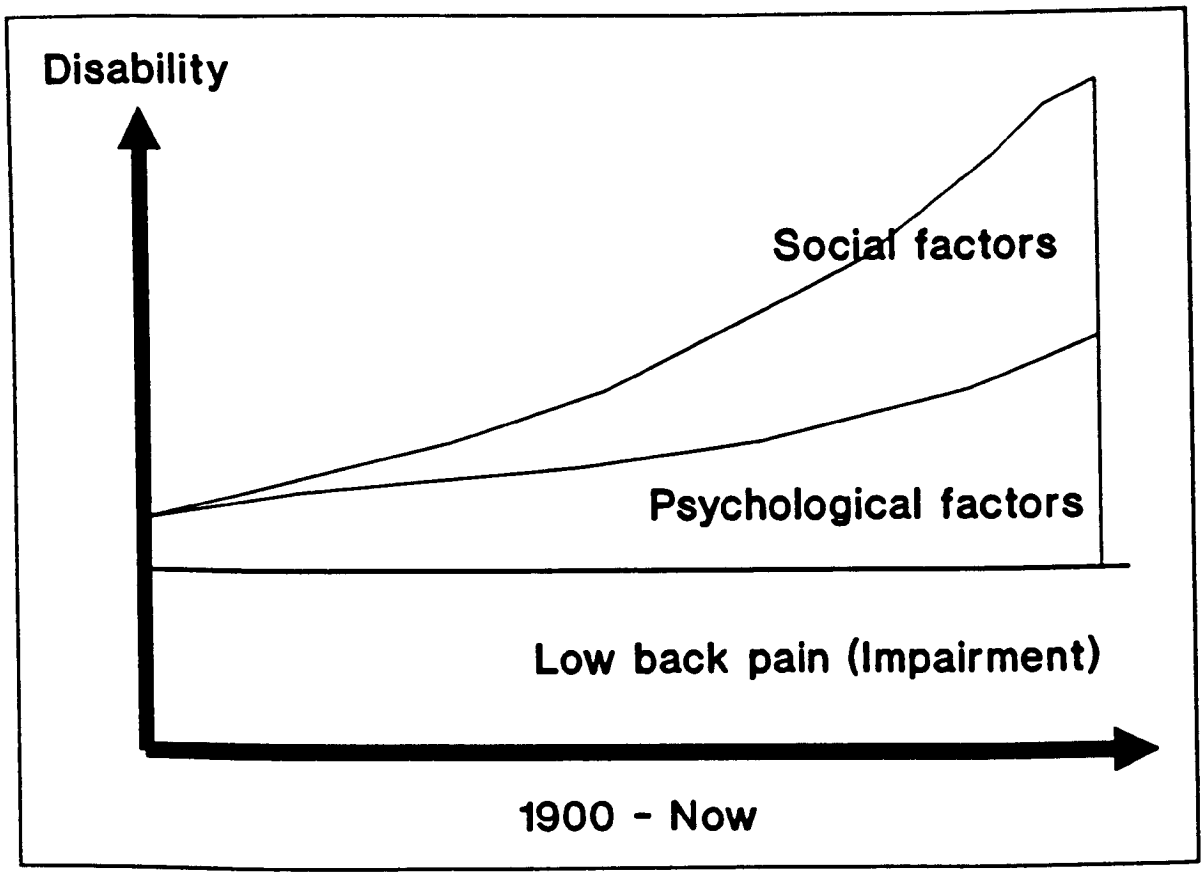


Figure 2 Changes in low back disability 1900 - 1990

this condition[48]. A new model of thought[49,20,50] is required to allow all the pieces of this jigsaw to fall into place.

1.3. The bio-psycho-social model

This new approach considers that the disability arising from any condition is a combination of physical impairment; psychological factors and social factors (figure 2). Using statistical methods to enable the proportions of a patient's disability produced by impairment and psychological factors, Waddell and Main[51] have shown that approximately 40% of a chronic low back pain sufferer's disability arises from physical impairment and another 30% from psychological factors. They did not have any measure of social disability, this requiring further examination. One interesting study examined the incidence of low back disability in the counties of the state of Washington[52]. The authors found that socioeconomic factors in each of the 39 counties accounted for over 30% of the variance in claim rate in two of the three years studied. In diagrammatic form the increased power of the Bio-Psycho-Social model may be seen

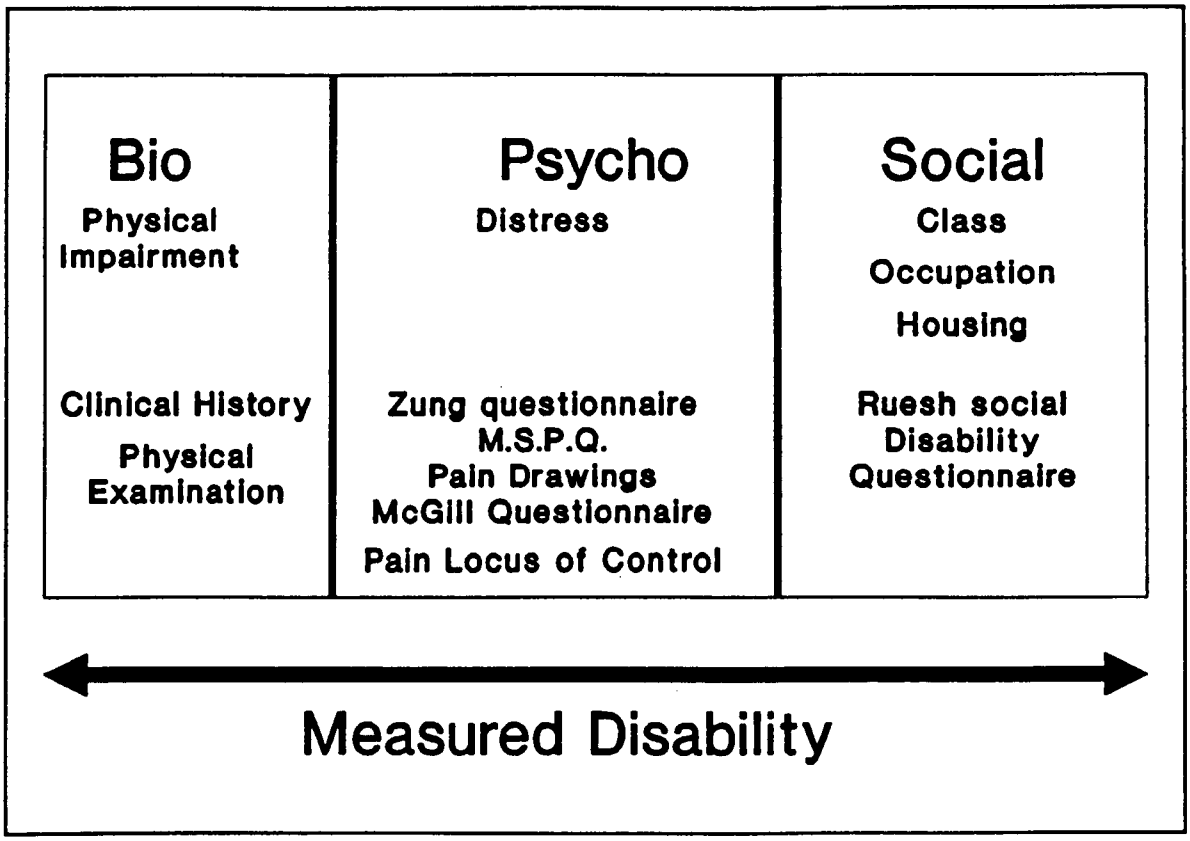


Figure 3 Components of disability

(Figure 4). Note that the proportions of physical impairment; psychological factors and social factors will vary between individuals, in different medical conditions and in different disability assessment systems.

2. Historical perspective on back disability

Disability implies a loss of ability to function which may be either at the place of work or at home. The measurement of disability has been performed by many methods including questionnaires and formulae derived from examination. These methods have only been in existence in the last thirty years so that our historical appreciation of the extent of low back disability rests not upon records of what individuals could not do, but the activities not undertaken and the resulting costs. Analysis of the Surgeon General's report for American forces and medical archives of the British forces indicates that low back disability was relatively uncommon forty years ago. Certainly there is evidence that the incidence of low back disability in Scandinavia is

increasing[53] and that the costs of the North American Workers Compensation schemes are escalating[28].

3. Ethnic perspective on back disability

Without the advanced forms of welfare seen in North America and Europe, there are few measures of low back disability which enable estimates to be made of the numbers of individuals who are affected in different communities. Amongst "western" countries differences do exist[54]. Only a survey would uncover the levels of disability in third world countries and differing cultural norms would make the use of instruments such as disability questionnaires difficult.

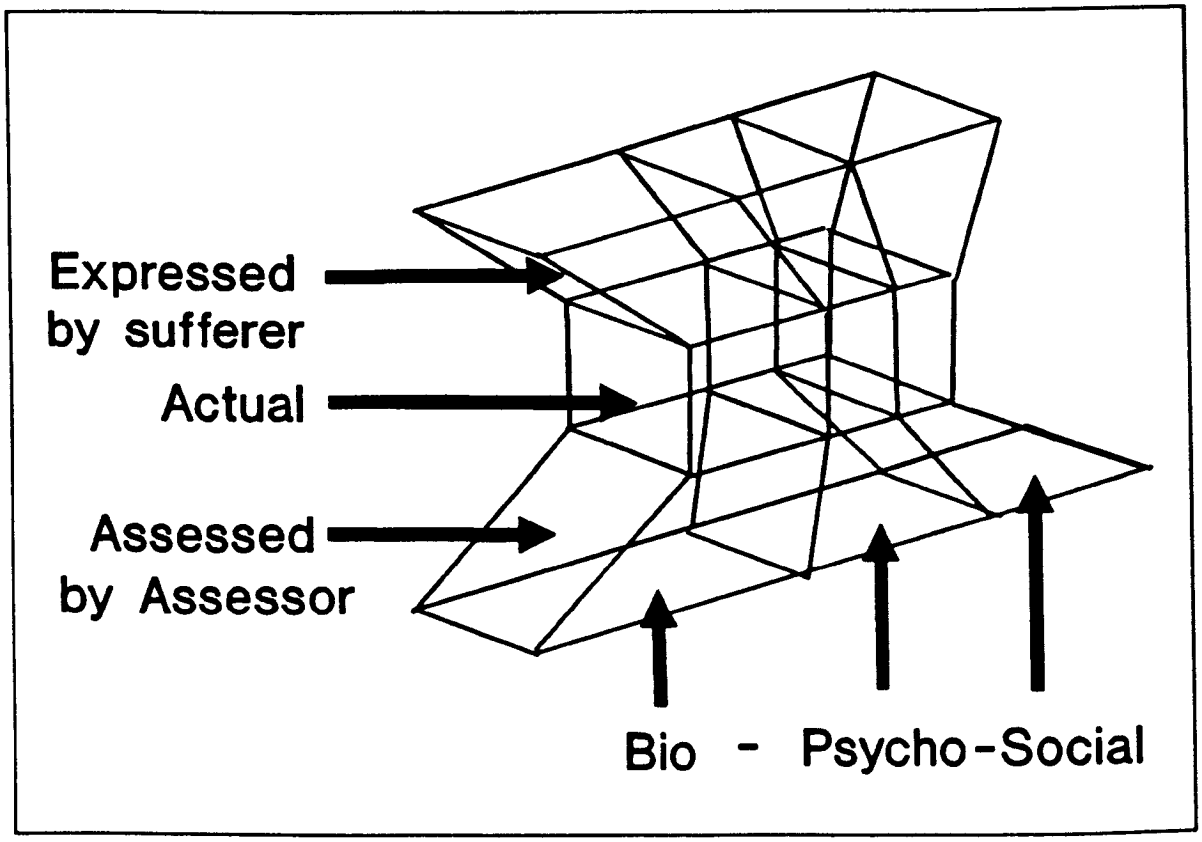


Figure 4 The Biopsychosocial model

Figure 4 attempts to illustrate the difficulty of assessing disability arising from the varied contributions of physical impairment; psychological distress and social factors not only in the subject but in the assessor too.

THE CONSERVATIVE TREATMENT OF LOW BACK PAIN

1. Historical accounts of treatment

Records of treatment for low back pain date back to the Edwin Smith papyrus and may be found scattered through the historical literature but the first author to write extensively on the treatment of musculoskeletal conditions was John Hilton[55] who's essays have had a profound influence on the teaching and practice of medicine in this country. Textbooks of orthopaedics such as Blundell Bankart's[40] espoused manipulative treatment and some surveys of treatment exist in the medical literature at the beginning of this century[56]. In 1934 Mixter and Barr[57] published their article concerning surgical decompression of the herniated nucleus pulposus. Within a few years, the medical literature contained several large surgical series of laminectomies not only for root entrapment as originally advised by Mixter and Barr but for those cases of leg and back pain with a less obvious cause[58].

The medical profession took on the task of treating back pain and sciatica.

2. Bedrest

Rest and let pain be your guide has been the touchstone for the treatment of mechanical low back pain for the last fifty years. Analgesia has been employed to ease pain whilst in bed but not to enable the patient to mobilise. A tradition of rest has been passed down from John Hilton[55]. Lecture 16 in his text gives an account of a child brought to Hilton with sacro-iliac tuberculosis which he treated with six months recumbency until the abscess burst and the cavity filled with granulations. There is no mention of back pain in the text and the bulk of the pathology is related to tuberculosis. With the importance of tuberculosis in the practice of orthopaedics at that time this was a worthwhile message. Unfortunately subsequent generations of doctors have learnt from this tradition, forming a considerable folk-lore which is most resistant to change.

Weisel[59] conducted a study which examined 200 combat troops who had suffered acute mechanical back pain with normal X-rays and no previous attacks of back trouble. Eighty soldiers were entered into a trial of bed rest as one treatment, versus continued ambulation without physical exertion as the alternative treatment, for up to fourteen

days. The authors noted "The drill sergeants made sure that the ambulatory patients were kept on their feet" and this may provide an explanation for the rather striking advantage found with bed rest. A novel and un-tested pain scale was used as the principle instrument for the quantification of progress which makes comparison with other papers difficult and lessens the utility of the results.

In the only good controlled trial of bedrest Deyo[60] found that seven days of bedrest was no better than two days and that patients were off work longer with longer convalescence. This trial was well organised and cannot be faulted in it's design.

3. Activation

Whilst avoidance of prolonged bedrest could be achieved with much reduced levels of functioning and activity than normal, activation expresses the concept of increasing activity levels in a positive fashion. Steps to increase activity could produce benefit by acting on behavioural, social and physical aspects of the patient's condition. As Troup and Videman point out, the interactions and confounding factors are complicated and as yet poorly understood[61].

3.1. The "Disuse Syndrome"

Richard Asher[62], writing between the wars, listed the evils of bedrest. This was directed at inpatient bedrest but much of the argument could be equally directed at those patients rested at home for prolonged periods. A similar and more up to date indictment of inactivity has been levelled by Bortz[63] who coined the term "Disuse Syndrome".

A consensus is beginning to develop regarding the treatment of acute mechanical low back pain which seeks to restrict the patient as little as possible after the initial few days of discomfort[64,20].

4. Modified return to work and return to modified work

Frequently patients recovering from an attack of low back pain have to return to work without any job modification. This may lead to an exacerbation of the attack and loss of confidence both in their back and their doctor, particularly if premature. One

approach has been to modify the work environment. Any modified work regimens require careful construction if they are to offer the worker a chance of returning to the workplace whilst still recovering. Modified work may of course be in an occupational therapy department. In the United States some insurance companies use this form of treatment for patients with acute and chronic low back pain[65]. Catchlove and Cohen[66] showed clear differences between those patients who had been directed to return to work after two months compared with those who were able to choose when to return. The study suffers from lack of randomisation and also unexplained differences in the follow up of the two groups which raises the question of whether the patients were recruited to the study sequentially, one group after the other. In other words, the control group seems to have been collected retrospectively whilst the study group was collected prospectively. It suggests a fruitful area for future research. There is not any hard evidence that a behavioural approach to early work return is effective.

Deacon and Congdon[67] describe a system for allocating back pain sufferers to temporary alternative work arrangements in a large chemical works. This system appeared to have two benefits which were not quantified. Firstly an atmosphere of trust and co-operation was established between employees and the company as the workplace was not seen as an hostile environment. Secondly, recuperating workers could return to work earlier and were able to continue at work during their recuperation. Similar beneficial effects of a modified return to work approach were reported by Fitzler and Berger[68] again with no quantification. Early intervention by industrial medical officers can reduce costs and absence significantly particularly where they intervene early in cases of prolonged absence[69]. It is not possible to separate the behaviourial component of modified return to work from the other complex effects which may be in play. The beneficial effects on social and behaviourial aspects of low back pain almost certainly exist but remain unquantified[64].

5. Behaviourial methods

There now seems to be evidence that a behaviourial approach to acute low back pain may provide better long term results than conventional methods. For the past twenty years Fordyce[70] in Seattle has been using behaviourial treatments for patients with

chronic low back pain. Fordyce has applied these principles to the early treatment of acute low back pain with interesting results[70]. One hundred and seven patients with less than three days of low back pain were randomised to receive a course of exercises, medication and activation. The difference between the two groups was that the study group were told to mobilise at a specified time; take their medicine regularly for the prescribed duration and perform exercises according to the physician's directions. No difference was noted at six weeks but at a year the conventionally treated group were significantly less well and was found to have significantly greater claimed impairment. The authors conclude that "Clearly, the findings of this study indicate that the physician who would rely on patient definitions of pain or illness is at peril to promote chronicity.".

This is supported by studies of patients with chronic pain. Linton[71] in a study of 30 patients showed that activity and pain are related on the basis of a questionnaire but there seems to be no evidence to support a connection on testing objectively as demonstrated when patients gave unexpectedly good responses to challenge on an exercise bicycle. This seems to support Fordyce's work[72].

6. Anti Inflammatory drugs

Non-steroidal anti-inflammatory drugs are commonly used in the treatment of acute low back pain. Like all treatments, these drugs have a considerable placebo effect. This effect depends upon social, psychological and cultural factors[73]. A Dutch study[74] showed that whilst 63% of patients were prescribed analgesics on their first visit with an attack of low back pain, other drugs (presumably including non-steroidal anti-inflammatories) were provided in only 7% of consultations.

Non-steroidal anti-inflammatory agents have been implicated in almost a quarter of the adverse drug responses reported to the Committee on Safety of Medicines[75] by the yellow card reporting system. As reliable denominators are not available for this information, it has to be treated with caution. Nevertheless some appreciation of the relative risk of various non-steroidals with regard to gastrointestinal complications may be gained[76]. A figure of 33 gastrointestinal reactions reported per million prescriptions

represents the mode for the drugs listed although the actual incidence must be higher than this. Ketoprofen, the drug chosen for the current study, was reported as producing 33.2 gastrointestinal reactions per million prescriptions with 5.3 other reactions per million. Slow release preparations and encapsulated forms of non steroidal anti inflammatory drug have been formulated to avoid gastrointestinal bleeding. Even suppository versions of these drugs may cause gastrointestinal bleeding so, by implication, the circulating drug and it's derivatives are probably responsible for mucosal damage[77].

Studies of non-steroidal anti-inflammatory drugs in low back pain include a prospective randomised study by Goldie[78] which showed no difference between indomethacin and placebo in fifty patients. A three way trial[79] on inpatients showed naproxen sodium to be slightly better than difusinal and significantly better than placebo. The number of patients was small (35 in total) without statistical power being reported in the results. Another trial examining piroxicam and placebo[80] showed significant benefit early during the acute attack. There does not seem to be a wide variation in the efficacy of one non steroidal compared with any other[81,82].

7. Corsets

Rigorous trials of corset treatment for acute low back pain have failed to show a beneficial effect[83,84,85].

8. Exercises

8.1. Exercise regimens

Many different exercise regimens, based on empirical principles, have been devised. Several trials of exercises have failed to show a role for this widely used method of treatment. Problems connected with most studies have been inadequate description of the exercises[83,86,87,88] and failure to monitor or report patient compliance[88,89,83]. No benefit compared with corset[83]; traction[83]; manipulations[83]; other exercises[86,88] or shortwave diathermy[88] was reported. Recent papers have been more rigorous and have still failed to show benefit[90,91]. Zybergold's study[90], which did not demonstrate any benefit from any form of exercise, looked at three groups with small numbers (eight, 10

and 10) so the statistical power was small however this was further confirmed by Gilbert's study[91] containing between 60 and 65 patient's in each group which also showed no benefit. As a control treatment in a factorial study design Deyo examined exercise and stretching for chronic low back pain[92]. Whilst the TENS failed to show a beneficial effect after a month, the exercise did. However, this effect was lost after two months as the subjects had largely abandoned their exercise regimen. One aspect of most of these studies is that they have been prescriptive as regards the form of exercise prescribed. It is quite possible that if an exercise regimen is prescribed to a heterogenous group of low back pain sufferers then either some will have inappropriate exercises whilst others might have the correct exercises. Furthermore if patients have a mixture of appropriate and inappropriate exercise they will neither benefit nor deteriorate. Thus, there is probably no place for handouts or "by rote regimens" in recommending an exercise regimen[93]. The possible role of activation which forms an element of the physiotherapists interaction with the patient may be a worthwhile effect of an exercise regimen but this has not been studied specifically.

8.2. Functional training

Definitions of functional training vary from paper to paper but generalised muscular fitness and cardiovascular fitness are the two main themes to these papers. One great difficulty with any assessment of fitness programs is the inevitable biases introduced by the non-compliance of less motivated subjects. Most passive control groups would be much less likely to make demands on subjects. The beneficial effect of cardiovascular fitness and physical training has been investigated in the prevention of attacks of low back pain. Cady[94] found, in a prospective study of 1652 firefighters over 3 years, that fitness grouped into average, middle and high was significantly related to back injury. The fittest were injured approximately eight times less frequently than those in the least fit group. Differences in the behaviour of the fittest and least fit may however explain much of the difference seen. For the patient with chronic low back pain functional training may be a useful form of treatment[95], working both to counter the effects of the "disuse syndrome"[63] and to effect behaviourial and social changes in the patients condition. The case for functional training seems to have been overstated in the literature so far[96,97]. The prospective Boeing findings go very much against the

possible use of fitness Feuerstein and colleagues[98] have explored the relationships between fatigue and low back pain at the indistinct border between back pain and what was formerly termed neurasthenia. Fibromyalgia[99] is yet another 'diagnosis in the making' which casts a shadow over the domain of back ache. Fatigue seems both to be a promoter-magnifier of pain and also a result of pain.

9. Back School

Like functional training there is no generally held definition of what comprises back school. Most of the studies are uncontrolled series. In chronic low back pain, a condition which has a tendency to wax and wane it is natural that patients present when their symptoms are worse so that an improvement following recruitment into a pain program might be expected. Hall and Iceton presented a very large series of patients who had undergone back school treatment but did not include control patients for comparison[100]. Klaber Moffet and colleagues[101] concluded that the back school had a significant role in the treatment of low back pain but their statistics show only that patients could answer a questionnaire on low back pain better if they had attended back school! Some evidence exists that the effects of back school are not long lasting and that there is no difference in efficacy between in and outpatient treatment[102]. Lankhorst and colleagues[103] found that after a year of treatment no statistical difference could be demonstrated between the detuned shortwave group and the back school group and felt that if it was to be used effectively, then it should be restricted to the sub acute and acute stages. In certain circumstances an aggressive rehabilitation program for acute low back pain may prove cost effective when compensation costs are taken into allowance[104].

Little hard evidence exists to support the concept of back schools although the literature abounds with reports of recovery rates in series of patients. Linton and Kamwendo[105] present a dismal review of the effectiveness of back schools.

10. Physical Therapy

10.1. Ultrasound, shortwave diathermy and interferential

Little evidence exists to either recommend or refute the use of these methods of treatment for acute low back pain.

10.2. Traction

Few studies have examined inpatient traction for low back pain but those which have, have shown no continuing benefit after the traction has been stopped[106].

10.3. Manual Therapy

10.3.1. Osteopathy/Chiropractory

The role of lay manipulators in the treatment of low back pain by manipulation is not yet clear. There is no good reason why they should not be as capable of applying manipulative treatment as a physical therapist or a medical practitioner. An American survey[107] showed in a large number of patients that an average of 19 treatments over 43 days was required to produce maximal benefit. This is actually little better than the natural history of the condition! One difference of importance between heterodox and orthodox practitioners may be their ability to discriminate between those causes of back pain which respond favourably to manipulation and those which require medical investigation and care. Case reports of adverse effects of chiropractory exist[108]. A Canadian[109] study showed no difference in the efficacy of manipulation provided by medical practitioners compared with chiropractors. Another controlled study showed no detectable significant benefit from osteopathic manipulation at four weeks following manipulation[110].

A Medical Research Council trial[111] of physiotherapy and chiropractory in the treatment of acute and chronic low back pain showed statistically significant differences in favour of chiropractic up to two years after treatment. The study design was pragmatic examining modalities of treatment rather than specific treatment measures. In the pilot study it became apparent that a complex design was required to allow for the differences in duration of symptoms seen in the patients attending chiropractic and physiotherapy services[112]. The size of the study was sufficient that a difference in

	Physiotherapy n=339	Chiropractic n=378
Maitland	243 (72%)	6 (2%)
Cyriax	42 (12%)	-
Chiropractic Manipulation	-	375 (99%)
Traction	86 (25%)	8 (2%)
Corset	13 (4%)	8 (2%)
Exercises	102 (30%)	33 (9%)

Table 2 Treatments employed in MRC trial of physiotherapy and chiropractic

disability of 1.73% was significant although the cliincal relevance of such a difference was never discussed. One of the most worrying features of the study was the failure to allow for initial psychometric measures in the evaluation of disability. If the bio-psycho-social model is appropriate then, almost by definition, no understanding of disability is possible without some measure of distress. The results of the initial assessment of "depressive symptoms, somatic awareness, and inappropriate symptoms" are not presented or used. The sixfold difference in patients declining entry to the study from the chiropractor referrals compared with the physiotherapy referrals should not have introduced any bias but is worrying. The chiropractic patients received almost 50% more treatments than the physiotherapy group (mean 9.1 vs 6.3) introducing the possibility that dose rather than potency of treatment was responsible for the differences seen. Almost all the chiropractic patients underwent chiropractic manipulations whilst the physiotherapy patients were treated by a variety of means (Table 2) reviewed elsewhere in this manuscript.

10.3.2. Manual forms of physiotherapy

The general history of manipulation for conditions of the lumbar spine starts with the Edwin Smith Papyrus[113]. Records of manipulation of the spine are infrequent after that time until the early part of the 19th century. In the Orient manipulation was fairly commonly practised[114] but little is recorded in the Occidental literature until about 1850. In Britain, Hugh Owen Thomas was lending credibility to folk medicine by manipulating fractures according to the methods of bone setters. He is not well known for spinal manipulation and this may be related to the absence of X-rays. Vigorous

manipulation of a patient with Pott's disease of the spine would not have enhanced his reputation.

10.3.3. Forms of manipulative therapy

Traditionally there have been two schools of manual treatment which sought to mobilise the spinal column; perhaps freeing adhesions and allowing muscles to work through their full and normal range. The late Dr. Cyriax[115] placed most emphasis on manipulation, employing mobilisation occasionally. When mobilisation was employed it was done by slow continued stretching of all the motion segments of the lumbar spine. Maitland's concept[116] of mobilisation differs from that of Cyriax. Here the therapist attempts to identify the motion segment responsible for the pain and to mobilise that or those segments by oscillatory movements.

Manipulation of a joint may be defined as a high velocity, low amplitude movement at the end of a range of movement outside the patient's control. Both the Maitland and Cyriax methods of manual therapy employ similar forms of manipulation.

10.3.4. Trials of manual therapy

Blundell Bankart[40] at the Middlesex hospital was applying rotatory manipulation of the trunk on a regular basis at the turn of the century and published his technique in monograph form. The section concerning the spine is quite clearly a masterpiece showing an understanding of spinal conditions little bettered in many modern texts. Bankart's registrar, E W Riches published the results of a series of manipulations of the spine performed on Bankart's patients[56]. One hundred and thirteen patients were reviewed in retrospect which was a rigorous scientific paper at that time.

Many clinical trials of manipulation have been performed. The placebo effect associated with hands on contact with the patient plays a large part in the outcome. Quantification of this is as yet not possible. The DHSS working group[117] reporting that "one would like to be able to isolate the influence of features like personal interaction or the laying on of hands from what the hands actually do when they are applied".

A trial by Glover[118] showed no significant lasting difference between patients who had undergone shortwave diathermy and those who had a rotatory manipulation followed by short wave diathermy. The manipulated patients were more comfortable 15 minutes after the treatment but this benefit was lost after three days. The trial by Doran and Newall[119], although widely quoted, does not describe the treatments used in enough detail to allow comment. Criticism of this study elsewhere[15] cites the bias which occurred due to the therapists excluding patients because of unsuitability for manipulation although there is no mention of this in the paper.

Difficulties in describing treatments are frequent amongst the studies of manipulation. Waterworth's study[134] randomised 108 patients into three groups. Thirty-six patients received a non steroidal anti-inflammatory drug the remainder being divided into two groups for physical therapy. Conservative physical therapy was administered as a combination of heat, ultrasound and flexion-extension exercises. Specialist techniques of manipulation of the lumbar spine consisted of a mixture of manipulation and the techniques advocated by McKenzie. Considerable confusion exists between the two groups of physical therapy as the bulk of McKenzie therapy depends upon the patient's movements - that is exercise - and not manipulation. Flexion and extension exercises form components of the McKenzie regimen and thus the distinction between the groups was diminished. A further difficulty was that the physiotherapists administering the specialist manipulative therapy had not been trained in the McKenzie techniques[120]. The study concluded that "the overall improvement ratings, time off work, and economic cost favoured the group treated with the non-steroidal anti inflammatory drug".

The single blind, randomized controlled clinical trial conducted by Godfrey Morgan and Schatzker[121] of rotational manipulation for back pain of recent onset included 81 adults. Control treatments were minimal massage and low level electrostimulation. Initial status and outcome were measured on scales quantifying symptoms, activities of daily life, mobility, tenderness to palpation, aggravation of pain by coughing or sneezing, limitation of motion on testing and forward flexion. Both treated and control patients improved rapidly in the 2-3 week observation period. On retesting there was

no statistically significant difference between the improvement scores of the treated or control groups on any of the scales. The authors claim that most of the patients had had their pain for 3 - 7 days at the time of initial examination which is exceptionally swift considering that the study was performed by a secondary referral centre. the physiotherapy arm of the trial employed the methods described by Maigne[122].

Farrell and Twomey's study[123] demonstrated faster recovery of function in the group undergoing manipulation, but there was no difference in function or comfort after three weeks. Hoehler's[124] study showed a similar result comparing massage with manipulation. Unfortunately, the attrition rate at three weeks was too high (27%) to enable any reliability to be placed on the lack of long term difference. A well conducted trial in Great Britain[125] showed no early benefit from manipulation compared with shortwave diathermy and placebo shortwave diathermy. Particular attention had been paid to administering equal amounts of sympathetic and encouraging contact with the patients in all groups.

Mathews[126] examined the benefit of Cyriax manipulation on 291 patients with back pain and asymmetric lumbar spinal movements. This would have included a number of patients with nerve root entrapment although uniradicular symptoms and neurological deficit were dealt with by other means. Long term follow up was not performed. There was clear benefit from manipulation compared with infra red heat treatment with 80% of manipulated patients having recovered compared with 67% of control patients.

Hoehler and Tobis[127] in a study of the psychological aspects of spinal manipulation found that a patient's failure to maintain improvement was related to certain scales on the Minnesota Multiphasic Personality Inventory (MMPI) psychometric questionnaire. Their multiple regression analysis for prediction of outcome identified psychological factors and, predictably, duration of attack as independent determinants.

To summarise, there is a role for manipulative therapy but no long lasting effect has been observed[128,129].

11. McKenzie Treatment

11.1. Limitations of manual therapy

The patient is essentially passive during traditional forms of manual therapy for low back pain. One and, in the case of Cyriax based manipulation, occasionally two therapists are required to treat each patient. On it's own neither, the Cyriax nor the Maitland regimen provides the patient with any insight as to methods of self help. These methods conform to the medical model of illness and it's treatment which has evolved over the past century[49,50]. A greater appreciation of the patient's psychological and social health (or disorder) has led to a fresh view of treatment in some of the conditions which fit the medical model least well.

11.2. Principles of McKenzie treatment

Robin McKenzie, a New Zealand physiotherapist developed an empirical method of categorising and treating patients based on his personal experience[130]. He used simple concepts to describe a series of active and passive movements which the patients could perform. Whilst exercises have been employed for back pain for many years, the McKenzie application of these techniques employs both flexion and extension exercises according to the patients response to these movements applied repeatedly. An axiomatic principle is that of centralisation of pain[131]. This implies that a specific repeated movement relieves referred pain in the thigh or calf eventually causing that pain to be localised in the back before being abolished. Centralisation of pain may result in pain in the lower back initially increasing in intensity, the significance lies in the distribution of the pain. Therapists are taught that when centralisation of pain has been observed, a favourable response to the McKenzie regimen may be predicted.

The assessment examines painful movements not structures or segments as in the purely manipulative modalities of treatment. In some ways the method is similar to the system employed by Moshe Feldenkrais[132] in the United States. The diagnostic categories allowed in the McKenzie regimen are postural; dysfunctional and derangement

syndromes. The majority of patients with acute mechanical back pain have one of seven derangement syndromes.

McKenzie has formulated a conceptual model based on behaviour of the intervertebral disc which is used to explain the syndromes he describes. The postural syndrome is said to be caused by prolonged stretching of ligamentous structures due to adverse postures such as slouching or sitting in a hunched position. This pain does not tend to radiate and only appears when the spine is held in the adverse position. Correction of this is by education and modification of ergonomic factors.

Dysfunction is thought to be a pathological variant of the postural syndrome where, with time repeated annular tears heal with fibrosis leading to adaptive shortening of some ligamentous structures. The sufferer then experiences postural pain when the spine is held in an extreme position although this position is within the 'normal physiological range'. Conceptually the treatment for this chronic sequela of disc injury is stretching to correct adaptive shortening and restore a sufficient range of motion to allow normal function within that range. A special instance of dysfunction is where symptoms are not caused by ligamentous scarring but by involvement of the adjacent nerve root and dural sheath in the fibrotic process. Here the pain is referred to the limb with little back pain and, again, progressive stretching is employed to allow the root sheath to move within a range of movement compatible with normal function.

The final category is that of derangement. McKenzie has conceptualised this as the result of nuclear displacement within the annulus. Repetitive trauma and prolonged flexion are invoked as factors allowing the nucleus pulposus to displace and even intrude into the lamellae of the annulus. McKenzie is fully aware of the lack of basic science available to authenticate this model and states that: *"In the case of the derangement syndrome, acceptance of the conceptual model will allow us to predetermine with good reliability the direction of the required therapeutic motion. A better explanation may exist and the present model may be altered but in the meantime, until that new explanation is forthcoming, this is a reasonable and reliable model upon which to base mechanical therapy."*[133](McKenzie's emphasis)

Seven derangement patterns are recognised. Derangement 7 is unusual in that it represents the condition which centralises in response to repetitive flexion. The remaining six derangements are differentiated by the presence of pain referred to the proximal or distal limb and by the presence of a 'lateral shift'. A lateral shift is said to be relevant if repeated movements in a coronal plane produce centralisation. These side gliding movements are combined in sequence with extension exercises as appropriate. Assessment of the relevance of lateral shift is problematical and is discussed on page 63.

Once a patient has been assigned to a syndrome, the treatment session takes place. At the start of the next treatment session, further assessment is required, especially with derangements as the patient may have altered their physical signs as a result of the therapist's and their own efforts.

11.2.1. Trials of McKenzie treatment

Only one other study[134] has attempted to examine the relative worth of non-steroidal anti-inflammatory drugs in comparison with McKenzie physical therapy. This showed that as regards time off work; treatment cost and improvement ratings non-steroidal anti-inflammatory drugs were better than physiotherapy. The physical therapists chose whether to manipulate the patients or apply the techniques described by McKenzie[130]. The trial was criticised heavily (mainly by the McKenzie Institute) on the grounds that the therapists were untrained in the McKenzie treatment regimen. A record of the criteria for manipulating or for applying McKenzie principles was not presented in the study. The assessment of patient improvement was not particularly objective with doctors completing a three point ordinal rating scale. Furthermore mention was not made of any attempt to blind the assessing doctor to the patient's treatment group . Apart from the trial reported by Waterworth there have been three trials of the McKenzie technique worth mentioning to date. In the first, Ponte and colleagues[135] examined the value of McKenzie physiotherapy for patients with mechanical low back pain of similar duration to those examined in the current study. Criticisms of this study relate to the lack of apparent randomisation in a blind way; the application of both treatments by the same therapists and the lack of any indication of the follow up

interval. Patients with spondylolisthesis; spondylolysis or congenital vertebral malformations were excluded as were those patients with a previous attack of low back pain within six months. Nevertheless the study showed significantly that patients treated with the McKenzie regimen were better with fewer treatments than the Williams regimen and that their pain scores; tolerance of sitting; flexion and straight leg raising were better than the patients treated with the Williams protocol. In view of the discussion in connexion with "rote" exercise regimens (see page 24) the choice of Williams exercises might have been inappropriate in so far as they may prolong discomfort.

Nwuga and Nwuga[136] examined the McKenzie regimen for prolapsed intervertebral disc using quite strict exclusion criteria. They found that McKenzie treatment was significantly better than Williams exercises. Some suspicion of bias arises because they only saw those patients with prolapsed intervertebral disc who had been referred to the physiotherapy department. Randomisation was by consecutive alternate allocations rather than truly random allocations. The recruitment rate was slow (average = one every 18 days). Only one physiotherapist treated the patients so that the therapists bias could easily have skewed the results. Happily the final assessment at six weeks following first treatment (that is 6-8 weeks from onset of pain) was by a blind assessor but because the randomisations were predictable and recruitment slow bias cannot be excluded.

Stankovic[137] prospectively compared the effect of McKenzie treatment with 'Mini Back School' in 100 patients. The mini back school consisted of a 45 minute session of instruction on posture and back care. Back school patients were advised to "keep on the move". Return to work was significantly sooner with the McKenzie patients but the exact nature of advice given regarding return to work for each group was not presented. A reduction in recurrent episodes of low back pain in the subsequent year was also reported although the author of the paper questioned the two groups personally and no mention of blindness at one year follow up was made. Disability assessments were not made, with pain being measured on a visual analog scale.

11.3.1. Possible Early advantages of McKenzie treatment

The emphasis using McKenzie treatment is upon showing the patient how to recover. Control over their back condition and consequently responsibility for their own back is returned to them. The element of responsibility was not initially appreciated as being fundamental but now appears to be one of the important potential benefits of the regimen. Once the therapist has shown the patient the appropriate exercise regimen there is less need for continuing supervision and intervention making the method more economical with therapist's time and enabling the patient to undergo "self treatment" as frequently as necessary.

11.3.2. Possible Late advantages of McKenzie treatment

In 1974 McKenzie saw a patient with a shoulder condition who had been treated for low back pain five years previously. When asked how the back pain was, the patient replied that although she still suffered from back pain she was able to control and abolish it by means of the exercises which she had been shown. From that chance conversation, McKenzie formulated the concept of self care and the role of the regimen as "first aid" for the back[138].

The possibility of patients being able to prevent; abort or treat a future attack of low back pain is another attractive feature of the method which has yet to be proven in a conclusive fashion[139]. A physical therapy regimen with prophylactic value would drastically alter any cost benefit analysis of physiotherapy in the treatment of low back pain and has major economic implications.

11.3.3. Research advantages of McKenzie treatment

An advantage of the McKenzie regimen is that the assessment is performed by observing and listening to the patient rather than by palpation. Other methods of physical assessment depend heavily upon restriction of movement; muscle spasm; the presence of tissue thickening and the site of pain. Although attempts have been made[140] to quantify the forces involved; and the accuracy of physical assessment methods are far too complicated to be reliably and repeatably described. In contrast, the McKenzie assessment may be distilled into twelve separate clinical decisions which

allows a decision tree to be constructed. Inter observer agreement may be examined and treatments described more accurately. The development and testing of this decision tree is described separately (page 60). No method of treatment is universally applicable to every case of low back pain and the assessment recognises this allowing patients to be classified as having a resolved problem; an unknown diagnosis or requiring review after a few days rest.

METHOD

STUDY OBJECTIVE

To determine the role of McKenzie treatment for simple mechanical low back pain and what is its effect when compared with similar subjects treated with non steroidal anti inflammatory drugs.

STUDY DESIGN

1. Prospective

A prospective study design was chosen as this helped to ensure uniform selection of patients with complete data collection.

2. Randomised

The use of two prospectively collected groups allowed the use of randomisation.

2.1. Method of randomisation

A database of treatment options was assembled using a commercial database[141]. This has a sort procedure which produces a random sort using the RAND function found in the C language compilation library[142]. In total ninety physiotherapy options and ninety control options were entered in sequential order and then a random sort performed. Thus the sequence of records in the database became the sequence of treatment assignment or randomisation. This database allowed the printing of adhesive labels and other stationery for allocation envelopes without the direct intervention of the study organiser. The same randomisation sequence was employed at both centres.

After the patient was assessed by the doctor who decided on the patient's eligibility for the trial, the patient was referred to the study nurse who opened the next randomisation envelope and either directed the patient to the study physiotherapist or gave the patient a study pack of non-steroidal anti-inflammatory drug with an advice sheet.

2.2. Consideration of selection bias

The following causes of bias were considered and accounted for:

1. The possibility exists that when offered a referral option such as an early access back pain clinic, the family practitioners sent only those patients who they felt to be appropriate or even those patients which the practitioner did not wish to see themselves.

2. The short interval between family practitioner consultation and referral to hospital was not thought to introduce bias by selecting only those patients who were able to have time off work or arrange to travel to the clinics.

The preceding points concern patient selection before randomisation and thus compromise the study's comparability with other work rather than the internal validity of the results.

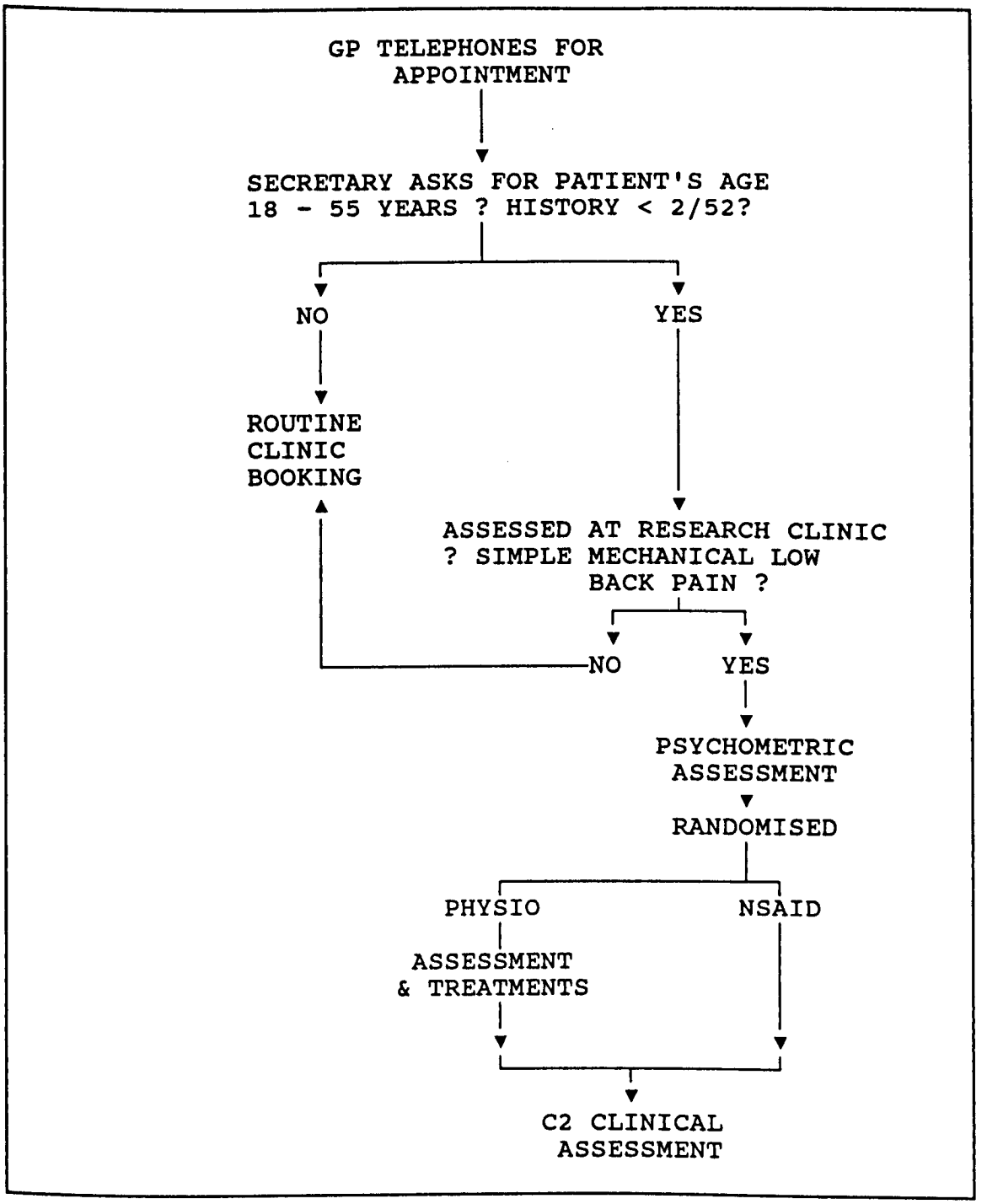
3. Unavoidable bias might have arisen from the social class of those patients who defaulted from clinic and were lost to follow up but this number was not great.

3. Control group

A no treatment group was discounted for two reasons. Firstly it was thought that patients should have some treatment for their acute low back pain attack and that not to do so might be unethical. This first consideration went against the use of a pharmacological placebo. Secondly patients who did not receive any form of treatment would see their own doctor for some form of medication; seek alternative forms of help privately or self medicate with proprietary non-steroidal anti-inflammatory drugs.

3.1. Placebo effects

Difficulties associated with the use of physical therapy placebo options are greater than those associated with the use of pharmacological placebo preparations. Both toxic and placebo effects are recognised in studies employing placebo control groups[73]. The notion that placebo preparations have no pharmacological action is generally accepted. Several



1 Flow diagram for patient recruitment

studies have attempted to assess physical therapy regimens by using physical therapy control groups. There have not been any studies of the characteristics of placebo physical therapy. One large study[143] employing a placebo group revealed but did not comment specifically on the number of patients defaulting from treatment as being much greater in the placebo group than in the physical therapy group.

Three effects summate to produce a placebo response to physical therapy. Firstly there is the patient's expectation of benefit which may be directly related to the pharmacological notion of a placebo. Secondly there is the laying on of hands which attends the interaction of a concerned therapist with the patient. This latter element is well recognised and it's magnitude, as yet, unmeasured[27]. Finally there is, what might be described as, the "laying on of resources". This effect (if it exists) depends upon the patient's equation of benefit being delivered in proportion to the health resources expended upon them. The complexity of physical therapy placebo effects precludes against their use in studies until extensive further research is performed to quantify these effects.

(1) The study question asked whether, as a total package, the McKenzie regimen on an outpatient basis is better than current General Practitioner treatment (i.e Non-steroidal anti-inflammatory agent). The question of whether - placebo effect excluded - drugs are better than physical therapy is not directly addressed. This is admittedly a pragmatic approach. The ability to separate the laying on of hands from what the hands actually do would be interesting but there is no possibility of providing manual therapy for low back pain other than by hand.

(2) Other forms of physical placebo treatment were problematical. Many patient's probably sense that lying under a heat lamp will not help them. Anything non-specific either doesn't have enough "laying on of hands" or might by chance either benefit of aggravate the patient's symptoms.

Possible placebo treatments

A. Short wave diathermy: No element of laying on of hands
weak element of laying on of resources
possible toxic effect with patients realising that
their treatment is sub optimal
Possible therapeutic effect of prone positioning.

B. Exercises: Good laying on of resources
Weak effect of laying on of hands
strong chance of physical exacerbation
or possible as yet unproven beneficial effect.

C. Ultrasound: Good laying on of resources
difficulties regarding intensity of US to be used
as there is some empirical evidence that low
intensity US may be more effective than high
intensity. Machines would have to be doctored so
that they did not work but showed a light.

D. Other forms of manipulation:

E. Traction:

4. Groups

4.1. Co-interventions

Both groups of patients received identical interviews, examination, questionnaires and follow up. A customised information sheet was provided for each group (see appendix 6). Roland and Dixon have reported on the use of booklets in low back pain[144].

4.2. McKenzie Physiotherapy Regimen

Those subjects allocated physiotherapy were seen by a senior research physiotherapist for assessment and treatment. Both research physiotherapists taking part in the study had attended courses on and were certified in the McKenzie methods of lumbar spinal exercise and manipulative therapy. Treatments continued until the physiotherapist was happy to discharge the patient. The duration and number of treatments was recorded. Patients were given a lumbar roll for postural support and a booklet[145] written for patients in connection with the McKenzie method of back care.

4.3. Ketoprofen Slow Release Regimen

Those subjects chosen to receive Non steroidal anti-inflammatory drugs were given a 28 day supply of Ketoprofen Slow Release 200mg.[146]. They were instructed by the research nurse and in their information sheet to take the tablets once each day with a meal. The subject was required to bring the foil packet back to the follow up clinic for assessment of compliance.

5. Prevention of bias during assessments.

5.1. Prevention of assessment bias by study administrator

The following precautions were taken to ensure that the assessing doctor was unaware of the allocations of treatment.

1. Randomisation slips were in sealed envelopes.

2. When assessed by the study doctor, the patients was categorised as suitable for the study or otherwise. Once a patient had been accepted into the trial, the doctor handed the patient a sealed envelope with the study number on the outside. This envelope contained the following:

(1) stamped addressed envelopes and questionnaires

(2) A letter to the GP outlining the guidelines for treatment of patients in that group

(3) An advice sheet for the patient appropriate to the group (see appendix 6).

(4) A card of assignment for the clinic nurse to either give the patient their non steroidal drug or refer the patient to the research physiotherapist

3. When the patient returned to clinic, the clinic nurse gave the patient a follow up questionnaire and told them that they were not to tell the doctor which treatment they had received until he asked them. This point in the follow up interview occurred after outcome variables had been enquired about and an examination performed.

4. The St. Thomas disability questionnaire was used throughout the study as was a visual analogue scale. By using this method of assessing disability, observer bias was reduced.

5. Any patient requiring hospital medical care during the study was withdrawn. All enquiries by the GPs and research physiotherapists were dealt with by a different medical officer to the study doctor.

5.2. Prevention of assessment bias by study physiotherapists

As a physical therapy placebo was deemed unsatisfactory for a control group, the physiotherapists did not have to administer a placebo treatment. Furthermore, because the physiotherapy modality to be studied had an element of "finding the correct movements" in the assessment it was felt that any assessment of control patients by the physiotherapists would lead to some control patients grasping the principles of physiotherapy treatment using that method. To be discharged by the physiotherapist after having been only assessed was thought to be potentially harmful to the outcome in the control group.

5.3. Precautions to prevent bias in subjects

No attempt was made to alter any aspect of either treatment in an attempt to conceal the nature of the treatment from the subjects. Subjects receiving non-steroidal anti-inflammatory drugs were given branded labelled drug.

Very rigorous measures were taken to prevent patients knowing the nature of the alternative treatment to which they were not assigned. At the time of gaining ethical consent patients were told that they were to receive a simple "family doctor type treatment". Patients were allocated their treatment and any queries answered by the study

nurses in a separate room. Follow ups occurring in the same clinic were held in rooms which were well separated from each other so that patients entering the trial could not overhear discussions with patients undergoing follow up.

6. Size of samples

Recovery rates gleaned from the literature were examined in a meta-analysis and power calculations performed on the rates of those not recovered at seven weeks post onset of low back pain. Sample sizes of 80 patients in each group were thought to enable detection of a significant difference ($\alpha = > 0.05$)[ff] with a 20% risk of missing a significant difference ($\beta = 0.2$)[fff,147]. There is no reliable data to be found in the literature concerning recurrence rates for low back pain and the calculation of sample size to examine effects on the incidence of recurrence was not possible. Results of follow up at six months were examined for type II statistical errors on a retrospective basis using a power table[148].

Proportional results require the following calculation[149] shown in Equation 1.

$$N = \frac{([P_0 \times (1 - P_0)] + [P_1 \times (1 - P_1)]) \times (Z_{\alpha/2} + Z_\beta)^2}{\Delta^2}$$

Equation 1 To calculate numbers required for specified difference

In the first forty patients the proportion of patients with a disability score of 2 or less at 70 weeks was .578 for the physiotherapy group and .364 for the non steroidal group. Thus :

$\Delta = .214$ $D^2 = .046$

$(Z_{\alpha/2} + Z_\beta)^2 = 7.8$ for $\alpha = .05$ and $\beta = .2$

and $([P_0 * (1-P_0)] + [P_1 * (1-P_1)]) = (.578[1-.578]) + (.364[1-.364])$

(ff) Alpha (α) is the risk accepted of falsely rejecting the null hypothesis.

(ffff) Beta (β) is the risk of falsely accepting the null hypothesis. It differs from alpha in that it has many values depending upon the size of the missed difference.

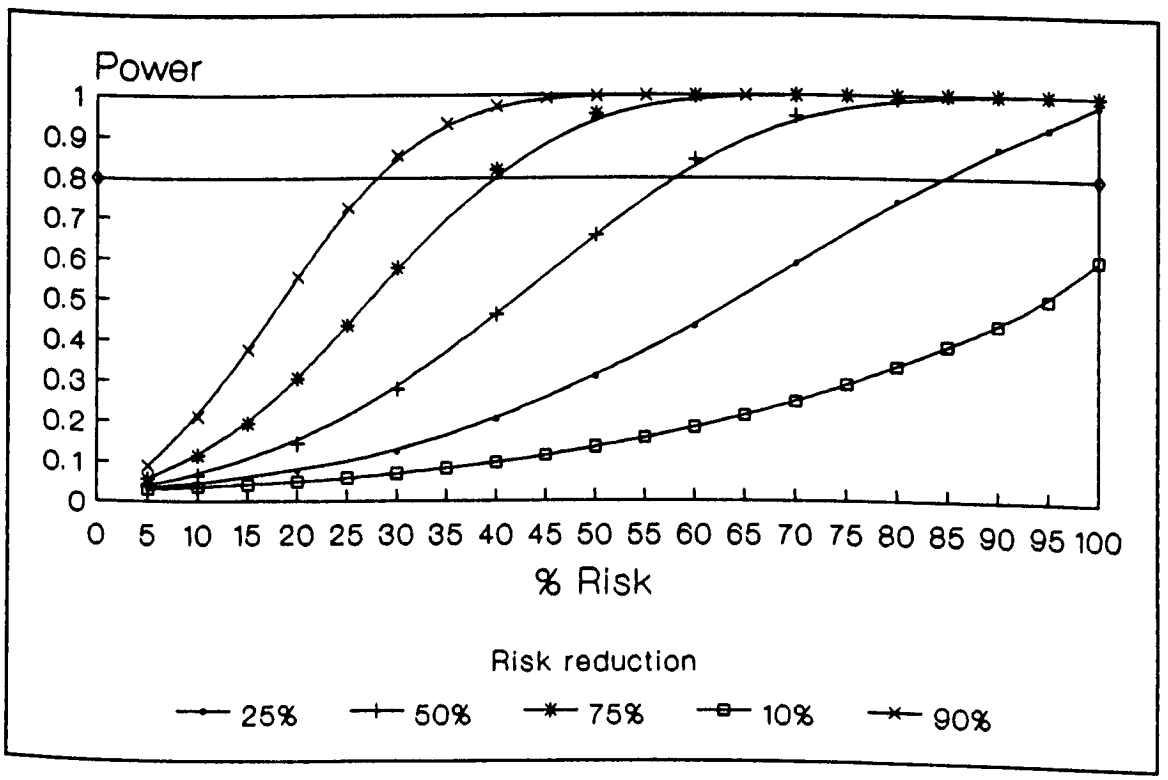
Thus N = 78 - rounded up to, say, 80 patients in each group.

A power table was constructed using a spreadsheet package[150] to enable the calculation of the value of ß or Power for various proportions of risk and differing reductions in those proportions based on equal groups of 80 subjects and a value of $\alpha=.05$. Equation 2 was used in the spreadsheet.

$$\beta = Prob|Z\rangle Z\frac{\alpha}{2} - \frac{P1-P2}{\sqrt{P1*(1-P1)}*\sqrt{P2*(1-P2)}}$$

Equation 2 Calculation for power curves for study

The power curves for n=80+80 and $\alpha=.05$ are shown below:



The conduct of the study was thus possible making the following assumptions:

(1) 44 Clinic weeks per year allowing for bank holidays and annual leave.

(2) Follow up during study of two months with subsequent follow up by post.

(3) Two clinics per week

(4) Ten per cent default rate

(5) Tenure of post 12 months maximum after start of study

(6) Two patients recruited per clinic

The average recruitment rate was initially lower than that assumed but rose to a level, with wide fluctuations, above the assumed level within a few months. An extra twenty patients were to be recruited to allow for attrition, contamination and defaulting. All subjects recruited in addition to the minimum number were to be included in the analysis.

7. Documentation

7.1. Inclusion/Exclusion criteria

7.1.1. Inclusions

Patients included in the study were those patients referred to the acute back clinic with back pain, with or without leg pain, aged between and including the ages of 18 and 55 years.

7.1.2. Exclusions

Inclusion criteria	Exclusion criteria
Low back pain Quebec groups I,II & III	Pathological causes Neurological features Pregnancy Poor spoken English >21 days of pain Previous spinal surgery Peptic ulceration Age <18 or >55 Refusal to give consent

Table 3 Inclusion and exclusion criteria for study entry

The exclusion criteria employed in the study are outlined in Table 3. Those patients who the physiotherapists were unable to diagnose reliably according to the schema described by McKenzie were not excluded. This was because it was not possible to

identify the corresponding group in the drug group. If the proportion of "undiagnosable patients had proved to be substantial then this would introduce the possibility of considerable bias in the results. Rather the patients who were "undiagnosable" were recorded to allow separate analysis.

7.2. Assessment of patients

7.2.1 Diagnostic methods

Other than history and physical examination, the special investigations used consisted of occasional erythrocyte sedimentation rates and plain radiological films of the lumbar spine.

7.2.2. Instruments used

During the physical examination the following instruments were used. A 100 centimetre tape measure was used to measure forward lumbar flexion according to the method reported by McRae and Wright[151]. No validation studies were performed on this instrument as reliable data concerning validity; reliability and utility were already available. Criticism of the method by Portek and colleagues[152] was vigorously rejected by Wright[153] on the basis that the method examined depended upon identifying the posterior superior iliac spines not the dimples of venus as originally described.

Lumbar extension was measured using a draughtsman's flexible ruler[154].

Straight leg raising was performed with the patient supine, the leg being raised with the knee in extension and a gravity goniometer[155] held against the knee.

7.2.3. Instrument assessment

Reliability studies concerning the flexible ruler were performed and are reported on page 68. Goniometer reliability in the measurement of straight leg raising was assessed and is reported on page 73.

7.2.4. Psychometric questionnaires

The Zung self rated depression scale[156], shown on page 174 in appendix 4, was used to measure levels of depression. A pain drawing as advocated by Rainsford[157] was employed to detect illness behaviour and other altered expressions of pain. The modified McGill pain scale[158] was used to measure pain perception. Pain intensity was measured by means of a visual analog scale as used by Roland and Morris[159]. Visual analog scales have been shown to be valid when compared with experimental pain[160]. The full St Thomas disability questionnaire is presented in appendix 2. The St Thomas disability questionnaire[159] was used because it had been validated on a group of patients with acute low back pain and because the questionnaire was found to be simple to complete. Normal values were not available for this questionnaire and these were obtained and are presented on page 77. The relationship between the St Thomas disability questionnaire and the other commonly used English language back pain disability questionnaire is presented on page 75. The Modified Somatic Perception Questionnaire (MSPQ)[161] was employed to detect states of heightened bodily awareness. This is shown in full in appendix 4, page 176. In view of the proposed role of the physiotherapy in the alteration of a patient's sense of responsibility for their own treatment, a psychometric questionnaire was employed to detect personal levels of responsibility for pain[162]. The scale eventually chosen was that developed by Main[163] and is shown in full in appendix 4, page 177.

Item	Initial	7wks	6mo	1yr
History	●	●	-	-
Examination	●	●	-	-
St Thomas questionnaire	●	●	●	●
Pain locus of control	●	●	●	●
Visual analog scale	●	●	●	●
McGill pain scale	●	-	-	-
Pain Drawing	●	-	-	-
MSPQ	●	-	-	-
Zung depression scale	●	-	-	-
Customised questionnaire	●	-	●	●
Setting	Clinic	Clinic	Postal	Postal

Table 4 Timing of assessments

7.2.5. Social questionnaires

The assessment of social disability and handicap is much harder than that of physical impairment or psychological distress. Some scales have been developed but their use in low back pain has not yet been examined[164,165]. It was decided to examine only three aspects of social circumstance. Occupation was recorded verbatim so that conversion to the Registrar General's classification of occupations[166] could be performed.

It is recognised that there are different and perhaps better ways of differentiating the social status of individuals but a clear successor has not yet been found[167]. Age of leaving full time education was thought to be important in correlating with the subject's ability to adhere to and apply any exercise regimen which they might be given. The retrospective Boeing study[30] clearly reinforced the message provided by Beals and Hickman[35] that a subject's opinion of their work environment is important in the outcome of an attack of low back pain. A simple 4 option box questionnaire was used to examine this point with the following options:

I like my work

a. Almost all of the time
b. Most of the time
c. Occasionally
d. Almost never

7.2.6. Radiological assessments

All patients entering the trial were subjected to plain lumbar spine radiology unless they had had a recent lumbar spine X-ray. This consisted of a antero-posterior view of the lumbar spine and sacrum, a lateral view of the lumbar spine and sacrum and a coned lateral view of the lumbo-sacral junction. Vertebral levels were taken from the last fully mobile level with the vertebral body above that level representing the fifth lumbar vertebra. Where the last mobile level lay at or above the inter-cristal line the vertebra above that level was termed the fourth lumbar vertebra. Those who were unsure of their last menses were not x-rayed.

7.2.7. Data recorded

All clinical data was collected at the time of interview by means of a Toshiba T1000 laptop computer and custom written study database software. Information and examination findings were thus always collected in the same order for all patients. A complete data set was sought for all patients. Prompts were available to ensure that the assessor always used the same phrases during interview although this was not often needed as the routine had been established during the running of pilot clinics. Data was exported directly in ASCII file format to the statistics software eliminating transcription errors. Data items recorded are to be found in Appendix 1.

7.3. Recruitment of patients

7.3.1. Informing referring doctors

On the 14th of March 1988 420 family doctors listed in the Family Practitioner Directory were contacted by personalised letter inviting them to take part in the

proposed study. Approximately equal numbers of doctors were contacted in the Nottingham and Mansfield & District Health Authority areas. All the practices circulated were contacted by telephone and at least one partner asked whether the letter had arrived and whether they had seen any suitable patients. An informal discussion ensued with the family doctors being able to ask any questions they might have had regarding the study. In June 1988 an article was placed in the Local Medical Committee news sheet reinforcing the content of the letter. The trial was described in lectures on the subject of acute low back pain given to the casualty officers at the Queen's Medical Centre Nottingham along with information on referral of patients. Casualty officers were allowed to refer patients if the patient had not been referred to the casualty department by their family doctor.

7.3.2. Location of study and pilot clinics

Clinics were held weekly at two sites: Harlow Wood Orthopaedic Hospital, Mansfield and The General Hospital, Nottingham. Pilot clinics ran from the beginning of April 1988 until the middle of August 1988 when the study started. During the pilot phase, secretarial and nursing staff were familiarised with the conduct of the study and the data collection software was developed and tested.

7.3.3. Administration of referrals

Receptionist Clinic Booking System

Family doctors were asked to contact the secretary in the Back Research Unit at Harlow Wood Hospital during office hours. The secretary checked that the patient complied with the entry criteria for the study and gave the practitioner an appointment for the patient within seven days. Patients excluded from the study by the appointment secretary were seen in a chronic back pain clinic if they failed to improve after eight weeks.

7.3.4. Timing of clinic visits and instruments

(A)Time 0 weeks Patient developed back pain

(B)Time <2 weeks

Family Doctor rang the Back Research Unit at Harlow Wood and a patient booking slip was made out by the receptionist. An appointment was given to the Practitioner over the telephone and the practitioner provided the patient with directions as to the clinic appointment and gave the patient a short referral note.

(C1) First outpatient consultation Time <3 weeks

Patient seen in the Acute Back Clinic for first out patient consultation.

The following instruments were used:

Study consent form (See page 184)
St Thomas Questionnaire (See page 172)[159]
Pain scale - Thermometer/matching word type[159].
Pain locus of control
Zung[156]
M.S.P.Q.[161]
Pain Drawing[157]
Short form McGill questionnaire[158]

On departure from the consultation, the patient took the following stationery:

St Thomas pain questionnaire + Stamped addressed envelopes (enough for a report of the patient's condition on each clinic day following consultation until C2[ff])

Letter to practitioner (Pamphlet drug for those on non steroidal agents and Pamphlet physiotherapy for

(ff) C2 denotes the second clinical consultation at seven weeks after the onset of low back pain.

those having physiotherapy)

Indication of randomisation for clinic nurse

Appointment booking for C2)

(C2) Outpatient follow up Time = 7 weeks

The patient returned as planned. The following instruments were re-applied:

St Thomas questionnaire (See page 172)

Pain scale

Pain locus of control

The patient was reassessed clinically and the second part of the computerised questionnaire completed. At this point the doctor breached the blindness of the follow-up assessment and had an unstructured discussion with the patient directed by the patient's questions and specific needs. In exceptional circumstances, the patient was brought back to the "chronic" back clinic as required outside the structure of the study. Otherwise, patients were discharged to their practitioners care.

(FU2) Six month postal follow up

A letter was sent to the patient with the following contents:

St Thomas questionnaire (appendix 2)

Pain locus of control questionnaire (appendix 4 page 177)

Analog pain scale

Six month questionnaire (appendix 7)

Stamped addressed envelope

(FU3) One year postal follow up

St Thomas questionnaire (appendix 2)

Pain locus of control questionnaire (appendix 4 page 177)

Analog pain scale

One year questionnaire (appendix 8)

Stamped addressed envelope

7.4. Clinical follow up

Clinical follow up was at 7 weeks after the onset of the index attack of low back pain to comply with the Quebec classification of low back pain (see page 13).

7.4.1. Data recorded at clinical follow up

Data items recorded at clinical follow up are listed in Appendix 1.

7.4.2. Rules for defaulters to clinic

It was anticipated that the majority of patients would be better within six weeks of onset of an attack of low back pain[11]. A significant default rate was thus to be expected. All defaulting subjects were contacted by telephone and given an appointment for the following week's clinic. Those who declined, were not contactable or who were not on the telephone were visited at home during the evening by the study doctor.

7.4.3. Rules for breaches of protocol

Patients in the physiotherapy group were not excluded if they obtained and took non steroidal anti inflammatory drugs but they and their doctors had been told that no non steroidal drugs were to be prescribed. The presence of this contaminating effect was recorded.

Those patients who developed dyspeptic symptoms or who simply stopped their non-steroidal drug prematurely were not excluded but had their "days of drug taken" recorded.

Patients taking non-steroidal anti-inflammatory medicine who obtained help from a physiotherapist or an osteopath during the study were excluded but the number of such patients was documented.

Patients not followed up within nine weeks of onset of low back pain were also documented and excluded from analysis.

Those patients whose diagnosis at first presentation failed to match their clinical state at follow up, such those with nerve root entrapment, were recorded but excluded from the final analysis.

7.4.4. Rules for inadvertent discovery of treatment allocation

Although patients were asked not to indicate the treatment they had been given, this occasionally happened before the point at which the follow up clinic data had been fully collected. These patients were not excluded from the analysis. The incidence of this was recorded.

7.5. Six month follow up

7.5.1. Data recorded at six months

In addition to the St Thomas disability questionnaire and the pain locus of control questionnaire an health services resources utilisation questionnaire was devised (appendix 7).

7.5.2. Administration of postal follow up

The study database was configured to produce reports indicating, in temporal order, the date of the six month and one year follow ups. The secretary at the back research unit sent out the questionnaires with a covering letter and alerted the study administrator if no reply was received within fourteen days of posting. Those patients not returning questionnaires were telephoned or visited at home.

7.6. One year follow up

7.6.1. Data recorded at one year

The same data was collected at a year as at six months.

7.6.2. Stopping rules for one year follow up

Follow up at one year of greater than 90% was chosen as an indication of the possibility of continuing the follow up period usefully to two years.

8. Missing Values

Missing data did not automatically exclude a subject from analysis. The statistical package[168] chosen for the bulk of the conventional statistical analysis enabled the missing values encountered to be recorded and allowed for.

9. Attrition

Aside from contamination, attrition occurred where patients developed different conditions requiring alternative treatment and where patients were untraceable to follow up.

10. Contamination

Was deemed to occur where a patient receiving drug underwent physiotherapy outside the study. Likewise, chiropractor manipulation excluded the patient from analysis.

Patients in the physiotherapy arm of the study receiving non steroidal drug were documented but not excluded.

11. Further episodes of low back pain.

No study subject was permitted to re-enter the study with a subsequent attack of low back pain. Subsequent attacks were recorded in the FU2 and FU3 questionnaires.

13. Rules for dealing with those patients who had not settled within 7 weeks (C2)

13.1. Physiotherapy group:

Further physiotherapy sessions were organised and the patient followed up in the back clinic unless the diagnosis had changed. The number of patients having further McKenzie therapy was documented.

13.2. Non-Steroidal Group:

Physiotherapy consisting of non-McKenzie treatments such as rotation manipulation or traction were used as appropriate. The nature and duration of such treatments was recorded.

14. Diagnosis changed

All subjects who were found on follow up to have another cause for back pain were identified and recorded in the statistical analysis.

15. Identification of confounding factors

A confounding factor is a variable in the sample being studied which has an effect on the outcome of the study but which is not related to the manoeuvre being studied. Three means of allowing for confounding factors are by exclusion; stratification and documentation. Exclusion criteria are set out above. Stratification increases the complexity of the study and, for any given size of sample decreases the power of the study in producing reliable results within each stratum. Where very large sample sizes are employed then stratification may be useful. Stratification was not thought to be beneficial in the pilot study as there was no confounding factor known to exist in the sample with regard to low back pain which is so influential as to require separate consideration (unlike the MRC chiropractory - physiotherapy trial[111]). Extensive documentation was employed in the study to account for known and suspected confounding variables such as educational level; social class and previous attacks of back pain.

16. Outcomes to be studied

Changes in disability scores

Changes in pain responsibility

Frequency of recurrent attacks of low back pain

Requirement for medical and paramedical help

17. Ethical - Data protection issues

The study protocol was given ethical committee approval before the start of the study from the following ethical committees:-

(1) Queen's Medical Centre, Nottingham

(2) Central Nottinghamshire Health Authority, Mansfield.

No patient entered the trial without signing a consent form (see appendix 10) approved by the ethical committee in that centre. The computing aspects of the study with regard to both data collection and data use was approved and registered for the purposes of the data protection act (Number HW0049). Registration was performed at both the Nottingham and the Mansfield centres.

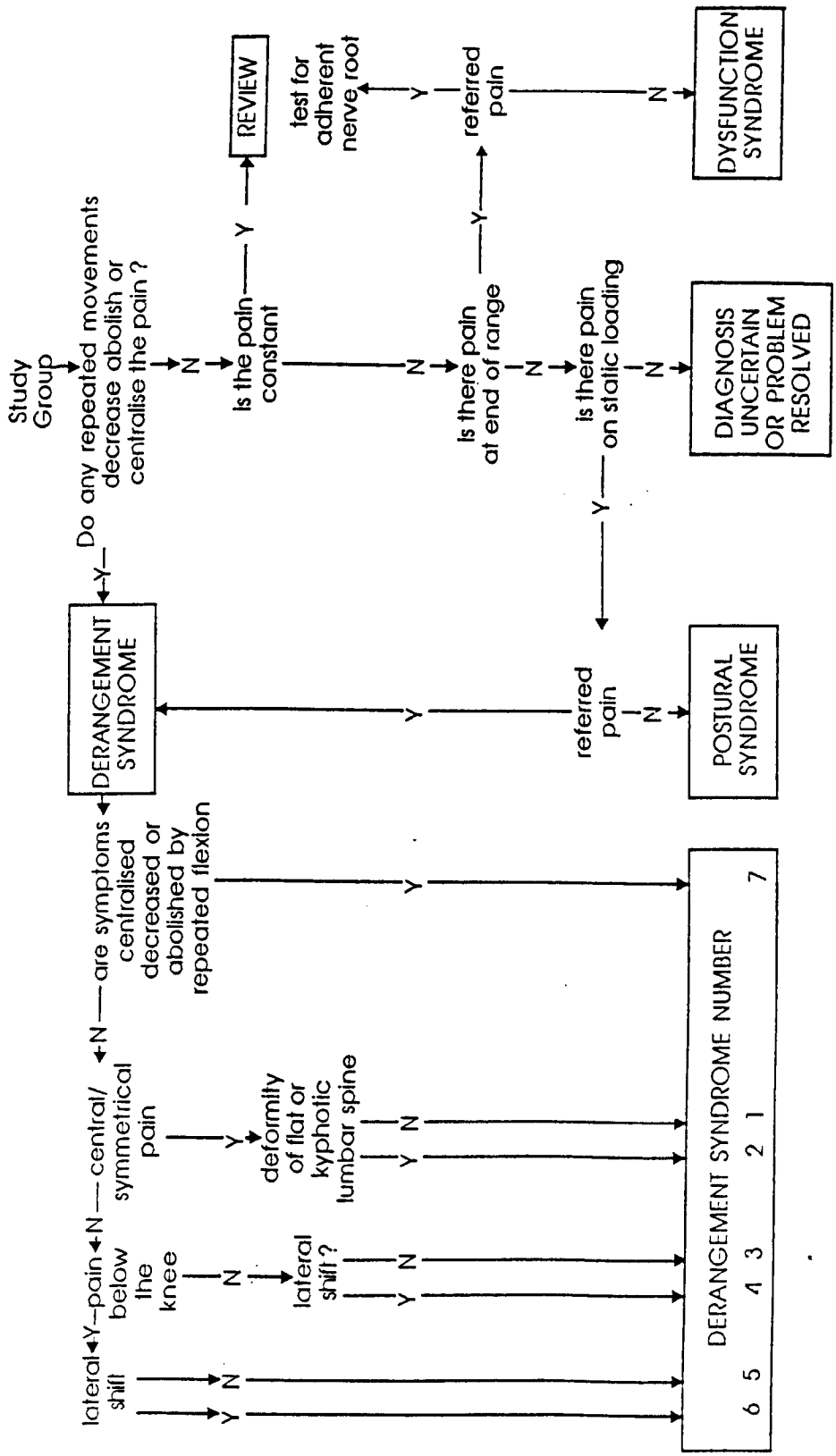
RELIABILITY OF MCKENZIE PHYSIOTHERAPY ASSESSMENTS

1. Introduction

To enable the investigation of physical therapy assessments, a flow diagram, or algorithm, was constructed. The McKenzie regimen was employed to enable physical assessments to be performed with minimal physical contact. A study of correlation between two physical therapists is reported here with precautions against contamination by visual or verbal means. With the exception of the detection of relevant lateral shift and pain at end of range, correlation was 80% or greater. Reducing the seven diagnostic categories of acute mechanical low back pain to five, for the purpose of description, increased diagnostic agreement from 58% to 84%. The McKenzie regimen forms an ideal model for examining and describing methods of empirical mechanical diagnosis by physical therapists.

Research concerning physical therapy for acute low back pain has not yet shown convincing benefit for any form of manipulative method. Some studies found that rotatory manipulation could produce comfort compared with controls but this effect is not lasting[123,169]. The Quebec Task Force on Spinal Disorders[11] could not find an acceptable trial of manipulation or mobilisation which showed scientific evidence of benefit. Difficulties in evaluating physical therapy for mechanical low back pain include the problem of providing satisfactory treatments and the variability of assessments and procedures. Before studies of physical treatments may be described accurately, examination of the assessment method and it's reliability is required. Appreciation of unreliable elements in an assessment method allows research to be focused on areas of inaccuracy and avoids imprecision in reporting methods and results. Considerable work has been performed on the reliability of manual assessment[140]. Unfortunately the complexity of some methods of physical diagnosis prevents the assessment of the diagnostic process as a whole. To enable the investigation of physical therapy assessments a flow diagram, or algorithm, was constructed[170]. The McKenzie regimen was employed to enable physical assessments to be performed with minimal physical contact.

McKenzie diagnostic algorithm



The purpose of this study was to examine the McKenzie method of empirical mechanical diagnosis and to quantify the reliability of various mechanical diagnoses.

2. Materials and Methods

Forty one patients with low back pain referred to the physical therapy department for treatment were chosen. There were no specific inclusion criteria other than the presence of low back pain. Sources of referral included both family and hospital doctors. Twenty three women and 18 men were seen. Their ages varied from 18 to 68 years with a mean of 42 years. the duration of symptoms varied from a few days to years. Both therapists taking part in the study had attended instructional courses organized by the McKenzie Institute (U.K.) and were certified in this form of assessment and therapy. No questioning or examination by the therapists was allowed prior to the start of the correlation studies. The assessments took place in an empty gymnasium without other patients present. An adjudicator was present as well as the therapists and the patient. Physical therapists were randomly allocated to act as assessor or observer. A screen was positioned so that the observer could see the patient but not the assessor. The adjudicator was positioned so as to view the patient and both physical therapists.

The assessor examined the patient, according to the methods described by McKenzie[130]. Standardised forms of questioning were not used as it was felt that this would be too restrictive and artificial. Leading questions were avoided. When the assessor had finished assessing the patient with regard to the algorithm both therapists were instructed by the adjudicator to give an answer to each algorithm question on the path to their diagnosis. Answers were given by means of cards. The assessor was allowed one of two responses (Y or N) whilst the observer was allowed one of three (Y,inconclusive,N). At the time of questioning the therapists were seated on either side of the screen and were instructed not to speak. The observer was always questioned first and could request an amplification of the point under consideration. When therapists disagreed on a point in the algorithm they were not told until after they had reached their respective final diagnoses.

3.1 Statistical analysis of data.

Reliability statistics are more suited to large populations rather than the small numbers generated by questions at the periphery of the diagnostic algorithm. The Kappa statistic was used for those items with twenty pairs of data or more[171,172]. Where there were smaller numbers of pairs, simple percentage agreements were used.

4. Results

Percentage agreement was generally good on all but two points of the algorithm (Table 5). A poor kappa statistic was generated for the question of pain constancy because the almost invariable answer to this item was no. A cumulative error led to a higher level of disagreement in the final diagnosis (Table 6). Some of this was due to one therapist being unwilling to make a diagnosis and placing the patient in a category of diagnosis uncertain rather than a different diagnosis (Table 7). The overall results are presented in three categories with those cases where one therapist was unable to make a diagnosis whilst the other therapist did being itemised separately (Table 8). In those intermediate cases where a definite diagnosis was reached by one therapist and the other categorised the patient as having an uncertain diagnosis a pattern emerged (Table 9). This shows the effect of attitude and philosophy in the interpretation of the algorithm. Therapist 1 tended to categorise patients into an uncertain category when assessing whilst therapist 2 always categorised patients as an assessor and categorised patients into uncertain or resolved less often than therapist 1.

Examining only those patients thought to have a derangement, there was a 53% agreement as to diagnosis. The detection of a relevant lateral shift proved to be little more reliable than chance. If this question was ignored and derangement 6 was amalgamated with 5 and 4 with 3, agreement increased to 83%. Those patients who did not have pain which responded to repeated movements were less reliably classified because of difficulties in detection of pain at end of range of movement. Furthermore those patients with dysfunctional and postural causes for low back pain tended to be the more chronic sufferers where mixed pictures of diagnostic categories were present.

5. Discussion

This work illustrates the difficulty associated with achieving reliable assessments. It may be that the empirical mechanical diagnosis is not closely related to the outcome of therapy but any inaccuracy will make at least a small difference to the efficacy of therapy. In those categories where diagnostic correlation between therapists was poor there are several possible explanations. Certainly the "profile" of pain experienced by a patient through a range of movement is difficult to quantify objectively and is an understandable stumbling block to accuracy. Even methods which rely on telemetry such as recording simultaneous electrogoniometer and grip strength (as an analogue of pain) measurements would require an arbitrary definition of what level of pain is significant and where the "end of a range" of movement starts. This implies that either a radical new method of assessment of end range pain will have to be developed or assessment of this point will remain an art rather than a science. Detection of relevant lateral shift may be more amenable to improvement. Examination of the patient in the prone position would allow the exclusion of structural lists but even postural lateral deviations may not play a part in the mechanical diagnosis and thus exercise prescription.

Whilst an overall level of agreement of 58% may not seem particularly good, there are several reasons why this represents an advance on previous reported methods. Firstly the ability to rationalise an assessment depends upon simplicity which, unlike most other regimens, is possible with the McKenzie method. It is probable that if other methods of empirical mechanical diagnosis could be studied the results would be even less favourable. The highest accuracy was seen in the derangements which tend to be acute mechanical disorders (Quebec type I,II,III, or simple mechanical backache[9]). Those conditions without a favourable response to repeated movement tended to be more chronic conditions where rather than a "pure" single diagnostic category, a mixture was seen. The diagnosis, if one was made, reflected the major component. Furthermore in the chronic patients factors other than mechanical ones are more likely to be present such as social and psychological influences on the patient's response.

The McKenzie regimen represents an ideal empirical mechanical assessment model to enable more rigorous study of physical therapy assessments. With a clearly described method of allocating treatments, increased consistency both in time and between study centres should improve the quality of studies which seek to recruit sufficiently large numbers of patients to achieve results with useful confidence limits. Descriptions of treatments provided may be provided in study results with an indication of the reliability of each diagnostic category.

Correspondence of McKenzie Physiotherapy assessments:
Final algorithm diagnoses.

Diagnoses recorded	Total diagnoses	Cases agreed on	
Review	1	0	
Adherent nerve root	7	1	
Dysfunction	14	5	Note that perfect agreement would lead to exactly twice the number of total diagnoses as cases agreed on.
Diagnosis uncertain or resolved	22	6	
Postural syndrome	2	1	
DERANGEMENTS			
1	12	5	- 5
2	1	0	- 0
3	10	2	
			>- 4
4	3	0	
5	7	3	
			>- 6
6	3	1	
DERANGEMENT	36	11 (61%)	
MODIFIED (5/6 & 3/4)	36	15 (83%)	
TOTAL	82	24 (58%)	
TOTAL MODIFIED	82	28 (68%)	

Table 6 Agreement on algorithm diagnoses

Correspondence of McKenzie Physiotherapy assessments:
Individual algorithm questions

Element of algorithm	No.of times asked	% Agreement	Kappa
Do any repeated movements decrease or centralise or abolish the pain	41	90	.51
Is the pain constant	21	95.2	.00
Pain at end of range	20	70	.00
Referred pain	4	100	***
Pain on static loading	9	100	***
Do symptoms centralise on repeated flexion	16	100	***
Central/Symmetrical pain	15	93.3	***
Pain below the knee	9	100	***
Deformity of flat or kyphotic lumbar spine	5	80	***
Lateral shift	9	55	***

(*** = Numbers insufficient to allow for stable Kappa estimations)

Table 5 Agreement on algorithm questions

Other 'diagnosis'	Cases
Derangement 3 Dysfunction Adherent root Review	2 4 3 1

Table 7 Cases where diagnosis differed with one therapist concluding that the diagnosis was inconclusive or the problem had resolved

Outcome	Number of *Cases*	Percentage
Agreement	24	58
One Therapist Uncertain	10	24
Disagreement	7	17

Table 8 Overall Agreement of diagnosis

Uncertain Therapist	Therapist 1	Therapist 1	Therapist 2	Therapist 2
Acting as -	Assessor	Observer	Assessor	Observer
Cases	4	-	1	5

Table 9 Those cases where one therapist was uncertain

RELIABILITY AND REPRODUCIBILITY OF FLEXIBLE RULER

1. Introduction

Unlike most other physiotherapy regimens, the McKenzie technique lays emphasis on the performance of extension exercises. In order to measure lumbar lordosis a method was required which fulfilled the criteria laid out in Table 10.

1. Simple to apply
2. Repeatable Inter observer
   Intra observer
3. Used in other studies and easily repeated in later studies in other centres
4. Quick and non-invasive
5. Preferably inexpensive

Table 10 Criteria for a measure of lumbar extension

The Following methods were considered (Table 11):

Method	Simple	Repeatable	Used elsewhere	Quick Non-invasive	Inexpensive
Double goniometer	N	Y	Y	Y	N
Ant. Skin Marking	Y	N	N	Y	Y
Post Skin Marking	N	?	N	Y	Y
Kyphometer	N	Y	N	Y	N
Flexicurve	Y	?	Y	Y	Y
Radiology	N	Y	Y	N	N

Table 11 Possible methods of lumbar extension measurement

Method Double Goniometer, Posterior skin approximation[173,174], Flexicurve[175], Radiology[176]. Note this table is a personal judgement as comparable data for all these methods was lacking.

Of all the proposed measurement instruments used in the study, the flexicurve extension measurements seemed to be the least well validated by others and required a validation study in it's own right.

2. Materials and Methods

The studies listed in Table 12 were performed:

Study 1:	Pilot study interobserver agreement
Study 2:	Second interobserver agreement study
Study 3:	Intraobserver study of measuring errors on paper
Study 4:	Intraobserver study of measuring errors

Table 12 Flexible ruler accuracy studies

A flexible ruler (flexicurve) measuring 42.5 cms. was purchased for £2.10 in a stationery shop. It had a cross sectional size of 9mm by 9mm. Ribs intended for drawing against were removed to allow close approximation to the skin. Dimples at 5 cms. intervals were left on one side. A minimum radius of 2 cms could be set in the ruler. Allowing for plastic deformation, the stiffness was found to be in the order of 0.004 NM Deg-1 in the plane of use.

2.1. Study 1 Pilot study inter observer agreement

Three groups of patients were used in a pilot study. They consisted of patients seen in (1) a scoliosis clinic; (2) an adult orthopaedic clinic all of whom were suffering from low back pain and (3) adults being treated for low back pain in a physiotherapy gymnasium. Assessments were performed by two physiotherapists; two consultant orthopaedic surgeons and four junior orthopaedic surgeons. No rules were dictated for use of the instrument which was straightened on a flat surface before being handed to the assessor. The principle investigator (AR) performed the first measurement in each case. The curves were transcribed onto paper and measured by drawing a tangent to the curve with a ruler at each end of the "lordosis" and then measuring the angle between the two lines with a protractor.

2.2. Study 2 Inter observer agreement

The following rules were formulated from the results of study 1 in an attempt to improve accuracy:

[1] The flexicurve should be straightened prior to application on the lumbar spine. this is best done by placing it on the surface of a table.

[2] The patient faces away from the observer with the medial malleoli together and hands resting in the region of the ipsilateral posterior iliac crest; the forearms supinated and the palms against the skin.

[3] The flexicurve is placed so that at least 10 cms. lies below the lumbar dimples of Venus with it's axis along the line of the lumbar spinous processes.

[4] With the fingers of one hand, the observer holds the flexicurve in position, fingers splayed apart to support the instrument throughout the observed lordotic portion of the spine.

[5] Whilst the observers free hand guides the patient into a fully extended position, the instrument hand applies even pressure throughout the length of the instrument covering the lordotic portion of the spine.

[6] Particular care should be exercised when the instrument is removed from the patient's spine with regard to the following points:

[6a] Women wearing brassieres may distort the instrument if it remains lodged beneath the strap or the waistband of the underpants. It is best to expose the natal cleft and support the instrument gently whilst the subject stands extracting the upper half when the erect posture has been regained.

[6b] Any measurements where the subject attempts to increase the lordosis by bouncing into extension should be regarded as spurious and discarded.

[6c] When the patient returns to the erect position, the observer should not be exerting any force tending to alter the curve. In particular, there should be no pressure exerted at each end of the curve or a falsely low reading will be obtained.

[7] Measuring the flexicurve measurement is accomplished by drawing along the convex side of the curve in the region which recorded the lumbar spine profile. The whole length of the instrument should be traced. If the flexicurve has not been straightened prior to application or if the observer has sought to record the profile of the sacral and thoracic region, no definite end-curve areas will be seen and the observation should be repeated.

[7a] Lines are drawn to best fit the end-curve areas of the tracing and the angle of their intersection taken as the lumbar lordotic curve in degrees.

The second study was carried out on patients attending a physiotherapy department and physiotherapy staff. The rules devised from the first study were employed, the technique being otherwise unchanged from study 1.

2.3. Study 3 Intra observer assessment of transcription errors

In order to assess the degree of error in measuring the curves once transcribed onto paper, curves were taken and photocopied twice. On separate occasions separated by more than 24 hours each curve was measured and the measurements compared.

2.4. Study 4 Intra observer study of measuring errors

Using the rules and methods employed in study 2 patients not suffering from back injury or pain and normal volunteers were measured on two occasions separated by more than 24 hours.

3. Results

STUDY	1	2	3	4
Subjects	30	31	16	35
Observers	5	3	1	1
Mean Diff	6.8	5.04	.937	2.68
1SD Diff	4.36	3.39	.854	2.8
%Agreement (1)	84.3	91.5	N/A	93.7

Table 13 Reliability studies (See note 1)

Note 1. As given by $\frac{100 \text{ X Lowest measurement}}{\text{Highest measurement}}$[172]

4. Discussion

Accuracy was improved from +/- 8.73 degrees (2S.D.) to +/- 7.86 degrees by adopting the guidelines set out above. Further improvements in accuracy should have been obtainable by skin marking techniques as used by Burton[175] but the simplicity of the current technique was thought to be valuable. One well organised study[177] has shown that there is no correlation between the lumbar lordosis and low back trouble, but the importance of extension in the treatment under study requires some form of assessment for extension lordosis.

RELIABILITY AND REPRODUCIBILITY OF GONIOMETER

1. Introduction

One of the physical measures of physical impairment used in the study was straight leg raising. This is performed by a variety of methods according to the training of the clinician performing the test. Measurement of the angle of inclination is generally performed by visual estimation at the time the patient experiences discomfort sufficient to preclude further elevation of the leg. In order to examine the errors inherent in the measurement of straight leg raising, a small survey of it's application in twenty five patients was performed.

2. Method

Straight leg raising was performed with the patient supine on a firm clinical examination couch. The leg being elevated with the knee in extension and a gravity goniometer[178] held against the knee by means of a firm velcro strap. The examiner was always on the other side of the patient to the goniometer. An assistant read the goniometer with the hip and knee in extension and the examiner then performed a straight leg raising test. The examiner continued to raise the leg until the patient expressed discomfort or the other knee began to rise off the couch. At that point the assistant was requested to record the goniometer reading. The sequence leg1; leg2; leg1; leg2 was adhered to throughout the survey. The presence of root tension signs and diagnosis was recorded.

3. Results

Twenty five patients were examined providing fifty pairs of results. Comparison of the first and second observations are presented in Table 14.

1st - 2nd reading	Observer A's Left	Observer A's Right	Observer B's Left	Observer B's Right
Mean	-.95	-1	-2.15	1.4
1SD	7.33	5.32	7.07	5.23
Max	18	11	13	11
Min	-13	-8	-18	-8

Table 14 Reliability of straight leg raising measurements

ANALYSIS OF STUDY OUTCOME MEASURE

CORRELATION OF ST THOMAS AND OSWESTRY DISABILITY SCORES

1. Introduction

A small correlation study is reported to indicate the relationship between the Oswestry low back disability questionnaire (see page 173) and St Thomas low back disability scores (see page 172)[159,179].

2. Method

Eighty patients seen in both acute and chronic low back pain clinics were interviewed and given both the St Thomas and the Oswestry Low Back Pain Disability questionnaires. In half of the group the St Thomas questionnaire was given initially and the remainder completed the Oswestry questionnaire first. The only inclusion was that patients had to be currently suffering from low back pain for two weeks or more.

3. Results

Figure 9 shows a plot of the St Thomas and Oswestry scores. It may be seen that the two scores correlate well for lower levels of disability but that for higher levels of disability the St Thomas questionnaire "runs out of descriptive power" leaving the Oswestry questionnaire to record higher levels of disability.

On the basis of this work it was decided that, for the disability levels encountered, the St Thomas questionnaire was adequate. It is less complex and quicker to complete, which is an advantage when seven other psychometric and social questionnaires are to be gathered. Because there are no questions connected with sexual function the St Thomas questionnaire is more acceptable for surveying the "normal population" which is mandatory before any statement concerning disability can be made. Whilst qualms might be expressed about a questionnaire which "runs out of observational power" in it's upper range this is irrelevant to the current study. A sensitive measure of disability

at the borderline of normality is the principle requirement for an instrument to observe the transition from intermittent recurrent low back pain to chronicity.

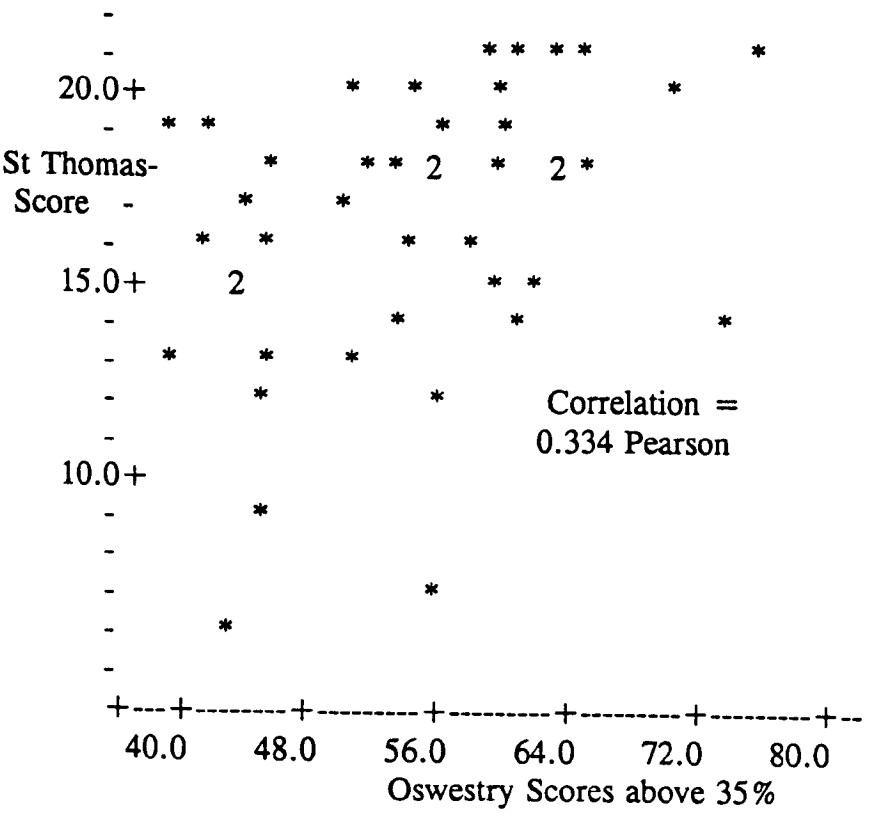


Figure 6 A plot of St Thomas and Oswestry scores in the high range

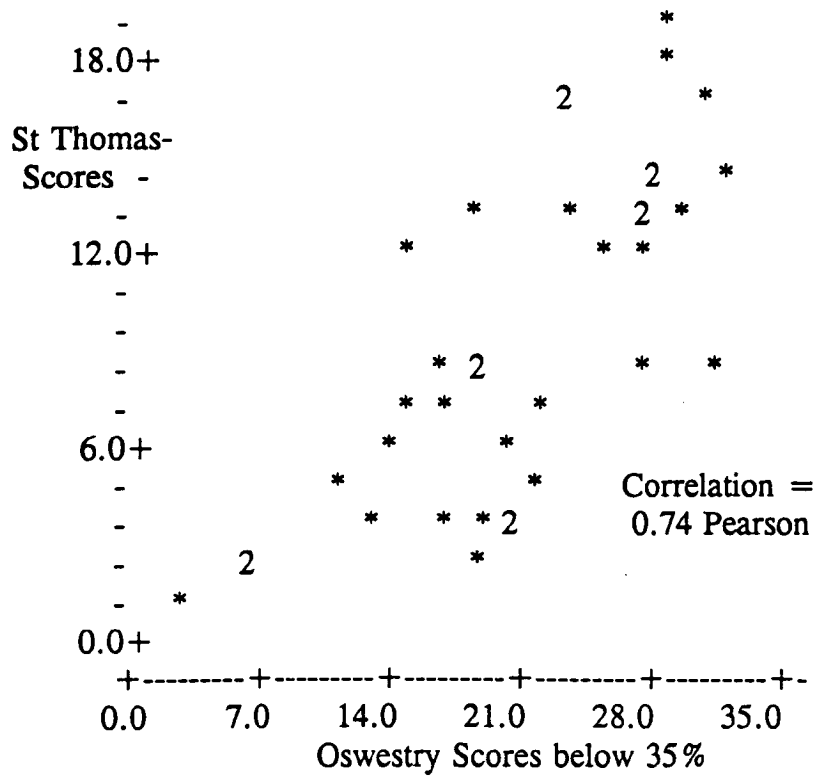


Figure 7 A plot of Oswestry and St Thomas scores in the low range

NORMAL VALUES FOR ST THOMAS DISABILITY QUESTIONNAIRE

1. Introduction

Low back pain is a ubiquitous feature of human existence. Any questionnaire designed to examine the prevalence of this condition in a "normal population" should score significantly[179,159]. Knowledge of the scores obtained from surveying subjects who are not currently seeking or receiving medical help for low back pain is important for deciding on normality values for studies. A survey of 200 "normal" subjects is reported.

The difficulty assessing treatments for acute low back pain is that the natural history of this condition is one of resolution, leaving in the majority of cases, little disability. Any trial has to allow for the relatively small numbers of subjects who are still suffering at the time of follow up. Furthermore the decision as to what constitutes "better" is often arbitrary to say the least. The first difficulty may be overcome with the use of disability questionnaire testing which allows sequential

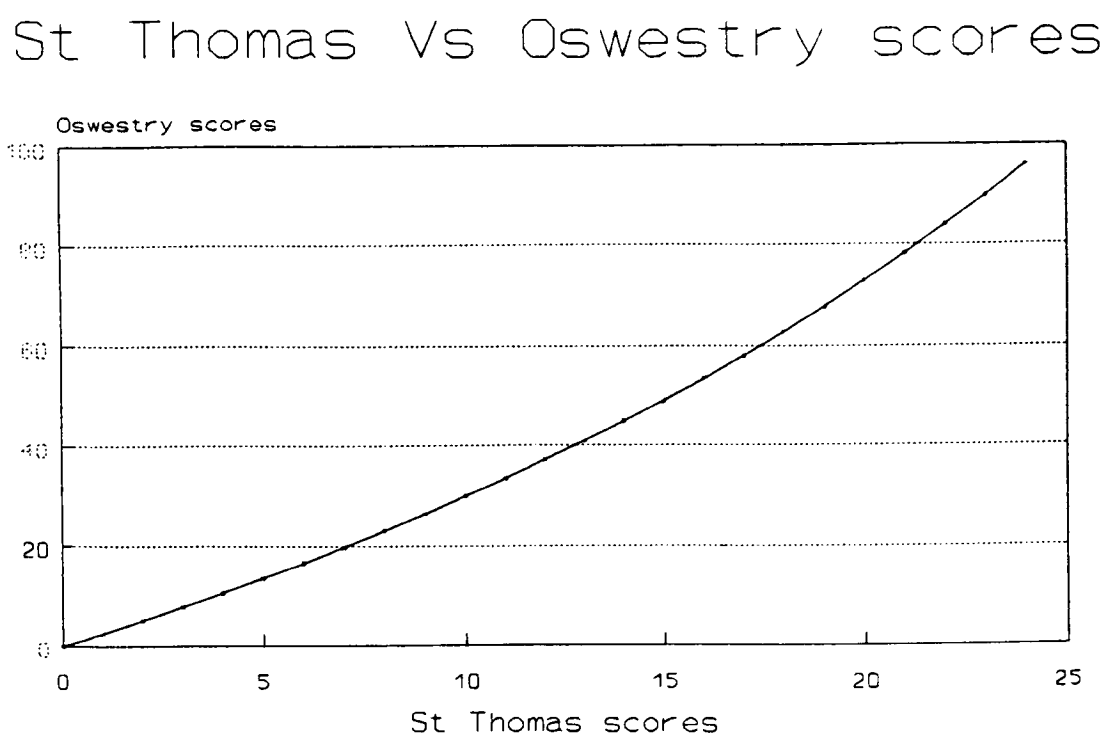


Figure 8 Relationship between St Thomas and Oswestry scores

assessment of the patient as they pass through the recovery process. The gradient of recovery may be observed and gradients for separate populations estimated. The second difficulty of deciding on normality has a statistical basis. Unlike assessment questionnaires such as the Zung modified depression score where a reasonably normal distribution of scores may be observed, back disability scores are measuring a state which is often absent, giving rise to extreme skewing of the results for normal population surveys. Parametric statistics are inappropriate at best and misleading at worse. Naturally, it is possible to present a patient's disability score with the interpretation that the patient's disability is greater than, say, 80% of the surveyed population but this does not contain any concept of normality. For a statement concerning the presence or absence of normality in this context, an informed but nevertheless arbitrary definition must be used.

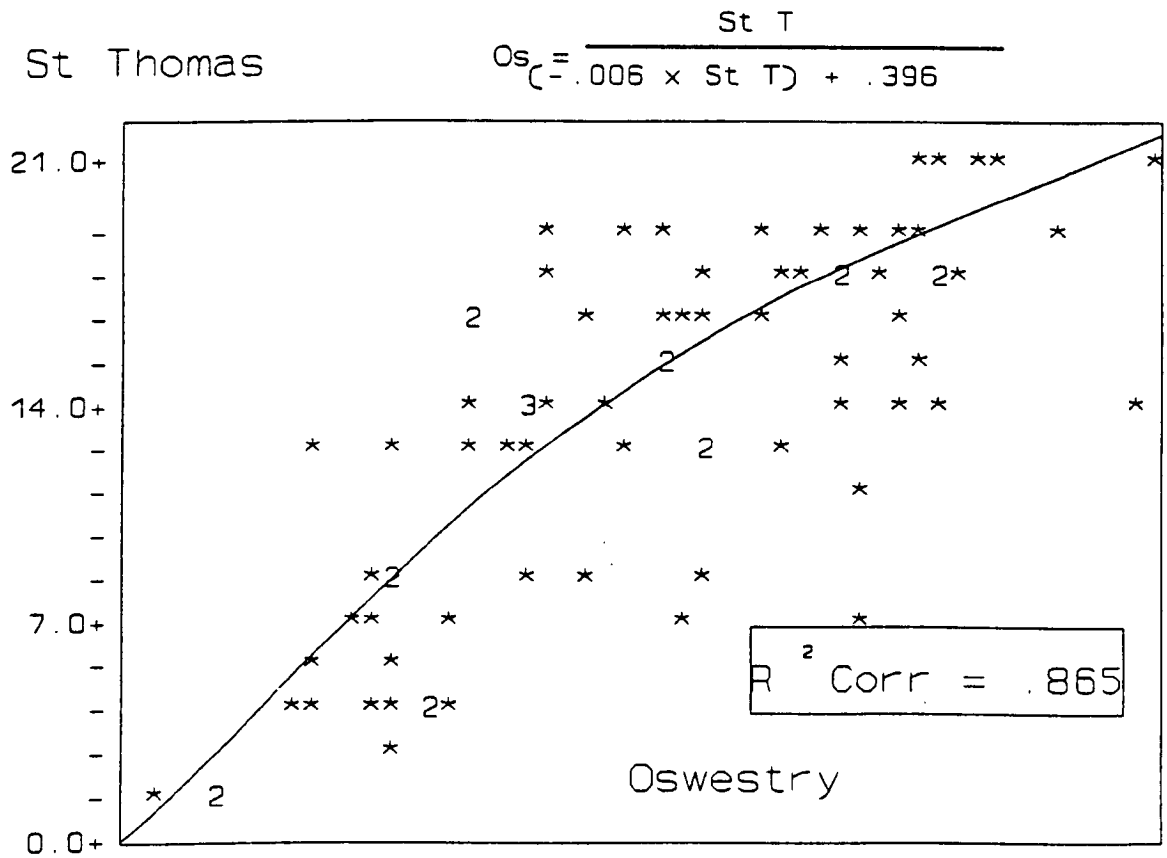


Figure 9 St Thomas - Oswestry correlation: actual data points

The St Thomas low back pain disability questionnaire (see page 172) has been developed and validated for a group of patients who are seeking medical help for low back pain at a primary health care level. Normal values for this questionnaire are not known[180]. The following series of subjects were examined and measured:

2. Materials and Methods

2.1. Survey 1.

One Hundred subjects between and including the ages of 18 and 55 years were provided with St Thomas questionnaires and instructed on how to complete them. Fifty were visitors to the hospital and the remainder were hospital workers. Nursing and medical staff were excluded as were subjects who were currently seeking medical treatment for low back pain. Those subjects who had undergone previous low back surgery but were not currently receiving medical help were also excluded.

2.2. Survey 2.

One hundred subjects between and including the ages of 18 and 55 years were sampled in two groups of 50. All were approached whilst actively walking in a shopping precinct on a Saturday. No resting subjects were approached and after questioning, neither the spouse nor those accompanying were questioned. All subjects were asked their age and whether they were currently seeking or receiving medical help for low back pain and excluded if appropriate. Those who had undergone low back surgery in the past were also excluded. Fifty males and fifty females were questioned.

3. Results:

Surveys 1 and 2.

Of the subjects surveyed in hospital, three refused to help with the study. The results are shown in table 1. A higher rate of refusal to comply was found in the second survey where approximately one in ten of those approached refused to help. The numbers scoring is shown in Table 15.

Score	Survey 1	Survey 2	Survey 1+2(%)
0	66	65	65.5
1	16	14	15
2	1	8	4.5
3	5	4	4.5
4	3	1	2
5	5	2	3.5
6	0	1	.5
7	0	2	1
8	1	0	.5
9	0	1	.5
10	2	2	2
11	0	0	0
12	0	0	0
13	1	0	.5
TOTAL	100	100	100

Table 15 Population values for the St Thomas disability questionnaire

The combined score results show that 94% of the population surveyed had scores of six or less but this would seem to be a rather high level of disability to accept as a normal value. In the absence of statistical methods to handle this data, visual inspection of the data in Figure 10 should allow each investigator to decide on the threshold values for normality and estimate the proportion of the normal population who would fall outside their definition of normality. An exacting definition of normality, to test any treatment rigorously, would be two or less which places 80% of the survey population within normality. This is represented in the graph in Figure 10.

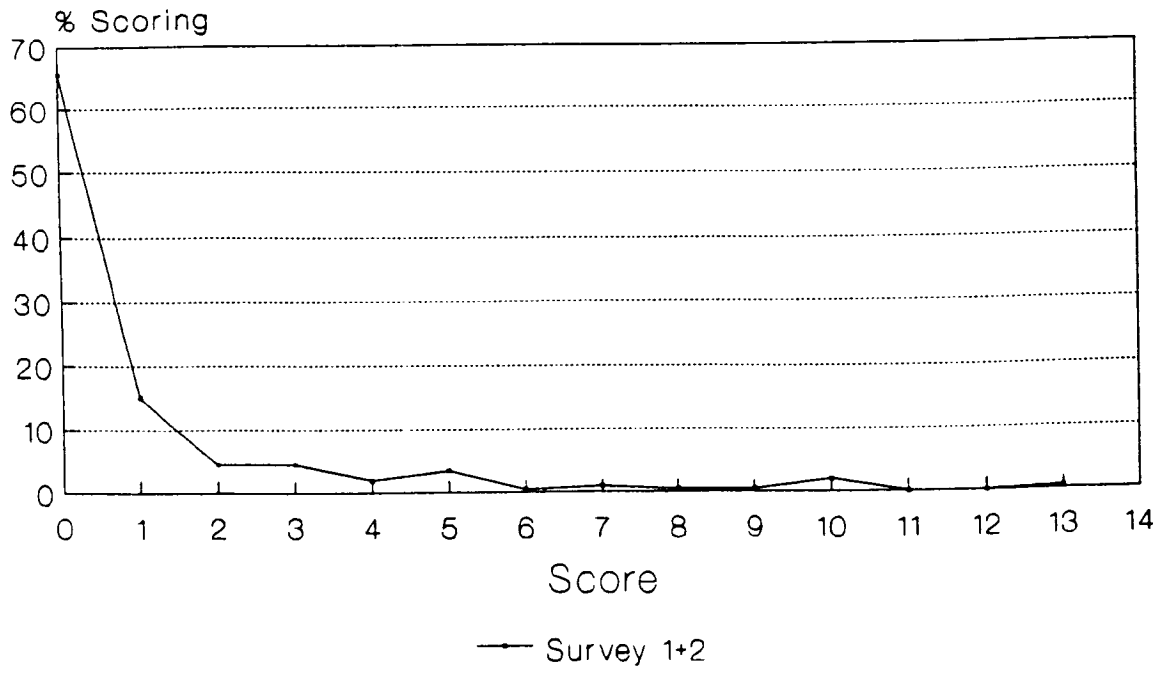


Figure 10 St Thomas scores - Normal values

CORRELATION OF DISABILITY SCORES WITH PSYCHOMETRIC SCORES AND QUALITY OF LIFE ASSESSMENT

1. Introduction

A series of 111 patients presenting to an acute low back pain clinic were assessed using the quality of life assessments advocated by Rosser and Kind[181]. They were then assessed with a battery of psychometric questionnaires including the St Thomas questionnaire; the Modified Zung Depression questionnaire; the Modified Somatic Perception questionnaire and a short form of the McGill Pain questionnaire. The quality of life rating was not used directly, rather the two component scales of distress and disability were examined. All patients included were between the ages of 18 and 55 years and were suffering a new fresh attack of low back pain of less than three weeks duration at the time of consultation.

2. Results

The St Thomas scores correlated poorly with the disability dimension of the quality of life matrix (Pearson = 0.048) and there was no correlation between the 'levels of distress (As assessed by A.R.) and the St Thomas score. Incidentally, there were no other significantly correlating features amongst the psychometric scores used. Either the author was not able to estimate a patient's levels of distress accurately, or those distress behaviours exhibited by the patient are unrelated to the conventional psychometric measures of distress.

For the 58 women surveyed, Their analog pain scales correlated reasonably well with the Zung depression scale and the MSPQ with the McGill pain score. Men showed a different pattern with Zung and McGill scales correlating with the MSPQ but no correlation between the McGill and Zung scales. Unlike the women, men provided visual analog ratings which correlated with their disability scores. Both groups showed a relationship between the distress and the disability scales of the quality of life matrix, but this is probably due to selection bias on the part of the assessor.

The significant relationships between variables in the females are shown in Figure 11.

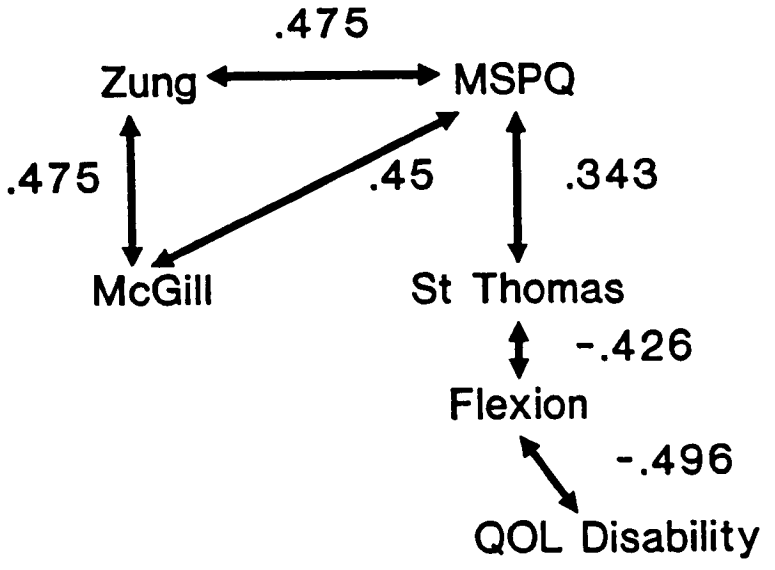


Figure 11 Disability relationships for women

A psychological triad of the McGill pain score, the Zung depression score and the Modified Somatic Perception Questionnaire stands in isolation from the linear group composed of the St Thomas disability score, forward lumbar flexion and the disability component of the quality of life assessment.

For males the relationships found were much more interdependent and extensive but the linear relationship between the St Thomas score, forward lumbar flexion and the disability component of the quality of life assessment persisted (Figure 12). It is interesting that in males a male assessor should be able to evaluate distress in some meaningful way in comparison with more objective measures such as psychometric scores or disability indices. The author's failure to subjectively document distress in women either indicates a failure on the part of the assessor (of the opposite sex) or the lack of any comparable objective measure of distress in the female.

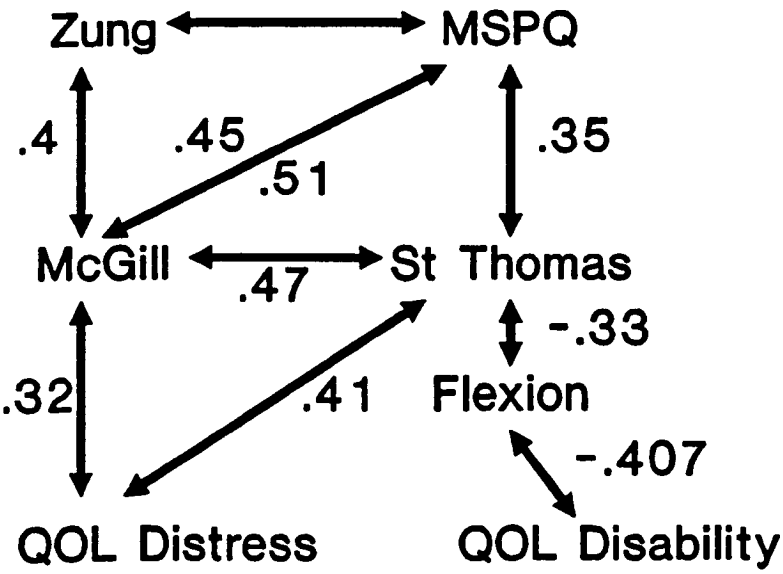


Figure 12 Disability relationships in males

THE MEASUREMENT OF REFERRED PAIN

1. Introduction

To examine the centralisation phenomenon it was necessary to develop a scoring system that would represent centralisation in a numerical form. Attempts have been made to correlate percentage of body area affected by pain with psychological state. The Quebec task force has used the degree of peripheralisation of pain to help classify activity related low back pain[11]. McKenzie uses these same divisions to subdivide his derangement syndrome[130]. The scale of measurement of pain distribution must have the same sign as pain intensity. The distribution score increases if pain spreads distally and reduces if it shrinks to a more proximal position.

2. Scoring system used

Figure 13 shows the pain distribution scoring system. It can be seen that central low back pain only is given a score of 1 (No pain at all is scored 0). Pain radiating from a central position laterally is scored 3. Pain spreading into the buttock above the gluteal fold and or pain felt anteriorly in an area adjacent to the inguinal ligament (such that a hand with fingers pointing infero-medially would have some part of it over the inguinal ligament) is scored as 5. Pain radiating distal to the gluteal fold but above the

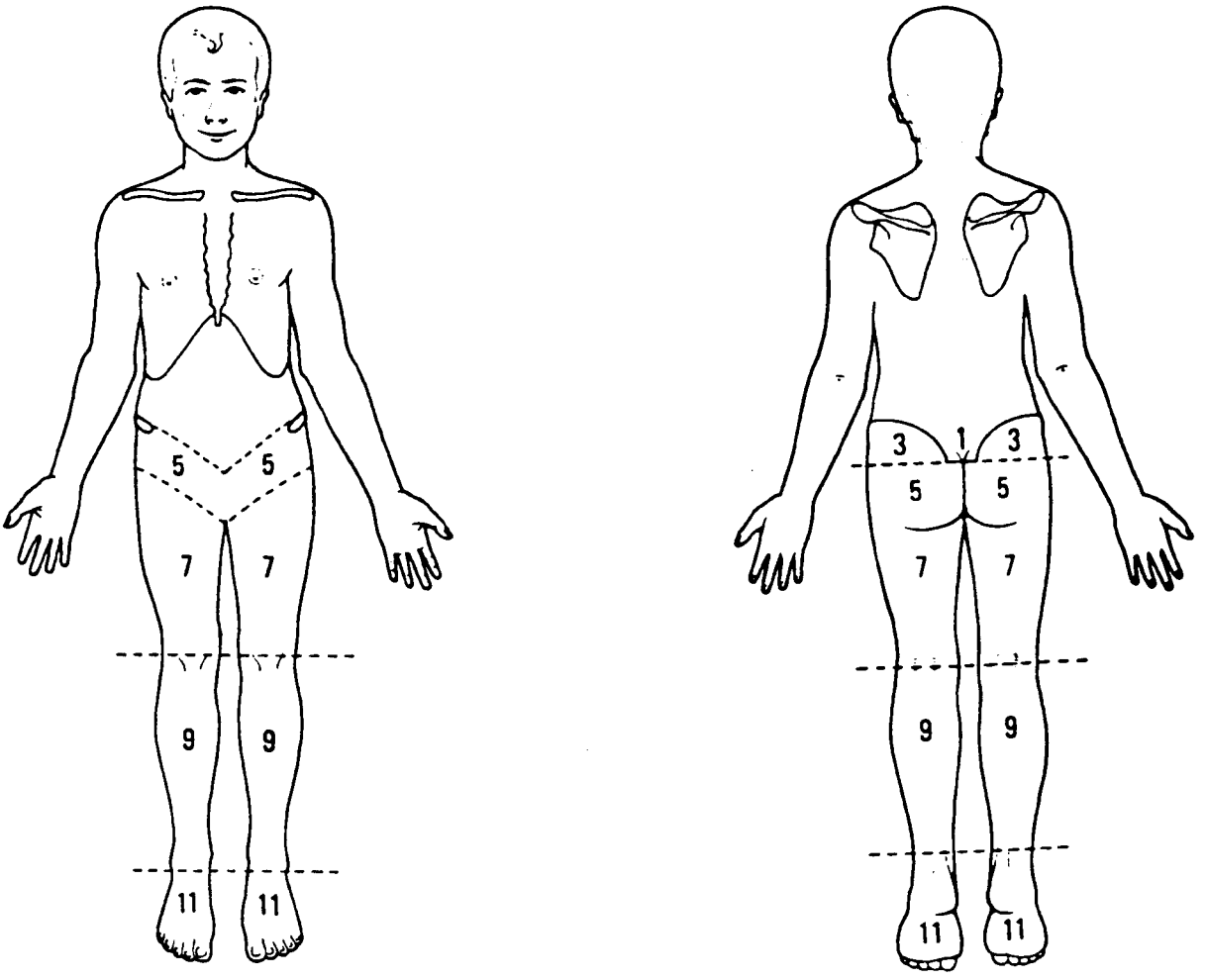


Figure 13 Pain distribution scoring diagram

knee joint line is scored as 7. Pain distal to the knee joint line but proximal to a line joining the malleoli is scored 9 . Pain distal to the line joining the malleoli is scored 11. Only pain in the most distal segment was scored. Bilateral or asymmetrical pain was summated and would always score an even number. Conversely unilateral pain would always score an odd number. It should be noted that for analysis this score, whilst graduated from least to worst pain, is not linear owing to the necessity of recording bilateral symptoms. This method of scoring was originally devised thinking that it would be more difficult to centralise bilateral pain . Experience has shown this is not always the case. Future investigation of pain distribution could be performed by scoring the most peripheral point only. Any attempt at correlating analog intensity scales and

this pain distribution scale has to be performed with mean values for the group rather than on a case by case basis owing to the non linear nature of the pain distribution scale.

Synchronous scoring of pain distribution and intensity allows the relationship between pain intensity and referred pain to be investigated.

3. Method

Pain Intensity was recorded by the patient on a 10 cm visual analog scale. The patient was requested to mark a point on a 10 cm line which would correspond to their current pain intensity. This was performed before treatment commenced and again after treatment on each visit to the physiotherapy department.

Pain distribution scores were also recorded pre and post treatment. These score sheets were completed by the physiotherapist after asking the patient to indicate the most distal pain site experienced at the moment of completing the form. The initial McKenzie syndrome, and any subdivision was recorded after first assessment. The physiotherapists completed their assessment on a diagnostic algorithm described on page 60.

4. Results

Mean pain intensity scores and distribution correlated increasingly well as those patients who were initially undiagnosable; then those who required more than six treatments and finally both groups were removed from analysis. Note that where pain intensity was 0 it had a distribution of 0. This would have led to a spuriously high correlation in groups. For this reason, scores of 0 were excluded from the correlation analysis. The initial pain distribution scores are shown in Table 16 and pain intensity scores in Table 17. The numbers; correlation coefficients and significance of the correlations seen are shown in Table 18. Graphical representations of the relationships of pain intensity and distribution before and after each treatment are seen in Figure 14, Figure 15 and Figure 16.

5. Discussion

There is a definite correlation between pain intensity and distribution. This correlation varies according to whether the patient responded well to McKenzie therapy or not. Those patients who either could not be diagnosed by means of McKenzie's schema or who proved resistant to treatment[ff] were found not to show the strong correlation seen in the group who were diagnosable or were treatable. Pain intensity reduced with time and treatment but the "untreatable" patients continued to suffer from peripheral pain. This dissociation suggests, perhaps, that a group who had unrecognised neurological features remained explaining the peripheral nature of the symptoms in the presence of improvements in intensity.

It is inferred from this finding that linkage between pain distribution in the limb (the arm is assumed to behave in a similar fashion) and pain intensity represents either a neurophysiological or a psychological phenomenon.

On the one hand increasing afferent stimulus, arising from damaged or inflamed structures in or adjacent to the lumbar spine, may lead to recruitment of internuncial neurones in adjacent sclerotomes and myotomes. An increasing pool of excited neurones extending increasing distances from the segment of the original pain stimulus.

A contrary explanation would be that with increasing intensity the patient would extrapolate their pain in terms of body surface area rather than verbally. Against this interpretation are the facts that it was the therapist who filled in the patient's report of pain and that this was done independently of the visual analog scale completion. Also, patients generally describe typical sequential patterns of pain distribution rather than haphazard variations which might perhaps result from cognitive spatial expression of pain intensity.

Insufficient knowledge exists as to the fundamental mechanisms of pain arising from the lumbar spine, in spite of the efforts made, to postulate a physical mechanism for

---

(ff) Required more than six treatments

referred pain. Local spread of chemical pain mediators to other segments is possible but represents armchair science rather than useful speculation at present.

Value	Frequency	Percent
0	6	6.8
1	16	18.2
3	17	19.3
5	4	4.5
6	22	25.0
7	7	8.0
8	1	1.1
9	6	6.8
10	1	1.1
11	2	2.3
12	2	2.3
14	2	2.3

Table 16 Initial pain distribution score on first treatment

Value	Frequency	Percent
0	6	6.8
1	8	9.1
2	10	11.4
3	18	20.5
4	10	11.4
5	9	10.2
6	9	10.2
7	8	9.1
8	7	8.0
9	1	1.1
10	1	1.1

Table 17 Initial pain intensity scores

Group	Number	Correlation	Significance
All patients	89	.48	None
Excluding the undiagnosable patients	74	.57	p= <0.01
Excluding the "untreatable" patients	47	.93	p= <0.001
Excluding the "untreatable" and undiagnosable	44	.98	p= <0.001

Table 18 Correlation between average pain intensities and distributions

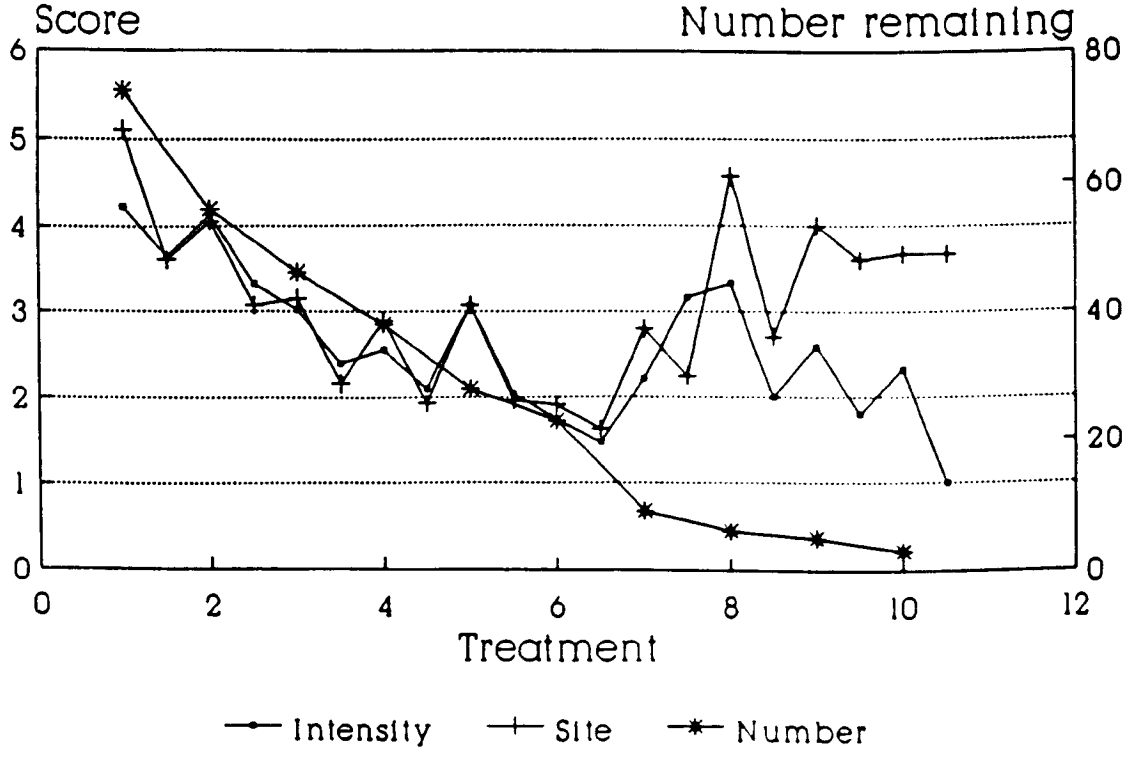


Figure 14 Only diagnosable patients (Correlation = .57 p= <.01)

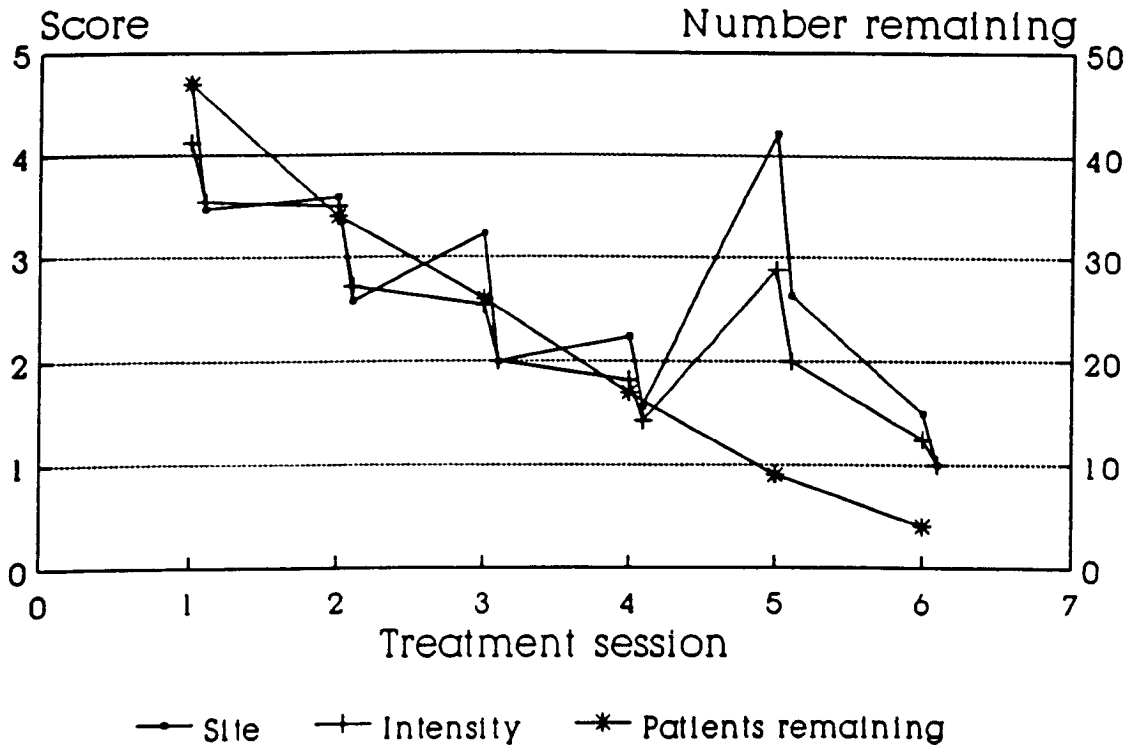


Figure 15 Excluding those requiring 7 or more treatments (Correlation = .93 $p < .001$)

From the table of initial pain distribution it can be seen that certain values occur more frequently than others. It may be expected that the low values on the scale should have the highest frequency, while the highest values occur less often. Some departures from this expected distribution are seen. This is due to the summation of pain distribution scores of asymmetrical and bilateral pain distributions.

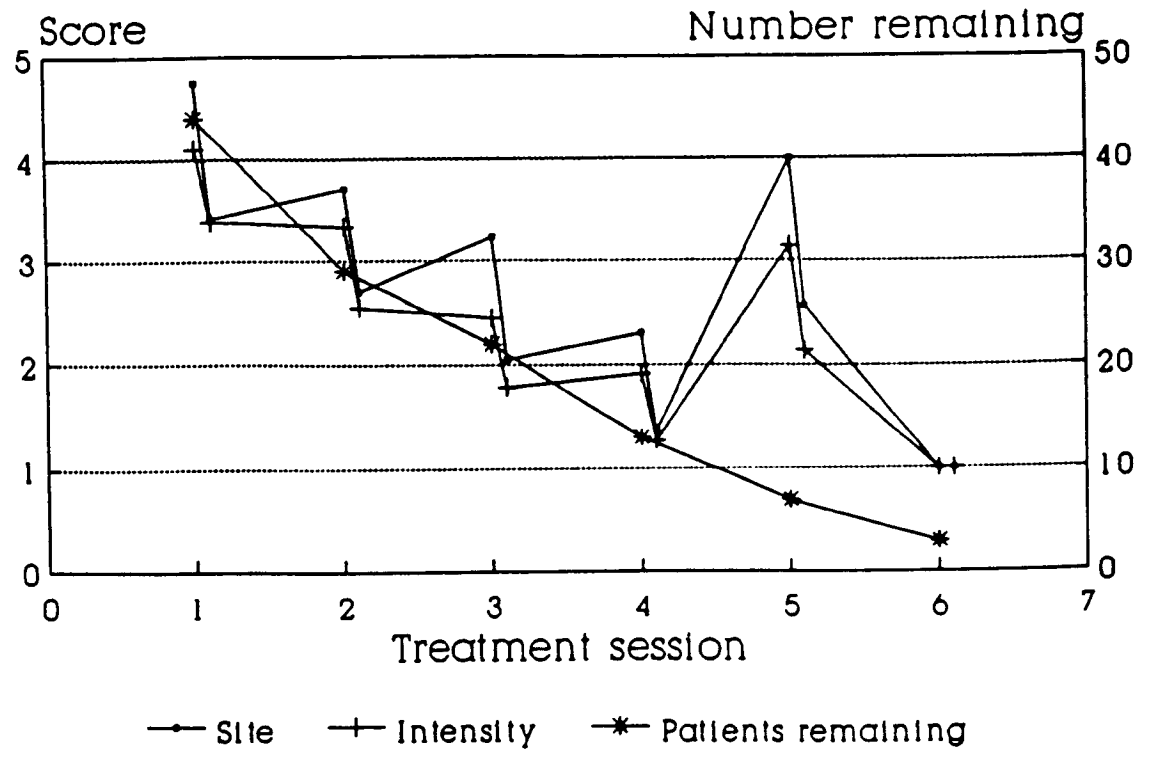


Figure 16 Diagnosable patients requiring 6 or fewer treatments (Correlation = .98 $p < .001$)

STUDY RESULTS

"In physical science a first essential step in the direction of learning any subject is to find principles of numerical reckoning and methods for practicably measuring some quality connected with it. I often say that when you can measure what you are speaking about, and can express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science....[182]

1. Statistical considerations

Criticisms of the use of the chi squared test for the analysis of trial outcome are not without foundation and so this form of statistical analysis has been avoided in the analysis of categorical measures of outcome in the study[183].

The Chi squared test was used however, to examine differences for pretest values of different variables in the drug and physiotherapy groups. Naturally if one examines a sufficient number of variables in an attempt to exclude differences between the two groups, by chance alone, one in twenty of the variables will show a significant difference in the absence of bias in the study design. This is the practical result of stating the value of alpha as being less than 0.05 - the accepted risk of falsely rejecting the null hypothesis is less than one in twenty

Two approaches to outcome assessment and significance testing have been adopted. The first examines the reduction of disability a priori looking at the effect of the interventions in the reduction of disability over the current attack. Whilst it may be said that strongly skewed data should be analysed by means of non-parametric tests the numbers in each of the groups in this study are sufficient to allow examination of the results by parametric methods. Although a t-test could be used in the analysis, the factors which had not been controlled in the randomisation procedure are not easily allowed for. Thus the data will be examined by an analysis of covariance method to use

a regression model of features measured after selection for the study but before randomisation.

A degree of trial and error is required to find the measures which explain the outcome data (other than the allocation of physiotherapy or drug treatment) however the principle is clear. Only those factors which significantly (of F ratio significance $< .05$) explain the outcome variable under consideration are included. This is important, rather than including everything in a large regression model, as with each extra factor included, the degrees of freedom drops by one even if that factor does not "pull it's weight" in explaining the outcome. This leads to different factors being used to explain the difference in outcome when looking at disability scores at seven weeks compared with the change in disability scores or personal responsibility scores.

The Wilcoxon-Mann-Whitney U test was used in the analysis of the Better/Same/Worse outcome measures which are considerably less precise than the disability score assessment.

The second approach is to look only at the outcome rather than progress made towards that outcome. Either the disability score at any point or the proportion disabled at that time may be employed. The latter is difficult but not impossible. As outlined in the philosophical discussion concerning diagnosis on page 5, there is no hard line indicating the boundary of normality however it is possible to examine the community who are not seeing a doctor about low back pain and who have not had a previous spinal operation to discover the distribution of score values. This was done and is presented on page 79. Some inferences may now be made using the same dichotomy of score values from the community not suffering to the two groups in the study as well as between the two groups.

The disability level accepted was a score of 2 or less on the St Thomas disability questionnaire to indicate "normality" and three or more to indicate disability. This places 85% of the community sample in the "normal category and 15% as disabled (a cut off point at the 5-6 level renders 95% of the survey population 'disabled'). The line

is arbitrary, but stringency in allocation of disability has two important consequences. The generally held notion of acute low back pain is that it is a condition which tends to resolve spontaneously. To see whether this is true, it is important to examine the boundary between normality and abnormality in a very detailed fashion. Secondly there is a purely statistical motive in that were the assessment to be concerned with marked disability on a coarse scale - crippled versus not crippled - by seven weeks after onset of low back pain the proportions of patients still disabled would be so small that the prospect of achieving an analysis with any worthwhile power would be diminishingly small (see power table for this study, page 45). The main disadvantage of using proportions disabled as outcome measures is that covariance cannot easily be allowed for. The dramatic influence of depression and heightened somatic awareness on disability outcome seven weeks after onset of pain is thus completely ignored with a resulting degree of clouding of the result.

2. Description of subjects

2.1. Biological differences between groups

The distribution of males and females between the two groups, shown in Table 19. Table 20 shows that there were no significant differences in the ages of patients entering the two groups.

	Male	Female
NSAID	57	28
Physiotherapy	52	37

Table 19 Sex distribution between groups

2.2. Flexion and extension at entry into trial

Years	Mean Age
NSAID	35
Physiotherapy	35

Table 20 Mean age in each group

Neither forward lumbar flexion as measured by the method of McRae and Wright[151] or lumbar extension as measured with the flexible ruler (page 68) showed differences between the two groups (Table 21 and Table 22). Straight leg raising was equally restricted in both groups (Table 23).

Flexion at entry into study	Mean (Cms)	Range (Cms)	Standard Deviation
NSAID	5	7	2
Physiotherapy	5	8	2

Table 21 Flexion at entry into study

Lumbar extension at entry into study	Mean (Degrees)	Range (Degrees)	Standard Deviation
NSAID	41	73	16
Physiotherapy	43	80	15

Table 22 Extension at entry into study

Straight leg raising at entry into study	Left side (Degrees)	Right side (Degrees)
NSAID	64	63
Physiotherapy	64	64

Table 23 Straight leg raising at entry into study

List at entry into study (p=.74 NS)	Left	None	Right
NSAID	10	67	8
Physiotherapy	9	74	6

Table 24 List at entry into study

2.3. Physical impairment at entry into trial

Physical Impairment was calculated according to the method described by Waddell[184] using his formula derived from a regression analysis of the components of physical impairment. As all the patients entered into the trial had no root pain and no history of previous spinal surgery, two of the elements of the formula could be ignored in the calculation. The presence of leg pain along with straight leg raising on left and right hand sides with forward lumbar flexion allowed an estimate of total percentage physical impairment (Table 25). Sex differences were seen in physical impairment (Table 26).

Percentage Physical impairment	Mean	Standard Deviation
NSAID	9.00	7.71
Physiotherapy	8.23	7.11

Table 25 Physical impairment at entry into study

Percentage Physical impairment at entry by sex	Male Mean	Female Mean
NSAID	9.58	7.81
Physiotherapy	7.98	8.59

Table 26 Physical impairment at entry into study - by sex

2.4. Bedrest and disability at entry into trial

Contrary to expectation, there was no gross difference in the disability scores of those patients who rested in bed for two days or more compared with those patients who mobilised sooner. This may be related to the fact that most of the patients were mobile

at the time of entry into the study which could be up to 21 days after the onset of the back pain.

St Thomas disability score at entry into study - relationship with bedrest	Mean (Out of 24)	Standard Deviation
Less than one day in bed	11	6
More than one day in bed	11	5

Table 27 Mean disability score at entry into study - St Thomas.

2.4.1. Bedrest before entry into trial

Patients who had rested in bed for two days or more were evenly distributed between the two groups (Table 28).

Bedrest for more than 48 hours by group	Less than 48 hours	More than 48 hours
NSAID	50	36
Physiotherapy	53	36

Table 28 Bedrest taken before entry into study

2.5. Radiological differences at entry into trial

Lumbo-sacral disc degeneration (Table 29); spondylolisthesis (Table 30); spina bifida occulta (Table 31); sciatic scoliosis (Table 32) and facet joint degeneration (Table 33) were all noted. There was a significantly higher incidence of L5/S1 disc degeneration seen in the non steroidal anti inflammatory group (Chi square = 8.2 p=.004).

Lumbosacral disc degeneration on initial X-Ray by group **(Chi-Square=8.2 p=.004)**	Normal	Degenerate
NSAID	38	35
Physiotherapy	57	18

Table 29 Disc Degeneration at entry into study

Spondylolysis/listhesis by group	No Lysis	Lysis only	Grade I listhesis
NSAID	68	2	3
Physiotherapy	72	2	1

Table 30 Presence of spondylolisthesis at entry into study

Spina bifida occulta (p=.66)	No	Yes
NSAID	68	5
Physiotherapy	72	3

Table 31 Presence of spina bifida occulta at entry into study

Sciatic scoliosis on initial X-Ray (p=.37)	No	Yes
NSAID	85	11
Physiotherapy	85	4

Table 32 Presence of radiological list at entry into study

Facet joint degeneration on initial X-Ray (p=.31)	Normal	Degenerate
NSAID	78	8
Physiotherapy	86	3

Table 33 Presence of facet joint degeneration on entry into study

2.6. Factors explaining disability scores at entry into trial

Disability scores at entry into the study showed no differences between the two groups according to a two tailed T-Test (Table 35). Interesting sex differences were observed

Disability at entry into trial (2 Tailed T-Test p=.61)	Mean (Out of 24)	Standard Deviation
NSAID	11	5
Physiotherapy	11	6

Table 35 Mean disability scores on entry into study

in the explanatory regression analysis of factors contributing to initial levels of recorded disability. Initial St Thomas disability levels were similar in both groups (Mean = 11). Regression analysis indicated that in men initial disability levels depended principally

	Ketoprofen	McKenzie
Expressed plan to return to work	50%	40%
Male sex	67%	58%
Gradual onset	29%	23%
Medico-legal factors	8%	10%
Paid employment	90%	89%
Heavy job	51%	59%
First attack	33%	30%
Clinical lumbar list	22%	16%
Spondyloly/listhesis	5.8%	3.3%
Leg pain	46%	43%
Quebec group I	52%	56%
Quebec group II	36%	35%
Quebec group III	11%	8%

Table 34 Characteristics of patients on entry - categorical data.

on the analog pain score (see Equation (3)). The number of days off work before initial consultation was also indicative of disability to a small extent but cause and effect is difficult to identify in this instance. In women, initial disability was difficult to attribute to any feature except physical impairment as calculated for chronic low back pain according to the method described by Waddell which did explain 17% of the variance seen (see Equation (4)).

$$Disability=(Analog\times 2.2)+(DistressQUALY\times 1.8)+(Zung\times .14)+.257$$

Equation (3) Regression equation for initial male disability

Analog = initial pain scale; Distress QUALY = subjective quality of life assessment for distress and Zung = Zung self rated depression scale score

$$Disability=(Impairment\times .306)+8.3$$

Equation (4) Regression equation for initial female disability

Impairment = Percentage physical impairment

2.7. Differences between psychometric scores for each group

Psychological factors at entry into the trial did not show any large difference in mean values for any of the psychometric scales employed. Both groups showed similar levels of dependency upon psychological measures to reduce their perception of pain (Table 36) and responsibility for pain control (Table 37) as measured by the pain locus of control questionnaire.

Pain locus of control - cognitive control score at entry into trial (p=.95)	Mean	Standard Deviation	Range
NSAID	10	5	20
Physiotherapy	9	5	21

Table 36 Cognitive control scores at entry into study

Pain locus of control - pain responsibility score at entry into trial (p=.95)	Mean	Standard Deviation	Range
NSAID	6	3	11
Physiotherapy	6	3	13

Table 37 Pain responsibility scores at entry into study

Depression scores, one of the two important psychometric scales as regards disability outcome, was equally distributed between groups for males (Table 38). Females had higher levels of depression on average in the drug group than in the physiotherapy group (Table 39) although this was not significant on 2 tailed T-Testing. The other major psychometric predictor of outcome as regards disability was the Modified somatic

Zung self rated depression scale at entry into trial (Males)	Mean	Standard Deviation	Range
NSAID	16	7	30
Physiotherapy	16	10	45

Table 38 Zung self rated depression scale scores at entry into study - males

Zung self rated depression scale at entry into trial (Females)	Mean	Standard Deviation	Range
NSAID	22	9	38
Physiotherapy	18	8	38

Table 39 Zung self rated depression scale scores at entry into study - females

perception questionnaire (Table 40)(Table 41).

The Zung depression inventory was significantly and positively correlated with scores from the Modified Somatic Perception Questionnaire ($r=.57$, $p=<.0001$ SPSS correlation). This correlation is more marked in males than females and explains the sex differences in regression formulae for disability at seven weeks after onset of pain. Neither the modified McGill pain score (Table 42) nor the Analog pain score (Table 43) revealed differences between groups at entry into the trial. The McGill pain score showed a slight trend towards increasing severity with increasing Quebec grades (Table 44).

Modified somatic perception questionnaire (Males) (2 tailed T-Test p=.47)	Mean	Standard Deviation	Range
NSAID	6	4	16
Physiotherapy	7	6	31

Table 40 MSPQ scores at entry into study - males

Modified somatic perception questionnaire (Females) (2 tailed T-Test p=.89)	Mean	Standard Deviation	Range
NSAID	8	7	30
Physiotherapy	8	6	26

Table 41 MSPQ scores at entry into study - females

McGill pain score at entry into study (2 tailed T-Test p=.27)	Mean	Standard Deviation	Range
NSAID	12	8	43
Physiotherapy	12	8	37

Table 42 McGill score at entry into study

Analog pain score at entry into study	Mean	Standard Deviation	Range
NSAID	2	1	4
Physiotherapy	2	1	4

Table 43 Analog pain scale score at entry into study

McGill pain score by Quebec category at entry into study 1 = Back pain only 2 = Back +thigh pain 3 = Back + calf pain	Mean score
1A	11
1B	8
2A	16
2B	13
3A	13
3B	17

Table 44 McGill pain score by Quebec classification groups

2.8. Efficacy of previous treatments

Table 45 indicates the perceived efficacy of treatments previously employed or experienced by those patients experiencing a recurrent attack of low back pain.

	Made worse	No effect	Helpful	Curative	Not tried
Exercises	4	4	6	-	105
Corset	2	4	3	-	110
Analgesics	1	19	29	2	68
Physiotherapy	2	3	10	4	100
Bedrest	5	8	30	13	63

Table 45 Efficacy of treatments used for previous attacks

2.9. Differences in occupational factors between groups

Similar proportions of unemployed subjects were seen in each group (Table 46). The subjects rated their work as heavy in similar proportions in each group (Table 45, Table 47). A higher proportion of the drug group had expressed plans to return to work but this was not significantly different from the physiotherapy group (Table 48).

Employment status	Not employed	Employed
NSAID	8	78
Physiotherapy	9	80

Table 46 Employment status at entry into the study

2.10. Differences in nature of current attack between groups

These were not significantly different between the two groups with regard to rapidity of onset (Table 49); bending or lifting incident (Table 50) or a blow or fall as the identified causal mechanism (Table 51).

Would you describe your job as heavy (p=.308)	Not Heavy	Heavy
NSAID	39	39
Physiotherapy	32	48

Table 47 Self rated description of work - light or heavy

Have you set a date for returning to work (p=.39)	No date set	Date set
NSAID	40	38
Physiotherapy	47	33

Table 48 Expressed intention to return to work

Was the onset instantaneous (p=.48)	Gradual	Sudden
NSAID	25	60
Physiotherapy	21	68

Table 49 Nature of onset of attack

Was the attack precipitated by a bending or lifting incident (p=.77)	No	Yes
NSAID	44	41
Physiotherapy	49	40

Table 50 Nature of precipitating incident - bending or lifting

Did the attack start after a blow or fall (p=.15)	No	Yes
NSAID	81	5
Physiotherapy	77	12

Table 51 Nature of precipitating incident - blow or fall

2.10.1. Proportion of first attacks .

Is this your first attack of low back pain (p=.836)	Recurrence	First attack
NSAID	57	28
Physiotherapy	62	27

Table 52 First attack of low back pain - by group

2.11. Differences in the distribution of pain at onset

Referred pain (p=.903)	No referred pain	Referred pain
NSAID	46	39
Physiotherapy	50	39

Table 53 Presence of referred pain at entry into study

More than half the patients when seen had not experienced referred pain (Table 53) and only a small proportion had experienced pain below the level of the knee (Table 54). An even mixture of Quebec classification diagnoses was seen in the two groups (Table 55).

Presence of pain below knee (p=.54)	No pain below knee	Pain Below Knee
NSAID	75	10
Physiotherapy	82	7

Table 54 Presence of pain below the knee at entry into study

2.12. Litigation in respect of the attack under study

As patients had only sustained their current attack of low back pain in the preceding three weeks there were no established claims being pursued. When questioned directly about their intentions, 16 of the subjects indicated that they were considering making a claim for some form of compensation for their injury (Table 56).

Quebec classification by group	NSAID	Physio-therapy
1A	21	28
1B	25	22
2A	13	15
2B	18	17
3A	4	5
3C	5	2

Table 55 Treatment allocations by Quebec classification

Is a claim to be issued in connection with this incident (p=.868)	No	Yes
NSAID	78	7
Physiotherapy	80	9

Table 56 Medicolegal factors identified at entry into study

2.13. Interference with activities of daily living Table 57

2.14. Age of leaving full time education

School leaving age was recorded to examine the effect of educational attainment on exercise compliance. The group receiving physiotherapy had a mean age of leaving full time education of 15.9 years compared with 16.4 years in the drug patients (2 tailed t-test Sig NS (.058)).

Activity	NSAID % able to	Physio therapy % able to	Chi Square
Car travel - 30 minutes	48	52	.65
Sit - 30 minutes	40	30	.23
Walking - 30 minutes	39	29	.23
Sleeping	30	26	.8

Table 57 Limitation of activity at entry into study

Acute on chronic symptoms (p=.8)	Acute	Acute on chronic
Pain not centralised on first treatment	25	3
Pain centralised on first treatment	57	4

Table 58 Centralisation in acute cases and those cases thought to have a chronic background problem by the physiotherapists

2.15. Mechanical diagnosis and initial response of physiotherapy patients

Centralisation (page 31) was unrelated to the existence of previous attacks of low back pain (Significance = .99 Chi-Square); the presence of calf pain (Significance = .55 Chi-Square) and of thigh pain (Significance = 1.0 Chi-Square). A traumatic onset to the index attack with either a blow to the back or a fall did not correlate with the absence of centralisation (Significance = 1.0 Chi-Square)(Table 59). Likewise, a bending or lifting injury did not correlate significantly with centralisation (Significance = 1.0 Chi-Square). The physiotherapists involved in the study recorded the presence of background chronic pain (the study doctor had not detected this) but this occurred

so infrequently that the numbers are insufficient to draw any conclusions about the likelihood of centralisation in this group (Table 58). The sex of the patient did not affect the likelihood of centralisation on the first visit (Table 60). Whilst it might be expected that the earlier a patient is seen by a physiotherapist the easier treatment will be, this was not borne out in reality.

Did the attack start after a blow or fall (p=1.0)	No	Yes
Pain not centralised on first treatment	24	4
Pain centralised on first treatment	53	8

Table 59 Centralisation and precipitating incident

Centralisation by sex (p=.69)	Male	Female
Pain not centralised on first treatment	15	13
Pain centralised on first treatment	37	24

Table 60 Centralisation by sex and occurrence on first treatment

No striking trend is seen in the number of treatments required by patients before they were discharged from physiotherapy care (Table 61). Those patients who centralised on

their first treatment by the physiotherapist tended to have one of the lesser derangements (1-2) (Table 62).

	Number of treatments (Mean)
Adherent nerve root	5
Derangement 1	6
Derangement 2	6
Derangement 3	6
Derangement 4	6
Derangement 5	7
Derangement 6	6
Derangement 7	4
Dysfunction	5
Diagnosis uncertain	6

Table 61 Number of treatments required for each McKenzie diagnostic category

There was a slight tendency for the patients who centralised or experienced reduction of their pain on the first physiotherapy treatment to have lower levels of disability on the St Thomas disability score (10.4 as opposed to 12.5) but this was not significant when examined with a two tailed T-Test (P=.078). The physiotherapists identified three patients who they felt that the back pain was not of lumbar spine origin and these three did not centralise or experience a reduction in their pain on the first visit (Chi square = 3.8 Significance = .049). It must be noted that the physiotherapists would have used the lack of centralisation in their assessment to confirm that the patient's condition was not a derangement. Whilst centralisation is not seen in conditions causing pain from outside the lumbar spine, not all spinal pain is characterised by centralisation. A degree of bias is thus quite possible in the physiotherapists assessment of the site of origin of the patient's symptoms.

Pain centralised or abolished on first treatment	No	Yes
Adherent nerve root		1
Derangement 1	7	30
Derangement 2	3	2
Derangement 3	3	19
Derangement 4		2
Derangement 5	4	5
Derangement 6	1	
Derangement 7		1
Dysfunction	2	1
Diagnosis uncertain	8	

Table 62 Centralisation on first treatment by McKenzie diagnostic category

McKenzie diagnosis	Mean Flexion (cms)
Adherent nerve root	6
Derangement 1	5
Derangement 2	4
Derangement 3	5
Derangement 4	3
Derangement 5	5
Derangement 6	7
Derangement 7	4
Dysfunction	8
Diagnosis uncertain	5

Table 63 Flexion at entry into study by McKenzie diagnostic category

There was no difference in mean age of those patients who centralised on their first visit to the physiotherapist and those patients who did not (Significance = .49).

	St Thomas disability score (Mean)
Adherent nerve root	5
Derangement 1	11
Derangement 2	13
Derangement 3	12
Derangement 4	11
Derangement 5	11
Derangement 6	7
Derangement 7	11
Dysfunction	7
Diagnosis uncertain	11

Table 64 St Thomas disability score by McKenzie diagnostic category at entry into study

	1A	1B	2A	2B	3A	3B
Adherent nerve root			1			
Derangement 1	15	13	2	4	3	
Derangement 2	1	1	2	1		
Derangement 3	5	5	5	5	1	1
Derangement 4	1			1		
Derangement 5			5	2	1	1
Derangement 6	1					
Derangement 7	1					
Dysfunction	1	1		1		
Diagnosis uncertain	3	2		3		

Table 65 Quebec classifications by McKenzie diagnostic categories

2.16. Behaviour of symptoms during physiotherapy treatment

A close correlation was observed between patients referred pain distribution and pain intensity (see page 88).

	Age (Mean)
Adherent nerve root	23
Derangement 1	34
Derangement 2	33
Derangement 3	37
Derangement 4	40
Derangement 5	36
Derangement 6	31
Derangement 7	31
Dysfunction	42
Diagnosis uncertain	30

Table 66 Age by McKenzie diagnostic category

Attacks suffered in past year	(Mean)
Adherent nerve root	1
Derangement 1	1
Derangement 2	1
Derangement 3	1
Derangement 4	1
Derangement 5	1
Derangement 6	2
Derangement 7	2
Dysfunction	0
Diagnosis uncertain	2

Table 67 Frequency of attacks over year preceding entry into study by McKenzie category

Did the attack start instantaneously	Gradual onset	Sudden Onset
Adherent nerve root		1
Derangement 1	9	28
Derangement 2	1	4
Derangement 3	5	17
Derangement 4	1	1
Derangement 5	1	8
Derangement 6		1
Derangement 7		1
Dysfunction	1	2
Diagnosis uncertain	3	5

Table 68 Rapidity of onset of attack by McKenzie category

3. RESULTS - Seven Weeks

3.1. Attrition at seven weeks

By seven weeks after onset of pain, 175 of 180 patients were examined and assessed. One patient was untraceable whilst another had developed a fifth lumbar nerve root entrapment. One McKenzie physiotherapy patient and two NSAID patients had undergone physiotherapy outside the study and were thus excluded. These patients are detailed below:

Patient number 11: Allocated to drug treatment but decided to arrange private physiotherapy as she was not improving. (Contamination)

Patient number 27: Allocated to physiotherapy but wished to have physiotherapy at a private hospital near to his home. (Non-compliance)

Patient number 34: Allocated to physiotherapy but developed an L_5 root entrapment between randomisation and follow up eventually requiring surgical decompression. (Changed diagnosis)

Patient number 102: Patient allocated physiotherapy but wanted to have physiotherapy privately. (Non-compliance)

Patient number 110: Allocated to drug treatment but did not attend for follow up and had moved from his initial address. Extensive attempts to track the patient failed. (Lost to follow-up)

3.2. Missing case analysis at seven weeks

Analysis at seven weeks does not show any difference of note although the small number of missing cases makes analysis difficult.

Those patients left consisted of 109 men and 66 women with a mean age of 35 years. Of the patients reviewed at seven weeks, 86 had received ketoprofen and 89 had undergone McKenzie treatment. Eight (8.9%) of the physiotherapy patients had been

undiagnosable according to the diagnostic algorithm on their first assessment by the study physiotherapists.

3.3. Compliance at seven weeks

3.3.1. Compliance with physiotherapy

The average number of treatments for each McKenzie diagnostic category in shown in

	Number	Treatments (Mean)
Adherent root	1	5
Derangement 1	37	4.4
Derangement 2	5	6
Derangement 3	22	4.5
Derangement 4	2	6
Derangement 5	9	7.2
Derangement 6	1	6
Derangement 7	1	4
Dysfunction	3	5
Diagnosis uncertain	8	5.8

Table 69 Mean treatments for each McKenzie category

Table 69. Although numbers are small, an uncertain diagnosis did not lead the physiotherapists to see patients more often. Derangements 6 and 7 had only one patient in each and no conclusions can be drawn regarding ease of treatment for these patients. Of the remaining derangements, derangement 5 required most treatments although it is unclear whether the physiotherapists were mis-treating derangement 6 on the basis of initial incorrect assessment (see page 61) or whether the more distal pain presentation simply takes longer to correct. Twelve of the physiotherapy patients defaulted from treatment although they were all contacted for follow up. They had had an average of two treatments at the time of defaulting.

3.3.2. Compliance with non steroidal anti inflammatory drug

In the advice sheet for patients in the drug arm of the trial, there was a paragraph indicating that if the patient experienced dyspeptic symptoms, they should stop the ketoprofen. At seven week follow up the remaining ketoprofen was reclaimed in it's blister pack to ascertain compliance (Table 70). Dyspeptic or allergic symptoms thought to be related to the drug were recorded. Of 86 patients taking drug 23 noted dyspeptic symptoms. Two patients reported an allergic reaction to the drug but no confirmation of the validity of that claim was available. The presence of either dyspepsia or an

	Cumulative percentage
One week or less	20
Two weeks or less	30
Three weeks or less	43
Less than four weeks	50
Full course	100

Table 70 Compliance with non steroidal anti inflammatory drug

allergic reaction led to the patients discontinuing their medication as advised (12 days mean drug usage as opposed to 21 days, 2 tailed T-Test $p < .0001$).

3.4. Physical measures of outcome

Forward lumbar flexion was found to improve to a greater degree with McKenzie treatment than with ketoprofen (Table 71). An analysis of covariance using initial flexion showed this difference to be significant (Anova SPSS, Significance of $F = .003$). Lumbar extension (Table 72) was increased significantly more in the McKenzie group than in the ketoprofen group when the initial level of extension was allowed for using an analysis of covariance (Anova SPSS, Significance of $F = .002$). Straight leg raising improved with both treatments, there being no significant difference between the two groups (Table 73 and Table 74).

Forward lumbar flexion at seven weeks 2 tailed T-Test p=.002)	Mean (Cms)	Standard Deviation	Range (Cms)
NSAID	6.5	1.32	7
Physiotherapy	7.13	1.32	7

Table 71 Flexion at seven weeks

Lumbar extension at seven weeks (2 tailed T-Test p=.002)	Mean (Degrees)	Standard Deviation	Range (Degrees)
NSAID	50	16	88
Physiotherapy	57	14	84

Table 72 Lumbar extension at seven weeks

Left sided straight leg raising at seven weeks (2 tailed T-Test p=.44)	Mean (Degrees)	Standard Deviation	Range (Degrees)
NSAID	74.4	15	79
Physiotherapy	76	12	52

Table 73 Left sided straight leg raising at seven weeks

There was a tendency for the patients with a traumatic onset to their attack to have a poorer outcome in terms of disability at seven weeks (Table 75). With a two tailed T-Test showing no significant difference (p=.146). Interestingly the difference in response was more noticeable in the physiotherapy group (p=.104) than in the drug group (p=.505) indicating the possible different modes of action of the two treatment modalities with non-steroidal playing a part in the treatment of generalised inflammation

Right sided straight leg raising at seven weeks (2 tailed T-Test p=.074)	Mean (Degrees)	Standard Deviation	Range (Degrees)
NSAID	74	14.2	68
Physiotherapy	78	10.9	58

Table 74 Right sided leg raising at seven weeks

following tissue trauma and the McKenzie physiotherapy acting on annular tears (if indeed a bending or lifting incident is indicative of annular damage). None of the patients who the therapists were uncertain about as regards diagnosis had sustained their back pain as a result of a blow or fall.

Disability by type of precipitating incident	Cases	Mean (Out of 24)	Standard Deviation
Blow or fall	17	4.705	6.04
Bending or lifting	157	3.06	4.19

Table 75 Outcome at seven weeks by nature of precipitating incident

Examination of perceived progress over the first seven weeks after onset of low back pain by patients was examined using the Mann-Whitney statistic for the better/same/worse outcome. There was no significant difference between groups when this rather coarse analysis was employed (p=.097) although the trend favoured physiotherapy. Dichotomising the disability scores also led to a loss of information regarding outcome with no significant difference between the two groups (Table 76). Disability at seven weeks following onset of low back pain was examined to identify important covariates which could help to explain differing levels of disability. This was performed with a stepwise regression analysis using the SPSS PC+ statistics package examining men and women separately.

Disability at seven weeks dichotomised at the 2-3 level	Disabled (%)	Normal (%)
NSAID	21.1	28
Physiotherapy	20.6	30.3

Table 76 Disability dichotomised - seven weeks

3.5. An explanation of disability at seven weeks

Disability seven weeks after onset of low back pain depended heavily upon initial psychological factors in both men and women.

3.5.1. Regression equation for females

The regression formula to explain disability is different to the one derived for men. Again the SPSS PC+ stepwise method was used (Equation (5)).

$$Disability=(MSPQ\times.305)+(Zung\times.222)+(IntDisab\times.272)-5.83$$

Equation (5) Regression equation for female disability at seven weeks
IntDisab = Disability recorded at entry into study

For women, as men, the modified somatic perception questionnaire provided the major explanation of variance (Adjusted R^2 = .37) but the other explanatory variables were not common with men. Depression as measured by the Zung depression scale was a separate element to the full regression model because the linear association seen very clearly in men between high levels of somatic perception and depression were not encountered in women. Initial disability levels were also important. The final model gave an explanation of 57% of the variance in disability in women even after correction for shrinkage.

3.5.2. Regression equation for males

Regression analysis to examine the components of disability at seven weeks following onset of low back pain in men was performed using the stepwise regression method in the SPSS PC+ statistics package (Equation (6)).

$$Disability=(MSPQ\times.304)+(Zung\times.113)-1.058$$

Equation (6) Regression equation to explain male disability at seven weeks

MSPQ = Modified Somatic Perception Questionnaire Zung = Zung Self Rated Depression Scale

In men variation in the modified somatic perception questionnaire, which was closely correlated with the Zung depression scale, explained a third of the variance in eventual disability (Adjusted $R^2=.32$). Days off work at the time of initial consultation slightly increased the power of the model to explain disability at seven weeks after onset of low back pain. The data collected at the outset of the study allowed a much better explanation of the disability seen in women compared with the men. This is inspite of the larger numbers of men in the study. One possible cause of this difference is that occupational factors play a more important part in explaining male disability. As most of the occupational information was of a categorical nature, a regression model is not naturally suited to examine these variables however by substituting dummy variables (0=light work, 1=heavy work) the influence of some occupational factors could be examined. No further understanding of disability was gained by these means.

The design of the study had not allowed for these psychological variables by means of

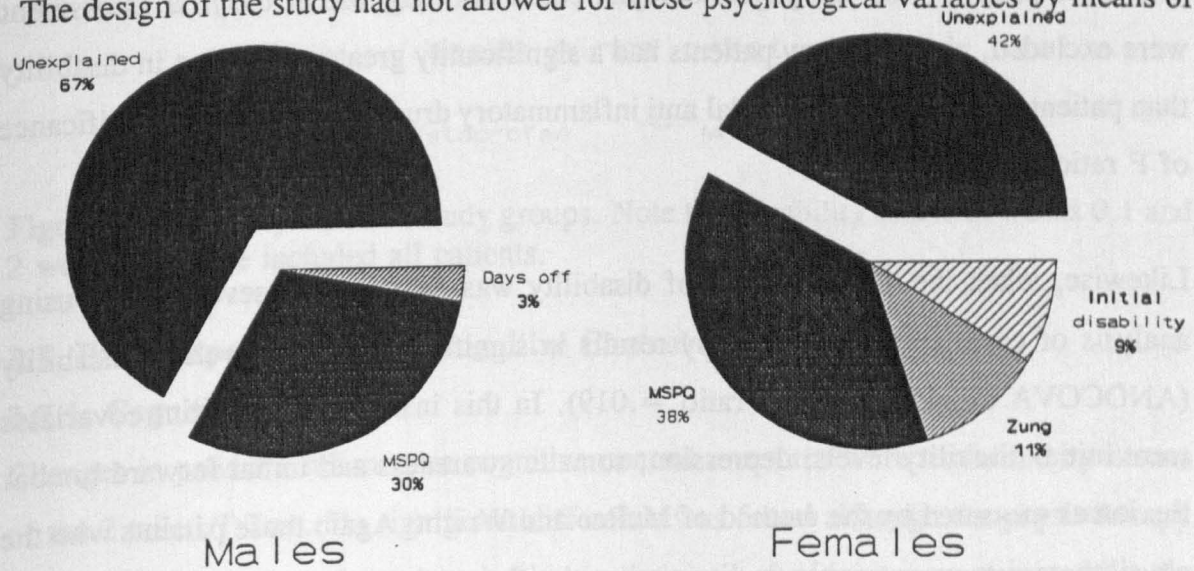


Figure 17 Explanation of variance of disability at seven weeks by regression analysis by sex.

stratification. Men and women were combined allowing identification of the the two features which explained disability at seven weeks best. These were the Zung depression

score and the modified somatic perception questionnaire. Disability at seven weeks after onset of pain was examined by means of analysis of covariance to allow for the lack of stratification with respect to psychological features which have such an important effect on outcome.

3.6. Disability analysis at seven weeks

Disability measures for all patients in the study were only available from the third week after onset of pain. Both groups showed a marked trend towards resolution (Figure 18). Examination of the disability levels at seven weeks shows lower levels in the physiotherapy group (Table 77).

The St Thomas Disability score at entry into the trial; the Modified Zung depression inventory at entry and the Modified Somatic Perception Questionnaire were found to act as significant covariates in the analysis of variance in disability changes between entry into the trial and the seven week follow up. The difference between the two groups was not significant (ANOCOVA SPSS, Significance of F ratio = .09).

When the patients who the physiotherapist could not diagnose at the *first* assessment were excluded, physiotherapy patients had a significantly greater reduction in disability than patients receiving non steroidal anti inflammatory drugs. (ANOCOVA Significance of F ratio = .034).

Likewise, when the absolute level of disability was examined at seven weeks using analysis of covariance physiotherapy results in significantly lower levels of disability (ANOCOVA Significance of F ratio =.019). In this instance the relevant covariates were initial disability levels; depression; somatic awareness and initial forward lumbar flexion as measured by the method of McRae and Wright. Again those patients who the physiotherapists were unable to diagnose at the *first* visit were excluded.

Disability at seven weeks	Mean (Out of 24)	Standard Deviation	Range
NSAID	4	5	22
Physiotherapy	3	4	22

Table 77 Disability - St Thomas - at seven weeks

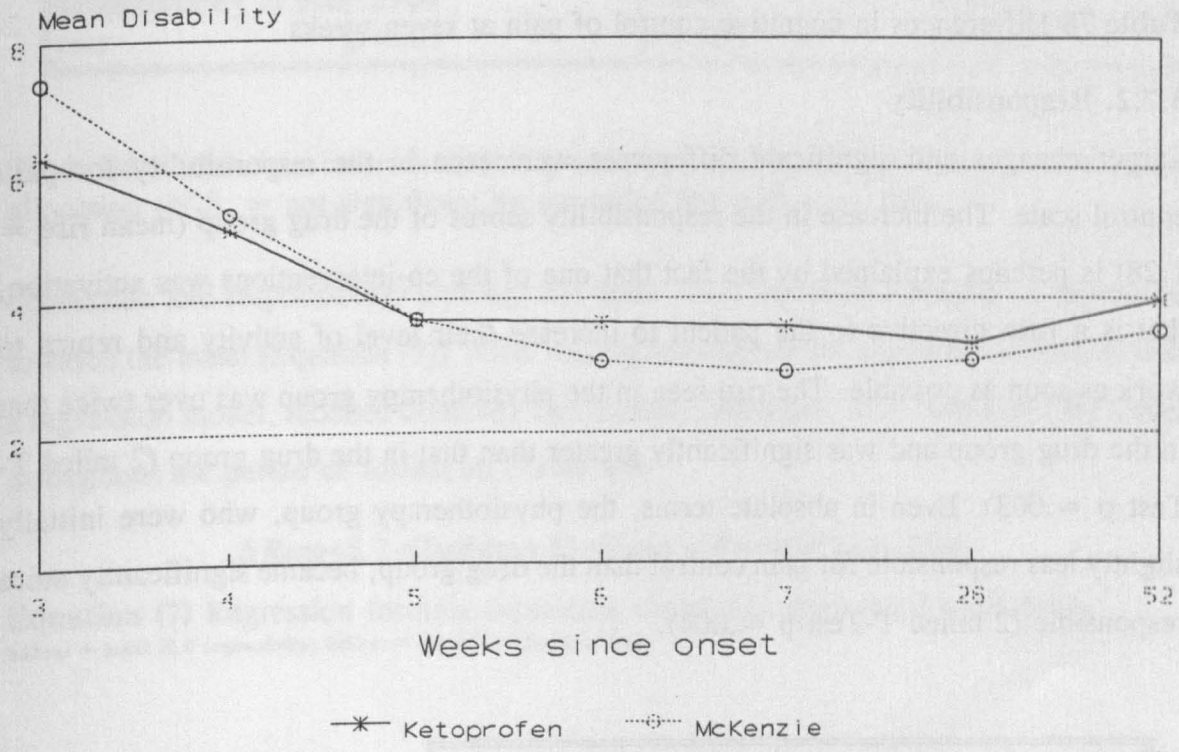


Figure 18 Disability levels in study groups. Note that disability scores at weeks 0,1 and 2 would not have included all patients.

3.7. Pain Responsibility and Cognitive Control score changes

3.7.1. Cognitive control

Changes in patient's reliance on cognitive control measures were examined by means of the 2 tailed T-Test. No significant difference was found although the physiotherapy patients tended to experience a reduction in their use of cognitive measures whilst the drug patients increased their reliance on physical means (2 tailed T-Test p = .145). The magnitude of the change seen was not large.

Pain locus of control score changes from entry to seven weeks - Cognitive control	Mean change	Standard Deviation
NSAID	.714	4.93
Physiotherapy	-.376	4.74

Table 78 Differences in cognitive control of pain at seven weeks

3.7.2. Responsibility

Larger changes and significant differences were seen in the responsibility for pain control scale. The increase in the responsibility scores of the drug group (mean rise = 1.28) is perhaps explained by the fact that one of the co-interventions was activation, that is a firm directive to the patient to increase their level of activity and return to work as soon as possible. The rise seen in the physiotherapy group was over twice that in the drug group and was significantly greater than that in the drug group (2 tailed T-Test p =.003). Even in absolute terms, the physiotherapy group, who were initially slightly less responsible for pain control than the drug group, became significantly more responsible (2 tailed T-Test p =.004).

Pain locus of control changes from entry into study to seven weeks - pain responsibility	Mean change	Standard Deviation
NSAID	1.11	2.78
Physiotherapy	2.37	2.59

Table 79 Differences in pain responsibility at seven weeks

A search for the important factors in the increase in personal responsibility for pain was performed using multiple regression with dummy variables substituted for categorical data such as sex. The important factors were initial levels of cognitive control;

Correlations Pearson r	Disability at seven weeks	Disability at six months	Disability at one year
Initial responsibility	-.3321 p<.01	-.2191 N.S.	-.2529 N.S.
Responsibility at seven weeks	-.4760 p<.001	-.1716 N.S.	-.2722 p<.001
Responsibility at six months	-.2133 N.S.	-.5081 p<.001	-.5202 p<.001
Responsibility at one year	-.2908 p<.01	-.3948 p<.001	-.4443 p<.001

Table 80 Correlations between disability and responsibility with allowance for treatment allocation (N.S. = not significant by one tailed test with $\alpha = .01$)

depression and responsibility although the latter could represent a degree of regression towards the mean (Equation (7)). After making allowances for treatment allocation with a regression model, reduced disability significantly correlated with responsibility scores throughout the period of follow up (Table 80).

$$\Delta Resp = 5.7 - (IntResp \times .5) - (Zung \times .08) + (IntCont \times .088)$$

Equation (7) Regression formula explaining changes in personal responsibility.
IntResp = Initial PLC responsibility; IntCont = Initial PLC Cognitive control

3.8. Work absence

Those patients who had received drug treatment returned to work earlier than those who underwent physiotherapy (2 tailed T-Test p = .001) (Table 81). The physiotherapy patients took a week longer than the ketoprofen patients to return to work (4.1 weeks physiotherapy 2.96 weeks ketoprofen). Multiple regression analysis indicated that the number of days off prior to entry into the study; the number of weeks off in the previous year of employment and the initial levels of disability helped to explain time off work at the seven week follow up. These factors were used in an analysis of covariance which confirmed a significant difference (ANCOVA SPSS, Significance of F=.001).

Weeks off work from onset of attack to seven weeks	Mean (Weeks)	Standard Deviation
Physiotherapy	2.96	2.04
NSAID	4.03	2.06

Table 81 Work absence at seven weeks

There was no significant difference comparing those who described their jobs as physically heavy and those whose jobs were less arduous ($p = .232$). This may however reflect poorer sick leave arrangements for manual workers than for those with lighter jobs. A planned date for return to work at initial trial entry correlated with significantly reduced absence from work ($p = .000$) (Table 82).

Work absence by plan to return to work	Mean (Weeks)	Standard Deviation
No plan to return to work	4.27	1.68
Plan to return to work	2.81	2.25

Table 82 Relationship between intention to return to work when entering the study and work absence

The relationship between satisfaction with work and continued absence from work at follow-up was examined with the Mann-Whitney U statistic and showed no significant association ($p = .426$) . There was a tendency for those patients with more extensive pain distributions to fare less well as a whole but this is not significant (Table 83). Factors such as job satisfaction and the nature of the work did not significantly predict early return to work.

3.9. Analog pain scores

The analog pain score was recorded at the seven week follow up. The physiotherapy patients had lower levels of analog pain score than the ketoprofen group but this difference was not significant even when the initial levels of analog pain score were taken into account in an analysis of covariance. These differences had disappeared by

the six month but reappeared at a year. Again an analysis of covariance was used with initial levels of analog pain score. The differences seen were not significant (ANCOVA SPSS, Significance of F=.125) and did not become so even when those physiotherapy patients who the therapists could not diagnose at first assessment were excluded (ANCOVA SPSS, Significance of F=.067).

Disability at seven weeks by Quebec classification	Mean
1A	2
1B	3
2A	4
2C	4
3A	3
3C	5

Table 83 St Thomas disability scores at seven weeks by Quebec classification grouping

4. RESULTS - Six months

4.1. Disability at six months

At six months only the modified somatic perception questionnaire score at entry into the study gave any explanation of disability (Adjusted R^2 = .26). This was used in a further analysis of covariance to examine the effect of treatment allocation on disability six months after the onset of the index attack. There was no significant difference seen between the two groups (ANOCOVA significance of F=.99) and between the two groups when those initially undiagnosable physiotherapy patients had been excluded from analysis.

4.2. Analog pain scale at six months

Initial levels of depression gave a small degree of explanation of pain scale scores at six months. Even with this further degree of clarification, there was no significant difference in pain scale scores between the groups (ANOCOVA significance of F=.606).

4.3. Frequency of recurrent attacks at six months

Age of school leaving and initial pain scale scores gave a small degree of explanatory power to an analysis of covariance comparing recurrent attacks between the two groups. The physiotherapy group reported more recurrent attacks although this was not significant (ANOCOVA significance of F=.176).

4.4. Work absence at six months

In the first six months, McKenzie physiotherapy was not shown to significantly reduce recurrent attacks or time off from work (Unpaired two tailed T-test p=.85). No reduction was seen in the number of visits made to hospital or the family doctor in connection with low back pain.

4.5. Opinion concerning subsequent usefulness of treatment

The six month postal follow up letter asked whether the patients thought that their treatment had been helpful to them during subsequent attacks of low back pain. Those

who had received McKenzie treatment found their initial treatment helpful on subsequent occasions significantly more than the patients who received ketoprofen (Chi squared statistic = 17.75 p=.0014). It is self evident that unless a patient is prescribed a subsequent course of ketoprofen, they cannot obtain further benefit from this treatment.

5. RESULTS at one year

5.1. Attrition at one year

At a year a further 33 patients had been lost to follow up giving an attrition rate of 18.3%.

5.2. Missing case analysis at one year

Analysis of missing cases showed that in both groups the non respondents at one year were significantly younger than those who answered and returned their follow up questionnaires (SPSS Unpaired two tailed T-Test p=.005). The physiotherapy non responders were also significantly more depressed and had higher levels of somatic awareness as measured by the modified somatic perception questionnaire at their initial assessment than the responders (SPSS Unpaired two tailed T-Test p=.02 MSPQ and p=.01 Zung). In the drug group these differences were not significant. This raises the possibility of bias at final follow up but all patients were re-mailed and any who failed to respond to this were contacted by telephone if traceable.

5.3. Disability seen at one year

At a year following onset of low back pain the initial McGill scale and the time off in the previous year explained some of the variance in disability. No significant difference was seen in the disability experienced by the two groups (ANOCOVA significance of F=.599).

5.4. Analog pain scale measures at one year

Initial levels of pain and the initial McGill score explained a fifth of the variance in analog pain scale results at one year. The physiotherapy patients experienced less pain (mean .9 as opposed to 1.25) than the drug patients. This was not significant (ANOCOVA significance of F=.221) even when the physiotherapy patients who could not be diagnosed initially by the physiotherapists were discarded (ANOCOVA significance of F=.097).

5.5. Frequency of recurrent attacks at one year

The number of attacks experienced in the ninth to twelfth months following onset were reduced by 28% in the physiotherapy group but this was not significant (Unpaired two tailed T-test p=.248).

5.6. Psychological aspects at one year

There was no difference between the two groups with regard to pain locus of control cognitive control scores (Unpaired two tailed T-Test p=.982). Responsibility scores remained elevated in the physiotherapy group. This was significant when compared with the drug group (Unpaired two tailed T-Test p=.013).

5.7. Compliance with physiotherapy exercises at one year

Responses obtained from the questionnaire shown in appendix 9 give an indication of the long term use of lumbar roll and exercises. Extension in standing was the most frequently cited exercise still used. Flexion in lying was performed about half as often as extension in lying (Table 85). About a third of subjects reported using a lumbar roll at home or whilst in motor cars but only 11% reported ever using their lumbar rolls at work (Table 84). Use of a lumbar roll at one year was found not to correlate with any of the variables recorded with the exception of the number of attacks experienced over the previous three months and initial physical impairment. It should be noted that this use of regression analysis using ordinal data is not as statistically rigorous and does not have the same validity as analyses examining nominal data such as disability or depression scores. For the purposes of regression analysis, a score of 9 was daily use of a roll at home; in the car and at work and 0 was no use of a lumbar roll. In the case of exercises 9 equals use of all three exercises surveyed on a daily basis and a score of

$$Roll\ use = .21 + (Attacks \times .21) - (Impair \times .077)$$

Equation (8) Regression equation for lumbar roll use.
Impair = initial % physical impairment; Attacks = Number of attacks between ninth and twelfth months

0 is total lack of exercise use. The number of recent attacks explained 16% and initial

	Percent
Roll used whilst driving	
Daily	9.0%
Often	6.7%
Occasionally	16.9%
Never	43.8%
Not indicated	9.0%
Roll used at home	
Daily	10.1%
Often	7.9%
Occasionally	27.0%
Never	32.6%
Not indicated	7.9%
Roll used at work	
Daily	3.4%
Often	1.1%
Occasionally	6.7%
Never	58.4%
Not indicated	15.7

Table 84 Lumbar roll use at one year

physical impairment 6% of the variance in roll usage (Equation (8) Adjusted $R^2 = .22$).

In addition to the number of attacks experienced over the previous three months exercise use was related to initial levels of physical impairment and the age of leaving school. In this regression equation (Equation (9)) the frequency of recent attacks explained about 10% of the variance; initial physical impairment 10% and the age of school leaving about 9% leaving 70% of the variability unexplained.

$$Exercise = (.18 \times Attacks) + (.557 \times School) - (.1 \times Impair) - 4.9$$

Equation (9) Regression equation for exercise use

Attacks = number of attacks between the ninth and twelfth months; school = age of leaving full time education and impair = initial % physical impairment

	Percent
Extension in lying	
Daily	7.9%
Often	23.6%
Occasionally	40.4%
Never	13.5%
Flexion in lying	
Daily	3.4%
Often	7.9%
Occasionally	27.0%
Never	37.1%
Not indicated	10.1%
Extension in standing	
Daily	24.7%
Often	14.6%
Occasionally	30.3%
Never	11.2%
Not indicated	4.5%

Table 85 Use of exercises at one year

6. SUMMARY of RESULTS

Measure	Finding	Statistical test
Initial levels of distress	Predicts almost 50% of variance in 7 week disability	Stepwise regression
Seven week disability	No significant difference (All patients)	ANOCOVA
Seven week disability	Physio better than drug (Only diagnosable physiotherapy patients)	ANOCOVA
Seven week pain scores	No difference	ANOCOVA
Seven week, six and twelve month responsibility	Physio better than drug	2 tailed t-test
Seven week lumbar extension	Physio better than drug	2 tailed t-test
Seven week work absence	Drug better than physio	2 tailed t-test
Pain distribution and intensity	Significantly correlated in physio patients	Pearson
One year pain scores	No difference	ANCOVA
One year disability	No difference	ANCOVA
Seven week lumbar flexion	Physio better than drug	2 tailed t-test

Table 86 Summary of important results

7. LIMITATIONS OF STUDY

7.1. Resulting from inadequate power

The findings of this study were marred by insufficient sample size. This was an unfortunate consequence of erratic behaviour of the two groups during the study with the initial fifty patients in the pilot study showing marked differences in response. The later quarters showed little and then moderate differences which countered the marked and spuriously highly significant differences seen initially. No alteration in the conduct of either arm of the study could be identified to account for the variability of treatment effect seen.

7.2. Resulting from inadequate study design

Lack of repeated measure of depression and somatic awareness may have limited the possibility of explaining disability at follow up. The advantages of having this extra information were offset by concern at increasing compliance with follow up questionnaire completion and the possibility of mixing cause and effect with the use of contemporaneous psychometric measures. With the exception of very detailed social questioning and an enquiry into self employed status, no extra information seemed necessary.

DISCUSSION

1. The Prevention of Chronicity

1.1. Does a Rubicon exist

"For, although common Snarks do no manner of harm,
Yet I feel it my duty to say,
Some are Boojums-' The Bellman broke off in alarm
For the Baker had fainted away"[185]

A definition of chronicity is required before any discussion of it's prevention can take place. A state of low back pain and disability which has become established and is resistant to correction might be a useful meaning to the term but strictly chronicity refers to time. Without doubt prolonged low back disability and chronic course are linked[20] but cause and effect mix to make the use of a 'resistance to treatment' type of definition inappropriate. On this basis a Rubicon between the acute\subacute state and chronicity must exist at the defined boundary whether this be at seven weeks[11] or at six months[20]. As there is an exponentially diminishing recovery curve there is a chance of a chronic patient becoming better after seven weeks under the Quebec classification and even at six months.

The Rubicon might then be thought of as a division between those individuals who by dint of their biological, psychological or social make-up are prone to disability. The Boeing study[30] clearly indicated that there is a small group of patients who suffer a great deal of disability and consume a large amount of resources when compared with the average case of low back pain. Other evidence supports this contention [186,31]. We may never be able to disentangle cause from effect reliably. A further difficulty is that if the Biopsychosocial model of illness is accepted for low back disability, the factors which govern whether a patient will be susceptible or prone to becoming chronic vary so widely as to prevent the identification of the rubicon as a discrete entity. Those factors which tend to produce chronicity might be identifiable at an early stage allowing concentration of resources on the "at risk patient" [187] [188] [189]. In short, any division possible would only separate - at an early stage - those patients at high risk of

chronicity from those at low risk. In this study 45% of disability at seven weeks after the onset of symptoms was explained by initial psychological factors with a small contribution from initial disability and a history of previous attacks.

1.2. Does early treatment prevent chronicity

There are several reasons why early treatment of low back pain may prove an effective method of preventing chronicity. If steady deterioration were to occur to the patients level of functioning then, provided that reversal of deterioration was straightforward, there would be no adverse effect from allowing natural history to sift out those patients who are going to improve anyway. In reality there are a number of events in the deterioration of a low back pain patient which are discontinuous. These are difficult to quantify on an individual basis but are dealt with in a qualitative sense by catastrophe theory [190]. Simply presented, the events occurring at the time of redundancy may be seen in Figure 19. Slow reduction in the patient's level of function occurs until they are

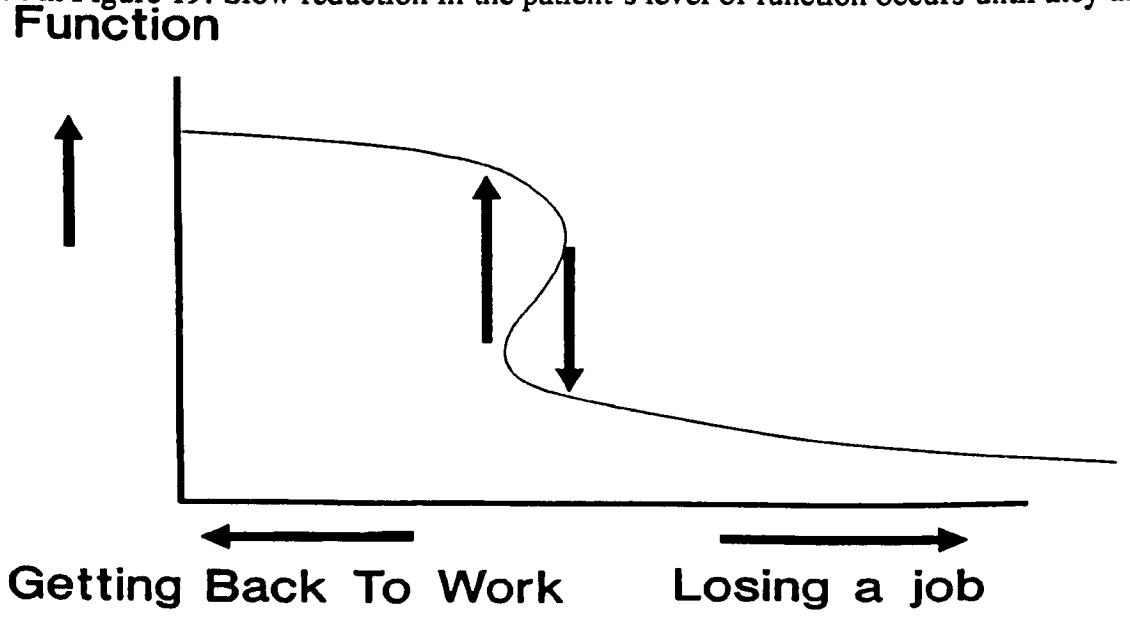


Figure 19 Catastrophe representation of redundancy and re-employment

no longer able to carry out their job. A sudden reduction in their functioning occurs as they are off work or lose their job. The return to full function cannot, however, follow the same path when the patient improves as they have to be fit enough to be certain to stay at work or acquire another job. Deterioration in function is a mixture of continuous worsening of ability coupled with a series of discontinuous events. The ability to

prevent progression of small amounts of deterioration might thus have dramatic effects on maintenance of function. This provides a qualitative explanation of the Boeing study findings that once a patient's condition is chronic there is a tendency to consume a disproportionate amount of medical resources.

Another difficulty is that improvement in some features of low back disability may be a more difficult process than remaining in status quo or even deteriorating. Loss of physical fitness which is related to low back disability can only be reversed by increasing activity which, in the presence of continuing low back pain, will tend to produce more discomfort than inactivity.

1.3. Does avoidance of inactivity prevent chronicity

The cause and effect relationships between severity and excessive bedrest are problematical. There would need to be a prospective trial of prolonged bedrest for at least three weeks to allow any potential toxic effect to be observed. Not only would there be ethical problems associated with this form of study but the compliance rate would, one suspects, be very poor. Whether patients with potentially chronic back ache remain in bed longer because of their condition or have chronic back ache resulting from prolonged bed rest will probably never be known. Extrapolation of Deyo's work[60] cannot be relied to give an answer but is suggestive of a potentially toxic effect. Certainly, retrospective studies would not be able to disentangle cause and effect as regards bedrest and chronicity.

1.4. Would the cost outweigh the benefit

The commonplace nature of low back pain attacks especially those which resolve without referral to medical services means that extensive treatments to prevent chronicity if administered too early would consume vast resources. The exact point at which treatment should be provided at full intensity depends upon a cost benefit analysis of the effects of disability and the availability of treatment resources.

The point at which treatment is delivered to prevent chronicity may be brought forward without upsetting any cost benefit calculations if the individual patient's risk of crossing

the Rubicon into chronicity is higher than average. Certainly in the current study the use of depression and somatic awareness scores obtained initially would have enabled more focused application of resources if these had been limited.

1.5. Do patients continue to use McKenzie training after discharge

One argument for McKenzie's approach is that by educating the subject as to the movements and postures required for their particular condition they might be able to effect a cure in the event of a recurrence without recourse to medical or paramedical help in the future. Several assumptions underlie this hope.

Firstly an exercise regimen which works has to be found to treat the subject in the first attack. secondly the subject has to be able to remember the exercises which they employed previously. and thirdly the subject has to be suffering from a pain source producing identical symptoms to the first attack encountered at the time the exercise regime was formulated. The ability of a subject to self treat even one subsequent separate attack of low back pain would drastically alter any cost - benefit equation in the costing of physiotherapy for low back pain.

The one year questionnaire examined the use of exercise and posture in a superficial fashion but some information has been gathered from which inferences may be made.

Exercises seem to be used as treatment for recurrent acute attacks rather than as a maintenance program to prevent further attacks. Frequent recurrent attacks are associated with a greater compliance rate. It seems unlikely that the exercises are promoting an increased frequency of attacks. The reason for this "crisis strategy" is probably complex being related not only to the subject's understanding of the use and purpose of the exercises but also to their social and occupational circumstances. Flexion in lying, which should form part of the subject's long term exercise program, is seldom used. On an anecdotal basis flexion exercises are often avoided because they exacerbate acute pain. Acute derangements, which formed a large proportion of the original attacks, tend more often to be ones which respond to extension rather than flexion. Flexion is only introduced once the acute stage is over (and vice versa for extension

derangements). Subjects are either ignorant of the role of flexion or are giving up their exercise program as soon as a degree of relief is achieved.

The age of leaving school was also found to be positively related to exercise use. It is most important not to confuse this with intelligence - no measure of IQ was made in the original or subsequent assessments. Nevertheless further education after minimum school leaving age may well be related to the subject's ability to comprehend and apply the lessons in self care provided by the physiotherapist. Responsibility for pain control, as measured by the pain locus of control questionnaire, did not seem to be related to the use of exercise or postural modification.

Lumbar roll use showed a dramatic difference between use at work and outside work. Very few subjects used their rolls or a substitute such as a rolled up towel at work. In part this reflects their occupation as many of those included in the study had active jobs where sitting was not required. It may be that some employers are unsympathetic to their workers ergonomic requirements and discourage the use of lumbar rolls.

In view of the relationship between previous educational experience and exercise compliance a better educational approach to the question of repeat self treatment might be devised. Factors other than the frequency of exercise use are important for answering questions about education. For example do subjects have the knowledge to use a belt or have a family member apply resistance to extension if necessary or do they know about shifting their hips to one side if centralisation fails to occur. Co-operative studies with educational psychologists are required to enable progress and refinement of the teaching methods currently used by physiotherapists.

2. How does McKenzie Physiotherapy work

2.1. Biological Aspects

2.1.1. Concept of nuclear flow

McKenzie, for many years, postulated that the rôle of extension exercises was to cause the nucleus pulposus to move anteriorly. His contention and model for the effect of spinal exercises is shown in the following two diagrams:

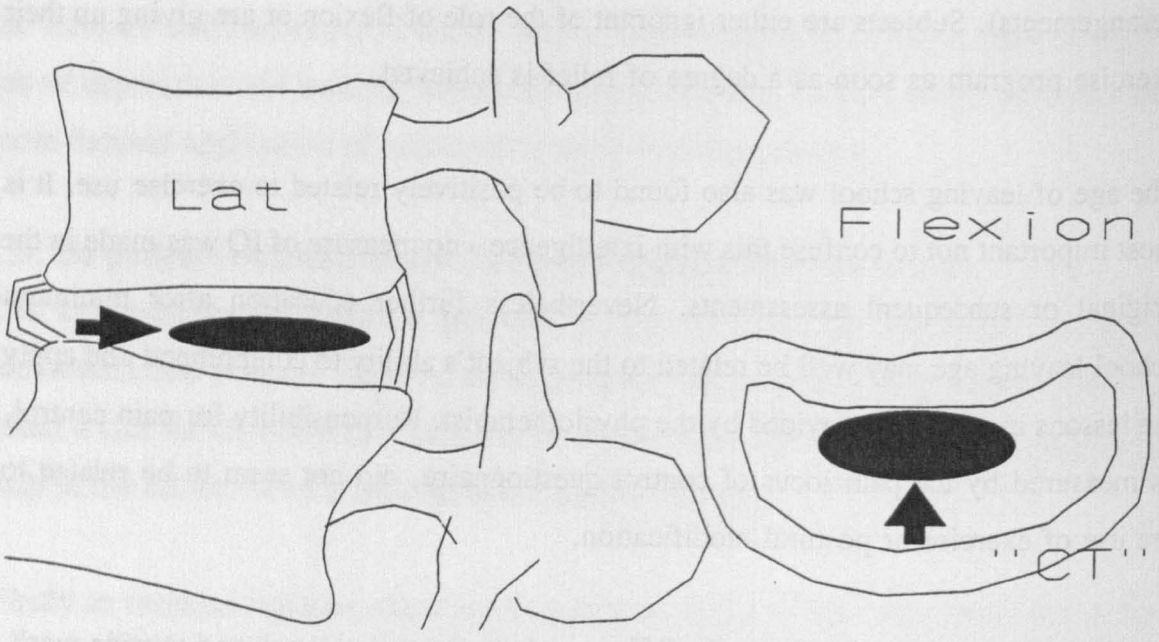


Figure 20 The possible effect of flexion on nuclear position

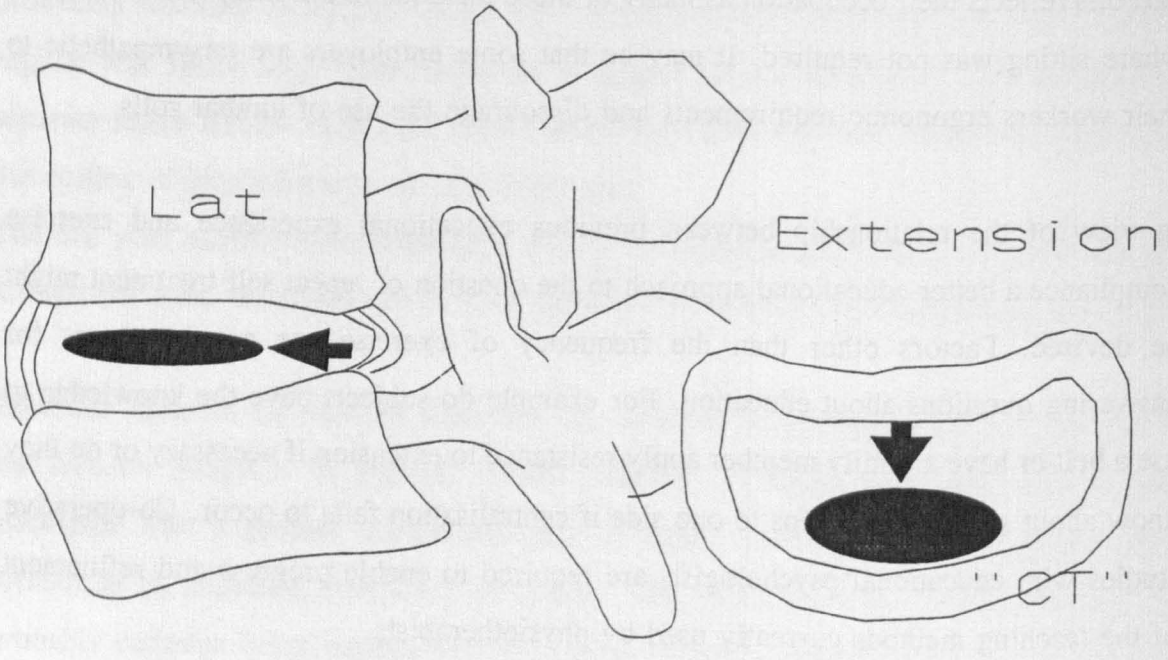


Figure 21 The possible effect of extension on nuclear position

A number of studies have attempted to evaluate the effect of lumbar extension on nuclear position but the results have been unclear to date. Cadaveric discogram studies have the advantage of allowing good fixation of the vertebral bodies to control motion but have the disadvantage of an artificial system[191]. In vivo discography is a more

realistic system but rotation artefact makes the interpretation of flexion and extension lumbar films difficult and the fundamental question of whether the dye corresponds to the nucleus pulposus completely remains. Magnetic Resonance Imaging of the lumbar spine has the disadvantage of poor resolution which would certainly not be sufficient to detect the magnitude of movement possible in the nucleus. Rotation artefact persists as the cause of inaccuracy but the possibility of repeated examination would allow a summation technique to be used, thus eliminating signal noise resulting from rotation. It is anticipated that the resolution of the future generations of MRI scanners will make them increasingly useful in addressing this question.

2.1.2. Concept of evacuating the annulus

Mechanical factors related to the position of nuclear material may still be important if spinal movement acts by evacuating nuclear fragments from within the lamellae of the postero-lateral annulus. This would not necessarily be visible on discographic studies.

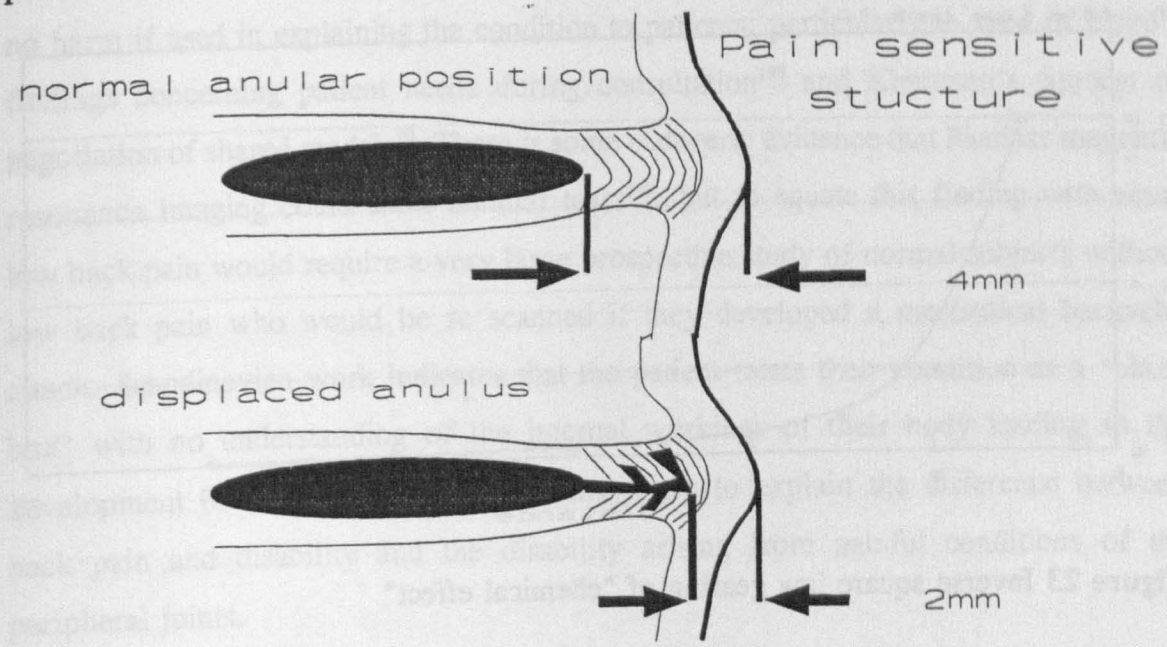


Figure 22 Annular tears may allow nuclear material to approach the nerve root

2.1.3. The Chemical Gearing Mechanism

The lack of visible movement of the "nuclear cloud" seen on flexion/extension discograms has led some to emphasise the rôle of chemical factors in the production of low back pain. Mooney has recorded the hydrogen ion concentration in the nucleus

finding low pH levels centrally and higher levels tending towards normal physiological levels towards the periphery[192]. Theoretically lactic acid production is a normal respiratory product of the anaerobically metabolising nucleus. This allows for the development of a theoretical mechanical-chemical model which produces a gearing of effect from movement of "posteriorly displaced" nuclear material. If the images produced by Adams and Hutton[193] occur in vivo then a seam of nuclear material intrudes into the annular fibres. The production of lactic acid and thus hydrogen ion may be considered to arise from a point source such that under steady state conditions, the concentration of hydrogen ion will be inversely related to the square root of the distance from the point source. Thus quite small and immeasurable (by current imaging techniques) movements could produce dramatic changes in hydrogen ion concentration at the outer annulus producing a gearing effect (Figure 23).

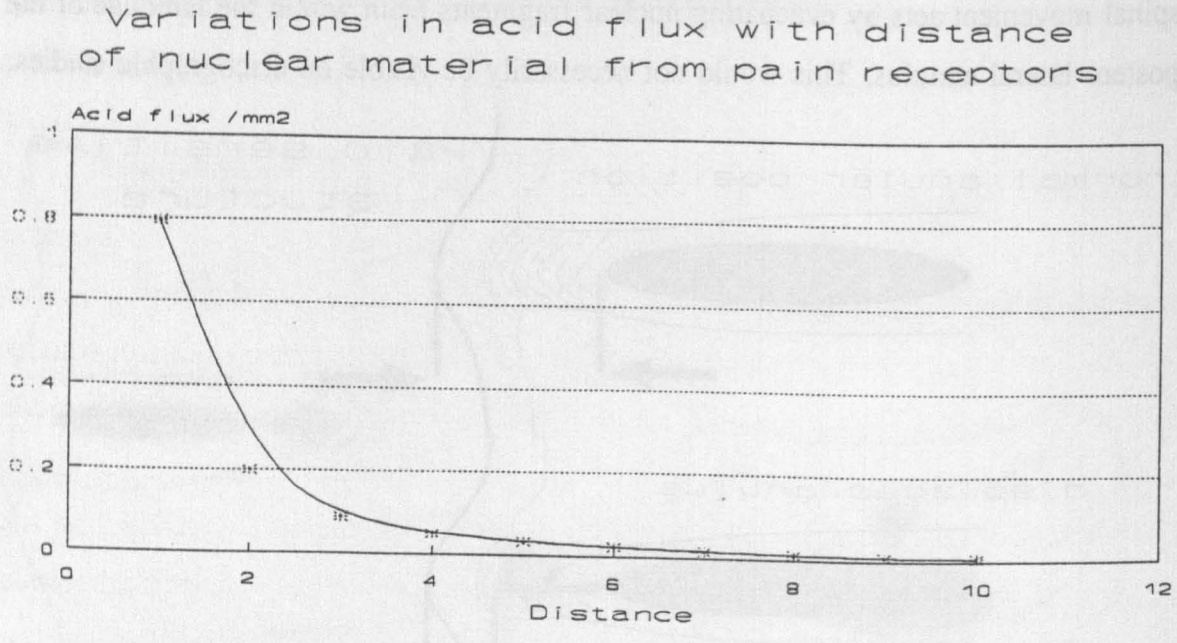


Figure 23 Inverse square law gearing of "chemical effect"

If this model applies then the mechanism of McKenzie therapy is to evacuate nuclear material from annular tears rather than to produce a mass movement of the nucleus within the annulus. Donelson has examined 85 patients in an uncontrolled series[131] and showed that those patients who did not centralise with McKenzie therapy had a poor outcome on a four point ordinal rating. The patients who did not show the centralisation phenomenon had a high incidence of annular leaks on discography whilst those who did

respond with centralisation were not discogramed. A complete annular tear preventing any hydraulic forces developing within the disc would be an explanation for the anecdotal poor response of patients with gross annular tears to McKenzie treatment

2.1.4. Concept of Ligamentous Disorder

Unlike the nuclear flow theory for the efficacy of McKenzie therapy the possibility that McKenzie extension exercises may beneficially increase the level of spinal flexibility are not supported by much experimental evidence. One study has shown, in a small group of male subjects with controls, that passive extension exercises can increase spinal flexibility in extension[194]. This might be an adverse effect if the literature examining risk factors in low back pain is consulted[195,196]. Michelle Battier and others failed to demonstrate a relationship between increased flexibility and the risk of low back pain in an industrial setting[197] The idea that the annulus is torn posteriorly and should be closed by means of spinal extension is an appealing one which should do no harm if used in explaining the condition to patients; particularly in view of Deyo's findings concerning patient needs during consultation[198] and Kleinman's concept of negotiation of shared models[10]. There is some cadaveric evidence that Nuclear magnetic resonance imaging could show annular tears[199], but to equate this finding with acute low back pain would require a very large prospective study of normal subjects without low back pain who would be re scanned if they developed a mechanical backache attack. Scandinavian work indicates that the patient treats their condition as a "black box" with no understanding of the internal workings of their body leading to the development of undue anxiety[200]. This may help to explain the difference between back pain and disability and the disability arising from painful conditions of the peripheral joints.

2.2. Psychological Aspects

It is clear that any researcher who studies this subject clinically ignores the psychology of acute low back pain at their peril. Failure to record and account for these factors confuses clinicians and confounds results. The modified somatic perception questionnaire and Zung self rated depression scale would appear to be useful core examinations in acute low back pain. The relatively small size of the sample (180)

prevents the extrapolation of these results to acute low back pain generally but is indicative of sex differences and alterations in the components of disability during an attack.

2.2.1. Responsibility for care

It is tempting to suggest that diminution in personal responsibility for back pain relief and care because of a supportive welfare state, is one of the underlying engines driving the increased incidence of low back disability which affects the western world. There is no supportive evidence for this. Nevertheless, on an anecdotal basis a significant number of patients have been restricted in their activity or have not worked, solely because they were waiting for specialist review. If patients had access to the information and treatment methods which they required then this impasse could be avoided[144]. The passivity which is related to the low levels of responsibility for back pain care runs counter to the current concept of activation in the treatment of acute low back pain. Acute low back pain has a tendency to recurrence with - in many cases - eventual long term remission. If, between attacks, patients have residual disability there is a possibility of cumulative disability resulting in increasingly severe subsequent attacks and possibly a greater risk of chronicity. If the concept of cumulative residual disability is to be believed, the treatment of each attack must be consistently good or else the patient becomes progressively more disabled. Whilst access to private treatment is usually acceptably rapid, cost and a perception of ineffective care may lead to patients deferring treatment during later attacks thus incurring the risk of further residual disability. Limited resources in a National Health Service setting would by the length of waiting times also allow attacks to go untreated. It is interesting that drug patients increase their levels of personal responsibility significantly at seven weeks. This may represent the result of advice to mobilise and return to work given to all patients before randomisation. The physical therapy patients displayed a significantly greater increase in responsibility at seven weeks after onset than the drug patients. Whereas the responsibility levels in drug patients decayed towards their original value at six months, the physical therapy patients showed sustained increases in responsibility. At one year after onset of pain the physiotherapy patients were still showing significantly elevated levels of responsibility whilst the drug group were less responsible than

originally. Following from the results presented on page 129, there seems little in the way of scope for altering the parameters which explain the increase in responsibility seen. What was not measured except in the most crude sense was the effect of physiotherapy 'manipulation' of the patient's attitudes and behaviour. Although as a package, the physiotherapy increased the patient's levels of responsibility for pain control it was not possible to examine which aspects of the patients physiotherapy care actually altered their perceptions and opinions. For this to be examined there would have had to have been a very careful analysis, probably with videotape recording of the patient's interaction with the therapist, scoring features such as indications of agreement and assertiveness on the part of the therapist. This form of detailed behavioural and psychological examination will be required if directed attempts to alter the way in which physical therapists alter patients psychological state.

2.2.2. Cognitive Methods for Coping

Whilst the cognitive aspects of the pain locus of control questionnaire show no striking alterations as was found in the responsibility question, but there are some interesting trends. By seven weeks the drug patients had increased their dependence upon cognitive mechanisms for controlling pain whilst the physical therapy group were, on the whole, unchanged. Six months after onset the drug patients showed a similar decay in cognitive control as they did with responsibility. Interestingly, the McKenzie patients showed a diminution of cognitive control function to below the base line. It is tempting to speculate that they used cognitive mechanisms to reduce their perception of pain less because they had a physical mechanism for controlling their symptoms although this represents a speculative line of thought.

A major and lasting effect of physiotherapy for low back pain was an alteration in patients attitude. Little emphasis has been placed on this aspect of *physical* therapy. Clearly an appreciation of these facts may enable more effective alteration of patient's behaviour.

2.3. Social Aspects

The social aspects of self help methods of pain control should not be underestimated although they have not been examined specifically. One Canadian study of back school in an industrial plant sought to examine the effectiveness of an exercise and posture program for industrial low back pain. The study had to be abandoned because it became clear that the control group were being educated by the study group in posture and general principles of back care[201].

3. Who does McKenzie physiotherapy work for?

3.1. Diagnostic systems

3.1.1. Relationship between McKenzie and Quebec Classifications

The current study has been examining those patients presenting with Quebec[11] groups 1-3 (a and b, w and i) these patients were found on the most part to have derangements. By definition those patients with Quebec group 3 low back pain have derangement 5 or 6 if they have a derangement and those with group 1 and 2 presentations have derangement 1,2,3 or 4. Derangement 7 is uncommon and could be found in any of the first three Quebec groups. It is claimed that McKenzie therapy works for cases of nerve root entrapment proven clinically (Quebec 4) but there is as yet no convincing evidenced that this is so.

3.1.2. Relationship between McKenzie and Pragmatic Classifications

As the pragmatic classification employed here does not attempt to further subdivide the patients in Quebec groups 1 to 3, patients falling into a diagnosis of "simple mechanical low back pain" if seen acutely, generally have a McKenzie derangement diagnosis.

3.1.3. Limitations to Correlating Medical and Physiotherapy Classifications of Low Back Pain.

It is vital to base any use of an empirical classification on certain philosophical foundations. Because an empirical classification provides a framework for viewing reality rather than a delineation of natural kinds of low back pain there will be a degree of overlap and "mis-match" between classifications. The importance of this rests on the fact that empirical classifications are used by specialist groups to divide their subject

in ways which are meaningful to them. The McKenzie classification is of no use to a medical person because doctors are not trained in the McKenzie methods of assessment and treatment. Likewise, facet joint arthropathy is only useful to the medical profession because we are able to excise, fuse or inject that joint. Indeed if, as a medical professional, one does not believe in the excision, fusion or injection of facet joints to produce relief from low back pain then the diagnostic category of facet arthropathy is of no use to you.

Patients with chronic symptoms are said by the proponents of the McKenzie system to be treatable by this method but there is no evidence to support this contention yet. A prospective single blind crossover trial for Quebec groups 1-3, subgroup C is to be undertaken in Wellington, New Zealand with three treatment groups consisting of non-steroidal anti-inflammatory drug; fully certified McKenzie practitioners and partially qualified McKenzie practitioners[202]

4. Provision of Care for Low Back Pain Sufferers

4.1. Treatment method

The current study has examined the use of non-steroidal anti-inflammatory drugs and physiotherapy according to the McKenzie principles. Where a physiotherapist, untrained in the McKenzie principles tries to perform treatments according to the McKenzie principles, it is suspected that the result would be no better than treatment with a non-steroidal anti-inflammatory drug. However in patients with acute low back pain of the type examined in this study, a suitably trained therapist should obtain significantly better results with those patients who are diagnosable initially when compared with non-steroidal anti-inflammatory drug treatment.

4.1.2. Immediate Benefits of McKenzie Treatment

A major immediate benefit derived from McKenzie treatment is that if suitable patients are selected, the physiotherapist can manage them throughout their clinical course. Whilst the current study has not shown a big difference between drug and physical therapy it should be remembered that both an effective control group and a condition which tends to resolve spontaneously was studied. Accordingly, if immediate benefit

is taken to mean the situation regarding disability at seven weeks, there is no great benefit from McKenzie treatment. Nevertheless, the McKenzie patients were comfortable sooner and showed a 15% reduction in the proportion disabled at seven weeks compared with drug. When those patients who could not be diagnosed according to McKenzie's schema were excluded, the difference became significance in an analysis of covariance. In summary, the immediate benefits of McKenzie physiotherapy are not substantial but manipulation has not been shown to increase comfort when compared with a control group for much longer than four weeks after treatment.

4.1.3. Late Benefits of McKenzie Treatment

There is little point in patients becoming more responsible for their pain control if this does not in turn produce a later reduction in health care utilisation. This has not been seen at six months. When asked "did the treatment you received in the Back Clinic help you with subsequent attacks of low back pain?" the answer was "yes" from the McKenzie treated patients and "no" from the drug treated patients (statistically significant at the 1% level). Whilst it may be argued that no drug could reduce residual effect which carried over during subsequent episodes, this rather underlines one of the late advantages of McKenzie treatment. Attrition and the relatively small number of patients in the study prevents one from concluding that there is no significant beneficial effect from McKenzie physiotherapy.

4.1.4. Disadvantages of McKenzie Treatment

McKenzie treatment was not universally successful in the group of patients studied with approximately 9% being undiagnosable on initial assessment. The results of the current study are discouraging with regard to time lost from work during physiotherapy treatment for the attack under study. Specific measures had not been adopted during the construction of the study to control the directions given by the physiotherapists regarding return to work. All treatments had been performed during normal working hours (08.30 - 16.30 Monday to Friday).

Physiotherapists trained sufficiently well in the McKenzie method are not common and represent - at present - a rare resource.

4.2. Cost implications

With financial considerations becoming more important in the future, those therapies which can be shown to produce benefit will inevitably become favoured compared with those which have no clear benefit. Accordingly, a process of natural selection may occur to favour those practitioners who have a specialist training in effective regimens such as the McKenzie approach to mechanical spinal disorders. Certainly, funding on heat lamps and interferential machines would have to be balanced by the "efficacy" of such modalities of treatment. Physiotherapists being employed as independent practitioners within a general practice setting would enable a much more responsive service to be provided where a therapist could see patients early enough to influence the clinical course in a favourable sense.

Apparently the trend is towards unification of physiotherapy and occupational therapy with all these groups becoming therapists. It is probable that for the decade following the introduction of this change, the provision of specialised manipulative care for locomotor disorders will be haphazard with therapists who are not originally trained as physiotherapists applying treatment methods. As a whole physiotherapy for musculo-skeletal conditions may be restricted in its funding and scope if cost benefit analyses of the speciality as a whole are not favourable. With various forms of therapy for mechanical backache being available, the large number of therapies which are ineffective for an acute bout of low back pain may lead to the prohibition of physical therapists from seeing low back pain patients although this would be an extreme development.

4.2.1. Costing of Physiotherapy in a General Practice Setting

In addition to the cost of employing a physiotherapist in a general practice, there are considerations of equipment and facilities. Manipulation of the spine depends upon the use of a plinth, which vary in price, but which typically equal the cost of a senior physiotherapist's salary for one month. Other electrical and ultra sound equipment is similarly expensive and a forward traction system may cost the equivalent of three or

four months salary. Consequently, any physical therapy which depends heavily upon traction or electromechanical measures incurs additional costs compared with a "bare hands" method. Furthermore, these costs are, to a certain extent, replicated if general practices syndicate to employ one therapist between three or four practices. This increases the cost of employing a therapist still further. The possibility of a physiotherapist reducing subsequent consultations for low back pain by increasing patients' responsibility and ability to care for themselves as well as instructing and educating the patient, may represent an as yet undocumented benefit. If family doctors have to compete for patients then the possibility of having a physical therapist "on the pay roll" might act as an inducement to patients to join or stay with that particular practice.

There is evidence that if physiotherapists obtain practitioner status they could deal with a third of all musculo-skeletal conditions without reference to a doctor[203]. The authors stated that patients with spinal pain represented a large category of these patients but no exact figures were presented. In the same paper a survey of a family doctors' opinions regarding the use of a physiotherapist practitioner showed that 80% were in favour whilst 18% thought the method had possibilities and two% were against on medico legal and political grounds. Substantial savings of family doctor time could be made if a third of all their patients are dealt with without their direct intervention. It is important to note that the subjects the physiotherapists encountered in this study were family doctor referral, this representing a more selected and possibly specialised group than would normally be treated in the GP's own surgery and that secondly that referrals requesting a consultant opinion or having any suspicion of serious pathology were not included in the study.

4.3. Administration of treatment

4.3.1. By family doctors

4.3.2. Requirements for Specialist Training by Family Doctors

The study was conducted in it's clinical part to use only facilities, (other than radiology), which are easily available to family doctors. There were no decisions made or altered as a result of radiological findings, so the use of radiology in this instance

could not be supported on a cost benefit or utility basis. Certainly if plain radiographs are obtained there should not be any delay in instituting treatment as based on the guidelines set out in this discussion whilst the X-ray report is awaited. Most general practitioners appear to rely upon radiographs in low back pain for reassurance either for themselves or for their patients[204].

For the age group seen in this study, the principle point requiring differentiation was between mechanical low back pain and nerve root entrapment. One man was rejected from entry into the trial because he had haematuria and dysuria and subsequently was found to have bacteriological evidence of a urinary tract infection.

Cotungo[38] differentiated between arthritic and neurological sciatica in his original medical description. Confused terminology now leads to difficulty in the use of the word sciatica with attendant diagnostic confusion. Furthermore The concept of disc prolapse also leads to imprecision with a mixing of cause and effect. The aim should be to identify those patients with an entrapment of a single nerve root whether by disc prolapse or by osteophyte or by abnormalities of vertebral alignment. Disc prolapse without root entrapment is not amenable to successful surgical treatment and resolves in many instances spontaneously[205]. As a consequence of these points, the family doctor has to decide whether there is a nerve root entrapment. Once the idea of sciatica being a differentiating feature is relinquished, progress becomes possible. The presence of objective neurological signs with root tension signs and leg pain worse than back pain, places the patient out side the remit of this discussion. No substantial evidence exists, as yet, that nerve root entrapment is amenable to the principles advocated by McKenzie.

To summarise, those patients with acute back ache of lesser magnitude than leg pain; with normal lower limb neurology and no root tension signs are suitable for the treatment methods outlined above. There is no special skill required to identify these patients beyond that possessed by family doctors.

4.3.3. Willingness to Train by Family Doctors

Whilst the basic clinical skills are common to all family doctors the underlying philosophy required to apply these differentiations is not universally held. The training of family doctors to enable this discrimination would be required before acute low back pain can be treated according to these guidelines. One study[206] examined the possibility of educating family doctors in the management of soft tissue lesions of the shoulder but failed to influence the load of referrals in the local rheumatology clinic. There were those doctors who took up the invitation to visit the clinic and learn the required techniques who no longer referred shoulder problems which did not require consultant treatment. The majority of doctors, however, ignored the invitation and continued to refer patients who could have been effectively treated in the GP's surgery. The point of note is that there was no incentive in this scheme other than a desire to improve the family doctor's own skills and service. In one survey of British practice[207], three quarters of rheumatologists indicated that they undertook family doctor training with half of them taking small groups. The author also noted that there was very little mention of the problems which family doctors encountered most often - notably low back pain.

Open access physiotherapy for low back pain has also met with similar problems in informing family doctors. Rates of attendance at introductory sessions are often low[208]. This is not a problem if the scheme is restricted to those doctors who have attended the induction courses. The ability to avoid the wait for and cost of an orthopaedic outpatient appointment should also act as an incentive. Formal studies of appropriateness of family doctor referrals are vulnerable to the Hawthorn effect[ff] so that reports of high compliance with referral recommendations should be treated with caution[209,210]. One group[210] however reported a sustained reduction in the referrals to physiotherapy from the rheumatology clinic on introduction of an open access scheme.

(ff) Hawthorn effect: Where performance of a task improves (or worsens) as a result of being observed.

4.3.4. Willingness to Train by Physiotherapists

The physiotherapists taking part in this trial were committed to the McKenzie approach during this study. They had a moderate amount of training in the method before joining the research team but had not practised this form of treatment regularly. During the six month period before the pilot study started, they practised and improved their assessment and treatment methods but lacked the depth of experience which would have arisen from further training. Only when the subjects they were unable to diagnose according to the algorithm were discarded, did their results compare significantly favourably with non steroidal drugs. The effect of better training on physiotherapist in the performance of McKenzie assessment and treatment is unknown. No evidence exists to suggest that a more highly trained and experienced therapist would be able to treat these patients who are undiagnosable but it is suspected that experience and further training would lead to a lower rate of undiagnosable patients.

It is anticipated that in the future new physiotherapy posts may be constituted which specify the form and extent of previous post-graduation training which physiotherapists have. As an example a job description may require a candidate to have attended the McKenzie A and B course and contained within its funding adequate monies to have the therapists fully trained and certified during the early tenure of the post. Pressure to fully train McKenzie therapists would be given impetus by the identification of increased benefit from a fully trained therapist compared with a partially trained therapist. Two aspects of efficacy arise when considering potential benefits of fully trained therapists. The method depends upon fully exploring patient generated forces to produce the corrective manoeuvre before proceeding to the application of therapist generated force when the patient is unable to complete the process themselves. If a patient can be shown how to centralise and abolish low back pain without the therapist touching them this is held, by McKenzie therapists, to greatly enhance the educational aspect of the therapy. If therapist generated force is required, this is withdrawn as soon as the patient is able to manage the condition themselves. The importance of attention to detail in the instruction of patients in the niceties of posture is emphasised during the advanced courses and plays a part, apparently in the of technique.

Clearly at some stage in the treatment process there must be a degree of quality control to ensure that patients with conditions which do not respond to treatment are excluded from the physiotherapy regimen. With the possible difficulties entailed in relying upon family doctor discrimination one possible solution is to enable the physiotherapist to act as a fully independent practitioner.

4.3.5. Role of Physiotherapists as Independent Practitioners

The principle currently exists[211] that medical personnel should state the diagnosis and indicate the treatment objective, leaving the physiotherapist to decide upon the exact nature of the treatment. Whilst this is a laudable statement, there are requirements which must be met before this can be effectively pursued. Increasing interest is being shown by spinal surgeons in North America in the possibility of using McKenzie physical therapists to select out those cases which would not fare well with conservative treatment for more intensive surgical treatment[212].

4.3.6. Requirement for Audit by Physiotherapists

In peripheral hospitals and clinics, many physiotherapists are continuing to treat low back pain with methods which have no proven efficacy. Physiotherapists must accept the need to assess their results in a critical fashion if they are to be allowed to practice independently. Recent expression of this by non physiotherapists[213] has led to fierce condemnation from within that profession[214].

4.3.7. Requirement for Skills Assessment by Physiotherapists

If any medication is prescribed it's efficiency or toxicity may only be assessed if the dose is known. No study of drug therapy would be reported without the dose being detailed. It is therefore surprising that whilst reports of physiotherapy for low back pain report the frequency and duration of treatments, an indication of the potency of the physiotherapist is not included. To pursue the drug analogy, the dose is not given in terms of milligrams but is implied in the effect produced in a fashion similar to animal assays of LD_{50} [ff]. Effective assessments of the skill of physiotherapists are being

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(ff) LD_{50} A dose of a substance which proves fatal to half the animal subjects given the substance.

developed with the aim of providing a better indication of skill than just the grade of the physiotherapist[215]. No evidence other than anecdotal accounts exists to document the increased efficacy of a fully trained McKenzie therapist compared with those who have only taken the introductory courses.

4.4. Application of treatment

4.4.1. Duration

A limit on the number of treatments which can be performed before review by the family practitioner or specialist should be set and seems to be about six on the basis of the data in the reported study. This, interestingly, is also the number of treatments by Stankovic reported[137] and near to the 6.5 treatments average reported by Rath[216]. An initial assessment takes forty minutes, if performed properly, with each subsequent treatment taking twenty minutes or less giving an upper treatment duration of 140 minutes. Examination of the relationship between pain intensity and distribution in those patients under treatment by the physiotherapists showed a dissociation between pain intensity and distribution if resolution had not occurred within six treatments.

4.4.2. Who to Treat

Only when the subjects who the physiotherapists could diagnose were unable to diagnose according to the algorithm (Appendix 1) were discarded, did results compare significantly favourably with non steroidal drugs. Treating patients by McKenzie's methods without a reliable diagnosis did not work in this study. For practical purposes, where resources are limited and the therapist relatively inexperienced, undiagnosable patients once assessed and found undiagnosable should, perhaps, not be treated further by the physiotherapist. There was no specific attempt to examine whether those patients who the physiotherapists were unable to diagnose on their first assessment could be diagnosed on their second visit or whether those who remained undiagnosable represent a group who are especially unresponsive to treatment.

4.4.3. Frequency of Treatments

Because of the rapid resolution of this particular condition, the full training effect of the physiotherapy may not be felt if an unduly long interval is accepted between treatments. This study did not address the effect of alterations in interval between treatments on efficacy.

4.4.4. Work Related Factors

All patients were directed by the doctor seeing them initially to return to work at the earliest possible opportunity[66]. Those patients who saw the physiotherapist returned to work a week later than those who were treated with non-steroidal anti-inflammatory drugs. Because the study doctor could not direct patients whilst under treatment, directives for return to work came from the physiotherapists rather than the doctor and the difference in work absence may relate to this. The complexities of inter-relationships between the work environment; disability; time required to attend the physiotherapy department and the exercise and postural regime prescribed to the physiotherapy patients is too complex to be unravelled without study directed at this question. Any future investigation should include specific instructions by the physiotherapist concerning return to work. Where early return to work is a priority, patients should be offered "out of hours" appointments. Negotiation with employers regarding time off for treatment is often difficult and full sick leave is often preferable for patients.

Duration of work absence is too complicated an outcome measure to be used in anything other than a pragmatic fashion. The adverse effect of physiotherapy cannot be ignored in this instance but should be correctable in future studies and treatment regimens if reduction of work absence is addressed as the major aim of treatment.

4.4.5. Community or Hospital Based Treatment

In so far as the patient does most of the therapy themselves, even those patients who attend the open access clinic are having more treatment at home than in hospital if properly motivated. As no specific equipment is required for McKenzie treatment, it is entirely suited for use in the community. Those patients who are included in the

present study are in an age group which is able to attend an outpatient hospital service unless acutely disabled. In the very early stages of an episode of low back pain, the patient is often so uncomfortable that a treatment session has to be postponed anyway. There is potential advantage in this form of physiotherapy being administered on a community basis. If it is accepted that the method seeks to show the patient how to cope with the recurrent attacks themselves then review in the home is advantageous. For example, extension in prone lying can be performed very successfully with a chair upturned so that its seat edge and back rests on the floor. This forms a ramp which can be covered with cushions for the patient to lie on. Many other examples of home circumstance can be turned to advantage to improve the efficacy of home care. In the study reported here it was commented, anecdotally, by some GPs that they did not refer their really acute patients because of the intensity of their symptoms precluding transport. Obviously a visit to the home by a community physiotherapist obviates the need for moving the patient.

5. Areas requiring further work

5.1. McKenzie Treatment

5.1.1. Educational Aspects of McKenzie Treatment

Retention of basic information may be an important aspect of treatment by the physiotherapist. Age of school leaving explained some of the exercise use by physiotherapy patients at a year after the onset of their pain. It may be that those patients with greater levels of formal education are more able to retain the information or use the booklets which they were provided with. Whilst McKenzie admits that teaching some people how to perform their exercises is difficult[217], this does not address the issue directly. Those patients who find difficulty in recalling the appropriate exercises and postures may require further education or a better method of presentation of information. The use of a shifted position which is sometimes required with some derangements is a nuance to treatment which demands a degree of experimentation. The patient has to move the pelvis either to the side of the referred pain or away form it during extension or flexion exercises when a relevant lateral shift is present. The difficulties of reliably identifying this are noted on page 61. The use of supplementary force requires further understanding from the patient. In this instance the patient is not

heavy enough to exert sufficient force on the extended spine to reduce the derangement and either another family member is required to lean on the lumbar spine or a fixed belt is needed. These techniques must be remembered before they can be applied.

5.1.2. Psychological Aspects of McKenzie Treatment

Development of responsibility may be possible and need specific attention in future research. Desensitisation to MSPQ seems unlikely as the McKenzie process depends upon assessment of pain and site rather than ignoring it. The patient is encouraged to examine what is happening within their bodies rather than observe it in a passive sense[200]. This also touches on the subject of anxiety and it's reduction by both explanation and control over symptoms. This has yet to be investigated and quantified.

5.1.3. The McKenzie Diagnostic System

Assessment of the lateral component as well as the assessment of end of range pain are discussed on page 61. Whilst the McKenzie diagnostic system has been simplified in the algorithm (page 60) it should be noted that the categories of postural dysfunction and derangement are not mutually exclusive. It is thus possible to have a patient with a long standing dysfunction who develops an acute derangement. No evidence exists of the frequency with which these mixtures occur or as to how reliably they may be diagnosed.

5.1.4. Administration of McKenzie Treatment

Frequency of treatments depends upon organisational as well as physiotherapy factors. Whilst the average frequency for treatments in the study was 2.1 per week this may not be possible in a practical situation. The balance between cost efficacy and the deterioration in symptoms seen in figure Figure 14 (page 87).

5.2. Other diagnostic categories of low back pain

Again the Quebec task force report[11] forms the framework for further work. Nerve root entrapment (Group 4) requires careful examination using the McKenzie treatment. A control group would be either a natural history group; a non-steroidal group or a fitness-activation group. Traction for nerve root entrapment (on a purely anecdotal

basis) very often produces an exacerbation of symptoms and would thus present inappropriate control against which to test McKenzie therapy. Kopp[218] has shown that lumbar extension can provide an indication as to whether operative measures are required to decompress nerve root entrapment. Unfortunately, they did not present their method for measuring lumbar extension which was absolutely crucial to evaluate the paper. Backache of greater than seven weeks duration also requires study and attention should be focused on the role of centralisation as a method of prediction of favourable results. The results from the current study show proportional reduction of error (Lambda) of 13% which was not significant (confidence interval 95% = 33 - minus 10%). In view of the observed close relationship between pain intensity and peripheralisation and the fact that low back pain tends to resolve spontaneously[11] it might be expected that even those who do not centralise because of physiotherapy measure would centralise themselves because of the self limiting nature of their condition.

5.3.Other Forms of Treatment

Certification and training of physiotherapists in the McKenzie method passes through four stages. The part A course centres on the lumbar spine and is an introduction. The part B course relates to the cervical and thoracic spine whilst the C and D courses represent fine tuning and a deeper level of understanding. It is to be anticipated that a therapist with the "complete" McKenzie training would have a higher success rate with the patients than a partially trained therapist. This has yet to be conclusively proven. A trial of treatment comparing therapists who have completed a part A course with therapists who had completed the full course and have been certified should be performed, with probably just Quebec groups 1, 2 and 3 being studied (duration A and B). A need for more complete understanding of the rôle of cardiovascular fitness in prevention of recurrent attacks of backache should be taken into account when further studies are planned. Whilst exercising to the Bruce protocols for cardiovascular fitness may be appropriate for a medical out patient, a patient with low back pain might have a rather variable performance, not because of cardiac insufficiency, but because of their back pain. No test independent of physical function has yet been devised which can produce an index "cardiac fitness". Isokinetic bicycle exercise is probably the best

system and technique currently available and is more likely to be of benefit in the treatment of chronic backache sufferers. Manipulation and mobilisation according to the Maitland principles requires assessment by controlled trial.

5.3. Basic Sciences

A better understanding of the mechanics, physiology and pathology of the annulus is required. The lack of phosphocreatine in the nucleus; an adverse signal to noise ratio and poor resolution prevents the examination of nuclear pH by means of NMR spectroscopy. Information concerning the rôle of hydrogen ion and other metabolites in the production of low back pain will depend upon the use of fine measuring probes. A reliable model for the examination of disc mechanics is required for analysis of the rupture mechanics of laminar disruption under prolonged flexion-compression forces. Elementary elasticity theory along with nuclear pressure measurement should allow accurate information to be gathered regarding the relative strengths of various portions of the annulus.

6. Summary

The trial discussed in this document indicates that McKenzie therapy produces between 10% and 20% less disability at the end of seven weeks compared with non-steroidal anti-inflammatory. This difference is not significant in this study owing to the numbers which were examined. Exclusion of initially undiagnosable patients led to the difference in disability at seven weeks becoming significant by an analysis of covariance.

At three to six months clear differences existed at very low levels of disability bordering normality with the McKenzie treated patients being significantly less often disabled than the drug patients. No statistically significant difference was seen between the number of recurrent attacks experienced by McKenzie patients than that experienced by drug patients, although the trend was in favour of McKenzie.

Responsibility clearly improved as a function of response to McKenzie treatment whilst those patients undergoing drug treatment increased their responsibility level significantly over the first few weeks after entering into the trial and then decayed to their original

levels. The latter response may be related to the encouragement they received by the doctor prior to randomisation, in an effort to encourage them to mobilise.

Cognitive control increased with the drug patients at seven weeks and then decayed to the base line, whilst the McKenzie group were unchanged over their first few weeks and then fell away over the subsequent months. It is tempting (although impossible to prove) to suggest that the McKenzie patients are using cognitive control methods less because they have the physical method of controlling their pain.

Time lost from work between onset of pain and seven weeks was significantly greater in the physiotherapy group.

7. Conclusions and Recommendations

7.1. Conclusions

7.1.1. Conclusions about the application of McKenzie physiotherapy

7.1.1.1. McKenzie physiotherapy produces significant benefit in disability reduction at seven weeks after pain onset when initial psychological distress is allowed for and when those patients who the physiotherapists were unable to diagnose on their *first* assessment were discounted.

7.1.1.2. McKenzie physiotherapy improved forward lumbar flexion and lumbar extension significantly when compared with those patients treated by means of drug.

7.1.1.3. Those patients treated by McKenzie therapy were absent from work for significantly longer than those patients who received drug treatment.

7.1.1.4. McKenzie physiotherapy treatment produces significant rises in pain locus of control responsibility scores when compared with those treated with a non-steroidal anti-inflammatory drug.

7.1.1.5. No statistically significant difference was seen in pain scale or disability results at six months or one year.

7.1.2. Conclusions about long term exercise compliance

7.1.2.1. Physiotherapy subjects appear to use exercises for treatment of acute attacks rather than prevention of further attacks.

7.1.2.2. Degree of education beyond minimum school leaving age and the frequency of recurrent attacks explains the use of exercises in part.

7.1.2.3. Lumbar roll use is explained to a small extent by the frequency of recurrent attacks.

7.1.2.4. Of the three exercises surveyed, extension in standing appears to be the most frequently practised possibly because of the ease with which this can be incorporated into everyday routine.

7.1.2.5. Lumbar spinal posture support is used much less frequently than exercises and is seldom used in the work environment.

7.1.2.6. Initial measures of depression; somatic awareness; and verbal pain expression did not explain compliance with exercises. At a year following onset of the attack studied, disability and pain locus of control responsibility scores provided no significant explanation of exercise or postural support use.

7.2. Recommendations The recommendations mentioned below only pertain to patients between the age of 18 and 55 years with a 3 week history of Quebec type 1,2 or 3 low back pain who have not been suffering continuous backache prior to the current attack.

7.2.1. There seems little to recommend the use of practitioners untrained in McKenzie's methods for this form of treatment in view of the relative lack of evidence to support substantial benefit from this method of treatment in patients who cannot be diagnosed. Training to the level of 'B' courses is required.

7.2.2. McKenzie therapists who have been fully trained should be able to deal with most non-pathological spinal conditions in a safe and effective fashion with benefit.

7.2.3. Either centralisation or a visual analogue scale should be used as a measure of progress and outcome and also as a monitor of treatment effect where these measures are used at the beginning and end of each treatment.

7.2.4. A limit on the number of treatments which can be performed before review by the family practitioner or specialist should be set and seems to be about six on the basis of the data in the reported study.

7.2.5. There is potential advantage in this form of physiotherapy being administered on a community basis.

7.2.6. Full cost efficacy could only be achieved if physiotherapists are allowed to act as independent practitioners, being referred patients directly from family doctors and having access to specialist opinions directly.

7.2.7. Those patients who cannot be diagnosed on initial assessment by the McKenzie schema should be (re)referred to a qualified medical practitioner for further assessment rather than be treated by McKenzie's principles on an expectant basis.

7.2.8. In acute and subacute low back pain[11] the modified somatic perception questionnaire and the Zung self rated depression scale should be used at a secondary referral level to allow the identification of those patients at risk of prolonged disability to enable more intensive treatment.

7.2.9. Physiotherapy should be available in ways which enable patients to continue with their work or return to work at the earliest possible opportunity.

7.2.10. Treatment should proceed without recourse to radiological investigation if patients, similar to those presented in this study, present no clinical suspicion of a pathological cause for their acute or subacute low back pain.

Appendix 1 - DATA ITEMS RECORDED IN DATABASE

No	Field Names	Length	
1	Patient's Name	19	
2	Hospital Number	6	
3	Age	2	
4	Sex	1	m=1 f=2
5	Telephone	11	
6	Date seen	10	C1
7	Date ref	10	Date on referral letter
8	Addresspt1	19	
9	Addresspt2	19	
10	Addresspt3	19	
11	General practiti	15	GP's name
12	StudyNo.	3	Sequential study number
13	ANALOG - WEEK 2	3	
14	ANALOG - WEEK 3	3	
15	ANALOG - WEEK 4	3	
16	ANALOG - WEEK 5	3	Analog pain results
17	ANALOG - WEEK 6	3	
18	ANALOG - WEEK 7	3	
19	Facet	1	Facet degeneration on x-ray
20	Sudden onset	1	Did this attack start suddenly
21	Bending/Lifting	1	Precipitation
22	Blow/Fall	1	Precipitation
23	Days since onset	2	Not more than 21 allowed
24	Back pain only	1	
25	Back+Thigh pain	1	
26	Pain below knee	1	
27	Medicolegal	1	Is there a claim in progress or being considered?
29	Sleep Disturbed	1	On the previous night
30	Walking affected	1	Can you walk for half an hour?
31	Sitting affected	1	Can you sit for half an hour?
32	Car trav affectd	1	Can you ride in a car/bus for half an hour?
33	Exercises given	1	Have you performed any exercises for your back pain during this attack?
34	Orthosis used	1	Have you worn a corset this time?
35	NSAID used	1	
36	Analgesics used	1	
37	Physio given	1	Have you received any physiotherapy for this attack of low back pain?
38	>2/7 Bedrest	1	Have you rested in bed for more than two days for this attack of low back pain?
39	Employed	1	Are you currently in employment?
40	SpouseOccupation	18	If 39=No What does your Husband/Wife do?

Appendix 1

41	McGILL C1	2	
42	Exercises	1	
43	Orthosisprev	1	Have any of these treatments made you
44	NSAIDprev	1	0=worse, 1=No change, 2=temporary
45	Analgesicsprev	1	relief, 3=cured 9=Not tried
46	PTprev	1	In the past?
47	Bedrestprev	1	
48	PRIVATEprev	1	
49	OFF2+	1	Have you ever been off work for more
50	Occupation	36	than 2 weeks with low back pain
51	TimOffYr	2	How many weeks off in past 12/12
52	DoffNow	2	How many days of in this attack
53	Heavy	1	Is you job physically heavy?
54	PlanWk	1	Have you set a date for getting back
55	Attack1	1	Is this your first attack
56	LIST	1	Sciatic list L/N/R
57	FLEXION	2	Cms flexion 5+=Normal @C1
58	EXTENSION	2	Degrees extension @C1
59	SLR Left	2	@C1
60	SLR Right	2	@C1
62	Radiology?	1	Has the patient been x-rayed
63	Spond?	1	Spondylolysis=0 listhesis=1-4 No=9
64	DiscDegn L1-L2	1	Y/N
65	DiscDegn L2-L3	1	Y/N
66	DiscDegn L3-L4	1	Y/N
67	DiscDegn L4-L5	1	Y/N
68	DiscDegn L5-S1	1	Y/N
69	SBO?	1	Y/N
70	Scoliosis	1	Y/N
71	Cognitive score1	2	Pain locus of control scores
72	Control score 1	2	@C1
73	Zung	2	Modified Zung @C1
74	St Thomas Clinic	2	St Thomas score @C1
75	MSPQ	2	MSPQ @C1
76	ANALOG C1	2	
77	ENJOY WORK	1	Do you enjoy your job A/M/O/Never
78	Left School aged	2	
79	Date Followed up	10	C2
80	DRUG DAYS	2	Days of Ketoprofen taken
81	RTN>WK WKS	1	Weeks back at work by C2
82	DYSPEPSIA	1	
83	ALLERGY	1	
84	Cog AT C2	2	
85	Con AT C2	2	
86	Zung C2	2	
87	MSPQ AT C2	2	

88	McGill AT C2	2	
89	GPVis C1-C2	2	How many times have you needed to see GP / Physiotherapist
90	PT C1-C2	2	
91	GPQ WEEK 1	2	
92	GPQ WEEK 2	2	St Thomas scores - 2nd week
93	GPQ WEEK 3	2	
94	GPQ 6/12	2	
95	ATTACKS AT 6/12	2	How many subsequent attacks
96	GPVis AT 6/12	2	
97	Cog AT 6/12	2	
98	Con AT 6/12	2	
99	LIST @ C2	1	Examination findings at the C2 Clinic follow up
100	FLEX C2	2	
101	SLRL C2	2	
102	GPQ WEEK 4	2	
103	GPQ WEEK 5	2	
104	GPQ WEEK 6	2	
105	GPQ WEEK 7	2	
106	SLRR C2	2	
107	ANALOG AT 6/12	2	
108	QUALY @ C1	6	Quality of life assessments at C1 and C2 scored as a single number.
109	QUALY @ C2	6	
110	BETTER/SAME/WORS	1	At C2 compared with C1
111	EXTENSION @ C2	2	
112	NSAID given	1	Other than Ketoprofen in control group
113	PRIVATE given	1	Osteopathy/Private physiotherapy given
114	BEDREST taken	1	More than 2 days of bedrest C1-C2

Appendix 2 - THE ST THOMAS DISABILITY QUESTIONNAIRE[159]

1. I stay at home most of the time because of my back.

2. I change position frequently to try and get my back comfortable
3. I walk more slowly than usual because of my back

4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use the handrail to get upstairs.

6. Because of my back, I lie down to rest more often

7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly than usual because of my back.

10. I only stand up for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.

12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all of the time.

14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or tights) because of the pain in my back.
17. I only walk short distances because of my back pain.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.
20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.
23. Because of my back pain, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

Appendix 3 - THE OSWESTRY LOW BACK DISABILITY QUESTIONNAIRE[179].

Please read:
This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage in everyday life. Please answer every section, and mark in each section

Mark only the one box which applies to you. We realise you may consider that two of the statements in any one section relate to you, but please just mark the box which most closely describes your problem.

SECTION 1 - Pain
I can tolerate the pain I have without having to use pain killers.
The pain is bad but I manage without taking pain killers.
Pain killers give complete relief from pain.
Pain killers give moderate relief from pain.
Pain killers give very little relief from pain.
Pain killers have no effect on the pain and I do not use them.

SECTION 2 - Personal care
I can look after myself normally without causing extra pain
I can look after myself normally but it causes extra pain.
It is painful to look after myself and I am slow and careful.
I need some help but manage most of my personal care.
I need help every day in most aspects of self care.
I do not get dressed, wash with difficulty and stay in bed.

SECTION 3 - Lifting
I can lift heavy weights without extra pain.
I can lift heavy weights but it gives extra pain.
Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, eg on a table.
Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
I can lift only very light weights.
I cannot lift or carry anything at all.

SECTION 4 - Walking
Pain does not prevent me walking any distance.
Pain prevents me walking more than 1 mile.
Pain prevents me walking more than ½ mile.
Pain prevents me walking more than ¼ mile.
I can only walk using a stick or crutches.

SECTION 5 -Sitting
I can sit in any chair as long as I like.
I can only sit in my favourite chaire as long as I like.
Pain prevents me from sitting more than 1 hour.
Pain prevents me from sitting more than ½ hour.
Pain prevents me from sitting more than 10 minutes.
Pain prevents me from sitting at all.

SECTION 6 - Standing
I can stand as long as I want without extra pain.
I can stand as long as I want but it gives me extra pain.
Pain prevents me from standing for more than 1 hour.
Pain prevents me from standing for more than 30 mins.
Pain prevents me from standing for more than 10 mins.
Pain prevents me from standing at all.

SECTION 7 - Sleep
Pain does not prevent me from sleeping well.
I can only sleep well by using tablets.
Even when I take tablets I have less than six hours sleep.
Even when I take tablets I have less than four hours sleep.
Even when I take tablets I have less than two hours sleep.
Pain prevents me from sleeping at all.

SECTION 8 - Sex life
My sex life is normal and causes no extra pain.
My sex life is normal but causes some extra pain.
My sex life is nearly normal but is very painful.
My sex life is severely restricted by pain.
My sex life is nearly absent because of pain.
Pain prevents any sex life at all.

SECTION 9 - Social life
My social life is normal and gives me no extra pain.
My social life is normal but increases the degree of pain.
Pain has no significant effect on my social life apart from limiting my more energetic interests eg dancing etc.
Pain has restricted my social life and I do not go out as often.
Pain has restricted my social life to my home.
I have no social life because of pain.

SECTION 10 - Travelling
I can travel anywhere without extra pain.
I can travel anywhere but it gives me extra pain.
Pain is bad but I manage journeys over two hours.
Pain restricts me to journeys of less than one hour.
Pain restricts me to short necessary journeys under 30 minutes.
Pain prevents me from travelling except to the doctor or hospital.

Appendix 4 - PRINCIPLE PSYCHOMETRIC QUESTIONNAIRES

1. Zung Self Rated Depression Scale[156]

Please indicate for each of these questions which answer best describes how you have been feeling recently.
Please answer all of the questions.

Zung	Never	Now and then	Quite often	Most of the time
I feel downhearted and sad				
Morning is when I feel best				
I have crying spells or feel like it				
I have trouble getting to sleep at night				
I feel that nobody cares				
I eat as much as I used to				
I still enjoy sex				
I notice that I am losing weight				
I have trouble with constipation				
My heart beats faster than usual				
I get tired for no reason				
My mind is as clear as it used to be				
I tend to wake up too early				
I find it easy to do the things I used to				
I am restless and can't keep still				
I feel hopeful about the future				
I am more irritable than usual				
I find it easy to make a decision				
I feel quite guilty				
I feel that I am useful and needed				
My life is pretty full				
I feel that others would be better off if I were dead				
I still enjoy the things I used to				

Appendix 4

2. Modified Somatic Perception Questionnaire

Please describe how you have felt during the PAST WEEK by putting a tick (✓) in the appropriate box.
Please answer all questions.
Do not think too long before answering.

MSPQ	Not at all	A little/ Slightly	A Great Deal/ Quite a bit	Extremely/ Couldn't be worse
Heart Rate increasing				
Feeling Hot all over	0	1	2	3
Sweating all over	0	1	2	3
Sweating in a particular part of body				
Pulse in neck				
Pounding in head				
Dizziness	0	1	2	3
Blurring of vision	0	1	2	3
Feeling faint	0	1	2	3
Everything appearing unreal				
Nausea	0	1	2	3
Butterflies in stomach				
Pain or ache in stomach	0	1	2	3
Stomach churning	0	1	2	3
Desire to pass water				
Mouth becoming dry	0	1	2	3
Difficulty in swallowing				
Muscles in neck aching	0	1	2	3
Legs feel weak	0	1	2	3
Muscles twitching or jumping	0	1	2	3
Tense feeling across forehead	0	1	2	3
Tense feeling in jaw muscles				

Appendix 4

3. Pain Locus of Control Questionnaire

This is a questionnaire to find out how you see the causes and control of your pain. Please rate each statement by marking a tick (✓) in the box which best shows how much you currently feel the statement applies to you.

Pain Locus of Control	Very True	Some what true	Some what untrue	Very untrue
I need my medication to control my pain	R0	R1	R2	R3
My pain will often go away If I let myself relax physically	C3	C2	C1	C0
No matter what I do, I cannot seem to have an effect on my pain				
I can make pain decrease if I concentrate on painfree parts of my body	C3	C2	C1	C0
I need the help of others to control my pain				
I can sometimes reduce pain by imagining that the pain I feel is really pleasant stimulation				
Only I can help myself with pain	R3	R2	R1	R0
My pain level will go down if I remain passive and don't respond to it	C3	C2	C1	C0
My doctors can help me with my pain	R0	R1	R2	R3
Sometimes I can reduce my pain by not paying attention to it	C3	C2	C1	C0
I am responsible for how pain affects me	R3	R2	R1	R0
I can make pain go away by believing it will go away	C3	C2	C1	C0
My pain just comes and goes, regardless of what I do or think				
My pain will decrease if I think of things going on around me	C3	C2	C1	C0
Being in pain is never my choice	R0	R1	R2	R3
I can reduce my pain if I imagine a situation in which I have been pain-free in the past	C3	C2	C1	C0
Medication helps me control my pain	R0	R1	R2	R3
My pain will get better if I think of pleasant thoughts	C3	C2	C1	C0
My pain is out of control				
Just slowing down and regulating my breathing often helps my pain.	C3	C2	C1	C0

Appendix 5 - QUALITY OF LIFE ASSESSMENT TABLES

Tables for the calculation of quality adjusted life years [181,219,220]

DISABILITY

I No disability
II Slight social disability
III Severe social disability +/- slight impairment of performance at work. Able to do all housework except very heavy tasks
IV Choice of work or performance at work very severely limited. Housewives and old people able to do light housework only but able to go out shopping
V Unable to undertake any paid employment Unable to continue any education. Housewives able to perform a few simple tasks
VI Confined to a chair or wheelchair or able to move around the house only with support from an assistant
VII Confined to bed

DISTRESS

A No distress
B Mild
C Moderate
D Severe

	Distress			
Disability	A	B	C	D
I	1.000	0.994	0.989	0.944
II	0.989	0.986	0.973	0.973
III	0.983	0.979	0.953	0.913
IV	0.975	0.957	0.939	0.882
V	0.961	0.945	0.873	0.390
VI	0.851	0.817	0.657	-0.624
VII	0.733	0.716	0.000	-2.291
VIII	-0.326	-	-	-

Table 90 A quality of life disability - distress matrix

Appendix 6 - ADVICE SHEETS (DRUG & PHYSIOTHERAPY VERSIONS)

All patients on recruitment into the study were given an advice sheet in an attempt to try to prevent poor compliance and breaches of trial protocol. The sheets are similar except for the specific sections ([3] onwards which concerns the treatment allocated).

(DRUG VERSION)

Back Pain Research Unit,
Harlow Wood Orthopaedic Hospital,
Near Mansfield,
Nottinghamshire.

Dear Patient,

Back pain is a very common complaint which strikes one in three adults at some time in their lives. Fortunately, it is a condition which settles with time. The underlying cause of the pain varies but in most cases is never found. Any of the components of the back may give rise to pain including the ligaments; the muscles; the joints or the nerves.

The typical attack of back pain settles within six weeks. During the attack there are several ways in which you can help yourself - and your back.

[1] Rest for a couple of days if necessary but after two days in bed even the fittest person starts to stiffen up. Stiffness with back pain is a very miserable combination. Within the first week of back pain rest for a couple of days getting up for toilet purposes only. If you have already been suffering for more than a week, it is probably too late to rest.

[2] After resting in bed or if you have had your pain for more than a week, start to get back to everyday activities. It won't be possible to do everything but each day you should try to do a little more. It is important that you maintain correct posture at all times as this will hasten you recovery.

[i] Try to stand tall:

(Diagram of erect and slouched posture)

[ii] Always sit in a firmly upholstered or wooden chair, not in an armchair which allows you to slump. Sit up straight and do not slump:

(Diagram of sitting in armchair and on hardbacked chair without lumbar roll)

[iii] Try not to stoop for any activity. Get down on your knees to work on low jobs, stand up straight for jobs at waist height and above. Make sure that your work surface is at the correct height to prevent you from stooping.

[iv] For the first two weeks avoid:
LIFTING BENDING AND TWISTING

After two weeks you can start to lift, but do not lift heavy objects until your back is better. When you do start to lift heavy weights, work gradually up to the heaviest weight over a period of a few days. It is very important to lift everything correctly - even very light objects.

[3] You have been provided with a course of tablets which have a beneficial effect upon low back pain. They are anti-inflammatory and pain killing. The tablets should be continued until you are seen in clinic or until your back ache gets better. Your doctor will provide you with a fresh supply of tablets once your first pack runs out. Please remember to keep this medicine safe if there are children in the house.

[4] These tablets should be taken regularly once a day with breakfast. An occasional side effect associated with their use is that of heart burn or stomach upset. If you have these symptoms then simply stop the tablets and see your own doctor

[5] During your recovery, you are bound to be sore when you are active. This is a sign to ease up - not stop everything. Also if you are doing well and suffer a brief relapse over a few days, this is not unexpected and will settle.

[6] If you find that your bed mattress is not giving you enough support, the simplest way to firm it up is to move the mattress onto the floor.

[7] When you feel able to return to work, do so.

[8] Please come to the clinic to be seen. It will be of benefit to you even if you have recovered completely.

[9] You have been given a number of charts to fill in and return to the Back Research Unit. These are to let us know how you are getting on. **One week from today** fill in a questionnaire and post it to us. Then, another week later, fill in another form and post that to us.... and so on until we see you in clinic again.

Appendix 6

(PHYSIOTHERAPY VERSION - Differing portion)

[3] Take simple pain killers like paracetamol if you need anything

[4] During your recovery, you are bound to be sore when you are active. This is a sign to ease up - not stop everything. Also if you are doing well and suffer a brief relapse over a few days, this is not unexpected and will settle.

[5] You have been asked to come up to the acute physiotherapy clinic for assessment and treatment by the physiotherapist.

[6] If you find that your bed mattress is not giving you enough support, the simplest way to firm it up is to move the mattress onto the floor.

[7] When you feel able to return to work, do so.

[8] Please come to the final follow up clinic to be seen. It will be of benefit to you even if you have recovered completely.

[9] You have been given a number of charts to fill in and return to the Back Research Unit. These are to let us know how you are getting on. **One week from today** fill in a questionnaire and post it to us. Then, another week later, fill in another form and post that to us.... and so on until we see you in clinic again.

Appendix 7 - SIX MONTH QUESTIONNAIRES

At six months after entry into the trial, all patients received a postal follow up containing the St Thomas Disability Questionnaire; a visual analog pain scale and the pain locus of control questionnaire. In addition all patients received the following questionnaire:

1. Are you still seeing your family doctor for low back pain?

Yes or No ☐

2. Have you had any attacks of low back pain since you were last contacted by the back clinic?

Yes or No ☐

and if Yes, how many ☐

3. Have you had to change your job because of your back trouble?

Yes or No ☐

4. Has the treatment you were given at the back clinic helped you with more recent attacks?

Yes or No ☐

5. How often have you had to see your own doctor because of low back pain since you were last contacted by the back clinic?

Approximately:

Number ☐

6. Have you been seen in hospital by a doctor since the back clinic last contacted you?

Yes or No ☐

Appendix 8 - ONE YEAR QUESTIONNAIRE

All patients completed the St Thomas Disability questionnaire; the analog pain scale and a pain locus of control questionnaire. In addition, physiotherapy patients completed a questionnaire on compliance. The frequency of low back pain attacks was assessed with the following questions:

Please answer the following questions:

1. How many attacks of low back pain have you suffered over the last three months

approximately ☐

2. Since you were last seen in the back clinic, how many weeks have you lost from work because of back pain

approximately ☐ weeks
or
I do not have a paid job ☐

Appendix 9 - COMPLIANCE ASSESSMENT SHEET

The following questionnaire was used to examine physiotherapy patients at one year following onset of attack. Photographs taken from McKenzie's self treatment booklet[145] were included. Exercise 1 Extension in lying (Fig 4:3(d)); Exercise 2 Flexion in lying (Fig 4:5(b)); Exercise 3 Extension in standing (Fig 4:4(b)) and an illustration of a lumbar roll (Fig 7:4) with the word "ROLL" printed adjacent to the illustration.

	I use this exercise			
	Daily	Often	Occasionally	Never nowadays
Exercise 1				
Exercise 2				
Exercise 3				

	I use a lumbar roll or a rolled towel when:			
	Daily	Often	Occasionally	Never nowadays
Driving				
At home				
At work				

Appendix 10 - STUDY CONSENT FORM

Back Pain Research Study

Back pain is a very common form of ailment which the majority of the population suffers from at some time or other. Many different treatments are used for this condition but there is no firm information as to which is best.

This study is trying to find out which form of treatment is best. You will be seen by a doctor and examined. If you are suitable for any of the treatments being used, he will give you an envelope to give to the clinic nurse who will give you a fact sheet and details of your treatment.

You will be given a supply of questionnaires and stamped addressed envelopes to send back to us at weekly intervals. We will see you again between four and six weeks after your first visit. Please come to the follow up clinic, even if you are feeling much better.

All information collected during this study will be treated with the same care and strict confidence which applies to all medical records.

I agree to help in the study

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