

Outcome of recent onset low back pain

Liset HM Pengel, MSc (Hum Mov)

Thesis presented for the degree of

Doctor of Philosophy

The University of Sydney

September, 2003

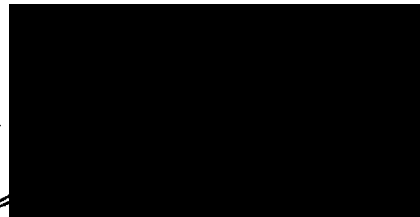
CANDIDATE'S STATEMENT

I, Liset HM Pengel, hereby declare that this submission is my own work and that it contains no material previously published or written by another person except where acknowledged in the text. Nor does it contain material which has been accepted for the award of another degree.

In addition, ethical approval from the University of Sydney Human Research Ethics Committee was granted for a trial involving humans presented in this thesis. Subjects were required to read a subject information document and informed consent was gained prior to study enrolment.

Name Liset HM Pengel

Signed



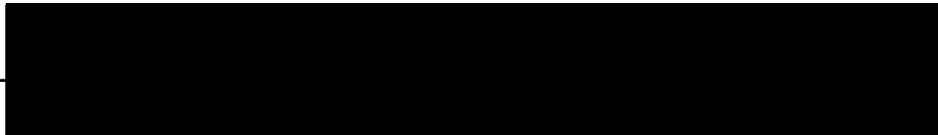
Date

10/10/2003

SUPERVISOR'S STATEMENT

As supervisor of Liset HM Pengel's doctoral work, I certify that I consider her thesis '*Outcome of recent onset low back pain*' to be suitable for examination.

Signed _____



Date 22/10/03

Date 22/10/03

A/Prof Kathryn Refshauge
School of Physiotherapy,
Faculty of Health Sciences,
The University of Sydney.

A/Prof Chris Maher
School of Physiotherapy,
Faculty of Health Sciences,
The University of Sydney.

TABLE OF CONTENTS

CANDIDATE'S STATEMENT.....	I
SUPERVISOR'S STATEMENT	II
TABLE OF CONTENTS.....	III
ABSTRACT	V
PUBLICATIONS AND PRESENTATIONS.....	VIII
ACKNOWLEDGMENTS	IX
PREFACE	X
CHAPTER 1	1
INTRODUCTION.....	1
Low back pain: the problem.....	2
Classification of low back pain.....	3
Treatment	4
Outcome assessment in low back pain.....	6
Prognostic factors.....	7
CHAPTER 2	10
PROGNOSIS OF ACUTE LOW BACK PAIN.....	10
CHAPTER 3	16
SYSTEMATIC REVIEW OF CONSERVATIVE INTERVENTIONS OF SUBACUTE LOW BACK PAIN	16
CHAPTER 4	27
RESPONSIVENESS OF PAIN, DISABILITY AND PHYSICAL IMPAIRMENT OUTCOMES IN SUBJECTS WITH LOW BACK PAIN.	27
Abstract	28
Introduction.....	30
Methods.....	32
<i>Study population</i>	32
<i>Outcome measures</i>	33
<i>Statistical analysis</i>	35
Results.....	36
Discussion	40
CHAPTER 5	43
RANDOMISED CONTROLLED TRIAL COMPARING THE EFFICACY OF EXERCISE AND/OR ADVICE FOR SUBACUTE LOW BACK PAIN	43

Abstract	44
Introduction	46
<i>Intervention</i>	46
<i>Predictors of outcome and of response to intervention</i>	49
Methods	51
<i>Selection of patients</i>	51
<i>Randomisation</i>	54
<i>Intervention</i>	54
<i>Outcomes</i>	57
<i>Predictors of outcome and response to treatment</i>	59
<i>Statistical analysis</i>	62
Results	64
<i>Compliance, side-effects, and cointerventions</i>	68
<i>Predictors of outcome</i>	78
<i>Predictors of response to treatment</i>	81
Discussion	85
<i>Efficacy of intervention</i>	86
<i>Sham intervention</i>	91
<i>Adverse effects</i>	91
<i>Predictors</i>	92
CHAPTER 6	95
CONCLUDING REMARKS	95
Overview of the main results	96
Directions for future research	98
REFERENCES	100
APPENDIX 1	109
TRIAL PROTOCOL:	109
“EXERCISE OR ADVICE FOR SUBACUTE LOW BACK PAIN?”	109
APPENDIX 2	165
STANDARDISED PHYSICAL ASSESSMENT	165
APPENDIX 3	173
TREATMENT MANUAL FOR SUBACUTE LOW BACK PAIN TRIAL	173

ABSTRACT

The aim of the thesis was to describe the outcome of short-term low back pain. A systematic review of the prognosis of acute low back pain, ie low back pain of less than 3 weeks duration, included 15 studies of variable methodological quality. Rapid improvements in pain (mean reduction was 58% of initial scores), disability (58%) and return to work (82% of those initially off work) occurred within the first month. There were further improvements until 3 months, after which levels for pain, disability and return to work remained nearly constant. Seventy-three percent of people had at least one recurrence within 12 months. The systematic review confirms the widely held view that acute low back pain patients improve rapidly, however, recovery is not complete and recurrences are common.

A systematic review of conservative interventions for subacute low back pain included 13 studies evaluating manipulation, back schools, exercise, advice, TENS, hydrotherapy, massage, corset, cognitive behavioural treatment and coordination of primary health care. Most of the studies were of low methodological quality and did not show a significant effect of intervention. For low back pain of 6 weeks to 3 months duration, no evidence of high internal validity was found but when other methodological criteria were considered, evidence was found for the efficacy of advice. Furthermore, there is evidence that when a broader view is taken of the duration of subacute low back pain (7 days to 6 months), other treatments (eg, manipulation, exercise, TENS) may be effective.

A responsiveness study was conducted for a pain scale (0-10), the 24-item and two modified 18-item versions of the Roland Morris questionnaire, the Patient Specific

Functional Scale (PSFS) and physical impairment measures. The measures were completed at baseline and then again after 6 weeks by 155 subjects. Responsiveness was evaluated using different analysis strategies. The most responsive outcome proved to be the PSFS (effect size (ES) = 1.6) followed by the numerical pain scale (ES = 1.3) and 24-item Roland Morris questionnaire (ES = 0.8). The responsiveness of the two 18-item Roland Morris versions was equal to the 24-item version. However, the physical impairment measures were not very responsive (ES 0.1 - 0.6). Ranking of the responsiveness indices was consistent across all statistical analyses. The findings suggest that more emphasis should be placed on change in pain and disability scores than on change in physical impairments.

A randomised controlled clinical trial evaluated the efficacy of exercise and advice for patients suffering from subacute low back pain, ie pain between 6 weeks and 3 months duration. In addition, predictors of outcome and response to treatment were evaluated. Subjects (n=259) were allocated to exercise and advice (n=64), sham exercise and advice (n=60), exercise and sham advice (n=68) and sham exercise and sham advice (n=67). Two-hundred and thirty-one subjects attended the 6-week follow-up. All groups had improved on the primary outcomes. There was a significant effect of exercise and advice for pain and global perceived effect. However, differences were small, ranging from 0.5 to 0.8 points on 11-point scales and unlikely to be clinically worthwhile, although a definite conclusion would require consideration of the long-term outcomes which are not yet complete. There was no interaction effect. None of the predictors could significantly predict outcome at 6 weeks. Self-efficacy was the only factor to significantly modify the response to

exercise for global perceived effect (2.4 points, CI 0.7 to 4.1). However, after Bonferroni correction the effect of self-efficacy was no longer significant.

PUBLICATIONS AND PRESENTATIONS

Parts of the work presented in this thesis have been published and/or presented in the following forums:

PUBLISHED PAPERS

Pengel HM, Maher CG and Refshauge KM (2002). "Systematic review of conservative interventions for subacute low back pain". *Clinical Rehabilitation*, 16:811-820.

Pengel LHM, Herbert RD, Maher CG and Refshauge KM (2003). "Acute low back pain: systematic review of its prognosis". *British Medical Journal*, 327:323-327.

Pengel LHM, Refshauge KM and Maher CG. Responsiveness of pain, disability and physical impairment outcomes in subjects with low back pain. Accepted for publication in *Spine* (Date of acceptance 8 July 2003).

ABSTRACTS

Pengel HM, Maher CG and Refshauge KM (2003). "Responsiveness of pain, disability and physical impairment measures in subjects with low back pain. 14th international WCPT Congress, World Physical Therapy, Barcelona, Spain: RR-PL-1319.

Pengel HM, Maher CG and Refshauge KM (2002). "The responsiveness of pain, disability and physical impairment measures in subjects with low back pain. *From Cell to Society, CoHS Research Conference*, Leura, Australia: 5-7.

Pengel HM, Maher CG and Refshauge KM (2002). "What works for subacute low back pain?" *VIIIth International Physiotherapy Congress*, Sydney, Australia: 139.

ACKNOWLEDGMENTS

I would like to extend my sincere appreciation to A/Prof Kathy Refshauge and A/Prof Chris Maher for giving me the opportunity to do my PhD under their supervision. The last 3 years have been an enormous learning experience. Thanks for your expertise, support and dedication. I look forward to collaborations in the future.

Special thanks to Dr Rob Herbert for his much appreciated assistance with parts of this thesis, even during his study leave.

Thanks to all the physiotherapists who treated and/or assessed subjects in the study; Jennie Hewitt, Toni Ralph, Carol Campanella, Jutta Jablonski, Stephanie Lanzarone, Paul van den Dolder, Sharon Parry, Wendy Annable, Sandra Walker, Sonia Haggman, Neha Bhatia, Liz Harvey, Bruce Anderson, Matt Squires, Sue Sellars, Lucy Thomas, Siobahn Reid, Jill Collier, Amanda Knight and Amanda Adams.

I would also like to thank the NHMRC for funding my scholarship, the NHMRC and Australasian Low Back Pain Consortium for funding the randomised controlled trial and The University of Sydney for waiving my tuition fees.

In addition, thanks to my dear friends Michelle, Sandra, Annie, Eileen and Katrina who made my time in Sydney invaluable, and my parents for their support throughout the past four years.

Finally, I would like to thank Mark for all the hours that you, cramped in economy, spent on planes to Sydney and for all the support you have given me in the past 3 years.

PREFACE

This thesis is comprised of six chapters. Chapter one provides a general introduction to the different topics of the thesis. Chapters two and three are systematic reviews published by the candidate. Chapter two is a systematic review of prognosis of acute low back pain and Chapter three is a systematic review of conservative treatments for subacute low back pain. These chapters are presented as the original published papers and have their own reference list. Chapter four reports the findings of a study investigating responsiveness of commonly used pain, disability and physical impairment measures. Chapter five reports on a randomised clinical trial evaluating exercise and advice for subjects suffering from subacute low back pain. Chapter six includes concluding remarks and recommendations for clinical practice and future research. The references of chapters one, four, five and six are listed at the end of this thesis.

CHAPTER 1

Introduction

Low back pain: the problem

Low back pain is a major health problem in modern society. Annual prevalence is estimated to be between 12 and 45%.¹ Furthermore, between 60 and 90% of the population will experience at least one episode of low back pain in their lifetime.^{1 2} The annual incidence of low back pain is generally reported as 5%.³ Prevalence and incidence estimates vary between studies partly because there is not a standard definition for an episode of low back pain, such as pain for more than a week or pain on most days during the past month^{4 5} Other reasons for variations in incidence and prevalence estimates are differences between countries⁶ and differences in study populations, eg an employed versus an unemployed population. In the US, 25% of people who experience an episode of low back pain seek medical attention, low back pain being the second leading cause for people to visit their general practitioner.¹

One of the consequences of low back pain is the huge cost of health care utilization and sick leave. In the Netherlands in 1991, the total direct medical costs of low back pain were estimated at US\$367.6 million and the total indirect costs for sick leave and disablement were estimated at US\$4.6 billion.⁷ However, costs for worker's compensation claims vary widely among workers. The distribution of claims by cost is skewed because 10-16% of claims account for up to 86% of total costs.^{8 9} Furthermore, the high total cost of claims is often associated with the length of the time off work; it has been shown that compensation claims lasting for more than 3 months are responsible for 90% of the total payments for low back pain.¹⁰

Classification of low back pain

Low back pain refers to pain localized in the lumbar spine.¹¹ Pain radiates distally in about 70% of cases.¹² Low back pain is normally triaged into one of the following categories: spinal cord or cauda equina lesion, nerve root compromise, possible serious spinal pathology, or non-specific low back pain.¹² Possible serious spinal pathology includes fractures, inflammatory disorders, infections or malignancies. Non-specific low back pain is spinal pain of unknown origin where the cause of pain cannot be identified by currently available clinical, radiographic or laboratory tests. Most cases (~85%) of low back pain are classified as non-specific.¹³ Specific causes of low back pain are uncommon; ~4% of cases are compression fractures, ~3% of cases are spondylolisthesis, ~0.7% of cases are malignant spinal neoplasms, ~0.3% of cases are ankylosing spondylitis, and ~0.01% of cases are spinal infections.¹³ The diagnostic triage system is widely used, eg it is promoted in clinical practice guidelines for the management of acute low back pain in 11 different countries.¹⁴

Non-specific low back pain is now commonly classified according to the duration of the pain; acute, subacute or chronic low back pain.^{3 15} However, there is not yet consensus on the definition of each phase. Acute low back pain has been described as pain of less than seven days,¹⁶ less than 3 to four weeks¹⁵ or less than 6 weeks.¹⁷ Subacute low back pain was defined by the Quebec Task Force on Spinal Disorders as pain lasting between seven days and seven weeks.¹⁶ But the most commonly used definition for the subacute phase was proposed by the Cochrane Back review group who defined subacute pain as pain lasting for more than 6 weeks but less than 3 months.¹⁷ However, more recent work suggests that the subacute phase may start

even earlier than 6 weeks, based on the return to work rate which shows a rapid return to work in the first 3 to four weeks after onset of pain.¹⁸ Chronic pain has been defined by the International Association for the Study of Pain as pain that has lasted for more than 3 months.¹⁹ This pain duration has been used in many studies to define chronic low back pain²⁰⁻²² and has also been endorsed by the Cochrane Back Review Group to classify chronic low back pain.¹⁷

Treatment

Low back pain is commonly treated according to its duration³ because different treatments have been shown to be effective for different stages of back pain. For example, a systematic review of exercise therapy for low back pain concluded that exercise therapy is ineffective for acute low back pain but is effective for chronic low back pain.²³

Acute low back pain is generally considered to have a favourable prognosis.^{3 12} It is typically reported that 80 to 90% of patients with acute low back pain recover within 6 weeks even without a prescribed intervention.¹² A prospective study of patients with low back pain lasting less than 72 hours found that 90% of patients recovered (the disappearance of both pain and disability) within 2 weeks and less than 2% developed chronic low back pain.²⁴ However, more recent studies suggest that the course of back pain is more complicated and consists of multiple recurrences.^{25 26} A prospective study of patients consulting their general practitioner for low back pain found that 3 and 12 months after presentation only 21% and 25% respectively, had completely recovered in terms of pain and disability.²⁵ In addition, although 97% of

subjects with back pain of less than 14 days duration returned to work after 1 month, 16% did not regard themselves as being completely recovered.²⁶ Furthermore, after one year, 15% of patients had been on sick leave because of recurrent complaints and after 6 and 12 months, 53% and 46% respectively, did not consider themselves as being completely recovered.²⁶ Because of the uncertainty in the literature about the prognosis of acute low back pain, a systematic review was conducted to determine prognosis for acute low back pain (Chapter 2).

Subacute low back pain has a less favourable prognosis than acute low back pain. Patients with subacute low back pain are unlikely to undergo spontaneous recovery and they are at risk of developing chronic low back pain, a condition known to be resistant to treatment. Therefore, it is particularly important that patients with subacute low back pain receive effective treatment to prevent progression to chronic low back pain.

Several countries have developed clinical practice guidelines that summarise evidence of treatment efficacy for low back pain.²⁷⁻²⁹ A comparison of clinical practice guidelines from 11 countries showed that guidelines do not distinguish subacute low back pain from acute low back pain¹⁴ with most treatment recommendations (except for manual therapy and exercise) for acute low back pain generalised to subacute low back pain. Treatment recommendations for low back pain of less than 3 months include the provision of advice and information, and prescription of medication (eg, paracetamol or nonsteroidal anti-inflammatory drugs) if necessary. Most guidelines do not recommend bed rest but some state that if bed rest is indicated it should not be for more than 2 days. Recommendations for the use of manual therapy vary. Some guidelines recommend manual therapy in the first 6

weeks after onset,^{27 29-33} while other guidelines do not recommend manual therapy at all,^{34 35} recommend manual therapy after 6 weeks,³⁶ or recommend manual therapy for chronic low back pain.³² Exercise is advocated by most guidelines after 4 to 6 weeks, although there is no consensus on the type of exercises.^{28 30-33 35-37} Exercise is also recommended for chronic low back pain^{30 32} with one guideline recommending a multimodal approach.³⁷

To date there has not been a systematic review that has specifically evaluated the efficacy of conservative interventions for subacute low back pain. Therefore a systematic review was conducted on conservative treatments for subacute low back pain (Chapter 3). Chapter 5 reports on a randomised controlled clinical trial comparing the efficacy of advice and exercise for subacute low back pain.

Outcome assessment in low back pain

A wide variety of outcome measures are currently used in low back pain research and new outcome measures are constantly being developed.³⁸ A review by Zanoli et al³⁹ found 92 health-related quality of life measures (eg, pain, function and patient satisfaction) for low back pain disorders. This wide variety in outcomes used makes it difficult to compare results between studies or to pool results of individual studies in a meta-analysis. An international group of experts suggested a standardised “core” set of outcome measures sampling the domains of pain symptoms, back-related function, well-being, disability (social role) and satisfaction with care.⁴⁰

Properties of outcome measures that determine usefulness include validity, reliability and responsiveness. Validity refers to the ability of an instrument to measure the

dimension it is designed to measure. There are many different types of validity, eg, construct validity, content validity or criterion-related validity. Reliability refers to consistency of the measurement, eg the intra-tester reliability, inter-tester reliability and internal consistency. Validity and reliability have been investigated extensively in commonly used pain, disability and physical impairment measures in low back pain research.⁴¹⁻⁴⁶

Responsiveness refers to the ability of an outcome measure to detect clinically meaningful change.⁴⁷ Clinical trials are designed to evaluate change in a patient's health status for different interventions and use of outcome measures that are able to detect that change is fundamental. Because responsiveness depends on the type of patient, it should be established in the population for whom change in health status will be assessed.⁴⁸ Chapter 4 reports a head-to-head comparison of the responsiveness of pain, disability and physical impairment measures for people suffering from subacute low back pain.

Prognostic factors

Treatment guidelines for acute low back pain advocate the identification of adverse prognostic factors.²⁷ The underlying premise is that subgroups of patients can be identified, so that specific interventions are used for the subgroup of patients at risk of developing chronic low back pain. For example, the New Zealand acute low back pain guide suggests the use of a questionnaire to screen patients for 'yellow flags' (eg, psychosocial factors) that, if present, are likely to increase the risk of developing chronic pain and disability.²⁷

Despite the large number of studies conducted to identify prognostic factors there is still no clear or consistent picture of factors that predict outcome over time. Factors identified as predictors of future outcome by one study, are found not to be relevant by other studies. One of the problems with identifying prognostic factors is that many prospective studies and systematic reviews are of low methodological quality. Prognostic factors should be studied in accordance with accepted methodological criteria, in particular the use of an inception cohort, adequate follow up (>80%) and use of appropriate statistical methods.^{49 50} Most studies of prognostic factors do not use a strict inception cohort. This introduces a bias because recovery in patients with acute low back pain can be rapid.¹² Inclusion of patients with back pain of at least four week's duration introduces a sampling bias because many patients have already improved and the study sample is no longer representative of people with acute low back pain. In addition, many studies have small sample sizes, resulting in a lack of power to identify significant prognostic factors. A meta-analysis of individual studies can address the power problem but pooling of studies is often difficult because of differences in study population, outcome measures and timing of follow up.

Despite these significant methodological problems, numerous prognostic factors have been proposed in acute low back pain guidelines. Reported adverse prognostic factors include high levels of initial pain,⁵¹ high levels of initial disability,^{26 52} psychological factors such as poor coping strategies or high anxiety levels,^{51 53-55} low levels of physical activity,^{51 55} longer duration of symptoms,^{51 52 394} pain radiating to the leg,⁵¹ widespread pain,^{51 52 394 55} and previous pain.²⁴

Prognostic factors have also been extensively reviewed for working populations to predict return to work or work-disability. The reported adverse prognostic factors include job dissatisfaction,⁵⁶⁻⁵⁸ poor coping strategies,^{59 60} functional disability,^{59 61} high pain levels,^{56 61} referred pain,^{61 62} previous sick leave or previous back pain^{57 60 61} and shorter job tenure.^{61 63}

Chapter 2 reports a systematic review of prognostic factors for acute low back pain and chapter 6 reports an evaluation of prognostic factors of outcome and response to treatment for subacute low back pain.

In summary, although much work has been done in the area of outcome of recent onset low back pain, there are still many gaps in the literature. This thesis reports on the first systematic review that evaluates the widely held view that 80-90% of patients with acute low back pain recover within 6-8 weeks. In addition, the efficacy of conservative treatments for subacute low back pain is evaluated in a systematic review (Chapter 3) and in a randomised controlled trial investigating the efficacy of exercise and advice (Chapter 5).

CHAPTER 2

Prognosis of acute low back pain

The work presented in this chapter has been published as:

Pengel LHM, Herbert RD, Maher CG and Refshauge KM. "Acute low back pain: systematic review of its prognosis". *BMJ* 2003;327:323-327.

Acute low back pain: systematic review of its prognosis

Liset H M Pengel, Robert D Herbert, Chris G Maher, Kathryn M Refshauge

Abstract

Objectives To describe the course of acute low back pain and sciatica and to identify clinically important prognostic factors for these conditions.

Design Systematic review.

Data sources Searches of Medline, Embase, Cinahl, and Science Citation Index and iterative searches of bibliographies.

Main outcome measures Pain, disability, and return to work.

Results 15 studies of variable methodological quality were included. Rapid improvements in pain (mean reduction 58% of initial scores), disability (58%), and return to work (82% of those initially off work) occurred in one month. Further improvement was apparent until about three months. Thereafter levels for pain, disability, and return to work remained almost constant. 73% of patients had at least one recurrence within 12 months.

Conclusions People with acute low back pain and associated disability usually improve rapidly within weeks. None the less, pain and disability are typically ongoing, and recurrences are common.

Introduction

Clinical practice guidelines promote the view that acute low back pain has a favourable prognosis—the 2000 UK guideline states that “90% [of cases] will recover within six weeks.”^{1,2} Yet these estimates are either unsubstantiated or based on individual studies. To date evidence of the prognosis of acute low back pain has not been systematically reviewed.

Many guidelines for acute low back pain advocate identification of adverse prognostic factors such as fear avoidance behaviours, leg pain, or low job satisfaction. Previous reviews of prognostic factors have been descriptive, do not use strict inception cohorts, or do not provide quantitative information of the predictive value of the factors.³⁻⁶

We aimed to systematically review published data on the course of acute low back pain and to identify clinically important prognostic factors. The term course refers to both the natural course and the clinical course of low back pain.

Methods

To be included studies had to be of a prospective design, describe the source of participants and method

of sampling, have an inception cohort of participants with low back pain or sciatica for less than three weeks, have a follow up period of at least three months, and report on symptoms, health related quality of life, disability, or return to work. Studies were excluded that recruited patients with specific diseases such as arthritis, fracture, tumour, or cauda equina syndrome (but not sciatica).

Identification of studies and assessment of methodological quality

Studies were identified through searches of Medline, Embase, and Cinahl to March 2002. We also searched personal files and tracked references of included studies through the Science Citation Index. The search strategies were those recommended by the Cochrane Back Review Group together with a strategy for searching Medline for prognostic studies.^{7,8} Keywords used were inception, survival, logistic, Cox, life tables, and log rank. We had no language restrictions.

Despite there being no widely accepted method for assessing methodological quality of prognosis studies and no empirical evidence of bias related to various methodological features of such studies, validity criteria have been proposed.⁹ Methodological quality was assessed by six criteria (table 1). Two raters independently assessed the quality. A third reviewer resolved disagreements.

Data extraction and analysis

Study characteristics extracted from eligible papers were target population, sample size, duration of low back pain at time of enrolment, description of interventions, duration of follow up, prognostic factors, and outcome measures. Outcome data extracted were pain, disability, return to work, and recurrences. Data were extracted for time points where follow up was at least 80%. Data on return to work were obtained from the stratum of participants off work at baseline. To facilitate comparison, pain and disability scores were converted to a 100 point scale. Ten studies were controlled trials. For these studies, data were extracted for the control group, defined as the group receiving the least active intervention. In one trial, outcomes were reported only for the whole study sample because at follow up no differences were found between the groups receiving manual therapy, intensive training, or medical care.⁹ Prognostic data from this study are therefore based on the outcomes of the three groups.

The Wilson score method was used to calculate the confidence intervals for a single proportion.¹⁰ When it

School of Physiotherapy, University of Sydney, PO Box 170, Lidcombe NSW 1825, Australia

Liset H M Pengel
PhD student

Robert D Herbert
senior lecturer

Chris G Maher
associate professor

Kathryn M Refshauge
associate professor

Correspondence to:
R D Herbert
R.Herbert@th.su.
usyd.edu.au

bmj.com 2003;327:323

Table 1 Assessment of methodological quality of studies detailing course of acute low back pain

Study	Defined sample*	Representative sample†	Complete follow up‡	Prognosis§	Blinded outcome¶	Statistical adjustment**
Cooper et al 1996 ¹² ; Tate et al 1999 ¹³	Yes	Yes	Yes	Yes	No	Yes
Coste et al 1994 ¹⁴	Yes	Yes	Yes	Yes	No	Yes
Dettori et al 1995 ¹⁵	Yes	No	No	Yes	NA	NA
Faas et al 1993 ¹⁶ ; Faas et al 1995 ¹⁷	Yes	No	Yes	Yes	NA	NA
Fordyce et al 1986 ¹⁸	Yes	No	No	No	NA	NA
Hazard et al 1996 ¹⁹ ; Reid et al 1997 ²⁰	No	Yes	Yes	Yes	Yes	No
Hazard et al 2000 ²¹	Yes	Yes	Yes	Yes	NA	NA
Hides et al 1994 ²² ; Hides et al 2001 ²³	Yes	No	Yes	Yes	NA	NA
Kienerman et al 1995 ²⁴	Yes	No	No	Yes	No	No
Malmivaara et al 1995 ²⁵	Yes	No	Yes	Yes	NA	NA
Rozenberg et al 2002 ²⁶	Yes	No	Yes	Yes	NA	NA
Schiøtz-Christensen et al 1999 ²⁷	Yes	No	Yes	Yes	No	Yes
Selerlis et al 1998 ⁹ ; Selerlis et al ¹⁸	Yes	Yes	Yes	Yes	No	Yes
Sieben et al 2002 ²⁹	Yes	No	No	Yes	NA	NA
Weber et al 1993 ³⁰	No	No	Yes	Yes	NA	NA

No=criterion clearly not satisfied or unclear if criterion is satisfied. NA=study did not evaluate prognostic factors.
 *Description of source of participants and inclusion and exclusion criteria.
 †Participants selected by random selection or as consecutive cases.
 ‡At least one prognostic outcome available from at least 80% of study population at three month follow up or later.
 §Studies must provide raw data, percentages, survival rates, or continuous outcomes.
 ¶Assessor unaware of at least one prognostic factor, used to predict prognostic outcome, at time prognostic outcome was measured.
 **For at least two prognostic factors with adjustment factor reported.

was possible to pool data across studies we obtained n weighted pooled means for continuous data and variance weighted pooled proportions for dichotomous data. The n weighted mean was used in preference to the variance weighted mean (the usual method of meta-analysis) because several studies did not provide variance data. Variance weighted pooled proportions were calculated using a random effects model.¹¹

Studies evaluating prognostic factors used a range of modelling procedures and many different covariates, making pooling across studies problematic.⁸ Prognostic data were therefore not pooled. Data on prognostic factors were extracted only if the study reported on at least 80% of participants. If possible, odds ratios with 95% confidence intervals were extracted or calculated from the data. A second reviewer checked the data extraction.

Results

The search retrieved 4458 articles, of which only 15^{9-12,30} fulfilled all inclusion criteria and were included in our review (table 2). Five studies were described in more than one report.^{9-12,15,16,17,19,20,22,25,28} Of the 15 studies, only one monitored patients with sciatica.³⁰ The studies included nine randomised controlled trials that evaluated exercise,^{9,15,16,18,22,25,25,28} manual therapy,^{9,28} an educational pamphlet,²¹ medical care,^{9,16,22,23,26} non-steroidal anti-inflammatory drugs,³⁰ and bed rest^{25,26}; one controlled trial that evaluated an early intervention in the workplace^{12,15}; and five cohort studies,^{14,19,20,24,27,29} one of which included an intervention by general practitioners.¹⁴ Patients were recruited from primary care,^{9,14,16,18,24,26-30} specialists,^{18,26} hospital emergency departments,^{9,15,18,22,23,26} and occupational healthcare providers.^{9,12,15,19-21,25,28,30}

Methodological quality

The two reviewers scored 84 quality criteria and agreed on 64 (76%). The intraclass correlation coefficient (2,1) for the total score was 0.52. Most studies defined the

sample (87%). Five studies (33%) explicitly described methods for assembling a representative sample. Eleven studies (73%) had follow up of at least 80%. All but one study quantified prognosis.¹⁸ Six studies reported prognostic factors. Of the six studies, one (17%)^{18,20} used blinded assessment and four (67%)^{18,14,27,28} performed statistical adjustment for prognostic factors.

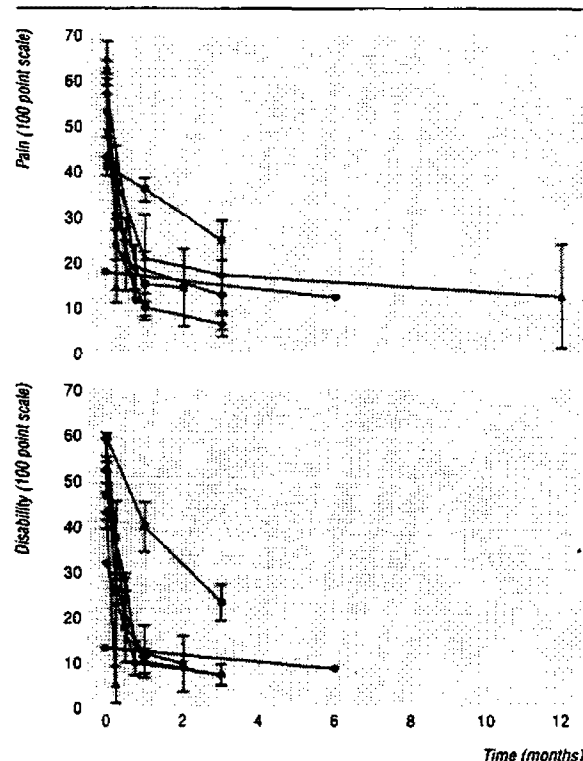


Fig 1 Means (95% confidence intervals) for pain (top) and disability (bottom) during 12 months after onset of acute low back pain

Table 2 Description of included studies on acute low back pain

Study	Participants (setting)	Design	Outcomes	Follow up
Cooper et al 1996 ¹² ; Tate et al 1999 ¹³	218 nurses with occupational back injuries for <2 days (Canada)	Controlled trial comparing early intervention with control* (nil)	Pain (0-100; n=158), disability (Oswestry; n=158), and time loss from work (n=218)	6 months
Coste et al 1994 ¹⁴	103 patients with low back pain for <72 hours, consulting general practitioner (France)	Cohort study, with intervention by general practitioner	Pain (visual analogue scale), disability (French version of Roland Morris), time spent in bed, date of recovery, return to work	8, 15, 30, 60, and 90 days
Dettoni et al 1995 ¹⁵	170 army employees with low back pain for <7 days presenting to army hospital (Germany)	Randomised controlled trial comparing flexion exercises, extension exercises, and control* (ice pack)	Pain (0-5), disability (Roland Morris), ability to return to full work, spinal mobility, satisfaction with care, recurrences	1, 2, 4, and 8 weeks and 12 months
Faas et al 1993 ¹⁶ ; Faas et al 1995 ¹⁷	473 patients with low back pain for <3 weeks, consulting general practitioner (Netherlands)	Randomised controlled trial comparing exercise, medical care, and placebo ultrasonography*	Pain (0-85), functional health status (Nottingham health profile), recurrences, medical care usage, days off work	3 and 12 months
Fordyce et al 1986 ¹⁸	107 patients with low back pain for <10 days, consulting general practitioner, emergency room, or orthopaedic clinics (United States)	Randomised controlled trial comparing exercises on pain contingent basis with exercises on time contingent basis	Sick or well score (composite score of work status, medical care usage, claims of impairment, pain drawings), activity levels, activities engaged in (activity pattern indicator)	6 weeks and 12 months
Hazard et al 1996 ¹⁹ ; Reid et al 1997 ²⁰	207 workers reporting occupational back injury within 11 days (United States)	Cohort study	Work status	3 months
Hazard et al 2000 ²¹	489 workers reporting occupational back injury within 11 days (United States)	Randomised controlled trial comparing educational pamphlet with control* (nil)	Work status, days off work	3 and 6 months
Hides et al 1994 ²² ; Hides et al 2001 ²³	41 patients with low back pain for <3 weeks presenting to emergency room (Australia)	Randomised controlled trial comparing stabilising exercises with medical care*	Pain (visual analogue scale), disability (Roland Morris), range of motion, activity, muscle atrophy, recurrences	1, 2, 3, and 4 weeks and 1 and 3 years
Klenerman et al 1995 ²⁴	300 patients with low back pain for <1 week, consulting general practitioner (United Kingdom)	Cohort study	Pain (0-10), disability (Oswestry)	2 and 12 months
Malmivaara et al 1995 ²⁵	186 workers with low back pain for <3 weeks, consulting for occupational health care (Finland)	Randomised controlled trial comparing exercise, bed rest, and advice*	Pain (0-10), disability (Oswestry), sick days, health related quality of life (0-1), range of motion	3 and 12 weeks
Rozenberg et al 2002 ²⁶	281 patients with low back pain for <72 hours, consulting general practitioner or rheumatologist (France)	Randomised controlled trial comparing bed rest with normal activity*	Pain (0-10), disability (Roland Morris), sick days, intensity of vertebral stiffness (Schöber's test), recurrences	Day 6 or 7 and 1 and 3 months
Schiøtz-Christensen et al 1999 ²⁷	524 patients with low back pain for <2 weeks, consulting general practitioner (Denmark)	Cohort study	Sick leave, sick days, functional recovery, complete recovery	1, 6, and 12 months
Seferlis et al 1998 ⁹ ; Seferlis et al 2000 ²⁸	180 patients with low back pain for <14 days, referred from general practitioner, occupational doctor, or emergency room (Sweden)	Randomised controlled trial comparing manual therapy, intensive training, and medical care*†	Pain (1-11), disability (Oswestry), physical examination, recurrences, sick leave	1, 3, and 12 months
Sieben et al 2002 ²⁹	44 patients with low back pain for <2 weeks consulting general practitioner (Netherlands)	Cohort study	Pain (0-10), disability (Dutch version of Roland Morris), fear of movement (Tampa), thoughts about pain (Dutch version of pain catastrophising scale)	3 and 12 months
Weber et al 1993 ³⁰	214 patients with sciatica for <14 days, referred by general practitioner or occupational doctor (Norway)	Randomised controlled trial comparing non-steroidal anti-inflammatory drug (piroxicam) with placebo*	Pain (0-100), disability (Roland Morris), sick leave	3 and 12 months

* Considered as control group for data extraction.

† Outcomes were reported for whole study sample, so prognostic data based on outcomes of three groups.

Course of low back pain

Most studies reported that pain decreased rapidly (by between 12% and 84% of initial levels, pooled mean 58%) within one month. Pain continued to decrease, albeit more slowly, until about three months (fig 1). Two studies that provided data beyond the three month follow up showed that pain levels remained nearly constant until the 12 month follow up.¹²⁻¹⁶ The pooled mean level of pain on a 100 point scale was 22 at one month and 15 between three and 12 months. A similar trend was seen for disability, which decreased by between 33% and 83% of initial levels (pooled mean 58%) within one month (fig 1). One study reported data on six month follow up.¹² The pooled mean level of disability on a 100 point scale was 24 at one month and 14 between three and six months.

Between 68% and 86% of participants initially off work returned to work within one month (pooled estimate 82%, 95% confidence interval 73% to 91%; fig 2).

One study reported data on six month follow up.²¹ The pooled estimate of the proportion of participants who returned to work, extracted from studies that reported return to work at three to six months, was 93% (91% to 96%).

The cumulative risk (one study, 135 participants) of at least one recurrence within three months was 26% (19% to 34%).²⁶ Two studies reported recurrences within 12 months.^{16, 22} The cumulative risk of at least one recurrence within 12 months varied from 66% to 84% (pooled estimate 73%, 59% to 88%). One study reported a cumulative risk of recurrence after three years of 84%.²³

One study included patients with sciatica.³⁰ In this sample, both back pain and leg pain decreased, on average, by 69% of initial scores within one month. Disability decreased by 57% of initial scores within one month. Data on long term pain and disability were not available.

Prognostic factors

Three studies reported on prognostic factors for at least 80% of the population.^{14, 19, 27} With one exception, odds ratios of significant prognostic factors ranged from 0.04 to 10.4. One study reported that scores of 0.48 or more on the Vermont disability prediction questionnaire were predictive of return to work at three months (odds ratio 76.3, 9.6 to 604.9; positive likelihood ratio 5.7, 3.9 to 8.5; negative likelihood ratio 0.07, 0.01 to 0.50).¹⁸

Discussion

Our review confirms the widely held view that most people with acute low back pain have rapid improvements in pain and disability within one month. Most of those off work with back pain also returned to work within one month. Further improvement occurred until about three months. Thereafter levels of pain, disability, and return to work remained almost constant, although only two studies provided follow up data beyond three months.^{12, 16}

Although most people return to work within 12 months, low levels of pain and disability persist. The studies did not report enough data to establish if levels of long term pain and disability reflect a small subgroup with high levels of pain and disability or a large subgroup with low levels of pain and disability. Nor is it clear whether chronic low levels of pain and disability are due to persistence of the original episode or to recurrent episodes.

Findings from previous reviews on prognostic factors of low back pain have been inconsistent.³⁻⁶ Putative prognostic factors include psychological factors such as distress,³ personal factors such as previous back pain,⁴ and work related factors such as job satisfaction.⁵ However, the evidence of the prognostic value of these factors comes mainly from studies that either did not recruit a relevant cohort or were methodologically weak. We located only one relevant, methodologically strong paper that provided evidence of a clinically useful predictor of outcome (in this case return to work) for primary care patients with acute low back pain. Hazard et al reported that scores of 0.48 or more on the Vermont disability prediction questionnaire were associated with a likelihood ratio of 5.7 and scores of less than 0.48 were associated with a likelihood ratio of 0.07.¹⁹ Given the low prevalence of failure to return to

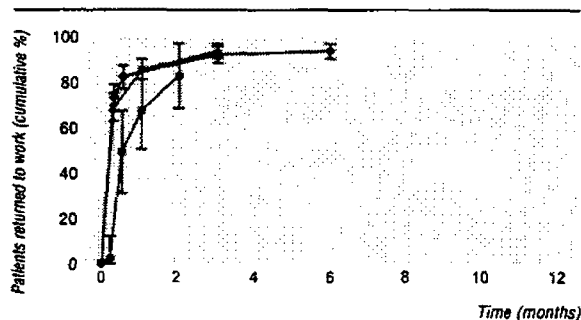


Fig 2 Means (95% confidence intervals) for return to work during 12 months after onset of acute low back pain of those initially off work. Reid et al¹⁶ report proportion returned to work, including those who returned to work and subsequently left work

What is already known on this topic

Clinical practice guidelines state that recovery from acute low back pain is rapid and complete

What this study adds

People with acute back pain experience improvements in pain, disability, and return to work within one month

Further but smaller improvements occur up to three months, after which pain and disability levels remain almost constant

Low levels of pain and disability persist from three to at least 12 months

Most people will have at least one recurrence within 12 months

work at three months (pooled estimate of 6%), this predictor may be of limited clinical utility. Moreover, the cut-off score of 0.48 was chosen by inspection of the data, which is known to inflate predictive accuracy.¹¹

Participants off work with low back pain have higher pain and disability scores than people who are working.³² Thus it may be sensible to consider separately the prognosis of those off work. It remains unclear if the prognosis of participants initially off work is worse than those who are not.

We included only studies that recruited inception cohorts of participants with low back pain or sciatica for less than three weeks. This policy may be sufficiently restrictive or too restrictive. A formal sensitivity analysis of participants with low back pain for less than one week and for less than three weeks showed that the reduction in pain and disability is similar in these two groups, justifying inclusion of studies with participants having pain for up to three weeks. However, inclusion of participants with low back pain for up to six weeks seems unjustified. Our data show that study participants had rapid improvements in pain and disability within one month. By six weeks, participants had already improved significantly; typically pain and disability were only a third of initial values. Moreover, many people no longer had back pain at six weeks, so those recruited with back pain for six weeks cannot be representative of all people who have back pain. We therefore believe it is justifiable to restrict our review to participants with low back pain for three weeks or less.

Contributors: LHMP designed the study protocol, located and selected studies, extracted and interpreted the data, wrote the paper, and approved the final manuscript. RDH designed the study protocol, extracted and interpreted the data, advised on the statistical analysis, and revised and approved the final manuscript. CGM and KMR designed the study protocol, assessed the quality of the trials, interpreted the data, and revised and approved the final manuscript. LHMP will act as guarantor for the paper.

Funding: LHMP's scholarship was funded by the National Health and Medical Research Council and the Australasian Physiotherapy Low Back Pain Trial Consortium. The guarantor accepts full responsibility for the conduct of the study, had access to the data, and controlled the decision to publish.

Competing interests: None declared.

- 1 Koes BW, Van Tulder MW, Ostelo R, Burton KA, Waddell G. Clinical guidelines for the management of low back pain in primary care: an international comparison. *Spine* 2001;26:2504-13.
- 2 Waddell G, Burton AK. *Occupational health guidelines for the management of low back pain at work—evidence review*. London: Faculty of Occupational Medicine, 2000.
- 3 Gatchel RJ, Gardea MA. Psychosocial issues: their importance in predicting disability, response to treatment, and search for compensation. *Neurol Clin* 1999;17:149-66.
- 4 Linton SJ. Occupational psychological factors increase the risk of back pain: a systematic review. *J Occup Rehabil* 2001;11:53-66.
- 5 Pincus T, Burton AK, Vogel S, Field AP. A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain. *Spine* 2002;27:E109-20.
- 6 Shaw WS, Pransky G, Fitzgerald TE. Early prognosis for low back disability: intervention strategies for health care providers. *Disabil Rehabil* 2001;23:815-28.
- 7 Van Tulder MW, Assendelft WJ, Koes BW, Bouter LM. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. *Spine* 1997;22:2323-30.
- 8 Altman DG. Systematic reviews of evaluations of prognostic variables. *BMJ* 2001;323:224-8.
- 9 Seferlis T, Nemeth G, Carlsson AM, Gillstrom P. Conservative treatment in patients sick-listed for acute low-back pain: a prospective randomised study with 12 months' follow-up. *Eur Spine J* 1998;7:461-70.
- 10 Newcombe RG. Two-sided confidence intervals for the single proportion: comparison of seven methods. *Stat Med* 1998;17:857-72.
- 11 DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986;7:177-88.
- 12 Cooper JE, Tate RB, Yassi A, Khokhar J. Effect of an early intervention program on the relationship between subjective pain and disability measures in nurses with low back injury. *Spine* 1996;21:2329-36.
- 13 Tate RB, Yassi A, Cooper J. Predictors of time loss after back injury in nurses. *Spine* 1999;24:1930-5.
- 14 Coste J, Delecoeuillerie G, Cohen de Lara A, Le Parc JM, Paolaggi JB. Clinical course and prognostic factors in acute low back pain: an inception cohort study in primary care practice. *BMJ* 1994;308:577-80.
- 15 Deutori JR, Bullock SH, Sutlive TG, Franklin RJ, Patience T. The effects of spinal flexion and extension exercises and their associated postures in patients with acute low back pain. *Spine* 1995;20:2303-12.
- 16 Faas A, Chavannes AW, van Eijk JT, Gubbels JW. A randomized, placebo-controlled trial of exercise therapy in patients with acute low back pain. *Spine* 1993;18:1388-95.
- 17 Faas A, van Eijk JT, Chavannes AW, Gubbels JW. A randomized trial of exercise therapy in patients with acute low back pain. Efficacy on sickness absence. *Spine* 1995;20:941-7.
- 18 Fordyce WE, Brockway JA, Bergman JA, Spengler D. Acute back pain: a control-group comparison of behavioral vs traditional management methods. *J Behav Med* 1986;9:127-40.
- 19 Hazard RG, Haugh LD, Reid S, Preble JB, MacDonald L. Early prediction of chronic disability after occupational low back injury. *Spine* 1996;21:945-51.
- 20 Reid S, Haugh LD, Hazard RG, Tripathi M. Occupational low back pain: Recovery curves and factors associated with disability. *J Occup Rehabil* 1997;7:1-14.
- 21 Hazard RG, Reid S, Haugh LD, McFarlane G. A controlled trial of an educational pamphlet to prevent disability after occupational low back injury. *Spine* 2000;25:1419-23.
- 22 Hides JA, Stokes MJ, Saide M, Jull GA, Cooper DH. Evidence of lumbar multifidus muscle wasting ipsilateral to symptoms in patients with acute/subacute low back pain. *Spine* 1994;19:163-72.
- 23 Hides JA, Jull GA, Richardson CA. Long-term effects of specific stabilizing exercises for first-episode low back pain. *Spine* 2001;26:E243-8.
- 24 Klenerman L, Slade PD, Stanley JM, Pennie B, Reilly JP, Atchison LE, et al. The prediction of chronicity in patients with an acute attack of low back pain in a general practice setting. *Spine* 1995;20:478-84.
- 25 Malmivaara A, Hakkinen U, Aro T, Heinrichs ML, Koskenniemi L, Kuosma E, et al. The treatment of acute low back pain—bed rest, exercises, or ordinary activity? *N Engl J Med* 1995;332:351-5.
- 26 Rozenberg S, Delval C, Rozvani Y, Olivieri-Apicella N, Kuntz JL, LeGrand E, et al. Bed rest or normal activity for patients with acute low back pain: a randomized controlled trial. *Spine* 2002;27:1487-93.
- 27 Schioutz-Christensen B, Nielsen GL, Hansen VK, Schodt T, Sorensen HT, Olesen F. Long-term prognosis of acute low back pain in patients seen in general practice: a 1-year prospective follow-up study. *Pain Pract* 1999;16:223-32.
- 28 Seferlis T, Nemeth G, Carlsson AM. Prediction of functional disability, recurrences, and chronicity after 1 year in 180 patients who required sick leave for acute low-back pain. *J Spinal Disord* 2000;13:470-7.
- 29 Sieben JM, Vlaeyen JW, Tuerlinckx S, Portegijs PJ. Pain-related fear in acute low back pain: the first two weeks of a new episode. *Eur J Pain* 2002;6:229-37.
- 30 Weber H, Holme I, Amlie E. The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam. *Spine* 1993;18:1433-8.
- 31 Altman DG, Lausen B, Sauerbrei W, Schumacher M. Dangers of using "optimal" cutpoints in the evaluation of prognostic factors. *J Natl Cancer Inst* 1994;86:829-35.
- 32 Truchon MFL. Biopsychosocial determinants of chronic disability and low-back pain: a review. *J Occup Rehabil* 2000;10:117-42.

(Accepted 1 June 2003)

CHAPTER 3

Systematic review of conservative interventions of subacute low back pain

The work presented in this chapter has been published as:

Pengel HM, Maher CG and Refshauge KM. "Systematic review of conservative interventions for subacute low back pain". *Clin Rehabil* 2002;16;811-820.

Systematic review of conservative interventions for subacute low back pain

Heloise M Pengel School of Physiotherapy, **Chris G Maher** School of Physiotherapy and Centre for Evidence-based Physiotherapy and **Kathryn M Refshauge** School of Physiotherapy, the University of Sydney, Sydney, Australia

Received 27th May 2002; manuscript accepted 20th July 2002.

Objective: To evaluate the effect of conservative interventions on clinically relevant outcome measures for patients with subacute low back pain. This is particularly important because effective treatment for subacute low back pain will prevent the transition to chronic low back pain, a condition that is largely responsible for the high health care costs of low back pain.

Design: Systematic review of randomized controlled trials.

Main outcome measures: Methodological quality of each trial was assessed. Effect sizes and 95% confidence intervals were calculated for pain and disability and risk ratios for return to work.

Results: Thirteen trials were located, evaluating the following interventions: manipulation, back school, exercise, advice, transcutaneous electrical nerve stimulation (TENS), hydrotherapy, massage, corset, cognitive behavioural treatment and co-ordination of primary health care. Most studies were of low quality and did not show a statistically significant effect of intervention. For the strict duration of low back pain (six weeks to three months), no evidence of high internal validity was found but when other methodological criteria were considered, evidence was found for the efficacy of advice. Furthermore, there is evidence that when a broader view is taken of the duration of subacute low back pain (seven days to six months), other treatments (e.g. manipulation, exercise, TENS) may be effective.

Conclusions: Our review identified a major gap in the evidence for interventions that are currently recommended in clinical practice guidelines for the treatment of subacute low back pain. Lack of a uniform definition of subacute low back pain further limited current evidence.

Introduction

It has been reported that 80-90% of patients with acute low back pain recover within six weeks.¹ Patients who still suffer from their low back pain

at six weeks are less likely to undergo recovery, with a substantial proportion progressing to develop chronic low back pain.² This condition is known to be resistant to treatment and is largely responsible for the high health care and socio-economic cost of low back pain.³ Therefore, it is particularly important that patients with subacute low back pain receive effective treatment.

A recent study showed that clinical practice

Address for correspondence: HM Pengel, School of Physiotherapy, University of Sydney, PO Box 170, Lidcombe NSW 1825, Australia. e-mail: hpen1533@mail.usyd.edu.au

guidelines do not distinguish subacute low back pain from acute low back pain,⁴ with treatment recommendations for acute low back pain (duration <6 weeks) generalized to subacute low back pain (duration 6–12 weeks). The treatments recommended in the guidelines include: advice, exercise, manipulation and/or analgesics.^{5–9} However, to date there has not been a systematic review that has specifically evaluated the efficacy of these interventions for subacute low back pain.

At present, only the effect of multidisciplinary biopsychosocial rehabilitation has been evaluated for subacute low back pain among working-age adults.¹⁰ The authors only included two studies and performed a qualitative analysis of the literature. They concluded that there is moderate evidence that multidisciplinary biopsychosocial rehabilitation offers some benefit for adults with subacute low back pain. The studies in this review were not pooled quantitatively, nor were other forms of treatment evaluated. The current review is the first to evaluate the effect of all conservative interventions for subacute low back pain on clinically relevant outcome measures (i.e. pain, disability and return to work).

Methods

Identification of studies

Studies were identified through searches of the following databases from the earliest record to April 2002: MEDLINE, AMED, EMBASE, DocOnline, INSPEC, CINAHL, Current Contents, PEDro, MANTIS, Chiroaccess, OSHROM, Sportdiscus, DARE, ACP journal club, Cochrane Database of Systematic Reviews, PsycINFO, Cochrane Controlled Trials Register and citation tracking of eligible studies via the Web of Science-Citation Index. To locate studies in MEDLINE and EMBASE, the search strategies recommended by the Cochrane Back Review Group were used.¹¹ References listed in retrieved articles were screened and an author of the only review on subacute low back pain¹⁰ was asked to review the list of identified studies.

Inclusion criteria

To be included the study had to meet the following five criteria:

- 1) *Design* Only randomized controlled trials (RCTs) were included.
- 2) *Study population* Subjects with subacute nonspecific low back pain with or without referral to the leg. Postsurgical or pregnant subjects were excluded. The most common definition of subacute low back is pain lasting between six weeks and three months.¹² But as there is still much debate on the time points at which acute low back pain becomes subacute or when subacute low back pain becomes chronic, an alternate definition was also used in this review. This definition used the earliest reported time for the transition from acute to subacute suggested by the Quebec Task Force on Spinal Disorders (i.e. seven days),¹³ and the latest reported time for the transition from subacute to chronic (i.e. six months).¹⁴ If a study used the duration of sick leave as an inclusion criterion, then this was presumed to be equivalent to the duration of the low back pain episode. If the duration was not clearly described, the study was excluded.
- 3) *Interventions* All types of conservative treatment were included (i.e. surgery was excluded).
- 4) *Outcome* Studies were required to report at least one of the following outcome measures: pain, disability, or return to work.
- 5) *Language* The study was published in English or Dutch.

Methodological quality assessment

The criteria list recommended by the Cochrane Collaboration Back Review Group was used to assess trial quality¹¹ (see Appendix). This list has been used in a number of systematic reviews of low back pain treatments and consists of internal validity criteria, descriptive criteria and statistical criteria. In recent publications only the criteria describing internal validity have been used to assess methodological quality, because there is growing belief that these criteria are the most important in assessing study quality.^{15–17} We calculated both the internal validity score and the score for all 19 criteria; however, our primary measure of quality was the internal validity score. We used a version of the internal validity scale that consisted of nine internal validity criteria.¹⁵

Two raters (HMP and CGM) independently assessed the quality of the studies and then met to resolve discrepancies. Every criterion of the quality list was scored as 'yes', 'no' or 'don't know', with the final quality score being the sum of 'yes' responses. Cohen's kappa was calculated to measure the agreement between the raters on each item and the intraclass correlation coefficient (2,1) was calculated for the total score of the internal validity criteria and all 19 criteria.¹⁸ The threshold for high-quality studies was a priori set at 50% or more of the maximum score.¹¹ We did not blind assessors of trial quality because there is no consensus on the need for this.^{19,20}

Data analysis

For every study, means and standard deviations for continuous outcomes (pain and disability) were extracted, as was the number of subjects who returned to work. If incomplete data were reported, letters were sent to the first author to obtain the additional data, but no extra data were received.

Effect sizes and risk ratios

Effect sizes (ES)²¹ with 95% confidence intervals (CI) were calculated as the difference between groups at every follow-up divided by the pooled estimate of the standard deviation from both groups. In three studies,²²⁻²⁴ the ES was calculated as the difference between groups for change scores because of limited data. Wherever possible, we selected the visual analogue scale (measure of pain) and the Roland Morris questionnaire (measure of disability) as outcomes because there is evidence for the validity of these measures.^{25,26} For one study that provided only the range, the standard deviation was estimated as a quarter of the range.²⁷ Risk ratios and 95% CIs were calculated for return to work data.

Pooled analysis

Clinical homogeneity among the studies was assessed by comparing the retrieved studies with respect to quality, low back pain duration, intervention, outcome measures and timing of follow-up. Only two studies were considered sufficiently homogeneous, and they were pooled by estimating the relative risk for return to work using a random effects model, using Revman 4.1 software.²⁸

Results

Literature search

The database searches retrieved 89 trials of which, on close inspection, 76 did not fulfil the inclusion criteria. As a result, 13 studies were included in this review (Table 1).^{22-24,27,29-41} A list of excluded studies is available from the authors. Reasons for exclusion were a lack of randomization, or not the study population or language of interest. In total, the 13 trials reported 33 intervention contrasts that were classified into one of the following categories: spinal manipulative therapy, back schools, exercise, advice, hydrotherapy, transcutaneous electrical nerve stimulation (TENS), corset and other.

Methodological quality

When the nine internal validity criteria were considered, trial quality ranged from 0 to 5 with only one study²² defined as high quality (Table 1). When considering all 19 criteria, the quality of the trials ranged from 6 to 12 with six studies considered high quality.^{22-24,32,34-36,41} In no study was the care provider or the patient blinded to the intervention. All studies used relevant outcome measures and had comparable timing of the outcome assessment in each group. There was exact agreement between the two raters on 62% of the internal validity criteria and 72% of all 19 criteria. The agreement on individual criteria, expressed as Cohen's kappa, ranged from -0.40 (blinded patient) to 1.00 (randomization, relevant outcome measures and comparable timing of outcome assessment).

Treatment efficacy

For most (81%) intervention comparisons the 95% CI for effect sizes of pain and disability included zero, which means that the experimental intervention was no more effective than the reference intervention. Six of the 13 studies provided return to work data (Table 1).

Low back pain of six weeks to three months duration

For the most commonly used definition of subacute low back pain, three studies^{32,35,36,38-40} were found but none of the studies were of high quality when applying the internal validity criteria.

Table 1 Intervention contrasts, follow-up and effect sizes

Citation and study population	Comparison of interventions	Quality score		Effect size (95% confidence interval)			RR (95% CI)
		IV	Total ^a	Pain	Disability	RTW	
Andersson ²⁸ 178 patients with nonspecific LBP of 3 weeks - 6 months duration, aged 20-59, patients receiving workers' compensation excluded, visiting HMO	Spinal manipulation: thrust, muscle energy, counterstrain, articulation, and/or myofascial release; 8 sessions over 12 weeks (n=93) versus Usual care: physician's care, e.g. analgesics, physical therapy (n=85)	2/9	9/19	0.1 (-0.2; 0.4)	-0.2 (-0.5; 0.2) ^b		
Berwick ²⁶ 222 patients with nonspecific LBP of 2 weeks - 6 months duration, aged 21-55, pain below knee excluded, visiting HMO	Low back school: a 4-h instruction about LBP and audiotape with instructions (n=72) versus Pamphlet: short pamphlet on low back pain (n=74)	2/9	9/19	0.3 (-0.1; 0.6) ^c -0.3 (-0.6; 0.1) -0.2 (-0.5; 0.2)	0.2 (-0.2; 0.6) ^f -0.1 (-0.4; 0.3) ^e -0.5 (-0.9; -0.2) ^f		
	Low back school plus compliance package: low back school plus instructions and reinforcement by phone and mail for 1 year (n=76) versus Pamphlet	2/9	9/19	0.2 (-0.1; 0.6) ^c -0.4 (-0.7; 0)	0.2 (-0.1; 0.6) ^f -3 (-0.6; 0.1) ^e		
	Low back school versus Low back school plus compliance package	2/9	9/19	-0.1 (-0.5; 0.2) 0.1 (-0.2; 0.5) 0.1 (-0.3; 0.4)	0.1 (-0.3; 0.4) ^f 0.1 (-0.3; 0.4) ^f 0 (-0.4; 0.3) ^f		
Chok ²⁷ 66 patients with nonspecific LBP of 7 days - 7 weeks with or without radiation, referred to physiotherapy, aged 20-55, patients involved in workers' compensation excluded	Endurance training: bilateral shoulder lifts, contralateral arm and leg lifts, hot packs, back booklet, back advice; 3x/week for six weeks (n=38) versus Education: hot packs, back booklet, back advice (n=28)	1/9	9/19	0.6 (0.1 to 1.2) ^d 0.5 (0 to 1.1) ^d	0.6 (0.1 to 1.2) ^d 0.6 (0.1 to 1.1) ^d		
Davies ³¹ 47 patients with nonspecific LBP of 3 weeks - 6 months' duration, interfering with their usual sporting activities, aged 15-45	Extension exercises & SWD: raising trunk in prone position plus SWD to lumbosacral spine; for 4 weeks (n=14) versus SWD: SWD to lumbosacral spine; for 4 weeks (n=15)	2/9	7/19	0.2 (-0.6; 0.9) 0.4 (-0.3; 1.1)	NA		
	Flexion exercises & SWD: lumbar isometric flexion exercises plus SWD to lumbosacral spine; for 4 weeks (n=14) versus SWD	2/9	7/19	0 (-0.7; 0.8) 0.6 (-0.2; 1.3)	NA		
	Extension exercises & SWD versus Flexion exercises & SWD	2/9	7/19	0.1 (-0.6; 0.9) -0.2 (-0.9; 0.6)	NA		
Hagen ³⁷ 457 patients sicklisted for 8-12 weeks because of nonspecific LBP with or without referral to the leg, or sciatica, aged 18-60	Advice: physical examination, information, reassurance and advice to stay active; 1 visit (n=237) versus Usual care: primary health care (n=220)	2/9	10/19	NA	NA	1.5 (1.2; 1.8) 1.4 (1.1; 1.8) 1.2 (1.1; 1.4)	
Haldorsen ³³ 223 patients sicklisted for 8 weeks-6 months for nonspecific LBP with or without referral to the leg, or sciatica, mean age 43 yrs	MN/CBT: physical treatment, cognitive behavioural modification, education, workplace-based interventions, telephone contacts; 6-h sessions, 5 days/week for 4 weeks (n=142) versus Usual care: physician's care, e.g. physiotherapy (n=81)	2/9	8/19	NA	NA	0.9 (0.7; 1.1)	
Herman ³⁴ 58 patients with work-related low back injury of 3-10 weeks duration, 46 men and 12 women	15 min of high-frequency TENS plus 15 min of acupuncture like TENS and rehabilitation: hydrotherapy, mobility and strengthening exercises and cardiovascular training (n=29) versus Placebo TENS and rehabilitation identical to intervention group (n=29)	3/9	11/19	0 (-0.5; 0.5)	0.2 (-0.4; 0.8)	2.0 (0.7; 5.9) 0.8 (0.6; 1.1)	
Hsieh ⁴¹ , Pope ²³ 164 patients with nonspecific LBP of 3 weeks - 6 months duration	Spinal manipulation: heat followed by lumbar and/or sacroiliac manipulation; 3x/week for 3 weeks (n=70) versus	3/9	11/19	0.5 (0.1; 1.0) [*]	1.3 (0.5; 2.0)		

<p>a health care centre, workers' compensation excluded, 62% male. Hsieh reported disability measures on a subgroup of 83 patients from Pope's study population</p>	<p>Spinal manipulation versus Massage: heat plus stroking massage of whole back without deep tissue manipulation; 3x/week for 3 weeks (n=37) Spinal manipulation versus Corset: worn during waking hours for 3 weeks (n=29) TENS versus Massage TENS versus Corset Massage versus Corset</p>	<p>3/9 11/19 3 weeks 0.3 (-0.2; 0.7)^a 1.5 (0.8; 2.2) 3/9 11/19 3 weeks 0.3 (-0.2; 0.8)^a 0.7 (0.0; 1.4) 3/9 11/19 3 weeks -0.3 (-0.8; 0.3)^a 0.4 (-0.4; 1.2) 3/9 11/19 3 weeks -0.2 (-0.8; 0.4)^a -0.8 (-1.4; 0.3) 3/9 11/19 3 weeks 0.1 (-0.5; 0.6)^a -0.9 (-1.6; -0.1)</p>	<p>NA NA 1.8 (1.6; 2.0) 1.2 (1.1; 1.4)</p>
<p>Indahl^{33,36} 975 patients sicklisted for 8-12 weeks for LBP with or without radiation</p>	<p>Advice: physical examination, information, reassurance and advice to stay active; 3 visits over one year (n=463) versus Usual care: conventional medical system (n=512)</p>	<p>3/9 10/19 200 days 5 year NA NA</p>	<p>1.8 (1.6; 2.0) 1.2 (1.1; 1.4)</p>
<p>Konrad³⁷ 170 factory workers with nonspecific LBP of 1-3 months' duration, with or without radiation</p>	<p>Balneotherapy: thermal water providing minerals (e.g. K⁺, Na⁺, Li⁺) heat and buoyancy; 3x/week for 4 weeks (n=38) versus Massage: massage and movement while underwater with hot water stream on affected area; 3x/week for 4 weeks (n=35) Balneotherapy versus Traction: traction applied underwater with patient's weight and traction belt; 3x/week for 4 weeks (n=44) Balneotherapy versus Control: patients were offered NSAIDs (n=53) Massage versus Traction Massage versus Control Traction versus Control</p>	<p>0/9 6/19 4 weeks 1 year 0.1 (-0.4; 0.6) 0.2 (-0.3; 0.7) 0/9 6/19 4 weeks 1 year -0.5 (-1.0; -0.1) -0.1 (-0.6; 0.3) 0/9 6/19 4 weeks 1 year 1.0 (0.6; 1.5) 0.2 (-0.2; 0.6) 0/9 6/19 4 weeks 1 year -0.6 (-1.1; -0.1) -0.3 (-0.8; 0.2) 0/9 6/19 4 weeks 1 year 0.9 (0.4; 1.4) 0 (-0.5; 0.5) 0/9 6/19 4 weeks 1 year 1.5 (1.0; 1.9) 0.4 (-0.1; 0.8)</p>	<p>NA NA 1.5 (1.1; 2.2) 1.4 (1.1; 1.8)</p>
<p>Lindstrom³⁸⁻⁴⁰ 103 blue collar workers, sicklisted for 6-12 weeks for nonspecific LBP</p>	<p>Graded activity: workplace visit, education and individually graded exercise programme using operant conditioning (n=51) versus Usual care: physician, e.g. analgesics, physical therapy (n=52)</p>	<p>3/9 8/19 post Rx 3 months 1 year NA NA</p>	<p>0.6 (0.2; 1.0)^a</p>
<p>Moffett²³ 187 primary care patients with nonspecific LBP 4 weeks-6 months' duration, aged 18-60</p>	<p>Exercise programme: strengthening, stretching, relaxation, education using cognitive-behavioural approach; 8 sessions over 4 weeks (n=89) versus Usual care: physician's care, included physiotherapy (n=98)</p>	<p>5/9 12/19 6 weeks 6 months 12 months 0.1 (-0.1; 0.3)^h NA NA</p>	<p>0.2 (0; 0.4)^a 0.2 (0.1; 0.5)^a 0.3 (0.1; 0.5)^a</p>
<p>Rossignol²⁴ Workers compensated for work-related LBP with absence from work between 4 and 8 weeks</p>	<p>CORE: complete examination, recommendations for clinical management and support to carry out recommendations by weekly phone contacts (n=54) versus Usual care: physician's care (n=56)</p>	<p>3/9 10/19 3 months 6 months 0.1 (-0.3; 0.5)^a 0.4 (-0.1; 0.8)^a</p>	<p>0.1 (-0.3; 0.5)^a 0.5 (0.1; 0.9)^a 1.1 (0.9; 1.3)</p>

IV, internal validity score; RTW, return to work; RR, relative risk; 95% CI, 95% confidence interval; NA, not available; HMO, health maintenance organization; SWD, short wave diathermy; MMCBT, multimodal cognitive behavioural treatment; TENS, transcutaneous electrical nerve stimulation; CORE, co-ordination of primary health care.
^aTotal methodology score using full list.
^bOswestry.
^cSickness Impact Profile - physical.
^dStandard deviation calculated from range.
^eEffect was calculated as the difference between groups for change scores.
^fBorg's category ratio scale.
^gWaddell's subjective disability index.
^hPain diary strength.

Two high quality studies were found when considering all 19 criteria.^{32,35,36} These studies demonstrated that advice was more effective than usual medical care for return to work rates at 3, 6 and 12 months and 5 years (relative risk ranged from 1.2 to 1.8).^{32,35,36}

Low back pain of seven days to six months duration

With our alternate definition of subacute low back pain, 10 studies^{22-24,27,29-31,33,34,37,41} were found but only one study was considered high quality when applying the internal validity criteria. The study compared an exercise programme with usual medical care and reported a positive effect of exercise on disability at six months (ES 0.2, CI 0.1-0.5) and 12 months (ES 0.3, CI 0.1-0.5). However, these were small effects, equating to 1.35 points (0.13-2.57) at six months and 1.42 points (0.29-2.56) at 12 months on the 24-point Roland Morris questionnaire (scores range from 0 to 24).²²

Three other high-quality studies were found when considering all 19 criteria.^{23,24,34,41} Spinal manipulative therapy^{23,41} improved pain (ES 0.5, CI 0.1-1.0) and disability scores (ES 1.3, CI 0.5-2) when compared with TENS, corresponding to 14.5 mm on a 100-mm visual analogue scale and 7.1 points on the 24-point Roland Morris questionnaire respectively. Spinal manipulative therapy also improved disability scores (ES 1.5, CI 0.8-2.2) (i.e. 4.7 points on the 24-point Roland Morris questionnaire) when compared with massage.^{23,41} In the same study, wearing a corset decreased disability immediately after treatment (ES 0.9, CI 0.1-1.6) (i.e. 4.9 points on the 24-point Roland Morris questionnaire) when compared with massage.^{23,41} However, in this study outcome was only measured at the immediate conclusion of the treatment so there is no information on whether the effect was maintained. Furthermore, the disability scores were based on a subgroup of the total study population (52%), but it is unclear how the subgroup was selected and if the selection affected the strength of the randomization. Co-ordination of health care for injured workers resulted in less disability at six months (ES 0.4, CI 0.1-0.9) when compared with usual medical care,²⁴ corresponding to 9.4 points on a 100-point Oswestry scale. Finally, rehabilitation combined

with TENS compared with rehabilitation alone enhanced return to work at five weeks (relative risk 2.0, CI 0.7-5.9).³⁴

Pooling

Because 11 of the 13 studies differed with respect to intervention, outcome measures and timing of follow-up measurement, data could not be pooled for these studies. Pooling of results was therefore performed for two studies^{32,35,36} that compared the effect of advice with usual medical care on return to work at a similar time of follow-up (200 days^{35,36} and six months³²). The pooled relative risk for return to work was 1.56 (1.22-1.99), indicating that at six months advice increased the return to work rate by approximately 60% if compared with usual care (Figure 1).

Discussion

Treatment efficacy

Low back pain of six weeks to three months duration

The present study showed that when quality was represented by internal validity criteria only, no high-quality evidence was found for the efficacy of any intervention. But when quality was represented by all 19 criteria (i.e. internal validity, descriptive and statistical criteria), two high-quality studies demonstrated the greater efficacy of advice on return to work when compared with usual medical care.

Low back pain of seven days to six months duration

With our alternate definition of subacute low back pain, the present study showed that when

Clinical messages

- Lack of well-designed studies and use of a uniform definition of subacute low back pain have limited current evidence.
- Some evidence was found for the efficacy of treatments currently recommended by clinical practice guidelines, e.g. advice, exercise and manipulation.

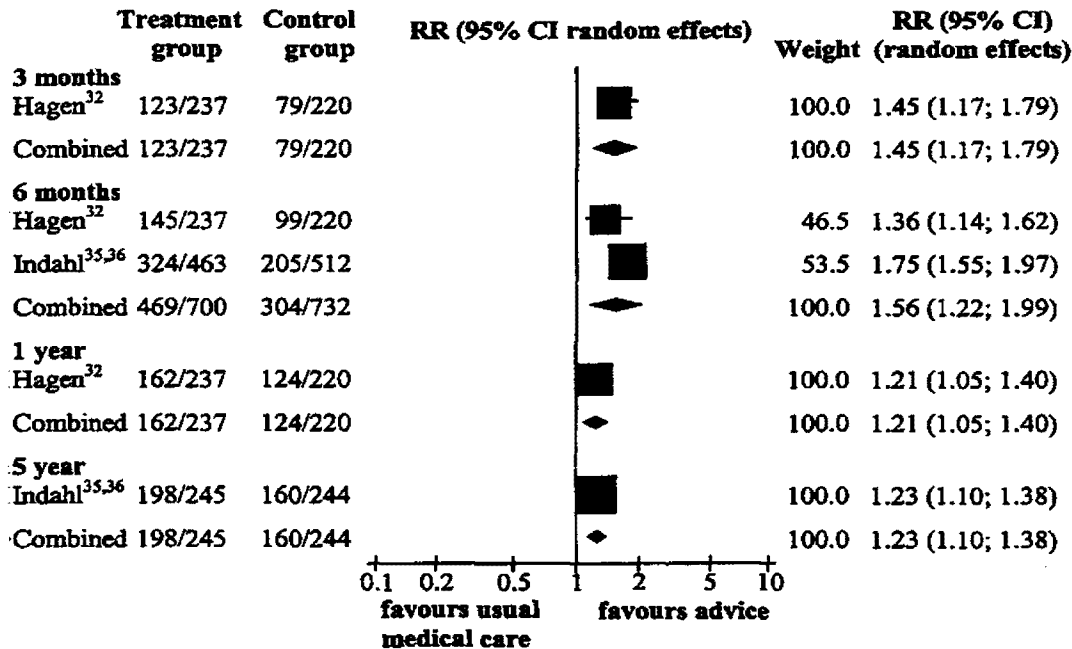


Figure 1 Risk ratios (RR) and 95% confidence intervals (CI) for advice compared with usual medical care for return to work.

quality was represented by internal validity criteria, high-quality evidence was found only for the effect of an exercise programme on disability, although the treatment effect was small.²² The minimal level at which true change can be detected at the 90% confidence interval is 4 points on the 24-point Roland Morris questionnaire scale.⁴² The upper limit of the 95% confidence interval of the improvement from exercise reported by Moffett *et al.*²² (2.6 points) is less than this value, meaning that it is not possible to detect the effect of exercise with certainty on individual patients in clinical practice. When the threshold for high internal validity was decreased from 50% to 40% (i.e. 4/9 criteria), no additional high-quality studies were found. However, when quality was represented by all 19 criteria, there was high-quality evidence that manipulation reduces pain and disability, that co-ordination of primary health care and wearing a corset decrease disability, and that TENS in combination with rehabilitation improves the return to work rate.

Acute versus subacute low back pain

Clinical practice guidelines for acute low back pain are often generalized to subacute low back pain. However, there is evidence that the subacute phase should be identified separately from the acute phase. A systematic review of exercise therapy for low back pain found strong evidence that exercise therapy is no more effective for acute low back pain than other active or inactive treatments.¹⁵ However, our review demonstrated that exercise is an effective treatment for subacute low back pain. This suggests that the acute and subacute phases of low back pain are different and that effective treatments should be identified specifically for each phase.

Clinical practice guidelines for management of subacute low back pain recommend advice, manipulation, exercise and/or analgesics. Our review confirms the efficacy of advice for subacute low back pain when the strictest definition is considered (six weeks to three months) and when all 19 criteria were applied to determine methodological quality. Furthermore, our findings confirm the efficacy of exercise when a

broader duration of subacute low back pain was considered (seven days to six months) using both internal validity and all 19 methodological criteria, and of manipulation when methodological quality was assessed using all 19 criteria. However, the effect of analgesics has not yet been evaluated for subacute low back pain.

Quality rating

The intraclass correlation coefficient (2,1) showed low reliability for methodological quality ratings. However, the agreement between raters in our study (62% on the internal validity criteria) is similar to that reported by those who developed the criteria (65%).¹⁵ When the raters met to resolve discrepancies, they attributed most of the disagreements to ambiguities in the scale.^{11,15} Revision or a more detailed description of the methodological criteria may improve the reliability of the quality ratings.

Previous work

The efficacy of multidisciplinary biopsychosocial rehabilitation for subacute low back in injured workers has been reviewed by Karjalainen *et al.*,¹⁰ but only two studies were included in their review.^{38-40,43} We did not include Loisel *et al.*⁴³ because their definition of subacute low back pain was based on accumulated sick leave over one year, which may not equate to the duration of a single episode of subacute low back pain. The study by Lindstrom *et al.*³⁸⁻⁴⁰ was scored as a low-quality study by Karjalainen *et al.*¹⁰ and this was confirmed by our findings. So while Karjalainen *et al.*¹⁰ concluded that there is moderate evidence for the efficacy of interventions they described as multidisciplinary biopsychosocial rehabilitation, we are less convinced by a single, low-quality study³⁸⁻⁴⁰ and would like to see this treatment examined in a high-quality study.

Conclusions

Identification of effective treatment for subacute low back pain is of great importance in preventing patients from developing a chronic condition. Despite this, little work has been directed at this phase of low back pain. The work that has been

completed is generally of poor design (low internal validity) and lacks the use of a uniform definition of subacute low back pain, resulting in limited evidence. For the strict definition of subacute low back pain (six weeks to three months duration), no evidence of high internal validity was found but when other methodological criteria were considered, evidence was found for the efficacy of advice. However, there is evidence that when a broader view is taken of the duration of subacute low back pain, other treatments (e.g. manipulation, exercise, TENS) may be effective.

Acknowledgement

The authors would like to acknowledge Dr Rob Herbert for his advice and help on the statistical analysis.

References

- 1 Waddell G. 1987 Volvo award in clinical sciences. A new clinical model for the treatment of low-back pain. *Spine* 1987; **12**: 632-44.
- 2 Waddell G. *The back pain revolution*. London: Churchill Livingstone, 1998.
- 3 Van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. *Pain* 1995; **62**: 233-40.
- 4 Koes BW, Van Tulder MW, Ostelo R, Burton KA, Waddell G. Clinical guidelines for the management of low back pain in primary care: an international comparison. *Spine* 2001; **26**: 2504-13.
- 5 ACC and National Health Committee. *New Zealand low back pain guide*. Wellington: National Health Committee, 1997.
- 6 Waddell G, Feder G, McIntosh A, Lewis M, Hutchinson A. *Low back pain evidence review*. London: Royal College of General Practitioners, 1996.
- 7 KNGF. Guidelines for low back pain of the Royal Dutch Physiotherapy Association. [In Dutch] *Ned Tijdschr Fysiother* 2001; **111**: 1-24.
- 8 Bigos S, Bowyer O, Braen G *et al.* *Acute low back pain problems in adults*. Clinical Practice Guideline no.14. AHCPR Publication no. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services, 1994.
- 9 NHMRC. *Acute pain management: scientific evidence*. Canberra: Ampersand editorial & design, 1999.
- 10 Karjalainen K, Malmivaara A, van Tulder M *et al.* Multidisciplinary biopsychosocial rehabilitation for

- subacute low back pain in working-age adults: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2001; 26: 262-69.
- 11 Van Tulder MW, Assendelft WJ, Koes BW, Bouter LM. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. *Spine* 1997; 22: 2323-30.
 - 12 Van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. *Spine* 1997; 22: 2128-56.
 - 13 Spitzer WO. Scientific approach to the assessment and management of activity-related spinal disorders: a monograph for clinicians. Report of Quebec Task Force on Spinal Disorders. *Spine* 1987; 12: 1-59.
 - 14 Woods CS, Kishino ND, Haider TT, Kay PK. Effects of subacute versus chronic status of low back pain patients' response to a functional restoration program. *J Occup Rehabil* 2000; 10: 229-33.
 - 15 Van Tulder MW, Malmivaara A, Esmail R, Koes B. Exercise therapy for low back pain: a systematic review within the framework of the cochrane collaboration back review group. *Spine* 2000; 25: 2784-96.
 - 16 Van Tulder MW, Ostelo R, Vlaeyen JW, Linton SJ, Morley SJ, Assendelft WJ. Behavioral treatment for chronic low back pain: a systematic review within the framework of the Cochrane Back Review Group. *Spine* 2000; 25: 2688-99.
 - 17 Van Tulder MW, Scholten RJ, Koes BW, Deyo RA. Nonsteroidal anti-inflammatory drugs for low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2000; 25: 2501-13.
 - 18 Fleiss J. *Statistical methods for rates and proportions*, second edition. New York: Wiley, 1981.
 - 19 Jadad AR, Moore RA, Carroll D *et al*. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996; 17: 1-12.
 - 20 Verhagen AP, de Vet HC, de Bie RA, Kessels AG, Boers M, Knipschild PG. Balneotherapy and quality assessment: interobserver reliability of the Maastricht criteria list and the need for blinded quality assessment. *J Clin Epidemiol* 1998; 51: 335-41.
 - 21 Cohen J. *Statistical power analysis for the behavioral sciences*, second edition. Hillsdale, NJ: L Erlbaum Associates, 1988.
 - 22 Moffett JK, Torgerson D, Bell-Syer S *et al*. Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. *BMJ* 1999; 319: 279-83.
 - 23 Pope MH, Phillips RB, Haugh LD, Hsieh CY, MacDonald L, Haldeman S. A prospective randomized three-week trial of spinal manipulation, transcutaneous muscle stimulation, massage and corset in the treatment of subacute low back pain. *Spine* 1994; 19: 2571-77.
 - 24 Rossignol M, Abenhaim L, Seguin P *et al*. Co-ordination of primary health care for back pain. A randomized controlled trial. *Spine* 2000; 25: 251-58.
 - 25 McGuire DB. The measurement of clinical pain. *Nurs Res* 1984; 33: 152-56.
 - 26 Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983; 8: 141-44.
 - 27 Chok B, Lee R, Latimer J, Tan SB. Endurance training of the trunk extensor muscles in people with subacute low back pain. *Phys Ther* 1999; 79: 1032-42.
 - 28 Review Manager (RevMan) [Computer file]. Version 4.1 for Windows. Oxford: The Cochrane Collaboration, 2000.
 - 29 Andersson GB, Lucente T, Davis AM, Kappler RE, Lipton JA, Leurgans S. A comparison of osteopathic spinal manipulation with standard care for patients with low back pain. *N Engl J Med* 1999; 341: 1426-31.
 - 30 Berwick DM, Budman S, Feldstein M. No clinical effect of back schools in an HMO. A randomized prospective trial. *Spine* 1989; 14: 338-44.
 - 31 Davies JE, Gibson T, Tester L. The value of exercises in the treatment of low back pain. *Rheumatol Rehabil* 1979; 18: 243-47.
 - 32 Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? *Spine* 2000; 25: 1973-76.
 - 33 Haldorsen EH, Kronholm K, Skouen JS, Ursin H. Predictors for outcome of a multi-modal cognitive behavioural treatment program for low back pain patients - a 12 month follow-up study. *Eur J Pain* 1998; 2: 293-307.
 - 34 Herman E, Williams R, Stratford P, Fargas-Babjak A, Trott M. A randomized controlled trial of transcutaneous electrical nerve stimulation (CODETRON) to determine its benefits in a rehabilitation program for acute occupational low back pain. *Spine* 1994; 19: 561-68.
 - 35 Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered. A randomized clinical trial. *Spine* 1995; 20: 473-77.
 - 36 Indahl A, Haldorsen EH, Holm S, Reikeras O, Ursin H. Five-year follow-up study of a controlled clinical trial using light mobilization and an informative approach to low back pain. *Spine* 1998; 23: 2625-30.
 - 37 Konrad K, Tatrai T, Hunka A, Vereckei E, Korondi I. Controlled trial of balneotherapy in treatment of low back pain. *Ann Rheum Dis* 1992; 51: 820-22.

- 38 Lindstrom I, Ohlund C, Eek C *et al.* The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioral approach. *Phys Ther* 1992; 72: 279–90.
- 39 Lindstrom I, Ohlund C, Eek C, Wallin L, Peterson LE, Nachemson A. Mobility, strength, and fitness after a graded activity program for patients with subacute low back pain. A randomized prospective clinical study with a behavioral therapy approach. *Spine* 1992; 17: 641–52.
- 40 Lindstrom I, Ohlund C, Nachemson A. Physical performance, pain, pain behavior and subjective disability in patients with subacute low back pain. *Scand J Rehabil Med* 1995; 27: 153–60.
- 41 Hsieh CY, Phillips RB, Adams AH, Pope MH. Functional outcomes of low back pain: comparison of four treatment groups in a randomized controlled trial. *J Manipulative Physiol Ther* 1992; 15: 4–9.
- 42 Stratford PW, Binkley J, Solomon P, Finch E, Gill C, Moreland J. Defining the minimum level of detectable change for the Roland-Morris questionnaire. *Phys Ther* 1996; 76: 359–65.
- 43 Loisel P, Abenhaim L, Durand P *et al.* A population-based, randomized clinical trial on back pain management. *Spine* 1997; 22: 2911–18.

Appendix – Methodological quality criteria

Each of the following criteria was scored as 'yes', 'no' or 'don't know'.

- 1) Were the eligibility criteria specified?
- 2) Was a method of randomization performed?
- 3) Was the treatment allocation concealed?ⁱ
- 4) Were groups similar at baseline regarding the most important prognostic indicators?ⁱ
- 5) Were the index and control interventions explicitly described?
- 6) Was the care provider blinded to the intervention?ⁱ
- 7) Were co-interventions avoided or comparable?ⁱ
- 8) Was the compliance acceptable in all groups?ⁱ
- 9) Was the patient blinded to the intervention?ⁱ
- 10) Was the outcome assessor blinded to the intervention?ⁱ
- 11) Were the outcome measures relevant?
- 12) Were adverse effects described?
- 13) Was the withdrawal/drop-out rate described and acceptable?ⁱ
- 14) Was a short-term follow-up measurement performed?
- 15) Was a long-term follow-up measurement performed?
- 16) Was the timing of the outcome assessment in both groups comparable?
- 17) Was the sample size for each group described?
- 18) Did the analysis include an intention-to-treat analysis?ⁱ
- 19) Were point estimates and measures of variability presented for the primary outcome measures?

ⁱ: criteria for internal validity.

CHAPTER 4

Responsiveness of pain, disability and physical impairment outcomes in subjects with low back pain.

The work presented in this chapter has been accepted for publication as:

Pengel LHM, Refshauge KM and Maher CG. "Responsiveness of pain, disability and physical impairment outcomes in subjects with low back pain". Accepted for publication in *Spine*.

Abstract

Study design: Cohort study.

Objective: To conduct a head-to-head comparison of the responsiveness of pain, disability and physical impairment measures in subjects with low back pain.

Summary of background data: Pain, disability and physical impairment measures are routinely measured in clinical practice and clinical research. However, to date a head-to-head comparison has not been performed.

Methods: A numerical pain scale (0-10), the 24-item and two modified 18-item versions of the Roland Morris questionnaire, the Patient Specific Functional Scale and physical impairment measures were completed by 155 low back pain patients at baseline and then again after 6 weeks together with an 11-point global perceived effect scale. Responsiveness was evaluated by using effect sizes (ES) and t-tests, correlating the change scores for each outcome with the global perceived effect score and by calculating Guyatt's responsiveness index.

Results: The most responsive outcome proved to be the Patient Specific Functional Scale (ES = 1.6) followed by the numerical pain scale (ES = 1.3) and 24-item Roland Morris questionnaire (ES = 0.8). The responsiveness of the two 18-item Roland Morris versions was equal to the 24-item version. However the physical impairment measures were not very responsive (ES 0.1 - 0.6). The ranking of the responsiveness indices was consistent across all statistical analyses.

Conclusions: Physical impairments are routinely measured in clinical practice and clinical research to determine outcome but the lower responsiveness indicates that this approach is not optimal. The findings suggest that more emphasis should be

placed on change in pain and disability scores than on change in physical impairments as outcome measures.

Introduction

Responsiveness is defined as the ability of an outcome measure to detect clinically important change in a patient's health status over time.⁴⁷ The use of responsive outcome measures is essential to measure efficacy of treatment in both clinical practice and clinical research.

Numerous strategies have been developed to assess the responsiveness of health status outcome measures.⁶⁴ However there is no single appropriate analysis strategy, the relevant strategy being specific to the study design.⁶⁴ Because different analysis strategies can result in different rankings⁶⁵, it is useful to conduct a range of analyses. When different responsiveness indices result in the same ranking of responsiveness, conclusions about the results can be drawn with more certainty.

When it is expected that the whole study population will improve over time, the analysis strategy is based on comparisons of pre- and post-treatment scores, eg effect sizes (ES). However, this does not take into account the possibility that some patients will undergo clinically important change but others will not. Therefore, a second strategy is to divide the study population into those patients who have improved and those who have not improved and evaluate if the outcome measure can discriminate between these two groups. This strategy requires an external measure that is accepted as evidence of clinically important change. Although there is no gold standard for measurement of clinically relevant change it may be accepted that the patient's own perception of change gives a reliable assessment whether clinically important change has occurred. A third strategy to evaluate responsiveness is to correlate the external criterion (ie the patient's perception of change) with the change

in the outcome measure.⁶⁴ The strength of the correlation is an indication of the responsiveness.

In patients with low back pain, pain and restriction in functional status are major problems. To measure change in pain and disability in the clinical setting it is important to use responsive outcome measures. Pain is usually measured by some form of the visual analogue scale. Functional disability can be measured in a number of ways, eg the Roland Morris questionnaire⁴³ (standardised activities) or the Patient Specific Functional Scale (activities nominated by the patient).⁶⁶

The responsiveness of the 0-100 visual analogue scale, the Roland Morris questionnaire and the Patient Specific Functional Scale has been evaluated in two studies, both using patients with low back pain of at least 6 weeks duration.^{67 68} However, the ranking of these three outcome measures was inconsistent across the two studies. In the first study, responsiveness was evaluated using ES and ROC curves, with the Roland Morris questionnaire being the most responsive outcome measure.⁶⁷ In addition the two different analysis strategies resulted in different rankings for the responsiveness of the pain scale and the Patient Specific Functional Scale.⁶⁷ The second study evaluated responsiveness using ES only and showed that the Patient Specific Functional Scale was the most responsive outcome measure, followed by the Roland Morris and the pain scale.⁶⁸ Additionally, in both studies the authors excluded the data of subjects who deteriorated. This is unfortunate because clinicians are as interested in detecting deterioration as they are in clinical improvement. Accordingly, the relative responsiveness of these three outcome measures remains unclear.

Physical impairment is also often used in both clinical practice and clinical research to assess treatment efficacy. Interestingly, the responsiveness of physical impairments for patients with low back pain has not been formally investigated. However, it is known that physical impairments do not correlate well with disability in patients with low back pain with correlations ranging between 0 and 0.5.^{44 69}

The aim of the present study was to perform a head-to-head comparison of self-report pain and disability measures and physical impairment measures in subjects with low back pain. The functional status instruments we investigated were the Roland Morris questionnaire, including the original 24-item version and two modified 18-item versions^{70 71}, and the Patient Specific Functional Scale. To evaluate responsiveness we used a range of different analysis strategies, including ES, t-test, correlation and Guyatt's responsiveness index (GRI).

Methods

Study population

The study population consisted of 156 subjects with subacute low back pain, ie low back pain of 6 weeks to 3 months duration. The subjects were participants in a randomised controlled trial evaluating the effects of different conservative treatments. Subjects were aged 18-80 years and were recruited via referral from health care professionals, from hospital waiting lists or advertisements in newspapers. Exclusion criteria included: spinal surgery in the past 12 months, pregnancy, specific spinal pathology (eg nerve root involvement, malignancy, inflammatory bone or joint disease), contra-indication to exercise, or poor English

comprehension. Potential subjects who reported osteoarthritis, spondylitis, spondylolysis, spondylolisthesis, disc protrusion/herniation/prolapse, spinal stenosis remained eligible. One hundred and sixty-four subjects were enrolled between January 2001 and August 2002, of whom eight (5%) did not attend the 6-week follow up, leaving 156 subjects in the study (Table 4.1).

Outcome measures

Pain, disability and physical impairment measures were taken at baseline and then again after 6 weeks of treatment. The 11-point global perceived effect scale was also administered at 6 weeks and served as the external criterion of clinically important change. Subjects scored their average pain over the past week on an 11-point box scale⁷² from 0 to 10 where 0 represents no pain and 10 represents the worst pain possible. Disability was measured by the Roland Morris disability questionnaire⁴³ and the Patient Specific Functional Scale.⁶⁶ The Roland Morris consists of 24 yes/no statements about activities of daily living that may be affected by low back pain. Each statement ticked scores one point, with the scores ranging from 0 (no disability) to 24 (extremely severe disability). In addition, we calculated the total scores of two 18-item Roland Morris questionnaires from the 24-item Roland Morris score.^{70 71}

When completing the Patient Specific Functional Scale⁶⁶, subjects specified three important activities that they were unable to perform or had difficulty with as a result of their back pain. Each activity was scored on a 0-10 scale for the day of the assessment, where 0 represented inability to perform the activity and 10 represented ability to perform the activity at pre-injury level. To present an overview of activities that are likely to be affected by back pain, we also listed the activities that subjects

Table 4.1 Description of the study sample at baseline (n = 156).

Characteristic	Summary count
Age in yrs: mean (SD)	49.3 (15.8)
Gender	88 female, 68 male
Sudden onset of low back pain: <i>n</i> (%)	96 (62 %)
Currently working: <i>n</i> (%)	71 (46 %)
No. who took pain killers in past 6 weeks: <i>n</i> (%)	92 (60 %)
Previous sick leave for low back pain: <i>n</i> (%)	34 (22 %)
Outcomes	
Pain	
Pain over past week (0 – 10): mean (SD)	5.5 (2.1)
Disability	
Roland Morris-24 item: mean (SD)	8.5 (4.9)
Roland Morris-18 item Stratford ^{70 71} : mean (SD)	7.1 (4.3)
Roland Morris-18 item Williams ^{70 71} : mean (SD)	7.0 (4.4)
Patient Specific Functional Scale (0 – 10): mean (SD)	3.6 (1.9)
Physical impairments	
Backward bending (deg): mean (SD)	21.4 (8.6)
Forward bending-fingertip to floor (cm): mean (SD)	16.4 (17.9)
adjusted for neutral standing [†]	0.76 (0.3)
Left side bending-fingertip to floor (cm): mean (SD)	48.8 (6.1)
adjusted for neutral standing [†]	0.26 (0.1)
Right side bending-fingertip to floor (cm): mean (SD)	48.6 (6.0)
adjusted for neutral standing [†]	0.25 (0.1)
Left straight leg raise (deg): mean (SD)	75.1 (19.7)
Right straight leg raise (deg): mean (SD)	73.8 (21.1)

† scores were expressed as a proportion of the neutral standing fingertip to floor distance

nominated as being impaired including the frequency with which they were nominated.

The physical impairments measured included range of motion measures⁴⁴⁻⁴⁶ and the straight leg raise⁴⁴. Range of motion was measured using the fingertip to floor method (forward bending⁴⁶ and lateral lumbar flexion⁴⁵) and the single inclinometer method (lumbar extension⁴⁴). Passive straight leg raise test was measured using an inclinometer.⁴⁴

The 11-point global perceived effect scale ranged from -5 (vastly worse) to 5 (completely recovered), with 0 being unchanged.

Statistical analysis

The change scores between baseline and the 6-week follow up were calculated for each outcome. The forward bending and side bending scores were expressed as the fingertip to floor distance and also as a proportion of the neutral standing fingertip to floor distance to account for subject height. For the Patient Specific Functional Scale, change scores between the baseline and 6-week follow up were calculated for each of the three nominated activities and then the three change scores were averaged.

All subjects in the study were expected to undergo improvement over a 6-week treatment period but it was unknown which group would benefit most from the treatment. Responsiveness was evaluated in different ways. Firstly, we computed the ES and used paired t-tests to compare the baseline and 6-week follow up scores for each outcome. The ES was calculated for each outcome measure with the ES

defined as the mean change divided by the standard deviation of the baseline score.⁶⁴ We calculated 84% confidence intervals for direct comparison of the ES. We chose 84% confidence intervals because non-overlapping 84% confidence intervals are equivalent to a Z test of means at the .05 level.⁷³ The second method of evaluating responsiveness entailed correlating change scores in each outcome with the global perceived effect scale⁶⁴, using Pearson's r with the 95% CI. Thirdly, we calculated the GRI.⁴⁷ The GRI accounts for score variability in stable patients and is calculated as the ratio of mean change of patients who reported self-perceived improvement divided by the standard deviation of change of patients reporting no improvement.

Results

The order of ranking of the responsiveness indices was consistent across all analysis strategies used to evaluate responsiveness (Table 4.2). The most responsive outcome measure of those studied was the Patient Specific Functional Scale (ES = 1.6) followed by the numerical pain scale (ES = 1.3) and the 24-item Roland Morris questionnaire (ES = 0.8). The two modified versions of the 18-item Roland Morris questionnaires were equally responsive (for both, ES = 0.7), and were similar to the original 24-item Roland Morris (ES = 0.8). When calculating the ES, the responsiveness of the Patient Specific Functional Scale and the numerical pain scale were significantly different from the Roland Morris questionnaire and physical impairments because the confidence intervals of the ES did not overlap.

Table 4.2 Responsiveness indices for pain, disability and physical impairments.

Analysis strategies used were effect size, paired t-Test, Guyatt's Responsiveness Index (GRI) and Pearson's r.

Outcome	Effect size (84% CI)	t-Test	GRI	Pearson's r (95%CI)
Pain				
Numerical rating scale	1.3 (1.2 to 1.4)	13.0	1.5	0.5 (0.4 to 0.6)
Disability				
Patient Specific Functional Scale	1.6 (1.4 to 1.8)	13.5	2.1	0.6 (0.5 to 0.7)
Roland Morris-24 item	0.8 (0.7 to 0.9)	10.2	1.0	0.5 (0.3 to 0.6)
Roland Morris-18 item Stratford ^{70 71}	0.7 (0.6 to 0.9)	9.8	1.1	0.5 (0.3 to 0.6)
Roland Morris-18 item Williams ^{70 71}	0.7 (0.6 to 0.8)	9.3	1.1	0.5 (0.3 to 0.6)
Physical Impairment				
Backward bending	0.6 (0.5 to 0.7)	7.0	0.9	0.3 (0.2 to 0.5)
Forward bending	0.2 (0.1 to 0.3)	3.0	0.4	0.2 (0.1 to 0.4)
adjusted for neutral standing	0.2 (0.1 to 0.3)	2.7	0.3	0.2 (0.1 to 0.4)
Left side bending	0.1 (0.0 to 0.2)	1.9	0.6	0.2 (0.0 to 0.3)
adjusted for neutral standing	0.1 (0.0 to 0.3)	1.9	0.4	0.2 (0.0 to 0.3)
Right side bending	0.1 (0.0 to 0.2)	1.9	0.7	0.1 (0.0 to 0.3)
adjusted for neutral standing	0.2 (0.1 to 0.3)	2.1	0.3	0.2 (0.0 to 0.3)
Left straight leg raise	0.2 (0.1 to 0.3)	3.0	0.2	0.1 (0.0 to 0.3)
Right straight leg raise	0.2 (0.1 to 0.3)	2.4	0.1	0.1 (0.0 to 0.3)

Table 4.3 Effect sizes of all physical impairments and of painful physical impairments only.

	All movements	Painful movements
Backward bending	0.6	0.7 (n=37)
Forward bending	0.2	0.3 (n=23)
Side bending (left; right)	0.1; 0.2	0.1 [†] (n=31)
Straight leg raise (left; right)	0.2; 0.2	0.5 [†] (n=25)

† Data from left and right side bending, and left and right straight leg raise were pooled to painful side bending and painful straight leg raise

The physical impairment measures were less responsive than the self-report pain and disability measures. Responsiveness for the physical impairments ranged from an ES of 0.6 for backward bending to 0.1 for side bending. After analysing data for painful physical impairments only, the effect sizes remained small (Table 4.3).

Inspection of the different activities specified by subjects in the Patient Specific Functional Scale produced a list of 325 activities. Pooling of similar types of activities resulted in 56 activity groups (Table 4.4). We aimed to categorise activities as precisely as possible (eg, playing tennis/squash) however this was not feasible when general answers were given (eg, playing sports). The most frequently specified functional activities were sitting (n=61), bending (n=56) and lifting (n=47).

Table 4.4 Activities nominated by patients for the Patient Specific Functional Scale with frequency of nomination.

activity	frequency	activity	frequency
sitting	61	ironing	4
bending	56	bathing baby	3
lifting	48	going up/down stairs	3
walking	30	laundry	3
vacuuming	24	lawn mowing	3
gardening	23	moving objects	3
standing	23	washing dishes	3
driving	16	weight lifting	3
sleeping	14	getting in/out of chair	2
putting on socks/shoes	11	kneeling	2
running	11	pulling	2
various sports	9	pushing	2
working	8	scrubbing	2
carrying	8	surfing	2
lying	7	taking bath/shower	2
getting in/out of bed	7	twisting	2
shopping	7	backward bending	1
cleaning bathroom	6	bike riding	1
housework	6	changing direction of movement	1
swimming	6	changing baby	1
making bed	5	crawling	1
playing tennis/sports	5	jumping	1
playing with children	5	leaning forward	1
mopping	5	opening window	1
playing golf	4	painting	1
reaching	4	sexual activities	1
sit to stand	4	turning patients	1
climbing	4	yoga	1

Discussion

The objective of the present study was to determine the outcome measures that are most responsive to change by conducting a head-to-head comparison of the responsiveness of pain, disability and physical impairment measures in subjects with low back pain. Overall, the most responsive outcome measure proved to be the Patient Specific Functional Scale followed by the numerical pain scale and 24-item and 18-item versions of the Roland Morris questionnaire. This was a consistent finding across the different statistical analyses employed. These outcome measures are all relevant to the patient and the findings strongly support their use.

There are two potential reasons why the Patient Specific Functional Scale is more responsive than the Roland Morris questionnaire. Firstly, the Patient Specific Functional Scale is tailored to the individual patient's specific disability whereas the Roland Morris questionnaire evaluates a range of common activities which may not be relevant to all individual patients. This is illustrated by the activities that were specified by subjects as being problematic. Activities that were often reported as being problematic, eg sitting and lifting, are not included as such in the Roland Morris questionnaire. Also, some items in the Roland Morris were infrequently specified by the patients. Eg, the Roland Morris has two items for getting out of a chair (items 7 and 12) yet only two of the patients specified getting in or out of a chair. Secondly, the ability to perform an activity is graded for the Patient Specific Functional Scale but is scored dichotomously (yes/no) for the Roland Morris questionnaire. The dichotomous scoring system may fail to detect small

improvements (or deteriorations) in functional ability that may be detected with the 11-point scale used with the Patient Specific Functional Scale.

The ability of the Patient Specific Functional Scale to measure change over time has previously been demonstrated across different study populations, ie in patients with back pain⁷⁴, knee pain⁷⁵ and neck pain⁶⁶. Additionally, the scale is quick and easy to administer, and its use can be strongly advocated in both the clinical setting and in clinical research.

The responsiveness indices of all versions of the Roland Morris were similar. The two 18-item versions were originally developed using item analysis in subjects with back pain of less than 70 days⁷¹ and less than 3 months duration⁷⁰ which might indicate that the modified versions are clinically more relevant than the original 24-item version for this particular duration of back pain. The results suggest that in patients with subacute low back pain, the shorter versions are a good alternative to the original 24-item Roland Morris as they are more efficient in terms of administration and scoring.

In contrast, the physical impairment measures were much less responsive than the pain and disability measures. This is an interesting result for both clinical practice and clinical research. Physical impairments are easy to measure and in clinical practice, physical impairments are routinely measured to monitor the recovery of individual patients. However, the lower responsiveness of physical impairment measures shows that this approach is probably not optimal to measure clinically important change in patients' health. A consequence of using less responsive outcome measures is a greater risk of either falsely concluding that change occurred (a 'false alarm') or falsely concluding that change did not occur (a 'miss').

In clinical research, physical impairments are also often used to measure change in health status. However, assessing these outcome measures requires the subject to attend the clinic and consequently makes clinical trials more time consuming and costly. Furthermore, the ES for the physical impairments is much smaller than for pain and disability measures which means that clinical trials using these outcome measures would require larger sample sizes. For example, when analysing change using a t-test with a power of 80% and an alpha level of .05, an outcome with an ES of 0.2 (eg, straight leg raise) would need 400 subjects per group whereas an outcome with an ES of 1.2 (eg, pain) would need only 12 subjects per group.⁷⁶

It has been suggested when measuring physical impairments, that it is important to record not only the range of motion but also the type and the degree of a patient's pain. To address this issue a post-hoc analysis was performed comparing the responsiveness of non-painful movements with painful movements (Table 4.3). The post-hoc analysis showed that the responsiveness indices of painful movements were similar to non-painful movements. However, because a much smaller number of subjects described individual movements as being painful, the results need to be interpreted with caution. Further research is needed to evaluate whether painful and restricted movements in the individual patient are more responsive than a standardised set of physical impairments.

These findings suggest that less emphasis should be placed on change in physical impairment as an outcome measure and more emphasis on change in disability and pain measures.

CHAPTER 5

Randomised controlled trial comparing the efficacy of exercise and/or advice for subacute low back pain

Abstract

Objective: To evaluate the efficacy of advice and/or exercise for patients suffering from subacute low back pain, and predictors of outcome and response to treatment.

Design: Randomised, single-blind controlled trial.

Setting: Six outpatient physiotherapy departments and one private physiotherapy clinic in Australia and New Zealand.

Participants: 259 subjects with non-specific low back pain of 6 weeks to 3 months duration were randomly allocated to exercise and advice (n=64), sham exercise and advice (n=60), exercise and sham advice (n=68) and sham exercise and sham advice (n=67). The exercise program consisted of 12 sessions and was an individualised, progressively increasing program to improve functional activities. The sham exercise consisted of 12 sessions of detuned pulsed ultrasound and detuned short-wave. Advice consisted of 3 sessions of information and instruction and sham advice of 3 ventilation sessions.

Main outcome measures: Primary outcomes were pain (0 to 10), Patient Specific Functional Scale (0 to 10) and global perceived effect (-5 to 5) scores at 6 weeks.

Results: Of the 259 subjects, 231 attended the 6-week follow up (89%). All groups improved on primary outcomes. Exercise significantly decreased pain scores (-0.8 points, CI -1.3 to -0.2) and increased global perceived effect scores (0.5 points, CI 0.1 to 1.0). Advice also significantly decreased pain scores (-0.8 points, CI -1.2 to -0.2) and increased global perceived effect scores (0.7 points, CI 0.3 to 1.2). There was no interaction effect. None of the variables significantly predicted outcome at 6 weeks. Self-efficacy was the only factor to significantly predict the response to exercise in

terms of global perceived effect. When a subject received exercise only, the effect of exercise was 2.4 points (95% CI 0.7 to 4.1) on the global perceived effect scale when the score on the self-efficacy scale was 0 at baseline. However, after Bonferroni correction self-efficacy was no longer a significant predictor of response to treatment.

Conclusions: At 6 weeks, there was a statistically significant effect of exercise and advice, however, differences may be too small to be considered clinically worthwhile. Twelve-month follow-up data will help clarify this issue. None of the variables studied significantly predicted outcome at 6 weeks. Self-efficacy may modify the effects of exercise.

Introduction

Low back pain is normally classified according to its duration: acute, subacute or chronic low back pain.³ Patients with subacute low back pain (low back pain of 6 weeks to 3 months duration) are unlikely to undergo spontaneous recovery, with a substantial proportion progressing to develop chronic low back pain, a condition for which treatment has been shown to be less effective and that is largely responsible for the high cost of low back pain. In New South Wales, Australia, the total cost for workplace back injuries covered by Workcover insurance was \$270million in 2000/2001.⁷⁷ Thus, any intervention that prevents the progression from subacute to chronic low back pain has the potential to save a significant proportion of this considerable expense. It is therefore particularly important that patients with subacute low back pain receive effective treatment.

Intervention

It is currently advocated, for example in most clinical practice guidelines for the management of low back pain, that patients with subacute low back pain should be managed with advice and/or exercise.¹⁴ A systematic review evaluating conservative treatments for subacute low back pain found that advice was an effective intervention for back pain of 6 weeks to 3 months duration.⁷⁸ Patients receiving advice were 1.2 to 1.8 times more likely to have returned to work after 3, 6 and 12 months, and 5 years than those who received usual physician care.⁷⁹⁻⁸¹ Evidence for the effectiveness of exercise was limited by the lack of a uniform definition for subacute low back pain and the low quality of studies.⁸²⁻⁸⁵

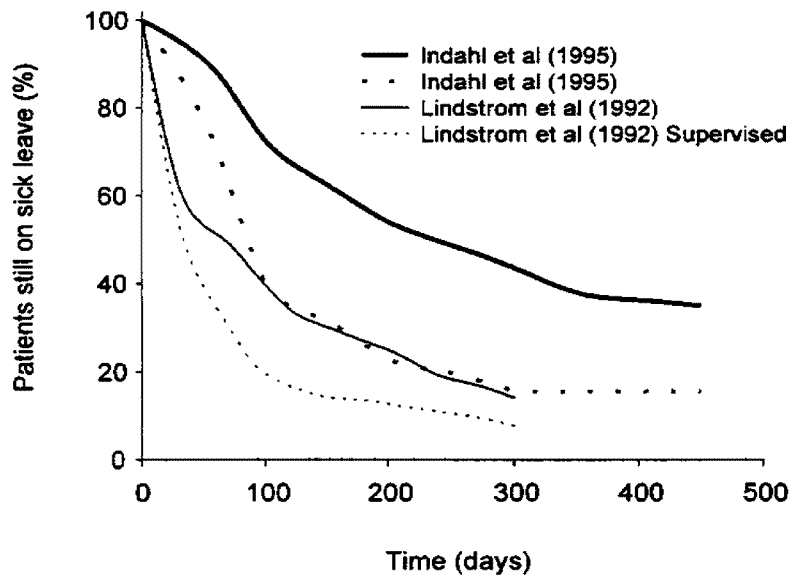


Figure 5.1 Rates of return to work reported by Indahl et al⁷⁹ and Lindstrom et al.⁸⁴

The promotion of advice and exercise by clinical practice guidelines, is primarily based on two clinical trials conducted in Scandinavia.^{79 80 84} Lindstrom et al⁸⁴ provided injured workers with a supervised graded exercise program whereas Indahl et al⁷⁹ simply provided advice on low back pain and encouraged subjects to return to light activity. In both trials a greater proportion of the active intervention group returned to work significantly earlier than the group randomised to usual physician care. However, other clinically relevant outcomes such as pain and disability were not assessed. A comparison of the rates of return to work from both trials suggests that supervised exercise may be more effective than simple advice (Figure 5.1).

It remains unclear, whether advice or supervised exercise is more effective than a placebo (eg a non-specific intervention, such as attention from a health care provider). Both interventions provided better results than physician care, so it may appear that the interventions were more effective than placebo. However, a trial conducted in the Netherlands found that physician care was actually less effective than sham physiotherapy treatment.⁸⁶ Furthermore, it is doubtful whether the findings of the two trials would generalise to Australasia (Australia and New Zealand) for a number of reasons. The comparison treatment in both studies was usual care by the attending physician, shown to have different outcomes in Norway and Sweden (Figure 5.1) and therefore probably also in Australasia. In addition, the Australasian context in which patients with low back pain are managed, including the structure of the health care, legal and welfare systems, differs markedly from those in both Norway and Sweden where the compensation system is considerably more generous. It is unclear therefore whether the treatment groups would benefit similarly in Australasia.

While there is some evidence for advice and exercise the two treatments have not been directly compared so the relative efficacy of the treatments has not been established. The first aim of the present study was therefore to conduct a head-to-head comparison of these two treatments to determine the efficacy of exercise and/or advice for subjects with subacute low back pain.

Predictors of outcome and of response to intervention

Clinical practice guidelines for the management of low back pain also advocate the identification of predictors to identify subgroups of patients who are at risk of developing chronic low back pain. Two types of predictors can be distinguished. Firstly, predictors of outcome inform us which patient characteristics will influence outcome over time. Secondly, predictors of response to intervention tell us which patient characteristics determine what type of patient will benefit from a particular intervention.

Predictors of acute low back pain have been widely studied.^{26 51 59 60} A systematic review of the prognosis of acute low back pain found the Vermont Disability Prediction Questionnaire to be a clinically useful predictor of outcome.⁸⁷ For subacute low back pain, two randomised controlled trials evaluated predictors.^{88 89} One randomised controlled trial compared advice to resume light activity with physician care,⁷⁹ and used discriminant analysis to evaluate whether medical, psychological or social factors could be used to identify those who had returned to work after 1 year⁸⁸ The study sample compared those who had returned to work (returners, 77%) with those who had not returned to work (non-returners, 23%) after one year. Medical variables provided 67% correct classification of non-returners. Classification of non-returners was most accurate (77% correct identification) when medical, anamnestic, socio-demographic, work ability and psychological variables were combined in the analysis. Typically, a non-returner had a lower score on internal health locus of control, had restricted lateral mobility, had reduced work ability for ordinary work, had more radiographs taken of the back, was less physically active, had more children and stayed in one job for a longer period.

Another randomised controlled trial, that compared a graded activity program with physician care,⁸⁴ evaluated the predictive value of industrial physical work demands by correlating physical work demands with the return to work rate and number of days off work.⁸⁹ Although no data were provided, the authors claim that there were no correlations between work demands, work postures at the work place or compression load of the spine and the number of days off work

The available data on prediction of outcomes in people with subacute low back pain are not very helpful. Haldorsen et al⁸⁸ provided only p-values for the predictor variable so it remains unclear how much the variable contributed to the prediction of outcome. Lindstrom et al did not publish any data at all.⁸⁹ In addition, predictors of return to work were evaluated in a working population so it remains unclear whether similar predictors of outcome can be used to predict either outcomes in a general population, or to predict other clinically meaningful outcomes such as pain or disability. Lastly, neither Haldorsen et al⁸⁸ nor Lindstrom et al⁸⁹ evaluated predictors of response to treatment so it remains unknown if there is an interaction between putative predictors and treatment.

The second aim of the present study was therefore to evaluate which variables predict outcome at 6 weeks and which variables influenced response to treatment at 6 weeks.

A multicentre international clinical trial was conducted with treatment sites in both Australia and New Zealand. The trial examined effects of exercise and advice on outcomes for people with subacute low back pain. Outcomes were reassessed at 6 weeks, 3 months and 12 months. To date, only the 6-week follow up has been

completed by all subjects and the present report is therefore restricted to the evaluation of treatment efficacy at 6 weeks (n=231).

Methods

The study design was an assessor-blind randomised controlled trial using a 2×2 factorial design with the two factors being exercise and advice. The study was conducted at outpatient physiotherapy departments of six public hospitals in Sydney, Australia, and in Auckland, New Zealand, and at one private physiotherapy clinic in Newcastle, Australia. The enrolment period was from January 2001 up to June 2003.

Selection of patients

Patients aged between 18 and 80 years of age with low back pain with or without pain referral to the leg that had lasted longer than 6 weeks but less than 3 months were invited to join the study. Potential subjects were recruited via referral from health care professionals, from hospital waiting lists or advertisements in newspapers. Exclusion criteria included; spinal surgery in the past 12 months, pregnancy, specific spinal pathology (eg nerve root involvement, malignancy, inflammatory bone or joint disease), contra-indications to exercise, or poor English comprehension. Potential subjects who reported osteoarthritis, spondylitis, spondylolysis, spondylolisthesis, disc protrusion/herniation/prolapse or spinal stenosis remained eligible. At the baseline visit, the study was explained in detail and informed consent was obtained. The study protocol was approved by the

relevant Human Research Ethics Committees at all sites including; University of Sydney, Bankstown Hospital, Concord Hospital, Royal North Shore Hospital, Royal Prince Alfred Hospital, Auckland University of Technology and Middlemore Hospital (Auckland).

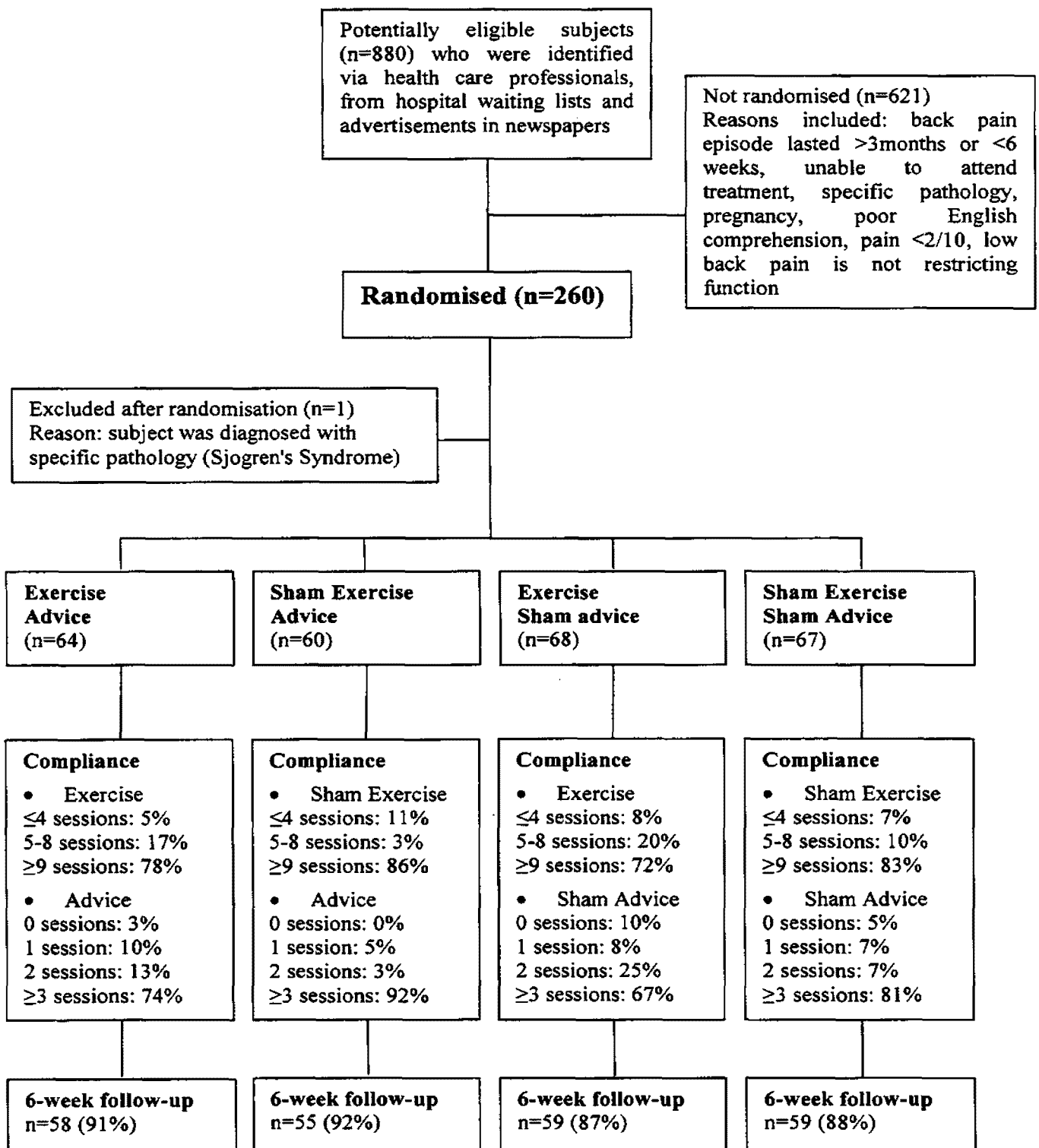


Figure 5.2 Flowchart of subjects' progress through the trial

Randomisation

After completing the baseline assessment subjects were randomly allocated to one of four intervention groups: exercise and advice, exercise and sham advice, sham exercise and advice, and sham exercise and sham advice. An allocation schedule was generated by computer. For each subject the next sequentially numbered sealed opaque envelope was drawn by the trial coordinator or the physiotherapist. Allocation was concealed from the referring medical practitioner and the trial staff member who determined eligibility. There was no stratification according to treatment centre.

Intervention

The interventions included exercise, sham exercise, advice and sham advice. All subjects received one exercise intervention (active or sham) and one advice intervention (active or sham).

Exercise. The exercise program was based on the program described by Lindstrom et al.⁸⁴ The program was an individualised submaximal, progressively increasing program that aimed to improve subjects' ability to complete functional activities specified by the subject as being difficult because of low back pain. The therapist used principles of cognitive behavioural therapy including setting progressively raised goals, shaping, encouraging self-monitoring of progress and self-reinforcement (Appendix 3). Each subject carried out a form of aerobic exercise (eg, walking or cycling), stretches, functional activities, activities to build speed, endurance and coordination, and trunk and limb strengthening exercises (Appendix 3). Exercises

were not restricted to the trunk but included the whole body. Subjects were also given an individualised home exercise program that was regularly evaluated by the physiotherapist, and subjects were encouraged to continue the home program after the intervention period finished.

Sham exercise. The control for exercise intervention consisted of detuned pulsed ultrasound (5 minutes) and detuned short-wave (20 minutes). The intervention was given in a credible manner by replicating the normal clinical routine for delivering ultrasound and short wave (Appendix 3). The physiotherapist was not expected to stay with the patient during the whole 20 minutes.

Advice. Advice sessions were based on the advice given by Indahl et al.⁷⁹ The therapist explained the benign nature of low back pain, addressed any unhelpful beliefs about back pain and emphasised that being overly careful and avoiding light activity would delay recovery (Appendix 3).

Sham advice. During the control for advice sessions, subjects were given the opportunity to talk about their low back pain and any other problems that they were having. The therapist responded in a warm and empathic manner, displaying genuine interest in the subject, however no advice about the low back pain was given (Appendix 3). Sessions were structured to promote the sense that they were planned and purposeful.

Subjects in all groups attended the physiotherapy department on 12 occasions over 6 weeks, ie three sessions per week in weeks 1 and 2, two sessions per week in weeks 3 and 4 and one session per week in weeks 5 and 6. At the first visit subjects received a standardised assessment (Appendix 2), irrespective of allocation. The standardised assessment included a thorough evaluation of the history of the low back pain,

functional status, social history and subjects' understanding of low back pain, and a physical examination. At each of the 12 sessions, subjects received the exercise or sham exercise intervention as allocated. In addition, on three occasions, in weeks 1, 2 and 4, subjects also received advice or sham advice as allocated. Advice or sham advice was not given during the exercise or sham exercise session, rather it was provided in a separate room before or after the exercise or sham exercise session.

To ensure consistent administration of each treatment, a treatment manual was developed (Appendix 3) and each physiotherapist was trained in the study protocol and interventions. Physiotherapists were educated by an experienced clinical psychologist about the principles of the cognitive behavioural approach they would use in the trial. To assess treatment validity, sample treatment sessions were tape recorded and assessed by one of the chief investigators. In addition, one of the investigators regularly visited each treatment site to personally monitor delivery of treatment.

Patients were not informed if the intervention they received was an active or sham intervention. Subjects' perceptions of treatment credibility were determined at the beginning and end of the trial with a questionnaire.⁹⁰ Treatment compliance was established by recording the number of appointments for each subject and the amount of time spent with each subject. Subjects were encouraged not to seek care from other health care providers. Subjects who dropped out of the treatment were encouraged to return for the follow up assessments.

Outcomes

At baseline, data were collected demographic, historical and social characteristics as well as treatment outcome measures (Appendix 1). At the 6-week follow-up, data were also collected on work-status, medication use, number of health care contacts, side-effects, adverse events and co-interventions (Appendix 1). Primary outcome measures, chosen a priori, included pain, disability and global perceived effect.

- *Pain* was rated as the average pain over the past week on an 11-point box scale where 0 represented no pain at all and 10 represented the worst pain possible.⁷²
- *Disability* was measured using the Patient Specific Functional Scale, where subjects specified three important activities that they were unable to perform or had difficulty with as a result of their back pain.⁶⁶ Each activity was scored on a 0-10 scale for the day of the assessment, where 0 represented inability to perform the activity and 10 represented ability to perform the activity at preinjury level. A summary score for the Patient Specific Functional Scale was calculated as the average score of the three activities.
- *Global perceived effect* was measured on an 11-point scale, ranging from -5 (vastly worse) to 5 (completely recovered), with 0 being unchanged.

The secondary outcome measures were the 24-item Roland Morris disability questionnaire⁴³ and the 21-item Depression, Anxiety and Stress Scale (DASS-21).⁹¹

- The *Roland Morris disability questionnaire* consists of 24 yes/no statements about activities of daily living that could be affected by low back pain. Each statement ticked is worth one point with the scores ranging from 0 (no disability) to 24 (extremely severe disability).

- The *DASS-21* consists of three subscales evaluating depression, anxiety and stress. Each subscale includes 7 statements about negative emotional symptoms. Subjects rated the extent to which they experienced each symptom over the past week on a 4-point severity/frequency scale. Scores for depression, anxiety and stress were calculated by adding up the scores for each subscale and multiplying this score by two, yielding a maximum score of 42 per subscale.⁹²

Subjects' perception of treatment credibility was determined after the first treatment by asking the following 4 questions⁹³: "How confident do you feel that this treatment can relieve your pain?", "How confident do you feel that this treatment will help you manage your pain?", "How confident would you be in recommending this treatment to a friend who suffered from similar complaints?", "How logical does this type of treatment seem to you?" Each question was rated on a scale ranging from 0 (not at all confident/not at all logical) to 6 (absolutely confident/very logical). At the 12 month follow-up subjects were also asked to rate how understanding, helpful and friendly they had found the therapist, and how helpful they had found the treatment on a 4-point scale.⁹⁰ In addition, they were also asked to identify the treatment components received.

Subjects were reassessed by a blinded assessor at the end of the 6-week treatment period. To evaluate the extent of unblinding, the blinded assessor was asked to guess the treatment allocation at each follow up assessment. Evaluation of success of treatment blinding showed that the assessor was unable to identify the correct treatment allocation in 61% of the assessments. The proportion of incorrect guesses differed slightly between the groups and was 55% for the exercise and advice group,

53% for the sham exercise and advice group, 65% for the exercise and sham advice group and 69% for the sham exercise and sham advice group.

A copy of each questionnaire can be found in Appendix 1 (Trial protocol).

Predictors of outcome and response to treatment

The predictors of outcome and predictors of response to treatment were chosen *a priori*. To minimize the type I error rate we restricted the number of predictors of outcome to 15 and the number of predictors of response to treatment to 5 (Table 5.1).

Predictors of interest covered factors in different domains, eg historical, psychological and social factors.

Table 5.1 Predictors of interest

Predictor	Response options	Description
<i>Demographic and Historical predictors</i>		
Age‡	in years	
Gender‡	male/female	
Previous episodes of low back pain‡	yes/no	
Duration of low back pain§	three categories: 6-8 weeks; 9-11 weeks; 3 months	duration of the current episode of low back pain
Pain at baseline‡§	0 (no pain) to 10 (worst pain possible)	average pain intensity over the past week on 0-10 VAS
Patient Specific Functional Scale at baseline‡§	0 (unable to perform activity) to 10 (able to perform activity at preinjury level)	average score on the 0-10 patient specific functional score of the number of activities
Pain referred to leg‡	yes/no	
Areas of pain other than back or leg‡	yes/no	other areas included neck, shoulder and/or upper back pain
Self-reported physical activity‡§	yes/no	undertaking moderate exercise 3x/week for at least 30 minutes prior to the start of low back pain episode
<i>Psychological predictors</i>		
Fear of movement (Tampa scale for kinesiophobia) ⁹⁴ ‡	Each of the items is scored between 1 (strongly disagree) to 4 (strongly agree).	17 statements about pain with each statement scored on a 4-point scale. Total score is sum score of items after inversion of items 4, 8, 12 and 16. Total score ranges from 17 to 68.

Table 5.1 Continued

Predictor	Response options	Description
Pain self-efficacy ⁹⁰ ‡§	Each activity is scored between 0 (not at all confident) to 6 (completely confident)	10 activities and patient rates how confident they are that they can perform the activities despite the pain. Total score is the sum score of individual items and ranges from 0-60.
Depression (DASS-21†) ⁹¹ ‡	Each item is scored between 0 (did not apply to me at all) to 3 (applied to me very much or most of the time)	21 items about psychological distress measured on subscales of depression, anxiety and stress. Total score is the sum score of individual items multiplied by two and ranges from 0-42.
Anxiety (DASS-21†) ⁹¹ ‡		
Stress (DASS-21†) ⁹¹ ‡		
Coping (PRSS*) ⁹⁵ ‡	Each item is scored between 0 (almost never) to 5 (almost always)	18 items consisting of subscales catastrophizing and coping which cover typical thoughts of people in pain. Subjects rate how often they have a particular thought when the pain is severe. Total score is calculated for each subscale as the sum score of individual items and ranges from 0-45.
Catastrophising (PRSS*) ⁹⁵ ‡		

† DASS: Depression, anxiety and stress scales

* PRSS: Pain Related Self-Statements

‡ Predictors of outcome

§ Predictors of response to treatment

Statistical analysis

A sample size of 208 subjects provided 80% power, assuming an alpha of 0.05 to detect a difference of 1 point on the 11-point global perceived effect scale, 1 point on the 0-10 Patient Specific Functional Scale and 1 point on the 0-10 pain scale. To allow for loss to follow up and treatment non-compliance we recruited 260 subjects. One subject was diagnosed with specific pathology after randomisation and was therefore excluded from the study,⁹⁶ leaving 259 subjects in the study. Although we had power to detect smaller differences, a clinically meaningful difference was defined as at least 2 points on the 11-point scales for pain, the Patient Specific Functional Scale and global perceived effect.

Data were analysed according to the intention-to-treat principle (ie, analyzing subjects for the treatment to which they were randomised). To ensure accurate data entry, each data point was double-checked and verified. Missing items were substituted by the average item score of the questionnaire or subscale. If the 6-week follow-up data were missing, the subject was removed from the 6-week follow-up analysis.

Treatment compliance was evaluated by calculating the number of sessions for each intervention and the mean session duration, including the mean amount of time spent individually with the subject.

Effects of exercise and advice including a possible interaction effect were analysed according to a 2×2 factorial design, ie the effects of exercise and advice were compared to the sham interventions. Linear regression was used to develop the model. The model was tested for a possible interaction effect between exercise and advice. Where there was no evidence of an interaction, the interaction term was

deleted from the model. Baseline scores of the primary and secondary outcomes were used as covariates, except for global perceived effect. Analyses were performed using SPSS version 10.0.

The number of predictors of outcome was restricted to 15. With this number of outcomes, the sample size gave an 80% probability of detecting moderate effects.⁹⁷ Predictors were chosen on the basis of clinical experience and outcomes of previous studies of predictors for LBP. Predictors were evaluated with univariate and multivariate models. Stepwise linear regression was used to develop the final model. To determine predictors of response to treatment five additional regression analyses were conducted. In each analysis, the interaction between the intervention factors (exercise and advice) and one of the five putative predictors was evaluated. A Bonferroni correction was used to correct for multiple testing so alpha was set at 0.01.

Results

A total of 880 potential subjects were identified by trial staff between January 2001 and June 2003. Subjects were recruited from hospital waiting lists (n=73), from a medical practitioner (n=1) and from advertisements (n=185). Of the 880 potential subjects, 621 were ineligible. Reasons for ineligibility were: duration of low back pain was less than 6 weeks or more than 3 months; unable to attend for treatment; unwilling to participate; specific pathology was identified; subject was pregnant; poor English comprehension; pain intensity was $<2/10$ or low back pain did not restrict function. Of the 259 subjects included in the trial, 64 were randomised to the exercise and advice group, 67 to the sham exercise and advice group, 60 to the exercise and sham advice group, and 68 to the sham exercise and sham advice group (Figure 5.1). The groups were similar for most baseline characteristics (Table 5.2). Primary outcomes were similar for those seeking medical care and those recruited from the community (Table 5.3). Of the 259 subjects 231 (89.8%) attended the 6-week follow-up.

Table 5.2 Baseline characteristics of the study population

	exercise and advice (n=58)	sham exercise and advice (n=55)	exercise and sham advice (n=59)	sham exercise and sham advice (n=59)	all subjects (n=231)
Age	50.3 (16.0)	52.3 (15.1)	48.6 (16.2)	50.3 (15.2)	50.3 (15.6)
Female: n (%)	25 (43%)	24 (44%)	27 (46%)	32 (55%)	108 (47%)
Low back pain duration: n (%)					
6-8 weeks	30 (52%)	27 (51%)	26 (45%)	24 (41%)	107 (47%)
9-11 weeks	18 (31%)	22 (42%)	22 (38%)	24 (41%)	86 (38%)
12 weeks	10 (17%)	4 (8%)	10 (17%)	10 (17%)	34 (15%)
Previous episodes of low back pain: n (%)	17 (29%)	18 (33%)	22 (38%)	20 (34%)	77 (34%)
Pain referred to the leg: n (%)	18 (31%)	23 (42%)	18 (31%)	17 (29%)	76 (33%)
Other pain areas than back or leg: n (%)	15 (26%)	14 (25%)	17 (29%)	11 (19%)	57 (25%)
Self reported physical activity: n (%)	16 (28%)	20 (36%)	15 (25%)	21 (36%)	72 (31%)
TAMPA [†] : mean (SD)	39.0 (8.1)	38.7 (7.4)	39.4 (8.9)	38.1 (8.0)	38.8 (8.1)
Pain self-efficacy [*] : mean (SD)	44.8 (12.4)	46.4 (11.1)	44.2 (11.6)	44.3 (12.8)	44.9 (12.0)
PRSS – coping [†] : mean (SD)	30.5 (7.0)	30.2 (8.6)	30.0 (7.5)	30.3 (5.8)	30.3 (7.2)
PRSS – catastrophising [§] : mean (SD)	17.1 (9.2)	17.6 (10.6)	17.8 (8.6)	18.2 (7.8)	17.7 (9.0)
Primary outcomes					
Pain: mean (SD)	5.4 (2.2)	5.5 (2.0)	5.3 (2.0)	5.4 (1.8)	5.4 (2.0)
Patient Specific Functional Scale [†] : mean (SD)	3.7 (1.9)	3.8 (1.8)	3.5 (2.0)	3.9 (1.6)	3.7 (1.8)
Global perceived effect ^{††} : mean (SD)	-0.4 (2.4)	0.3 (2.3)	-0.1 (2.7)	0.5 (2.3)	0.1 (2.4)
Secondary outcomes					
Roland Morris questionnaire ^{**} : mean (SD)	9.0 (4.8)	8.1 (4.1)	8.3 (5.1)	7.9 (5.4)	8.3 (4.9)
DASS – depression ^{††} : mean (SD)	6.6 (8.8)	7.4 (7.9)	7.2 (8.1)	7.0 (7.4)	7.1 (8.0)
DASS – anxiety ^{§§} : mean (SD)	4.7 (6.9)	5.3 (7.6)	6.6 (7.8)	5.2 (6.8)	5.5 (7.3)
DASS – stress : mean (SD)	9.3 (8.6)	11.0 (8.2)	12.7 (9.1)	11.9 (10.2)	11.2 (9.1)

- † TAMPA scale for Kinesiophobia: 17 (low fear of movement) to 68 (high fear of movement)
- * Pain self-efficacy questionnaire: 0 (low self-efficacy) to 60 (high self-efficacy)
- ‡ Pain-related self statement scale – coping: 0 (poor coping strategies) to 45 (strong coping strategies)
- § Pain-related self statement scale – catastrophising: 0 (low catastrophising) to 45 (high catastrophising)
- || Pain: 0 (no pain) to 10 (worst pain possible)
- ¶ Patient Specific Functional Scale: 0 (unable to perform activity) to 10 (able to perform activity at preinjury level)
- †† Global perceived effect scale: -5 (vastly worse) to 5 (completely recovered) with 0 being unchanged
- ** Roland Morris disability questionnaire: 0 (no disability) to 24 (high disability)
- ‡‡ Depression, anxiety and stress scales – depression: 0 (no depression) to 42 (high depression)
- §§ Depression, anxiety and stress scales – anxiety: 0 (no anxiety) to 42 (high anxiety)
- ||| Depression, anxiety and stress scales – stress: 0 (no stress) to 42 (high stress)

Table 5.3 Means (SD) of primary outcomes for those seeking medical care for back pain and those recruited from the community.

	Subjects seeking medical care (n=69)	Subjects recruited from the community (n=162)	p-value
Age	49.6 (17.6)	50.3 (14.9)	0.755
Female: <i>n</i> (%)	55%	44%	0.118
Low back pain duration: <i>n</i> (%)			
6-8 weeks	52%	44%	0.316
9-11 weeks	33%	41%	0.273
12 weeks	16%	15%	0.927
Previous episodes of low back pain: <i>n</i> (%)	73%	64%	0.215
Pain referred to the leg: <i>n</i> (%)	43%	29%	0.040
Other pain areas than back or leg: <i>n</i> (%)	22%	28%	0.315
Self reported physical activity: <i>n</i> (%)	54%	77%	0.001
TAMPA: <i>mean</i> (SD)	41.8 (8.1)	37.7 (7.7)	0.000
Pain self-efficacy: <i>mean</i> (SD)	39.6 (12.4)	47.3 (11.0)	0.000
PRSS – coping: <i>mean</i> (SD)	29.0 (8.5)	30.6 (6.7)	0.138
PRSS – catastrophising: <i>mean</i> (SD)	21.1 (9.3)	16.2 (8.7)	0.000
Primary outcomes			
Pain: <i>mean</i> (SD)	5.8 (2.1)	5.1 (1.9)	0.010
Patient Specific Functional Scale: <i>mean</i> (SD)	3.3 (1.7)	3.9 (1.9)	0.030
Global perceived effect: <i>mean</i> (SD)	0.1 (2.4)	0.2 (2.4)	0.707
Secondary outcomes			
Roland Morris questionnaire: <i>mean</i> (SD)	10.0 (5.6)	7.6 (4.4)	0.001
DASS – depression: <i>mean</i> (SD)	10.5 (9.4)	5.8 (7.0)	0.000
DASS – anxiety: <i>mean</i> (SD)	7.7 (8.0)	4.5 (6.9)	0.003
DASS – stress: <i>mean</i> (SD)	14.3 (14.3)	10.0 (8.5)	0.001

See footnote Table 5.2 for description of outcome measures

Table 5.4 Median scores for the four items of the treatment credibility scale for the four treatment groups.

	Exercise/ advice	Advice/ sham exercise	Exercise/ sham advice	Sham advice/ sham exercise	All subjects
Confident that treatment will relieve pain [†]	5	4	5	4	5
Confident that treatment will help manage pain [†]	5	5	5	4	5
Confident to recommend treatment to friend [†]	5	4	5	4	5
How logical is the treatment [†]	6	5	6	5	5

† Subjects were asked to rate each of the four questions on a 7-point scale with scores ranging from 0 (not confident/not logical) to 6 (absolutely confident/very logical)

Compliance, side-effects, and cointerventions

Subjects attended 9.9 ± 2.8 (mean \pm SD) exercise sessions and 10.3 ± 2.9 sham exercise sessions. The mean number of advice sessions was 3.0 ± 1.1 and the mean number of sham advice sessions was 2.5 ± 1.1 . Mean duration of an exercise session was 52 ± 15 min of which 31 ± 10 min were spent individually with the subject. Mean duration of a sham exercise session was 45 ± 20 min of which 20 ± 8 min were spent individually with the subject. The mean duration of an advice session was 20 ± 6 min and of a sham advice session was 19 ± 5 min.

At the end of the first treatment, patients rated perceived treatment credibility. Overall, the median scores for each of the four credibility items was 5 out of 6 (Table 5.4). On average, subjects receiving sham exercise with or without sham advice rated the credibility one point lower on three of the four items than the subjects receiving exercise.

At baseline, more than half of all subjects (53%) had already received some form of treatment. Treatments included physiotherapy, drug therapy, chiropractic treatment and acupuncture. Although subjects were asked not to seek additional treatment during the 6 weeks of treatment, four subjects (7%) in the exercise and advice group, three subjects (5%) in the advice and sham exercise group, seven subjects (12%) in the exercise and sham advice group and nine subjects (15%) in the sham exercise and sham advice group received co-interventions during the 6 weeks of treatment. The most frequently reported co-interventions were physiotherapy (including spinal manipulative therapy, massage, exercise, ultrasound/shortwave, traction and heat), drug therapy, acupuncture, chiropractic and osteopathic treatment.

Twenty-one subjects reported side-effects from the intervention: 10 subjects in the exercise/advice group, 3 subjects in the sham exercise/advice group, 6 subjects in the exercise/sham advice group and 2 subjects in the sham exercise/sham advice group (Table 5.5).

Three patients were diagnosed with pathology after randomisation; one patient was diagnosed with Sjogren's Syndrome after randomization, one patient had a myocardial infarction on his way to an appointment at the physiotherapy department and one patient was diagnosed with secondary cancer of the lumbar spine after

completing the 6-week follow-up. The patient diagnosed with Sjogren's Syndrome was excluded from the study.

Table 5.5 Reported side-effects for each group.

Exercise Advice	Sham Exercise Advice	Exercise Sham Advice	Sham Exercise Sham advice
muscle soreness post intervention (n=1)	muscle soreness post intervention (n=1)	muscle soreness post intervention (n=1)	numbness in legs (n=1)
pain post intervention (n=5)	feeling tired (n=1)	pain post intervention (n=3)	referred pain (n=1)
feeling tired (n=1)	weight gain and itch on scalp (n=1)	elbow pain (n=1)	
pain exacerbations (n=2)		pain during intervention (n=1)	
nausea during exercises (n=1)			

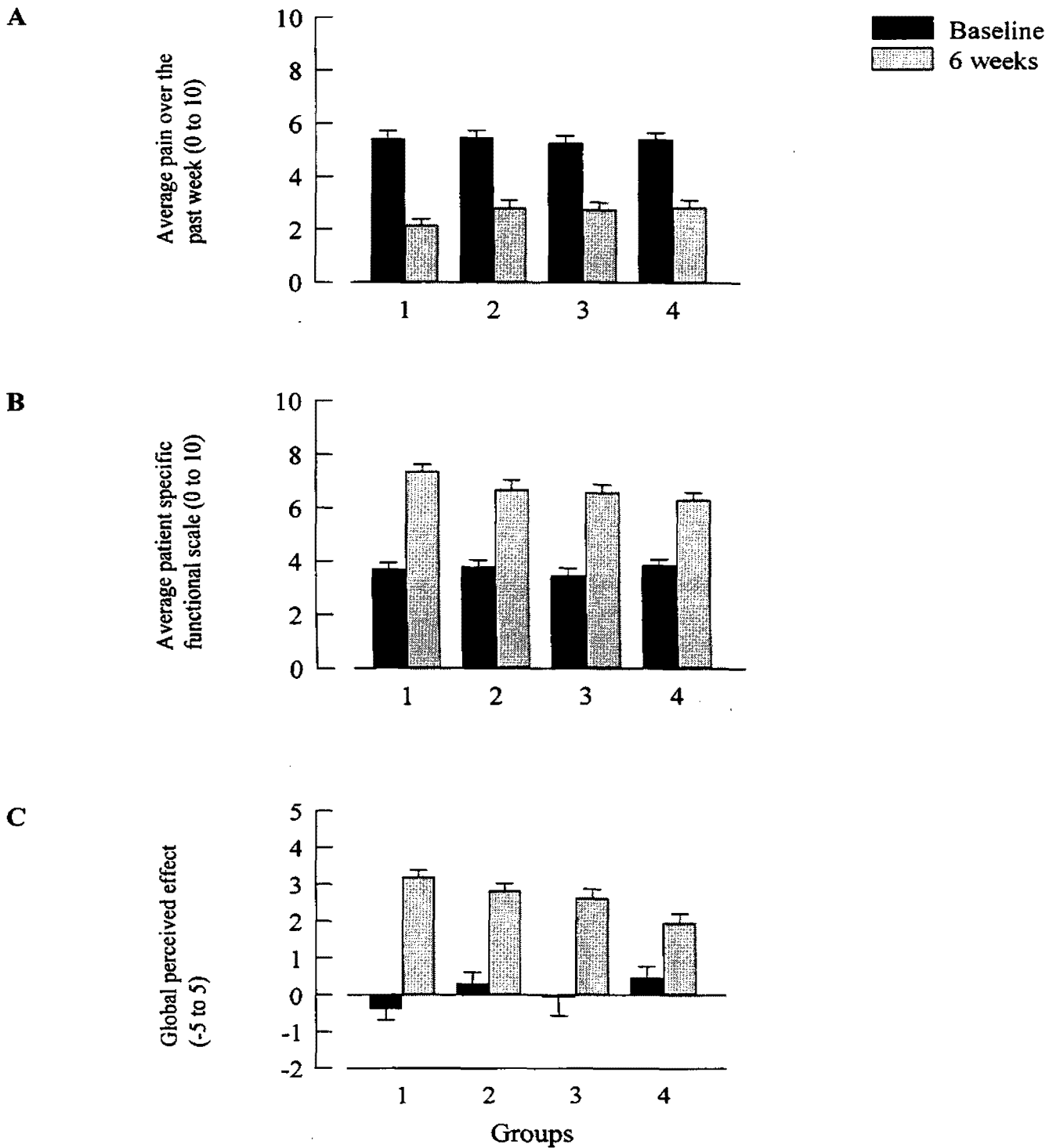


Figure 5.3 Baseline and 6 week follow-up scores for pain (A), the Patient Specific Functional Scale (B) and the global perceived effect scale (C). A decrease in pain and an increase in the patient specific functional scale and global perceived effect indicate improvement. Group 1=exercise and advice; group 2=sham exercise and advice; group 3=sham advice and exercise; group 4=sham exercise and sham advice.

Efficacy of treatment

All groups improved on average on the primary and secondary outcomes after 6 weeks of treatment (Figure 5.3; Tables 5.6 and 5.7). The primary analysis showed a significant effect of exercise on pain and global perceived effect scores. However, the effects were small, corresponding to a difference between exercise and sham exercise groups of -0.8 (95% CI -1.3 to -0.2) points on the 11-point pain scale and 0.5 (CI 0.1 to 1.0) points on the 11-point global perceived effect scale (Table 5.8). Both effects favoured exercise over sham exercise. The interaction effect was not significant.

The primary analysis also showed a significant effect of advice on pain and global perceived effect scores. The difference between subjects receiving advice and subjects receiving sham advice was -0.8 (CI -1.2 to -0.2) points on the pain scale and 0.7 (CI 0.3 to 1.2) points on the global perceived effect scale (Table 5.6). Both effects favoured advice over sham advice. The interaction effect was not significant. Neither exercise nor advice showed a significant effect on the Patient Specific Functional Scale.

The secondary analysis showed a significant benefit of exercise on the Roland Morris disability questionnaire, equating to a difference of -1.3 (CI -2.3 to -0.3) points on the 24-point scale between subjects who received exercise and those who did not (Table 5.7). There were no significant effects for advice on the Roland Morris disability questionnaire, or for exercise or advice on depression, anxiety and stress. At 6 weeks, more subjects in all groups scored within the 'normal' category for the depression, anxiety and stress scales than at baseline (Table 5.8).

Table 5.6 Means (SD), change scores (SD), percentage[†] improvement and effects of interventions at 6 weeks of primary outcomes for the four groups.

Outcome measures	Group Means (SD)				Effects (95% CI) [†]			
	exercise + sham advice (n=58)	sham exercise + advice (n=55)	exercise + sham advice (n=59)	sham exercise + sham advice (n=58)	exercise v sham exercise	sham advice v sham advice	exercise v sham advice	p value
Pain (0 to 10)								
baseline	5.4 (2.2)	5.5 (2.0)	5.3 (2.0)	5.4 (1.8)				
6 weeks	2.2 (1.9)	2.8 (2.2)	2.8 (2.0)	3.7 (2.1)	-0.8 (-1.3 to -0.2)	-0.8 (-1.2 to -0.2)	-0.8 (-1.2 to -0.2)	0.005
change score	-3.2 (2.7)	-2.7 (2.8)	-2.5 (2.1)	-1.7 (2.4)				0.004
% improvement	60%	49%	48%	32%				
PSFS (0 to 10)								
baseline	3.7 (1.9)	3.8 (1.8)	3.5 (2.0)	3.9 (1.6)				
6 weeks	7.4 (2.0)	6.7 (2.7)	6.6 (2.2)	6.3 (2.1)	0.5 (0.0 to 1.1)	0.5 (0.0 to 1.1)	0.6 (0.0 to 1.1)	0.060
change score	3.7 (2.4)	2.9 (2.8)	3.1 (2.5)	2.5 (2.4)				0.060
% improvement	99%	76%	89%	63%				
GPE (-5 to 5)								
baseline	-0.4 (2.4)	0.3 (2.3)	-0.1 (2.7)	0.5 (2.3)				
6 weeks	3.2 (1.4)	2.8 (1.5)	2.6 (1.8)	2.0 (1.9)	0.5 (0.1 to 1.0)	0.5 (0.1 to 1.0)	0.7 (0.3 to 1.2)	0.017
change score	NA*	NA*	NA*	NA*				0.017
% improvement	NA*	NA*	NA*	NA*				0.017

† percentages are percent of baseline scores

‡ effects are adjusted for baseline scores

* Subjects were asked to describe their back compared to when their episode *first started*.

CI confidence interval

PSFS Patient Specific Functional Scale

GPE global perceived effect

NA not applicable

See footnote Table 5.2 for description of outcome measures

Table 5.7 Means (SD), change scores (SD), percentage[†] improvement and effects of interventions at 6 weeks of secondary outcomes for the four groups.

Outcome measures	Group Means (SD)						Effects (95% CI) [†]	
	exercise + advice (n=58)	sham exercise + advice (n=55)	exercise + sham advice (n=59)	sham exercise + sham advice (n=58)	exercise v sham exercise	sham exercise v sham advice	p value	p value
Roland Morris								
baseline	9.0 (4.8)	8.1 (4.1)	8.3 (5.1)	7.9 (5.4)				
6 weeks	3.9 (4.7)	4.7 (5.0)	4.1 (4.0)	5.3 (4.6)	-1.3 (-2.3 to -0.3)*	0.011	-0.6 (-1.6 to 0.4)	0.219
change scores	-5 (5.1)	-3.4 (3.9)	-4.2 (4.5)	-2.6 (4.5)				
% improvement	57%	42%	51%	49%				
DASS depression								
baseline	6.6 (8.8)	7.4 (7.9)	7.2 (8.1)	7.0 (7.4)				
6 weeks	4.3 (9.2)	5.1 (8.0)	3.4 (5.6)	4.8 (7.8)	-1.0 (-2.6 to 0.7)	0.245	0.7 (-0.9 to 2.3)	0.397
change scores	-2.3 (7.7)	-2.3 (6.6)	-3.9 (5.3)	-2.2 (8.2)				
% improvement	35%	31%	53%	32%				
DASS anxiety								
baseline	4.7 (6.9)	5.3 (7.6)	6.6 (7.8)	5.2 (6.8)				
6 weeks	3.5 (7.3)	3.6 (5.9)	3.8 (5.3)	4.1 (4.9)	-0.4 (-1.6 to 0.8)	0.492	-0.6 (-1.1 to 1.2)	0.943
change scores	-1.2 (6.1)	-1.7 (5.0)	-2.7 (5.7)	-1.1 (6.0)				
% improvement	26%	32%	42%	21%				
DASS stress								
baseline	9.3 (8.6)	11.0 (8.2)	12.7 (9.1)	11.9 (10.2)				
6 weeks	5.4 (8.3)	7.3 (7.7)	7.0 (8.8)	7.8 (8.5)	-1.1 (-2.9 to 0.6)	0.207	0.1 (-1.7 to 1.9)	0.920
change scores	-4.0 (9.3)	-3.7 (7.0)	-5.7 (6.3)	-4.1 (8.8)				
% improvement	43%	33%	45%	35%				

† percentages are percent of baseline scores

‡ effects are adjusted for baseline scores

CI confidence interval

DASS Depression, anxiety and stress scales

See footnote Table 5.2 for description of outcome measures

Table 5.8 Number of subjects (percentage) in each category of the depression, anxiety and stress scales for the four groups.

	Baseline								6-weeks			
	exercise/ advice		sham exercise/ advice		exercise/ sham advice		sham exercise/ advice		exercise/ sham advice		sham exercise/ advice	
	n=58	n=55	n=58	n=55	n=59	n=59	n=58	n=55	n=59	n=59	n=58	n=59
Depression	normal	46 (80%)	38 (69%)	40 (68%)	41 (69%)	165 (71%)	48 (84%)	44 (80%)	53 (90%)	48 (82%)	193 (83%)	
	mild	3 (5%)	6 (11%)	8 (14%)	4 (7%)	21 (9%)	3 (5%)	3 (5%)	1 (2%)	4 (7%)	11 (5%)	
	moderate	5 (9%)	4 (7%)	5 (8%)	11 (19%)	25 (11%)	3 (5%)	6 (11%)	3 (5%)	3 (5%)	15 (6%)	
	severe	2 (3%)	5 (9%)	5 (8%)	2 (3%)	14 (6%)	2 (3%)	0	2 (3%)	2 (3%)	6 (3%)	
	extremely severe	2 (3%)	2 (4%)	1 (2%)	1 (2%)	6 (3%)	2 (3%)	2 (4%)	0	2 (3%)	6 (3%)	
Anxiety	normal	44 (77%)	39 (71%)	36 (61%)	44 (74%)	163 (71%)	52 (90%)	46 (84%)	47 (80%)	45 (76%)	191 (83%)	
	mild	2 (3%)	7 (13%)	6 (10%)	3 (5%)	18 (8%)	1 (2%)	3 (5%)	3 (5%)	1 (2%)	8 (3%)	
	moderate	7 (12%)	3 (5%)	9 (15%)	5 (9%)	24 (10%)	0	3 (5%)	5 (8%)	10 (17%)	18 (8%)	
	severe	2 (3%)	2 (4%)	4 (7%)	2 (3%)	10 (4%)	0	1 (2%)	3 (5%)	3 (5%)	6 (3%)	
	extremely severe	3 (5%)	4 (7%)	4 (7%)	5 (9%)	16 (7%)	5 (8%)	2 (4%)	1 (2%)	0	8 (3%)	
Stress	normal	47 (82%)	39 (71%)	36 (61%)	39 (66%)	161 (70%)	52 (90%)	47 (85%)	48 (81%)	48 (81%)	195 (84%)	
	mild	4 (7%)	5 (9%)	8 (14%)	6 (10%)	23 (10%)	2 (3%)	1 (2%)	3 (5%)	3 (5%)	11 (5%)	
	moderate	3 (5%)	8 (14%)	9 (15%)	5 (9%)	25 (11%)	1 (2%)	5 (9%)	44 (7%)	44 (7%)	13 (6%)	
	severe	2 (3%)	2 (4%)	5 (9%)	7 (12%)	16 (7%)	1 (2%)	2 (4%)	44 (7%)	44 (7%)	9 (4%)	
	extremely severe	2 (3%)	1 (2%)	1 (2%)	2 (3%)	6 (2%)	2 (3%)	0	0	0	3 (1%)	

Predictors of outcome

Univariate regression analysis of predictors for pain, Patient Specific Functional Scale and global perceived effect showed a number of significant predictors (Table 5.9). For pain, significant predictors included gender, a low back pain duration of 9-11 weeks, pain at baseline, pain referred to the leg, self-efficacy, catastrophising, depression, anxiety and stress. For the Patient Specific Functional Scale, significant predictors included a low back pain duration of 9-11 weeks, the Patient Specific Functional Scale score at baseline, TAMPAs, self-efficacy, catastrophising, depression, anxiety and stress. For global perceived effect, significant predictors included a low back pain duration of 9-11 weeks and anxiety.

Multivariate analysis showed that the model that best predicted pain intensity at 6 weeks included self-efficacy, exercise, advice, anxiety and pain at baseline (Table 5.10). The model that best predicted the Patient Specific Functional Scale score at 6 weeks included the Patient Specific Functional Scale score at baseline, self-efficacy and advice. The model that best predicted global perceived effect at 6 weeks included only exercise and advice.

None of the models produced clinically useful reductions in the prediction error (SD of residuals) of the outcomes at 6 weeks. For pain, the model reduced the SD of the outcome from 2.1 to 1.9 when self-efficacy, exercise, advice, anxiety and pain at baseline were taken into account. For the Patient Specific Functional Scale, the SD was reduced from 2.3 to 2.1 when the Patient Specific Functional Scale score at baseline, self-efficacy and advice were taken into account. Finally, the SD of the global perceived effect scale remained 1.7 when advice and exercise were included in the model.

Table 5.9 Univariate regression analyses of predictors of pain, Patient Specific Functional Scale and global perceived effect.

Predictor	Pain			PSFS			GPE		
	regression coefficient (95% CI)	p	R ²	regression coefficient (95% CI)	p	R ²	regression coefficient (95% CI)	p	R ²
Age	0.00 (-0.02 to 0.02)	0.75	0.00	-0.01 (-0.03 to 0.01)	0.49	0.00	0.00 (-0.01 to 0.02)	0.80	0.00
Gender	0.58 (0.03 to 1.13)	0.03	0.02	0.37 (-0.21 to 0.95)	0.21	0.01	0.19 (-0.27 to 0.64)	0.42	0.00
Low back pain duration									
9-11 weekst	0.70 (0.15 to 1.25)	0.01	0.03	-0.78 (-1.35 to -0.20)	0.01	0.18	-0.71 (-1.16 to -0.27)	0.00	0.04
12 weekst	0.20 (-0.58 to 0.98)	0.61	0.00	-0.20 (-1.01 to 0.61)	0.63	0.03	-0.35 (-0.99 to 0.29)	0.28	0.01
Previous episodes	0.27 (-0.32 to 0.85)	0.37	0.00	-0.47 (-1.09 to 0.14)	0.13	0.01	-0.37 (-0.84 to 0.11)	0.13	0.01
Pain at baseline	0.26 (0.12 to 0.39)	0.00	0.06	-0.01 (-0.15 to 0.14)	0.91	0.00	0.03 (-0.08 to 0.15)	0.59	0.04
PSFS at baseline	0.04 (-0.11 to 0.20)	0.56	0.00	0.28 (0.13 to 0.43)	0.00	0.06	-0.03 (-0.16 to 0.09)	0.60	0.00
Pain referred to the leg	0.78 (0.21 to 1.36)	0.00	0.03	-0.04 (-0.65 to 0.58)	0.91	0.00	0.18 (-0.30 to 0.66)	0.46	0.00
Other pain areas than back or leg	0.30 (-0.34 to 0.93)	0.36	0.00	0.22 (-0.45 to 0.89)	0.52	0.00	0.00 (-0.53 to 0.52)	0.99	0.00
Self reported physical activity	-0.41 (-1.00 to 0.18)	0.18	0.01	-0.02 (-0.64 to 0.60)	0.95	0.00	-0.06 (-0.54 to 0.43)	0.82	0.00
TAMPA	0.04 (0.05 to 0.72)	0.26	0.02	-0.05 (-0.08 to -0.01)	0.01	0.03	-0.01 (-0.04 to 0.02)	0.41	0.00
Pain self-efficacy	-0.05 (-0.06 to 0.02)	0.00	0.07	0.04 (0.2 to 0.06)	0.00	0.05	0.01 (-0.01 to 0.03)	0.35	0.00
PRSS – coping	0.00 (-0.03 to 0.03)	0.98	0.00	0.00 (-0.04 to 0.04)	0.89	0.00	0.01 (-0.02 to 0.04)	0.60	0.00
PRSS – catastrophising	0.06 (0.03 to 0.09)	0.00	0.06	-0.04 (-0.07 to 0.00)	0.03	0.02	-0.01 (-0.03 to 0.02)	0.46	0.00
DASS – depression	0.04 (0.00 to 0.74)	0.02	0.02	-0.04 (-0.08 to -0.01)	0.02	0.02	-0.02 (-0.05 to 0.01)	0.18	0.01
DASS – anxiety	0.07 (0.03 to 0.11)	0.00	0.06	-0.05 (-0.09 to -0.02)	0.01	0.03	0.07 (0.03 to 0.11)	0.00	0.06
DASS – stress	0.05 (0.02 to 0.08)	0.00	0.04	-0.04 (-0.07 to -0.01)	0.01	0.03	-0.02 (-0.05 to 0.00)	0.07	0.01

† Compared to 6-8 weeks duration

PSFS Patient Specific Functional Scale

GPE Global perceived effect

Table 5.10 Multivariate predictors of pain, Patient Specific Functional Scale and global perceived effect scores at 6 weeks.

Outcome	Predictors	Regression coefficient (95% CI)	p	R
Pain at 6 weeks	Self-efficacy	-0.03 (-0.05 to -0.01)	0.04	0.43
	Exercise intervention	-0.79 (-1.31 to -0.28)	0.00	
	Advice intervention	-0.74 (-1.25 to -0.22)	0.01	
	Anxiety	0.04 (0.01 to 0.08)	0.02	
	Pain at baseline	0.17 (0.02 to 0.31)	0.02	
	(Constant)	3.67 (1.98 to 5.34)	0.00	
PSFS at 6 weeks	PSFS at baseline	0.22 (0.07 to 0.38)	0.01	0.32
	Self-efficacy	0.03 (0.01 to 0.06)	0.12	
	Advice	0.61 (0.06 to 1.17)	0.03	
	(Constant)	4.25 (3.12 to 5.38)	0.00	
GPE at 6 weeks	Advice	0.81 (0.37 to 1.26)	0.00	0.28
	Exercise	0.50 (0.06 to 0.94)	0.03	
	(Constant)	2.00 (1.62 to 2.38)	0.00	

CI confidence interval

PSFS Patient Specific Functional Scale

GPE Global perceived effect

Predictors of response to treatment

Evaluation of predictors of response to treatment showed there were no significant interactions between putative predictors and intervention (exercise or advice) for pain or the Patient Specific Functional Scale at 6 weeks (Tables 5.11 and 5.12). However, only self-efficacy was found to significantly predict the response to exercise on the global perceived effect scale at 6 weeks (Table 5.13). When a subject received exercise only, the effect of exercise was 2.4 points (95% CI 0.7 to 4.1) on the global perceived effect scale when the score on the self-efficacy scale was 0 at baseline (Formula 5.1). Furthermore, the lower the self-efficacy scores at baseline, the greater the response to exercise and the higher the global perceived effect score at 6 weeks. However, after Bonferroni correction the effect of self-efficacy was no longer significant.

$$\begin{aligned} \text{Global perceived effect} = & 1.085 + 2.4 * \text{Exercise} - 0.0005 * \text{Advice} + \\ & 0.02 * \text{Self-efficacy} + 0.02 * \text{Self-efficacy} * \text{Advice} + \\ & 0.04 * \text{Self-efficacy} * \text{Exercise} \quad (\text{Formula 5.1}) \end{aligned}$$

Table 5.11 Predictors of response to treatment for pain at 6 weeks. Interactions between putative predictors and interventions (exercise and advice) are indicative of predictors of response to treatment

Outcome	Predictor	Interaction	Regression coefficient (95% CI)	p	R ²
Pain at 6 weeks	Pain at baseline	Advice	-0.23 (-0.50 to 0.03)	0.08	0.15
		Exercise	0.11 (-0.15 to 0.37)	0.41	
		(Constant)	1.87 (0.47 to 3.27)	0.01	
	PSFS at baseline	Advice	-0.15 (-0.44 to 0.15)	0.33	0.08
		Exercise	-0.24 (-0.54 to 0.06)	0.11	
		(Constant)	2.68 (1.50 to 3.86)	0.00	
	Physical activity	Advice	0.04 (-1.11 to 1.20)	0.94	0.08
		Exercise	0.32 (-0.84 to 1.49)	0.58	
		(Constant)	3.95 (3.17 to 4.74)	0.00	
	Duration 9-11 weeks*	Advice	-0.92 (-2.08 to 0.24)	0.12	0.11
		Exercise	0.17 (-0.99 to 1.33)	0.77	
		(Constant)	3.22 (2.52 to 3.91)	0.00	
	Duration 3 months*	Advice	0.09 (-1.53 to 1.72)	0.91	0.11
		Exercise	0.95 (-0.67 to 2.57)	0.25	
		(Constant)	3.22 (2.52 to 3.91)	0.00	
	Self-efficacy	Advice	-0.03 (0.07 to 0.01)	0.17	0.15
		Exercise	0.00 (-0.04 to 0.05)	0.91	
		(Constant)	5.12 (3.47 to 6.77)	0.00	

* compared to 6-8 weeks duration

CI Confidence interval

PSFS Patient Specific Functional Scale

GPE Global perceived effect

Table 5.12 Predictors of response to treatment for the patient specific functional scale at 6 weeks. Interactions between putative predictors and interventions (exercise and advice) are indicative of predictors of response to treatment

Outcome	Predictor	Interaction	Regression coefficient (95% CI)	p	R ²
PSFS at 6 weeks	Pain at baseline	Advice	0.15 (-0.14 to 0.44)	0.30	0.04
		Exercise	-0.02 (-0.31 to 0.27)	0.88	
		(Constant)	6.69 (5.14 to 8.23)	0.00	
	PSFS at baseline	Advice	0.05 (-0.26 to 0.35)	0.77	0.09
		Exercise	-0.04 (-0.35 to 0.27)	0.79	
		(Constant)	5.14 (3.93 to 6.36)	0.00	
	Physical activity	Advice	-0.67 (-1.91 to 0.56)	0.29	0.04
		Exercise	-0.13 (-1.37 to 1.11)	0.84	
		(Constant)	6.01 (5.17 to 6.85)	0.00	
	Duration 9-11 weeks*	Advice	0.54 (-0.71 to 1.78)	0.40	0.07
		Exercise	0.32 (-0.93 to 1.56)	0.62	
		(Constant)	6.79 (6.04 to 7.53)	0.00	
	Duration 3 months*	Advice	-0.68 (-2.42 to 1.06)	0.44	0.07
		Exercise	0.34 (-1.40 to 2.08)	0.70	
		(Constant)	6.79 (6.04 to 7.53)	0.00	
	Self-efficacy	Advice	0.03 (-0.02 to 0.07)	0.28	0.08
		Exercise	-0.02 (-0.07 to 0.03)	0.37	
		(Constant)	4.50 (2.71 to 6.28)	0.00	

* compared to 6-8 weeks duration

CI Confidence interval

PSFS Patient Specific Functional Scale

Table 5.13 Predictors of response to treatment for global perceived effect at 6 weeks. Interactions between putative predictors and interventions (exercise and advice) are indicative of predictors of response to treatment

Outcome	Predictor	Interaction	Regression coefficient (95% CI)	p	R ²
GPE at 6 weeks	Pain at baseline	Advice	0.05 (-0.17 to 0.28)	0.65	0.08
		Exercise	0.01 (-0.21 to 0.24)	0.92	
		(Constant)	2.02 (0.84 to 3.22)	0.00	
	PSFS at baseline	Advice	0.09 (-0.15 to 0.33)	0.46	0.08
		Exercise	-0.04 (-0.08 to 0.21)	0.76	
		(Constant)	2.20 (1.23 to 3.17)	0.00	
	Physical activity	Advice	-0.27 (-1.22 to 0.67)	0.57	0.08
		Exercise	-0.34 (-1.29 to 0.61)	0.48	
		(Constant)	1.88 (1.24 to 2.52)	0.00	
	Duration 9-11 weeks*	Advice	0.39 (-0.56 to 1.34)	0.42	0.12
		Exercise	0.36 (-0.59 to 1.31)	0.46	
		(Constant)	2.59 (2.02 to 3.16)	0.00	
	Duration 3 months*	Advice	0.54 (-0.79 to 1.87)	0.43	0.12
		Exercise	0.18 (-1.15 to 1.51)	0.79	
		(Constant)	2.59 (2.02 to 3.16)	0.00	
	Self-efficacy	Advice	0.02 (-0.02 to 0.05)	0.38	0.10
		Exercise	-0.04 (-0.08 to -0.01)	0.04 [†]	
		(Constant)	1.09 (-0.31 to 2.48)	0.13	

† Not significant after Bonferroni correction

* compared to 6-8 weeks duration

CI Confidence interval

GPE Global perceived effect

PSFS Patient Specific Functional Scale

Discussion

The present study is the first rigorous randomised controlled trial to investigate efficacy of exercise and advice for subacute low back pain by comparing both these interventions with a sham intervention. The findings provide high quality evidence that both exercise and advice are effective for decreasing pain and increasing global perceived effect in subjects with subacute low back pain. In contrast to other studies that evaluated interventions for subacute low back pain,⁷⁸ the present study controlled for bias using the following methodological features; concealed allocation, comparability of groups at baseline, avoidance of co-interventions, acceptable compliance for all groups, assessor blinding, acceptable drop-out rate and intention-to-treat analysis. In addition, the present study clearly defined the study population using the definition of subacute low back pain proposed by the Cochrane Collaboration Back Review Group.¹⁷

Presentation of the clinical trial in this thesis is restricted to the 6-week follow-up because the long-term outcome of the 3 and 12-month follow-ups is not yet available for all subjects. The aim of clinical trials is to find evidence of effective interventions with ongoing effects. This is particularly true for subacute low back pain where progression to chronic low back pain poses an enormous burden, suggesting that the long-term outcome is likely to be even more important than the short-term outcome. Indeed, other trials of low back pain that evaluated efficacy of interventions, have shown benefits at long-term follow up where no benefits were evident at short-term follow-up.^{85 98} It is therefore not possible to provide definitive conclusions as full appreciation of the effects of exercise and advice can only be given after completion of the final 12-month follow-up. Long-term outcome at 3 and

12 months will also clarify whether the effects of active and sham interventions are maintained equally well.

Efficacy of intervention

For both exercise and advice interventions, the active and sham forms resulted in large improvements in pain, disability and global perceived effect after 6 weeks of intervention. While the exercise and advice improved pain and global perceived effect scores significantly more than the sham interventions, the difference in outcome between the active and sham forms of both interventions was small, being less than 1 point on the 11-point pain and global perceived effect scales.

Subjects in the current study were recruited either by referral because they were seeking medical care for their back pain (recruited from hospital waiting lists) or from the community (responders to advertisements in newspapers). Subjects who were seeking care for their back pain had higher scores for pain, the Roland Morris disability questionnaire, depression, anxiety, stress, catastrophising and fear-avoidance, were less physically active and had lower self-efficacy scores than subjects responding to advertisements (Table 5.3). This confirms previous suggestions that patients seeking medical care have more severe problems than people in the community.⁹⁹ However, because subjects were evenly randomized to the groups, these small differences would not have affected the results.

While this study noted statistically significant effects of interventions, a couple of issues need to be considered when judging whether these effects are clinically meaningful. This involves a consideration of the minimum level of detectable change (MDC) and the minimally clinically important difference (MCID) for each

outcome. The first statistic describes how much a measure needs to change to be confident that the change is real and not due to measurement error whereas the second statistic describes the minimum change required for a patient to judge the effect to be clinically important.

The MDC for the Roland Morris questionnaire is 4 units¹⁰⁰ and for pain 15 units on a 0-100 scale¹⁰¹ (or 1.5 units on the 11-point pain rating scale used in the present study). All four treatment groups changed by amounts greater than these values so if these treatments were applied to individual patients in a clinic the changes over time would be measurable. From the patient's perspective the change in pain with each treatment is likely to be judged as clinically important as the MCID has been reported to be 2 points on the 11-point pain rating scale.¹⁰² It is acknowledged that not all of this change is due to the specific effects of therapy, with both sham interventions producing large improvements at 6 week follow-up. However when applying treatments to individual patients in a clinic the specific and non-specific effects of therapy cannot be separated.

The meaning of the effect of intervention should also be considered in terms of time and cost for both health care systems and patients. The exercise program used in the present study required exercise equipment and a considerable amount of therapist time throughout the 12 sessions. Furthermore, attending the 12 exercise sessions often conflicted with subjects' work and social obligations and required considerable amounts of travelling. However, advice consisted of 3 20-minute sessions and the effect of advice produced similar reductions in pain and global perceived effect as exercise. In terms of time and cost, providing patients with advice is a relatively simple and cheap intervention. Additionally, advice is easy to deliver as it can be

incorporated into the normal clinical encounter when patients consult a clinician for their back pain.

The efficacy of exercise for acute and chronic low back pain has been evaluated in a systematic review concluding that when exercise therapy was compared with inactive or placebo interventions, exercise was not effective for acute low back pain but was found to be effective for chronic low back pain.²³ However, few of the inactive or placebo interventions, controlled for therapist attention. Of the studies controlling for therapist attention, one high quality study¹⁰³ concluded that exercise was no more effective than placebo ultrasound for acute low back pain (<3weeks). For chronic low back pain, two high quality studies were found, with conflicting results; one study¹⁰⁴ concluded that exercise was more effective than transcutaneous electrical nerve stimulation (active or sham) while another study¹⁰⁵ concluded that exercise was no more effective than a placebo control consisting of semihot packs and light traction. Thus, when comparing exercise to a sham intervention, there is no evidence for the effectiveness of exercise for acute low back pain and conflicting evidence for the efficacy of exercise for chronic low back pain.

The present study is the only study of exercise for subacute low back pain to control for therapist attention by giving subjects in all groups the same number of treatments and the same amount of individual time with the therapist. Analysis of the number of treatment sessions and the session duration for all groups showed that these were indeed similar for active and sham groups. Thus, it can be concluded that the differences between the groups were not due to a difference in therapist attention. Therefore, the present study provided the first high quality evidence for an effect of exercise for subacute low back pain.

The magnitude of the within-group improvement found here for the exercise and advice group is similar to the improvement found in other studies for exercise interventions however the within group improvement for sham treatment is much larger than for the active control treatments used in other studies^{106 107}. For example O'Sullivan et al¹⁰⁶ and Reilly et al¹⁰⁷ reported reductions in pain of 54% and 58% for a supervised exercise program which is comparable to the 60% reduction in pain seen for the exercise and advice group in this thesis. However the reductions in pain in the control groups in these two studies^{106 107} were 0% and 3% which is markedly less than the 32% reduction in pain seen in the double sham group in this study. What is most intriguing is that in both O'Sullivan and Reilly's study the control treatments were active interventions that are part of contemporary practice. A consequence of the large improvement observed with sham treatment is that the effect size for exercise (active versus sham exercise) is small, whereas the large effect sizes reported by O'Sullivan¹⁰⁶ and Reilly¹⁰⁷ are probably inflated by the lack of improvement observed in the control group.

The exercise program used in the current study was designed to be the best possible implementation of exercise in that it was individualised to the patient, incorporated principles of cognitive behavioural therapy and aimed to improve the specific functional activities that were impaired as a result of back pain. Other exercise programs designed for patients with subacute low back pain, incorporated different components.^{84 108} Lindstrom et al⁸⁴ used a work-place visit and back school education, while Storheim's program¹⁰⁸ consisted of a much higher number of sessions. Future research should investigate which elements influence the efficacy of exercise interventions for low back pain.

Clinical practice guidelines for low back pain widely advocate provision of appropriate advice to patients.¹⁴ A systematic review evaluated the effect of advice as a single intervention for patients with low back pain.¹⁰⁹ It was concluded, based on one high quality study, that advice to stay active compared to bed rest or exercise may have small beneficial effects (<1 point on 11-point pain and disability scales) for patients with acute low back pain. The present study also found only a small benefit of advice on pain and global perceived effect. It is argued that the information component of advice is therapeutic,⁷⁹ however, the small difference between active and sham advice at the 6-week follow-up shows that the effects of advice are largely based on the interaction between the clinician and patient. Thus, while advice is widely promoted by clinical practice guidelines as a single intervention, advice alone only has a small additional effect over sham and should be complemented by other more powerful interventions.

To ensure internal validity in the present study, the outcome assessor was blinded to treatment allocation. The assessor correctly guessed the treatment allocation in 39% of the assessments, which is slightly more than chance (25%). The comparison of exercise and advice did not allow complete blinding of patients. However, patients were not told if they were allocated to the experimental or sham intervention, and the treatment credibility rating showed that subjects were successfully blinded. At the 12-month follow up, subjects were asked to nominate the treatment components they received. In addition, subjects were asked to rate the therapist in terms of friendliness, understanding and helpfulness, and the helpfulness of the treatment. When 12-month follow-up is complete, analysis of these outcomes will give more insight into the patient's perception of the interventions and the success of blinding subjects to the allocated active or sham intervention.

Sham intervention

Although use of a sham is vital to establish treatment efficacy, it has been argued that the use of a sham procedure is difficult, if not impossible to implement in trials of physical treatment. However, the present study provides evidence that a credible sham intervention can be developed and delivered in a clinical trial of physical interventions. The detuned short wave and ultrasound (sham exercise), and ventilation (sham advice) resulted in improvements of up to 40% in the primary outcomes. Subjects gave similar treatment credibility ratings for both active and sham interventions, and both the subjects and assessors remained blind to group allocation. Thus, the high credibility of the sham intervention and low rate of unblinding in the present study demonstrate that it is possible to employ sham interventions in trials of physical interventions. This finding is encouraging for future randomised controlled trials.

While the ventilation intervention used in the present study acted as a control for advice, other health care professionals may argue that ventilation is not an inactive intervention. In fact, treatments similar to ventilation are used by some professions to treat psychosocial health problems. However, there is no evidence that the ventilation intervention as used in the present study, improves pain or function for people with subacute low back pain. Thus the ventilation sessions are unlikely to have had an active effect in the present study sample.¹⁴

Adverse effects

Twenty-one subjects reported side-effects from the intervention. Some of the side-effects reported by the subjects are unlikely to have resulted from the intervention.

For example, subjects receiving advice and sham exercise reported muscle soreness after the intervention, weight gain and itch, and feeling tired. Side-effects reported by subjects in the exercise group were more likely to have resulted from the intervention, ie pain exacerbations, muscle soreness after the intervention, pain post intervention, feeling tired and pain during the treatment. The side-effects reported by subjects receiving exercise are commonly reported side-effects of exercise and do not raise any concerns.

Predictors

The univariate regression analysis showed that only anxiety and a low back pain duration of 9-11 weeks were significantly related to each of the three primary outcomes. However, multivariate regression analysis showed that none of the predictors of outcome produced clinically useful reductions in the prediction error of the outcomes at 6 weeks. For the predictors of response to treatment, only self-efficacy was found to significantly predict the response to exercise on global perceived effect.

Demographic, medical, historical and psychological variables are often reported to be predictive of outcome,^{27 54 57 110} however the systematic review evaluating predictors of acute low back pain reported in Chapter 2, found only one predictor of outcome at 3 months. Nevertheless, this predictor was of limited clinical use because of the low prevalence of failure to return to work.⁸⁷ In addition, the present study could not provide any evidence that predictors of adverse outcome exist for subacute low back pain. This uncertainty is not reflected in the clinical practice guidelines as each of the guidelines encourages the assessment of predictors of poor outcome.¹⁴ The New

Zealand Acute Low Back Pain Guide suggests that management of acute low back pain will be improved by identifying and addressing psychosocial ‘yellow flags’. However, this strategy ignores the limited evidence for predictors.

The only significant predictor of response to treatment was self-efficacy which modified the effects of exercise on global perceived effect, although after Bonferroni correction self-efficacy was no longer statistically significant. However, self-efficacy modified the effects of exercise considerably: the effect of exercise when considering self-efficacy was 2.4 points on the 11-point global perceived effect scale. Therefore, prescription of an exercise program for the treatment of subacute low back pain could be guided by self-efficacy scores.

Physical activity was not found to be a predictor of outcome or of response to treatment despite the significance of self-efficacy. This is surprising, because self-efficacy has been found to be strongly correlated with physical activity.^{111 112}

Physical activity in the present study was defined as activity of moderate intensity for at least 30 minutes 3 times per week. This definition was based on a recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine.¹¹³ The variable in its current format (dichotomous scale) may not have been optimal because different levels of physical activity have been associated with different levels of self-efficacy¹¹⁴. Converting the variable into a continuous scale allows subjects to grade the level of activity intensity and may be a more favourable format to measure the predictive value of physical activity.

In conclusion, none of the variables significantly predicted outcome at 6 weeks. However, self-efficacy may modify the response to exercise in terms of global perceived effect.

CHAPTER 6

Concluding remarks

Overview of the main results

The aim of this thesis was to evaluate outcomes for low back pain of recent onset. A major focus of the thesis was the effectiveness of exercise and advice for subacute low back pain. Evaluation of effective treatment for subacute low back pain is crucial as effective treatment will prevent transition to chronic low back pain, a condition with a low treatment success rate.

A systematic review of the prognosis of acute low back pain (ie low back pain of less than 3 weeks) showed that people with acute low back pain experienced rapid improvements in pain, disability and return to work within one month. Further improvements occurred until about 3 months. However, after 3 months levels of pain, disability and return to work remained nearly constant and recurrences were common. The review confirms the widely held view that most people with acute low back pain recover rapidly, however contrary to conventional understanding recovery is not complete. This finding suggests that the information on prognosis in all evidence-based clinical practice guidelines needs revision.

A systematic review of conservative interventions for subacute low back pain (ie low back pain between 6 weeks and 3 months) revealed a lack of agreement on the definition of subacute, and a generally poor quality of research. Most of the studies did not show a significant effect of intervention. None of the studies that included low back pain of duration 6 weeks to 3 months had high internal validity. When other methodological criteria were considered, evidence was found for the efficacy of advice. When a broader view was taken of the duration of subacute low back pain (7 days to 6 months), there is evidence that other treatments (eg, manipulation, exercise, TENS) may be effective.

A responsiveness study was conducted to evaluate the ability of pain, disability and physical impairment measures to detect change in a patient's health status over time. The most responsive outcome proved to be the Patient Specific Functional Scale followed by an 11-point pain scale and the Roland Morris disability questionnaire. However, the physical impairment measures were not very responsive. These findings suggest that more emphasis should be placed on change in pain and disability scores than on change in physical impairments.

The major study in the thesis was a randomised controlled clinical trial evaluating the efficacy of exercise and advice for patients suffering from subacute low back pain using a 2×2 factorial design. Additionally, within the trial predictors of outcome and response to treatment were evaluated. At 6 weeks, all subjects had improved on pain, the Patient Specific Functional Scale and global perceived effect. There was a significant benefit of exercise or advice for pain and global perceived effect. However, differences were small and may not be clinically worthwhile. None of the predictor models produced clinically useful predictors of the outcome at 6 week. So, self-efficacy was the only factor to significantly modify the response to exercise for global perceived effect. However, after Bonferroni correction the effect of self-efficacy was no longer significant.

In summary, prognosis of acute low back pain is for rapid improvement after onset, but recovery is incomplete meaning that patients may progress to the subacute phase. Although there is some evidence for the efficacy of exercise and advice for subacute low back pain, to date, these interventions do not seem to be very effective for the treatment of subacute low back pain because the additional effects of exercise and advice over sham interventions are modest. The findings from the trial also suggest

that there are no predictors that can be confidently used to predict outcome of an episode of subacute low back pain, or to predict response to treatment for subacute low back pain.

Directions for future research

The research conducted for this thesis suggests some directions for future research.

Chapter 2 described a systematic review of prognosis. The systematic review included randomised clinical controlled trials whose control groups were used to describe prognosis. The control group was defined as the group receiving the least active intervention. The definition led to a wide variety of control interventions as some control groups consisted of a placebo treatment, eg detuned ultrasound while other control groups consisted of interventions that are often advocated by clinical practice guidelines for the treatment of acute low back pain, eg advice. The five cohort studies included in the review were of low methodological quality or did not provide data on pain and disability, or return to work after 3 months. Thus, in order to establish the prognosis of acute low back pain in a homogeneous sample, a high quality cohort study is needed to evaluate the long-term prognosis of acute low back pain for clinically relevant measures.

A systematic review of conservative treatments for subacute low back pain showed that none of the interventions produced clinically worthwhile effects for pain, disability and return to work. The clinical trial presented in this thesis evaluated exercise and/or advice for subacute low back pain and concluded that these interventions are unlikely to produce clinically worthwhile effects related to the

specific intervention, although the non-specific effect was high, evidenced by the response to sham. The long-term outcome is not yet available and is required to confirm conclusions. Thus, there is an urgent need to develop more powerful interventions that can produce clinically worthwhile effects in subjects with subacute low back pain.

Establishing the efficacy of conservative interventions was hampered by a lack of a uniform definition of subacute low back pain in the reviewed randomised controlled trials. Future randomised controlled trials for subacute low back pain should adhere to a uniform definition of subacute low back pain to facilitate comparison between trials and enable meta-analysis of results. The current definitions of 'acute', 'subacute' and 'chronic' low back pain as defined by the Cochrane Back Review Group are not empirically derived and the definitions may not be the optimal method to categorise nonspecific low back pain. Research is needed to validate the system.

REFERENCES

1. Andersson GB. Epidemiological features of chronic low-back pain. *Lancet* 1999;354:581-5.
2. Hillman M, Wright A, Rajaratnam G *et al.* Prevalence of low back pain in the community: implications for service provision in Bradford, UK. *J Epidemiol Community Health* 1996;50:347-52.
3. Frymoyer JW. Back pain and sciatica. *N Engl J Med* 1988;318:291-300.
4. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003;102:167-78.
5. Andersson GBJ. The epidemiology of spinal disorders. In: Frymoyer JW, editor. *The adult spine: principles and practice*. Second edition. Philadelphia: Lippincott-Raven, 1997.
6. Volinn E, Diehr P, Ciol MA *et al.* Why does geographic variation in health care practices matter? (And seven questions to ask in evaluating studies on geographic variation). *Spine* 1994;19:2092S-100S.
7. Van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. *Pain* 1995;62:233-40.
8. Hashemi L, Webster BS, Clancy EA *et al.* Length of disability and cost of workers' compensation low back pain claims. *J Occup Environ Med* 1997;39:937-45.
9. Webster BS, Snook SH. The cost of 1989 workers' compensation low back pain claims. *Spine* 1994;19:1111-5.
10. Thomas SA, Stone WE, Greenwood K. Australian workers with back injury: a statistical overview. *Int J Rehabil Res* 1990;13:195-203.
11. Frank A. Low back pain. *BMJ* 1993;306:901-9.
12. Waddell G. *The back pain revolution*. London: Churchill Livingstone, 1998.
13. Deyo RA, Rainville J, Kent DL. What can the history and physical examination tell us about low back pain? *JAMA* 1992;268:760-5.
14. Koes BW, Van Tulder MW, Ostelo R *et al.* Clinical guidelines for the management of low back pain in primary care: an international comparison. *Spine* 2001;26:2504-13.

15. Frank J, Sinclair S, Hogg-Johnson S *et al.* Preventing disability from work-related low-back pain. New evidence gives new hope--if we can just get all the players onside. *CMAJ* 1998;158:1625-31.
16. Spitzer WO. Scientific approach to the assessment and management of activity-related spinal disorders: a monograph for clinicians. Report of Quebec Task Force on Spinal Disorders. *Spine* 1987;12:1-59.
17. van Tulder M, Furlan A, Bombardier C *et al.* Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *Spine* 2003;28:1290-9.
18. Frank JW, Brooker AS, DeMaio SE *et al.* Disability resulting from occupational low back pain. Part II: What do we know about secondary prevention? A review of the scientific evidence on prevention after disability begins. *Spine* 1996;21:2918-29.
19. Merskey H, Bogduk N, editors. *Classification of chronic pain. Descriptions of chronic pain syndromes and definitions of pain terms.* Second edition. Seattle: IASP Press, 1994.
20. Mannion AF, Muntener M, Taimela S *et al.* A randomized clinical trial of three active therapies for chronic low back pain. *Spine* 1999;24:2435-48.
21. Guzman J, Esmail R, Karjalainen K *et al.* Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ* 2001;322:1511-6.
22. Van Tulder MW, Ostelo R, Vlaeyen JW *et al.* Behavioral treatment for chronic low back pain: a systematic review within the framework of the Cochrane Back Review Group. *Spine* 2000;25:2688-99.
23. Van Tulder MW, Malmivaara A, Esmail R *et al.* Exercise therapy for low back pain: a systematic review within the framework of the cochrane collaboration back review group. *Spine* 2000;25:2784-96.
24. Coste J, Delecoeuillerie G, Cohen de Lara A *et al.* Clinical course and prognostic factors in acute low back pain: an inception cohort study in primary care practice. *BMJ* 1994;308:577-80.
25. Croft PR, Macfarlane GJ, Papageorgiou AC *et al.* Outcome of low back pain in general practice: a prospective study. *BMJ* 1998;316:1356-9.
26. Schiottz-Christensen B, Nielsen GL, Hansen VK *et al.* Long-term prognosis of acute low back pain in patients seen in general practice: A 1-year prospective follow-up study. *Fam Pract* 1999;16:223-32.
27. ACC and National Health Committee. New Zealand low back pain guide. Wellington: National Health Committee, 1997.

28. Waddell G, Feder G, McIntosh A *et al.* Low back pain evidence review. London: Royal College of General Practitioners, 1996.
29. Bigos S, Bowyer O, Braen G *et al.* Acute low back pain problems in adults. Clinical Practice Guideline no.14. AHCPR Publication no. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, 1994.
30. Malmivaara A, Kotilainen E, Laasonen E *et al.* Clinical Practice Guidelines of the Finnish Medical Association Duodecim. Disease of the Low Back, 1999.
31. Keel P, Weber M, Roux E *et al.* Kreuzschmerzen: Hintergründe, prävention, behandlung. Basisdokumentation. Bern: Verbindung der Schweizer Ärzte (FMH), 1998.
32. Danish Institute for Health Technology Assessment. Low-back pain. Frequency, management and prevention from HTA perspective. Copenhagen: Danish Institute for Health Technology Assessment, 1999.
33. Nachemson AL, Jonsson E, editors. *Neck and Back pain: The Scientific Evidence of Causes, Diagnosis, and Treatment*. Philadelphia: Lippincott Williams & Wilkins, 2000.
34. Borkan J, Reis S, Werner S *et al.* Guidelines for treating low back pain in primary care. The Israeli Low Back Guideline Group. *Harfuah* 1996;130:145-51.
35. Bogduk N. Draft evidence based clinical guidelines for the management of acute low back pain. Australia: National Health and Medical Research Council, 2000.
36. Faas A, Chavannes AW, Koes BW *et al.* NHG-Standaard Lage Rugpijn. *Huisarts Wet* 1996;39:18-31.
37. Handlungsleitlinie-Rückenschmerzen. Empfehlungen zur Therapie von Rückenschmerzen, Arzneimittelkommission der deutschen Ärzteschaft. (Treatment guideline-backache. Drug Committee of the German Medical Society). *Z Artztl Fortbild Qualitätssich* 1997;91:457-60.
38. Deyo RA, Andersson G, Bombardier C *et al.* Outcome measures for studying patients with low back pain. *Spine* 1994;19:2032S-6S.
39. Zanolli G, Stromqvist B, Padua R *et al.* Lessons learned searching for a HRQoL instrument to assess the results of treatment in persons with lumbar disorders. *Spine* 2000;25:3178-85.
40. Deyo RA, Battie M, Beurskens AJ *et al.* Outcome measures for low back pain research. A proposal for standardized use. *Spine* 1998;23:2003-13.

41. Jensen MP, Strom SE, Turner JA *et al.* Validity of the Sickness Impact Profile Roland scale as a measure of dysfunction in chronic pain patients. *Pain* 1992;50:157-62.
42. Jensen MP, Karoly P, O'Riordan EF *et al.* The subjective experience of acute pain. An assessment of the utility of 10 indices. *Clin J Pain* 1989;5:153-9.
43. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141-4.
44. Waddell G. Objective clinical evaluation of physical impairment in chronic low back pain. *Spine* 1992;17:617-28.
45. Pile KD, Laurent MR, Salmond CE *et al.* Clinical assessment of ankylosing spondylitis: a study of observer variation in spinal measurements. *Br J Rheumatol* 1991;30:29-34.
46. Gauvin MG, Riddle DL, Rothstein JM. Reliability of clinical measurements of forward bending using the modified fingertip-to-floor method. *Phys Ther* 1990;70:443-7.
47. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. *J Chronic Dis* 1987;40:171-8.
48. Kopec JA. Measuring functional outcomes in persons with back pain: a review of back-specific questionnaires. *Spine* 2000;25:3110-4.
49. Altman DG. Systematic reviews of evaluations of prognostic variables. *BMJ* 2001;323:224-8.
50. Laupacis A, Wells G, Richardson WS *et al.* Users' guides to the medical literature: V. How to use an article about prognosis. *JAMA* 1994;272:234-7.
51. Thomas E, Silman AJ, Croft PR *et al.* Predicting who develops chronic low back pain in primary care: a prospective study. *BMJ* 1999;318:1662-7.
52. Skargren EI, Oberg BE. Predictive factors for 1-year outcome of low-back and neck pain in patients treated in primary care: comparison between the treatment strategies chiropractic and physiotherapy. *Pain*. 1998;77:201-7.
53. Linton SJ. A review of psychological risk factors in back and neck pain. *Spine* 2000;25:1148-56.
54. Gatchel RJ, Gardea MA. Psychosocial issues: their importance in predicting disability, response to treatment, and search for compensation. *Neurol Clin* 1999;17:149-66.

55. Murphy KA, Cornish RD. Prediction of chronicity in acute low back pain. *Arch Phys Med Rehabil* 1984;65:334-7.
56. van der Giezen AM, Bouter LM, Nijhuis FJ. Prediction of return-to-work of low back pain patients sicklisted for 3-4 months. *Pain* 2000;87:285-94.
57. Truchon MFL. Biopsychosocial determinants of chronic disability and low-back pain: a review. *J Occup Rehabil* 2000;10:117-42.
58. Williams RA, Pruitt SD, Doctor JN *et al.* The contribution of job satisfaction to the transition from acute to chronic low back pain. *Arch Phys Med Rehabil* 1998;79:366-74.
59. van der Weide WE, Verbeek JH, Salle HJ *et al.* Prognostic factors for chronic disability from acute low-back pain in occupational health care. *Scand J Work Environ Health* 1999;25:50-6.
60. Linton SJ, Hallden K. Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. *Clin J Pain* 1998;14:209-15.
61. Shaw WS, Pransky G, Fitzgerald TE. Early prognosis for low back disability: intervention strategies for health care providers. *Disabil Rehabil* 2001;23:815-28.
62. McIntosh G, Frank J, Hogg-Johnson S *et al.* Prognostic factors for time receiving workers' compensation benefits in a cohort of patients with low back pain. *Spine* 2000;25:147-57.
63. Infante-Rivard C, Lortie M. Prognostic factors for return to work after a first compensated episode of back pain. *Occup Environ Med* 1996;53:488-94.
64. Stratford PW, Binkley FM, Riddle DL. Health status measures: strategies and analytic methods for assessing change scores. *Phys Ther* 1996;76:1109-23.
65. Wright JG, Young NL. A comparison of different indices of responsiveness. *J Clin Epidemiol* 1997;50:239-46.
66. Westaway MD, Stratford PW, Binkley JM. The patient-specific functional scale: validation of its use in persons with neck dysfunction. *J Orthop Sports Phys Ther* 1998;27:331-8.
67. Beurskens AJ, de Vet HC, Koke AJ. Responsiveness of functional status in low back pain: a comparison of different instruments. *Pain* 1996;65:71-6.
68. Beurskens AJ, de Vet HC, Koke AJ *et al.* A patient-specific approach for measuring functional status in low back pain. *J Manipulative Physiol Ther* 1999;22:144-8.

69. Deyo RA, Centor RM. Assessing the responsiveness of functional scales to clinical change: an analogy to diagnostic test performance. *J Chronic Dis* 1986;39:897-906.
70. Stratford PW, Binkley JM. Measurement properties of the RM-18. A modified version of the Roland-Morris Disability Scale. *Spine* 1997;22:2416-21.
71. Williams RM, Myers AM. Support for a shortened Roland-Morris Disability Questionnaire for patients with acute low back pain. *Physiother Can* 2001;53:60-6.
72. Ross RG, LaStayo P. Clinical Assessment of Pain. In: Van Deusen J, Brunt D, editors. *Assessment in occupational therapy and physical therapy*. Philadelphia: WB Saunders, 1997:123-33.
73. Tryon WW. Evaluating statistical difference, equivalence, and indeterminacy using inferential confidence intervals: an integrated alternative method of conducting null hypothesis statistical tests. *Psychol Methods* 2001;6:371-86.
74. Stratford P, Gill C, Westaway M *et al*. Assessing disability and change on individual patients: a report of a patient specific measure. *Physiother Can* 1995;47:258-63.
75. Chatman AB, Hyams SP, Neel JM *et al*. The Patient-Specific Functional Scale: measurement properties in patients with knee dysfunction. *Phys Ther* 1997;77:820-9.
76. Cohen J. *Statistical power analysis for the behavioral sciences*. Second edition. Hillsdale, NJ: L Erlbaum Associates, 1988.
77. Workcover New South Wales. New South Wales workers compensation statistical bulletin 2000/2001: Information Services Unit Workcover New South Wales, 2002.
78. Pengel HM, Maher CG, Refshauge KM. Systematic review of conservative interventions for subacute low back pain. *Clin Rehabil* 2002;16:811-20.
79. Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered. A randomized clinical trial. *Spine* 1995;20:473-7.
80. Indahl A, Haldorsen EH, Holm S *et al*. Five-year follow-up study of a controlled clinical trial using light mobilization and an informative approach to low back pain. *Spine* 1998;23:2625-30.
81. Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? *Spine* 2000;25:1973-6.

82. Chok B, Lee R, Latimer J *et al.* Endurance training of the trunk extensor muscles in people with subacute low back pain. *Phys Ther* 1999;79:1032-42.
83. Davies JE, Gibson T, Tester L. The value of exercises in the treatment of low back pain. *Rheumatol Rehabil* 1979;18:243-7.
84. Lindstrom I, Ohlund C, Eek C *et al.* The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioral approach. *Phys Ther* 1992;72:279-90.
85. Moffett JK, Torgerson D, Bell-Syer S *et al.* Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. *BMJ* 1999;319:279-83.
86. Koes BW, Bouter LM, van Mameren H *et al.* Randomised clinical trial of manipulative therapy and physiotherapy for persistent back and neck complaints: results of one year follow up. *BMJ* 1992;304:601-5.
87. Pengel LH, Herbert RD, Maher CG *et al.* Acute low back pain: systematic review of its prognosis. *BMJ* 2003;327:323.
88. Haldorsen EM, Indahl A, Ursin H. Patients with low back pain not returning to work. A 12-month follow-up study. *Spine* 1998;23:1202-7.
89. Lindstrom I, Ohlund C, Nachemson A. Validity of patient reporting and predictive value of industrial physical work demands. *Spine* 1994;19:888-93.
90. Nicholas MK. An evaluation of cognitive, behavioural and relaxation treatments for chronic low back pain. University of Sydney, 1988. Unpublished PhD thesis.
91. Lovibond SH, Lovibond PF. Manual for depression, anxiety and stress scales. Sydney: Psychology foundation monograph, 1993.
92. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the depression anxiety stress scales (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Ther* 1995;33:335-43.
93. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther Exp Psychiatry* 1972;3:257-60.
94. Miller RP, Kori SH, Todd DD. The TAMPA scale, unpublished report. TAMPA, FL, 1991.
95. Flor H, Behle DJ, Birbaumer N. Assessment of pain-related cognitions in chronic pain patients. *Behav Res Ther* 1993;31:63-73.

96. Fergusson D, Aaron SD, Guyatt G *et al.* Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;325:652-4.
97. Green SB, Byar DP. The effect of stratified randomization on size and power of statistical tests in clinical trials. *J Chronic Dis* 1978;31:445-54.
98. Rossignol M, Abenhaim L, Seguin P *et al.* Coordination of primary health care for back pain. A randomized controlled trial. *Spine* 2000;25:251-8.
99. Turk DC, Rudy TE. Neglected factors in chronic pain treatment outcome studies - referral patterns, failure to enter treatment, and attrition. *Pain* 1990;43:7-25.
100. Stratford PW, Binkley J, Solomon P *et al.* Defining the minimum level of detectable change for the Roland-Morris questionnaire. *Phys Ther* 1996;76:359-65.
101. Hagg O, Fritzell P, Nordwall A *et al.* The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J* 2003;12:12-20.
102. Farrar JT, Young JP, Jr., LaMoreaux L *et al.* Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001;94:149-58.
103. Faas A, Chavannes AW, van Eijk JT *et al.* A randomized, placebo-controlled trial of exercise therapy in patients with acute low back pain. *Spine* 1993;18:1388-95.
104. Deyo RA, Walsh NE, Martin DC *et al.* A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med* 1990;322:1627-34.
105. Hansen FR, Bendix T, Skov P *et al.* Intensive, dynamic back-muscle exercises, conventional physiotherapy, or placebo-control treatment of low-back pain. A randomized, observer-blind trial. *Spine* 1993;18:98-108.
106. O'Sullivan PB, Phytz GD, Twomey LT *et al.* Evaluation of specific stabilizing exercise in the treatment of chronic low back pain with radiologic diagnosis of spondylolysis or spondylolisthesis. *Spine* 1997;22:2959-67.
107. Reilly K, Lovejoy B, Williams R *et al.* Differences between a supervised and independent strength and conditioning program with chronic low back syndromes. *J Occup Med* 1989;31:547-50.
108. Storheim K, Brox JI, Holm I *et al.* Intensive group training versus cognitive intervention in sub-acute low back pain: short-term results of a single-blind randomized controlled trial. *J Rehabil Med* 2003;35:132-40.

109. Hilde G, Hagen KB, Jamtvedt G *et al.* Advice to stay active as a single treatment for low back pain and sciatica. *Cochrane Database of Systematic Reviews* 2003;3.
110. Vlaeyen JW, Kole-Snijders AM, Rotteveel AM *et al.* The role of fear of movement/(re) injury in pain disability. *J Occup Rehabil* 1995;5:235-52.
111. McAuley E, Jacobson L. Self-efficacy and exercise participation in sedentary adult females. *Am J Health Promotion* 1991;5:185-91.
112. Rovniak LS, Anderson ES, Winett RA *et al.* Social cognitive determinants of physical activity in young adults: a prospective structural equation analysis. *Ann Behav Med* 2002;24:149-56.
113. Pate RR, Pratt M, Blair SN *et al.* Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 1995;273:402-7.
114. Miller KH, Ogletree RJ, Welshimer K. Impact of activity behaviors on physical activity identity and self-efficacy. *Am J Health Behav* 2002;26:323-30.

APPENDIX 1

Trial Protocol:

“Exercise or Advice for Subacute Low Back Pain?”

INDEX

INTRODUCTION.....	111
RESEARCH PLAN.....	112
ASSESSMENT AND ALLOCATION	116
INTERVENTIONS.....	120
DATA ANALYSIS	123
INSTRUCTIONS FOR TREATMENT PROVIDERS	125

Introduction

Overview

Patients with *subacute* low back pain (LBP; LBP of 6 weeks to 3 months duration) are unlikely to undergo spontaneous recovery, with a substantial proportion progressing to develop a *chronic* LBP syndrome, a condition known to be resistant to treatment and to be largely responsible for the high cost of LBP. It is therefore particularly important that patients with *subacute* LBP receive effective treatment. It is currently being advocated, for example in most clinical guidelines for the management of LBP, that patients with *subacute* LBP should be managed with advice and/or exercise. However, because scientifically rigorous studies have not been undertaken, the efficacy of these treatments alone or in combination is not known. We will investigate the efficacy of exercise and advice in a randomised controlled trial using a factorial design. In addition, we will identify which patient factors predict response to each intervention.

Specific aims

The specific aims of the project are to:

1. Investigate the efficacy of exercise, advice and both treatments combined for subacute low back pain.
2. Identify clinical factors that predict response to each intervention.

Prediction of response to treatment

It is likely that sub-populations of patients with subacute LBP could be identified for whom different management strategies would be most effective. It is clear that the population of patients with subacute LBP is not homogeneous, rather it includes patients with varying signs, symptoms, attitudes and beliefs who experience widely divergent social and work environments. Three categories of factors have value for predicting recovery from acute LBP: demographic and historical factors, physical examination findings and psychosocial factors, however, the only prognostic evidence available for subacute LBP is the little information obtained from the clinical trials of Indahl et al (Indahl et al, 1995; Indahl et al, 1998) and Lindstrom et al. (Lindstrom et al, 1992)

Experimental hypotheses

The effect of exercise and advice > exercise alone > advice alone > control; where effect is measured in terms of global perceived effect, disability, pain and health care contacts.

A model that considers historical, clinical, social and psychological variables can be developed to accurately predict (<25% misclassification) the subjects who will respond to each treatment.

Research Plan

Methods and techniques to be used

The study design will be a single-blind randomised controlled trial using a 2x2 factorial design (Table 1). The two factors are exercise and advice with two levels for each factor, ie an active and an inactive intervention.

Table 1. Treatment cells showing the combination of active and sham advice and active and sham exercise.

A. Controls Advice sham Exercise sham	B. Exercise only Advice sham Exercise intervention
C. Advice only Advice intervention Exercise sham	C. Advice and Exercise Advice intervention Exercise intervention

Subjects will be randomised into a treatment group by computer generated random numbers with groups being balanced in blocks randomly varied in size (12, 16 or 20) to obtain roughly equal numbers. Randomisation will be centrally controlled to achieve concealed allocation with treatment codes placed in consecutively numbered sealed opaque envelopes.

Recruitment

Two hundred and fifty-nine adult subjects aged between 18 and 80 years with subacute LBP (between 6 weeks and 3 months duration) with or without pain referral to the leg will be recruited for the study. Subjects will be recruited from the pool of subjects referred for physiotherapy treatment of subacute LBP by a medical practitioner. Each patient with subacute LBP should be asked by the secretary of the physiotherapy department if they wish to take part in the study at the time they contact the department to make an appointment for treatment (A1.1). The secretary will ask the patient's age, the duration of the current back pain episode and if they had any spinal surgery in the past 12 months. In case of previous spinal surgery the new back pain episode must be clearly separate from the previous one. Previous patients at the clinic who have been treated for acute LBP but have not recovered and now have subacute LBP are also eligible, as are patients on the waiting list with subacute LBP. If the patient is eligible, he or she will be given Liset's mobile number. Please emphasise that if they take part in the trial they will NOT be placed on a waiting list but will instead be immediately enrolled into the trial.

A record will be kept of the number of invitations to participate, the number who volunteer to participate and the number of screened patients who are ineligible and the reason for their ineligibility (A1.2).

Screening

- *Exclusion criteria*

Subjects will be excluded if they are aged less than 18 or more than 80 years, have undergone spinal surgery in the past 12 months, report less than 2 on a 10-point pain scale (0=no pain, 10=worst pain possible), LBP is not restricting them in their daily activities, are pregnant, specific spinal pathology has been identified by the referring medical practitioner (nerve root involvement, inflammatory disorders, or malignancy), specific spinal pathology is suspected based upon the screening questionnaire, subjects have contraindications to exercise testing revealed by Physical Activity Readiness Questionnaire (PARQ), are unable to speak English and would need a translator.

For each subject the following need to be completed:

1. Inclusion/exclusion criteria sheet (A1.5)
2. Red flags screening questionnaire (see below and A1.6)
3. Physical activity readiness questionnaire (PARQ) (see below and A1.7)

- *Red flags screening questionnaire*

The action to be taken for a “yes” response to each question is listed below:

1. Is your general health good?
Clarify the nature of the health problem. Diseases of the cardiovascular and respiratory systems require clearance from a physiotherapist or medical practitioner.
2. Do you have any current disease process such as arthritis or cancer?
Clarify the nature of the disease. All inflammatory bone and joint diseases are exclusions. If the patient nominates that they have cancer seek clearance from referring medical practitioner.
3. Have you ever been treated for cancer?
Seek clearance from referring medical practitioner.
4. Have you lost more than 4 kgs (10 lbs) in the last 6 months?
If the weight loss is unplanned a medical practitioner or physiotherapist should screen for other features suggestive of cancer. If none others are found the patient remains eligible. If others are found please refer back to original medical practitioner.
5. Do you have any numbness or tingling in your buttock or genital region?
If yes arrange immediate screening by medical practitioner or physiotherapist for cauda equina syndrome.
6. Have you recently noticed any bladder or bowel problems ?
If yes clarify nature. Constipation, urge and stress incontinence that pre-date the LBP are OK. The only recent problem acceptable is constipation secondary to

analgesic use. All other recent problems require screening by medical practitioner or physiotherapist for cauda equina syndrome.

7. Do you have pain, swelling or redness in other joints?

A medical practitioner or physiotherapist should screen for active bone or joint disease.

8. Do you have any skin rashes?

Clarify if new or old. Skin rashes that predate LBP and are diagnosed and not relevant are OK. All new or undiagnosed rashes require a medical practitioner or physiotherapist to screen for other signs of active inflammatory joint disease.

9. Do you have eye discomfort, watery eyes, eye pain with light?

If yes a medical practitioner or physiotherapist should screen for other features suggestive of inflammatory arthritis.

10. Do you have weakness in your legs?

Perform a lumbar spinal nerve root neurological examination and also test Babinski and clonus. If the neurological examination is positive for upper neurone disturbance eg hyperflexia or clonus, the patient is not eligible.

11. Do you have balance problems?

Perform a lumbar spinal nerve root neurological examination and also test Babinski and clonus. If the neurological examination is positive for upper neurone disturbance eg hyperflexia or clonus, the patient is not eligible.

12. Have you had a recent fever (not including flu or cold)?

A medical practitioner or physiotherapist should screen for other features of inflammatory disease.

13. Have you had a recent infection?

A medical practitioner or physiotherapist should screen for other features of inflammatory disease.

14. Do you get pain in your legs that is caused by walking and relieved by resting?

A medical practitioner or physiotherapist should screen for cord compromise.

15. Is your back stiff in the morning for longer than half an hour?

If yes a medical practitioner or physiotherapist should screen for other features suggestive of inflammatory arthritis.

16. Are you currently taking any medication?

Clarify purpose of medication. If the drug is used to manage a disease of the cardiovascular or respiratory systems a clearance from the referring medical practitioner is required. Simple analgesics and NSAIDs are OK.

Physical activity readiness questionnaire (PARQ)

If a subject responds "yes" to questions 1, 2, 3, 4, 6 & 7 in the PARQ the staff member should ring the patient's referring medical practitioner and get clearance for exercise.

If the response to question 5 is positive the subject should be questioned as to the nature of the problem. If the potential subject reports that they have osteoarthritis, spondylitis, spondylolysis or spondylolisthesis, a slipped disc, disc protrusion/herniation/prolapse, spinal canal stenosis they remain eligible. If they report active inflammatory bone or joint disease eg active rheumatoid arthritis, ankylosing spondylitis, discitis, they are excluded. If the screener is not a physiotherapist or medical practitioner they need to seek advice on whether the nominated bone or joint disease is an inflammatory disease.

The screening can occur by phone. If a patient agrees to take part, he or she should contact Liset Pengel immediately on mobile phone no: 0407 954 248. Liset should explain the study to the patient and screen the patient for eligibility over the phone. If the subject passes all eligibility criteria please make an appointment for the baseline assessment and the first treatment, preferably both occurring at the first visit. The appointment with the trial coordinator should be scheduled for 1 hour and the first treatment appointment also for 1 hour.

If a subject is deemed ineligible please staple all 3 sheets together and write clearly on the front page the reason for exclusion. **It is essential that we keep a record of how many subjects were excluded.**

Assessment and allocation

Outcome measures

At the first appointment with trial coordinator please get patient to read a subject information sheet and sign an informed consent form. After consent is obtained the baseline measurements need to be taken. As the subject has not yet been allocated to a treatment group any trained trial member can do these measurements. Please follow the protocol for each measure (A1.8-1.21). Please complete the cover sheet to check that you have completed all measures.

Follow-up assessments will be coordinated by the trial coordinator. Follow-up outcomes need to be taken by a blinded assessor. While the assessor need not be the assessor who took the baseline assessments it is essential that they have NOT delivered treatment to the participant.

Concealed allocation

Eligible subjects will be randomised to the four study groups with allocation concealed from the referring medical practitioner and the trial staff member who determines eligibility. Liset Pengel will be responsible for concealed allocation. If Liset has performed the baseline assessments she will initiate the allocation herself. Liset will draw the next sealed sequentially numbered opaque envelope and write the patient's name across the seal. Liset will then record the patient's name and trial number on the trial allocation sheet. Liset will NOT be aware of the contents of the envelope or have access to the allocation schedule that lists the group allocation by trial subject number. Liset should then introduce the subject to the physiotherapist and hand deliver the allocation envelope to the physiotherapist. The envelope should be opened by slitting along the top so that the name across the seal remains legible.

If the baseline assessments have been done by someone else they should phone Liset to ask her to initiate group allocation. Liset will then phone the treating physiotherapist to provide the treatment group and immediately fax a copy of the allocation instructions.

If the allocation envelope is lost or Liset is unlocatable, the chief investigator not blinded to group allocation, A/Prof Kathryn Refshauge, should be contacted and she will allocate subject via the allocation schedule.

The opened envelopes and allocation sheets containing subjects, names, trial number and treatment group should be returned to A/Prof Kathryn Refshauge each fortnight.

A letter should be send to the referring medical practitioner that their patient has enrolled in the study. The medical practitioner will be requested not to seek treatment information (A1.3).

Staff roles at each site*Bankstown Hospital, Bankstown*

Duty	Staff
Recruitment	Liset Pengel/Clinic secretary
Routine screening	Liset Pengel
Physio/medical screening if initial screening reveals potential problem	Chris Maher/Kathryn Refshauge
Baseline assessment	Liset Pengel
Allocation	Liset Pengel/Kathy Refshauge
Treatment	Jennie Hewill/Toni Ralph/ Carol Campanella/Jutta Jablonski
Arranging follow-up assessments	Liset Pengel
Follow-up assessment	Liset Pengel/Chris Maher

Concord General Repatriation Hospital, Concord

Duty	Staff
Recruitment	Liset Pengel/Clinic secretary
Routine screening	Liset Pengel
Physio/medical screening if initial screening reveals potential problem	Chris Maher/Kathryn Refshauge
Baseline assessment	Liset Pengel
Allocation	Liset Pengel/Kathy Refshauge
Treatment	Stephanie Lanzarone/Paul van den Dolder
Arranging follow-up assessments	Liset Pengel
Follow-up assessment	Liset Pengel/Chris Maher

Royal North Shore, St Leonards

Duty	Staff
Recruitment	Liset Pengel/Clinic secretary
Routine screening	Liset Pengel/Matt Squires
Physio/medical screening if initial screening reveals potential problem	
Baseline assessment	Stephanie Lanzarone/Matt Squires
Allocation	Liset Pengel
Treatment	Stephanie Lanzarone/Bruce Anderson/ Matt Squires
Arranging follow-up assessments	Liset Pengel
Follow-up assessment	Liset Pengel

Royal Prince Alfred, Camperdown

Duty	Staff
Recruitment	Liset Pengel/Clinic secretary
Routine screening	Sharon Parry/Liset Pengel
Physio/medical screening if initial screening reveals potential problem	Sharon Parry/Sonia Haggman/Emily Goodison/Liz Harvey
Baseline assessment	Sharon Parry/Sonia Haggman/Emily Goodison/Liz Harvey
Allocation	Sharon Parry/Sonia Haggman/Emily Goodison/Liz Harvey
Treatment	Sharon Parry/Sonia Haggman/Emily Goodison/Liz Harvey
Arranging follow-up assessments	Liset Pengel
Follow-up assessment	Liset Pengel

St George, Kogarah

Duty	Staff
Recruitment	Liset Pengel
Routine screening	Liset Pengel
Physio/medical screening if initial screening reveals potential problem	Sue Sellars
Baseline assessment	Sue Sellars
Allocation	Sue Sellars
Treatment	Sue Sellars
Arranging follow-up assessments	Liset Pengel
Follow-up assessment	Liset Pengel

Middlemore Hospital, Auckland, New Zealand

Duty	Staff
Recruitment	Clinic secretary
Routine screening	Jill Collier
Physio/medical screening if initial screening reveals potential problem	Siobahn Reid
Baseline assessment	Siobahn Reid
Allocation	Peter McNair
Treatment	Siobahn Reid
Arranging follow-up assessments	Jill Collier
Follow-up assessment	Jill Collier

Newcastle, New Lambton Physiotherapy Centre (Private Practice)

Duty	Staff
Recruitment	Lucy Thomas/Liset Pengel
Routine screening	Lucy Thomas
Physio/medical screening if initial screening reveals potential problem	Lucy Thomas
Baseline assessment	Lucy Thomas
Allocation	Lucy Thomas
Treatment	Lucy Thomas
Arranging follow-up assessments	Lucy Thomas
Follow-up assessment	assessor

Interventions

All subjects will be informed that they can contact their physiotherapist at any time, and the number and length of phone contacts will be recorded. If subjects are concerned about their condition during the study, the physiotherapist will screen for potentially serious pathology and when appropriate refer subjects back to their medical practitioner who will be requested not to seek treatment information. If specific pathology is identified in the subsequent medical work-up, subjects will be withdrawn from the trial, otherwise subjects will return to the study. Subjects will also be encouraged not to seek care from other health care providers. Subjects who drop out of the study will be encouraged to return for outcome measurements.

Treatment validity

Treatment manuals will be developed and the physiotherapist trained to ensure consistent administration of each treatment. To assess treatment validity, sample treatment sessions will be tape recorded and assessed by one of the chief investigators. In addition, one of the investigators will regularly visit each treatment site to personally monitor delivery of treatment. Where deviation from the trial protocol are noted, supplementary training sessions will be undertaken.

Subjects' perception of treatment credibility will be determined at the beginning (A1.22) and end (A1.23) of the trial with a questionnaire. Treatment compliance will be established by noting the number of appointments kept for each participant (A1.24). The physiotherapist will complete normal patient records for each subject, specifically recording any adverse effects of treatment.

Intervention groups

The four interventions are:

1. Advice

Advice will be given on 3 occasions (baseline, 2/52, 4/52). Each session will last 0.5 hour.

Advice sessions were based on the advice given by Indahl et al. (Indahl et al, 1995) The treating physiotherapist will explain the benign nature of LBP, emphasise that being overly careful and avoiding light activity will delay recovery and address any unhelpful beliefs about the back pain. Subjects will be encouraged to set their own goals for activity resumption. On follow-up visits, the advice will be reinforced, compliance with the advice and achievement of goals established at the initial visit will also be ascertained.

Contents of the advice:

- Explanation of nature of LBP, clarify misconceptions
- Encourage activity explaining that it will enhance recovery
- Encourage subject to set own goals for exercise

- Advise subject against being over careful or afraid of the pain
- Advise subject that if they experience acute stabbing pain in the back they should treat it as a "cramp" with stretching and light activity
- Remove fear of pain and discourage sickness behaviour
- Discourage static work of back muscles, encourage flexibility
- Provision of lifting advice
 - (i) Avoid bending and twisting when lifting
 - (ii) Use legs when lifting heavy objects
 - (iii) Avoid excess carrying
 - (iv) Hold load close to the body
 - (v) For the rest of the time use the back and flex it
 - (vi) There is no reason to be afraid of using the back, do not be overcautious and try to be flexible as possible

Practical implementation of the principles and guidelines will be demonstrated by the physiotherapist.

Please see *Treatment Manual* for suggested wording of advice.

2. Supervised exercise program

Subjects will attend the physiotherapy department for 12 sessions over 6 weeks: 3 days per week in weeks 1 and 2, 2 days per week in weeks 3 and 4 and 1 day per week in weeks 5 and 6.

The exercise program was based upon the program described by Lindstrom et al (Lindstrom et al, 1992). The program is an individualised, submaximal, progressively increased exercise program designed to train those functions found to be inadequate for performance of work or home activities. When implementing the exercise program, the physiotherapists will use some of the principles of cognitive-behavioural therapy in their training and supervision role. That is, the physiotherapist will encourage skill acquisition by modelling the exercises, provide information, set progressively raised goals, encourage self-monitoring of progress, and verbally reinforce progress made by subjects towards their goals. Self-reliance by subjects will be fostered by encouraging them to engage in problem-solving to deal with difficulties rather than being reassured and given advice; by encouraging them to set activity goals at home which are relevant to them and by encouraging subjects to reinforce themselves for progress towards these goals. Fear of increased pain or even possible (re)injury will be addressed by discussion of the realistic chances of exercises causing injury, by ensuring that subjects set initial goals well within their capabilities (to maximise the chances of early success experiences), and by encouraging subjects to maintain a graded increase in exercises and other activities with regular rest breaks and frequent reflection on achievements.

A more complete description of the program is found in the *Treatment Manual*.

3. Sham Exercise

Subjects will attend the physiotherapy department for 12 sessions over 6 weeks: 3 days per week in weeks 1 and 2, 2 days per week in weeks 3 and 4 and 1 day per week in weeks 5 and 6.

The control for the exercise treatment will consist of 20 mins of detuned SWD and 5 mins of detuned ultrasound. This exercise control has been used by others because there is no known treatment effect from the detuned machines, but subjects viewed this as a credible treatment.

See *Treatment Manual* for precise details.

4. Sham Advice

Sham advice will be given on 3 occasions (baseline, 2/52, 4/52). Each session will last 0.5 hour.

To control for the therapist's interest and time with subjects during the advice sessions, placebo advice sessions will be given. During these sessions the therapist will encourage subjects to talk about the problems their LBP is causing, giving them the opportunity to discuss their LBP. However, no advice about the LBP will be given. In previous studies, this control was viewed as a credible treatment by subjects.

See *Treatment Manual* for precise details.

Data analysis

Measures of outcome and predictors of response to treatment will be taken by an assessor blinded to group assignment at baseline, 6 weeks, 3 months and 12 months. Occurrence of side-effects, co-interventions and success of blinding will be evaluated at each measurement occasion. The assessors will be debriefed at completion of the project.

Power analysis

A sample size of 208 subjects provided 80% power, assuming an alpha of 0.05 and beta of 0.2, to detect a difference of 1 point on the 7-point Global Perceived Effect Scale, 1 point on the 0-10 Patient Specific Functional Scale and 1 point on the 0-10 Pain scale. To allow for drop-outs and non-compliance we recruited 260 subjects. The projected sample size is based on descriptive data from previous papers that have described subjects with low back presenting for physiotherapy treatment.

Data entry

To ensure accurate data entry, each data point will be double entered i.e. by one research assistant and by the chief investigator who will remain blinded to group allocation throughout the study (A/Prof Chris Maher). We will also use filters to detect nonsensical entries, eg VAS scale values < 0 and > 100 . The allocation code will not be broken until all decisions about data analysis have been made.

Treatment efficacy

Primary outcomes for treatment efficacy include the Global Perceived Effect Scale, Patient Specific Functional Scale and Pain Scale at 6 weeks and 1 year.

Secondary outcome for treatment efficacy include Global Perceived Effect Scale, Patient Specific Functional Scale, and Pain Scale at 3 months, Roland Morris Disability Questionnaire and Depression Anxiety and Stress Scale (DASS) at 6 weeks, 3 and 12 months, length of absence from work when relevant and number of health care contacts for LBP in the last month at 6 weeks, 3 and 12 months.

The chief investigator who will analyse the data will be blinded to treatment allocation and the statistical analysis will be carried out using “intention-to-treat” analysis. Effects of exercise, advice, including a possible interaction effects were analysed using linear regression. Baseline scores of the primary and secondary outcomes were used as covariates. Analyses were performed using SPSS versions 10.0.. The effect of drop-outs on study results will be determined using a sensitivity analysis.

Prediction of outcome and response to treatment

The following three questions will be answered:

- A. How many subjects were recovered at 6 weeks and 12 months?
- B. Which predictors influence outcome at 6 weeks and 12 months?
- C. Which predictors influence the response to treatment at 6 weeks and 12 months?

A. Subjects are considered to be recovered if the following 3 criteria are all met:

- 1. Global perceived effect (GPE): 4 or 5 on GPE scale
- 2. Pain: 0 or 1 on 0-10 VAS
- 3. Disability: 9 or 10 on the 0-10 Patient Specific Functional Scale

B. Predictors of outcome

- 1. Age (yrs)
- 2. Gender (M/F)
- 3. Previous episodes of LBP (yes/no)
- 4. Past hospitalization for LBP (yes/no)
- 5. Initial pain (0-10 VAS)
- 6. Initial disability (0-10 Patient Specific Functional Scale)
- 7. Pain referred to the leg (yes/no)
- 8. Other areas of pain (other than back or leg) (yes/no)
- 9. Self-reported physical activity (yes/no)
- 10. Fear of movement (TAMPA score)
- 11. Psychological distress: depression (DASS)
- 12. Psychological distress: anxiety (DASS)
- 13. Psychological distress: stress (DASS)
- 14. Pain cognitions: catastrophizing (PRSS)
- 15. Pain cognitions: coping (PRSS)

C. Predictors of response to treatment

- 1. Initial pain (0-10 VAS)
- 2. Initial disability (0-10 PSFS)
- 3. Self reported physical activity (yes/no)
- 4. Pain referred to the leg (yes/no)
- 5. Pain self-efficacy

Instructions for treatment providers

Access to trial data

Treating physiotherapists will receive the following baseline questionnaires:

- PARQ/Screening questionnaire
- Tampa
- Roland Morris Disability Questionnaire
- Patient Specific Functional Scale

These measures are provided because it is recognised that most physiotherapists would collect this information prior to treatment and this will save asking the patient the same questions again.

Physiotherapists must collect all other information they need to administer the allocated treatment.

Medical records

Routine medical records must be kept for all patients in the trial. These will be stored in a locked filing cabinet solely devoted to trial records in each department. The treatment notes and the trial assessment sheets must be two separate files and must not be stored together or you will unblind the assessor. At the first visit on a separate piece of paper please write the following and arrange for it to be placed on their main record record file:

Mr Smith has volunteered to participate in the clinical trial Exercise or Advice for Subacute Low Back Pain? Ref: 00/071. To ensure blinding Mr Smith's physiotherapy treatment records will be kept in the locked trial filing cabinet until he has completed all treatments and follow-ups. After the twelve-month follow-up a copy of the treatment records will be placed on his medical record. If you have any queries please contact the chief investigator Dr Kathryn Refshauge ph 93519180.

NB please insert the relevant title and ethical approval number for each site:

- Concord Hospital (CSAHS). Ref no: CH62/6/20000-032 – “Exercise or Advice for Subacute Low Back Pain?”
- Prince of Wales Hospital (SESAHS). Ref no: 00/071 - “Exercise or Advice for Subacute Low Back Pain?”
- Royal Prince Alfred Hospital (CSAHS). Ref no: X00 – 0109 – “Exercise and Advice for Subacute Low Back Pain?”
- Bankstown Hospital (SWSAHS). Ref no: 00/046 - “Exercise or Advice for Subacute Low Back Pain?”
- Royal North Shore Hospital (NSH). Ref no: 0103-030M – “Exercise or advice for subacute low back pain?”
- St George Hospital (SESAHS). Ref no: 02/73 Refshauge – “Exercise or advice for subacute low back pain?”

The medical records should be as comprehensive as normal records. You need to record the results of any history and physical examination, a clear description of treatment provided, any missed appointments, any reported side-effects of treatment, how long each treatment took and the amount of therapist/patient contact. For example for US/SWD you could write "30 minutes treatment, 15 minutes of 1:1 contact". In the notes the sham advice session should be described as a "ventilation/support session" and you should note what topics arose. The sham exercise should be described as detuned pulsed ultrasound and detuned pulsed shortwave.

At the end of the first treatment session you need to administer the treatment credibility questionnaire and attach this to the records. On completion of all treatment one of the investigators will make a copy of the treatment record which will be stored at the trial office at CCHS. When the final outcome measures have been taken one of the investigators will arrange for the original copy of the records to be attached to the main medical file.

Discharge letter

On completion of treatment you need to write a discharge letter for the referring medical practitioner. In this letter you must not describe the actual treatment administered; just say something like 'the patient has now completed 12 sessions of physiotherapy treatment'. The discharge letter should in all other respects be similar to a normal discharge letter and include information on initial presentation and the response to treatment.

Delivery of treatment

It is important that each treatment is delivered with equal enthusiasm. Patients have consented to a trial that includes sham treatments so there is no ethical problem with delivering a sham treatment. For the shams to remain credible the therapist has to convincingly mislead the patient that the sham is actually a real treatment.

When you open the envelope with the treatment allocation always say something positive prior to describing the treatments they will get. Eg "oh good", "great", "OK this should really help". Say this no matter what treatments they will get. The four combinations of treatment should be described as

1. The treatments will be a supervised exercise program and advice on how to manage your LBP
2. The treatments will be a supervised exercise program and support sessions to help you manage your LBP
3. The treatments will be electrotherapy treatment: pulsed ultrasound and pulsed shortwave diathermy plus advice on how to manage your LBP
4. The treatments will be electrotherapy treatment: pulsed ultrasound and pulsed shortwave diathermy plus support sessions to help you manage your LBP

If the patient directly asks you if they have been allocated to the sham treatment say "no I have used these treatments on a lot of my patients and I find they really help". Do not tell them about the design or that there are two active and two sham treatments otherwise they will be easily unblinded. Do not tell them we are comparing advice to exercise or again they will be unblinded. Tell them that we are testing a range of physiotherapy treatments. If they push you for a number either say '8' or avoid answering the question.

Please follow the treatment manuals exactly. If you have any concerns about the treatment please contact one of the chief investigators.

How to deal with problems that may arise

1. Your patient fails to attend a treatment session or rings to cancel a treatment session

If your patient fails to attend you will need to contact them within 24 hours to arrange another appointment. If this is not the usual practice at your hospital then let the patient know you are contacting them because they are in the trial and it is important that they complete the treatment. Record the non-attendance in the medical records with DNA if they failed to attend or UTA if they contacted you first. If they fail to attend their last appointment please contact them and arrange a final appointment ASAP. Record the dates of the appointments on their record sheet.

2. Your patient presents for a follow-up visit and complains that their condition is getting worse or not improving.

If your patient complains of worsening pain or that they are not improving please re-screen them for serious pathology and if there is no indication of this reassure them as you would a normal patient. Then strongly encourage the patient to continue with the treatment. If they are insistent that they are worsening and would like alternative treatment ask them if they could speak with one of the investigators or co-investigators. Please contact the associate investigator on your site to talk to the patient. It is the patients right to cease participation at any time or to seek additional pain relief. In either case encourage the patient to return for follow-up measures.

3. Your patient tells you that they are seeking concurrent treatment (physio, medication etc).

Please record the details and encourage the patient not to drop out of the trial.

4. Your patient informs you once they have commenced the trial that they are going on holidays for a short period.

Tell them to have a lovely holiday! It is essential that they can be followed-up even if they miss treatments. This is called 'intention to treat'. Discuss this with the patient and organise their follow-up in advance with the on-site assessor. Record the details of missed treatment sessions.

5. Your patient informs you once they have commenced the trial that they are going overseas indefinitely.

Ask them to provide a forwarding address so we can assess outcome with the questionnaires.

6. **Your patient dies or becomes severely mentally or physically incapacitated preventing them from either continuing treatment or assessment.**
Record the details.
7. **During the course of the treatment you and your patient develop an intense dislike for each other which you feel is compromising their care.**
Speak to your on-site investigator or if necessary to the chief investigator. See if it is possible for your patient to continue care with another therapist on site.

Instructions for outcome assessments

All outcomes need to be assessed blind. At each occasion please ensure that you complete the assessment summary sheet to ensure that outcomes are not missed.

Blinded data analysis

Chris Maher will remain blinded to treatment allocation throughout the trial so that he can manage the blinded data analysis. The consequence of this is that Chris is unable to perform any treatments.

A1.1 Instructions for receptionists at clinics

Clarify that the patient has LBP, is aged 18-80, the current episode is greater than 6 weeks and less than 3 months. For subjects who have had previous spinal surgery the new back pain episode must be clearly separate from the previous one.

If Yes offer the following information:

The University of Sydney is currently conducting a large international study that is trying to find out the best way to manage low back pain. Our department is one of the sites where treatment is taking place. If you volunteer for the study you will receive expert care and follow-up from the trial staff who are all experts in their field. Currently our department has a waiting list of ?weeks but if you volunteer for the study you will bypass the waiting list and receive immediate care from the trial staff. Are you interested in taking part?

If the person says No please respond:

That is fine, I have been asked to record the reasons why people decline to take part. What should I record?

A1.3 Letter for referring medical practitioner

School of Physiotherapy
Faculty of Health Sciences
Cumberland Campus C42

Subacute Low Back Pain Trial

PO Box 170
Lidcombe NSW 1825
Telephone: (02) 9351 9562
or 0407 954 248
Facsimile: (02) 9351 9601
Email: hpen@mail.usyd.edu.au

[Date]

Dear Dr [name]

Re: [patient name]

We would like to inform you that your patient [patient name] has enrolled in our subacute low back pain (ie, low back pain of between 6 weeks and 3 months duration) trial. The trial is funded by the National Health & Medical Research Council and we are looking to recruit 300 subjects. We are evaluating a range of physiotherapy treatments including exercise, advice and electrotherapy. Subjects are randomised to one of the treatment groups and they receive 6 weeks of free treatment by one of our own expert physiotherapists. Treatment is provided at [hospital name] where they bypass the waiting list.

To ensure blinding we are unable to specify the exact physiotherapy treatment your patient will be receiving. We will provide a discharge summary at the end of the 6 weeks treatment phase to keep you informed of their progress. We plan to monitor the patient for the next 12 months and if you wish we are happy to provide a written update on their status based upon our assessment. If you require this long term follow-up please contact the trial office c/o Liset Pengel.

If you have any concerns regarding [his/her] participation in the study or you would like any further information, please do not hesitate to contact me on 9351 9562 or 0407 954 248. If you would like to talk to the chief investigators on any matter I would be happy to arrange this.

Kind regards,

[name therapist/trial coordinator]

A1.4 Overview of intervention and follow up visits

	Weeks														
	0	1				2				3	4	5	6	12	52
Study visit		1											2	3	4
Exercise visit		1	2	3	4	5	6	7	8	9	10	11	12		
Advice visit		1			2				3						
Inclusion/exclusion criteria sheet	X														
Screening questionnaire	X														
Physical activity readiness Questionnaire	X														
Informed Consent		X													
ACC Low Back Pain Questionnaire		X													
Pain and Global Perceived Effect Questionnaire		X											X	X	X
TAMPA		X													
Pain Related Self Statement Questionnaire		X													
Patient Specific Functional Scale		X											X	X	X
Roland Morris Disability Questionnaire -- 24 item		X											X	X	X
Pain Self-Efficacy scale		X													
DASS		X											X	X	X
Treatment credibility scale		X													
Treatment allocation													X	X	X
Treatment evaluation scale															X

A1.5 Inclusion/exclusion criteria summary sheet

Please screen patients by phone if possible or if you are at the clinic at the same time as the patient it may be done in person.

Inclusion Criteria

All patients with subacute non-specific low back pain (ie between 6 weeks and 3 months duration) referred to physiotherapy department by medical practitioner.

Exclusion criteria

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | duration of LBP<6/52 |
| <input type="checkbox"/> | <input type="checkbox"/> | duration of LBP>3/12 |
| <input type="checkbox"/> | <input type="checkbox"/> | Aged less than 18 |
| <input type="checkbox"/> | <input type="checkbox"/> | Aged greater than 80 |
| <input type="checkbox"/> | <input type="checkbox"/> | NESB and requires translator |
| <input type="checkbox"/> | <input type="checkbox"/> | Spinal surgery for current episode of LBP. |
| <input type="checkbox"/> | <input type="checkbox"/> | Diagnosis of specific spinal pathology by referring medical practitioner |
| <input type="checkbox"/> | <input type="checkbox"/> | Suspicion of specific spinal pathology from screening questionnaire |
| <input type="checkbox"/> | <input type="checkbox"/> | Contraindication to exercise detected by PARQ (see below) |
| <input type="checkbox"/> | <input type="checkbox"/> | Upper motor neurone signs (any of clonus, babinski, hyper-reflexia) |

Average pain past week (at least 2/10 to be eligible):

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain possible

- Pain is restricting daily activities
- Red flags screening questionnaire negative
- PARQ negative

Comments:

If subject is declared ineligible please state reason below:

A1.6 Red flags screening questionnaire

1. Is your general health good? Yes No
If no, what problems do you have?: _____
2. Do you have any current disease process such as arthritis or cancer? Yes No
If yes, please specify (eg, where): _____
3. Have you ever been treated for cancer? Yes No
If yes, please specify: _____
4. Have you lost more than 4 kgs (10 lbs) in the last 6 months? Yes No
If yes, please specify: _____
5. Do you have any numbness or tingling in your buttock or genital region? Yes No
If yes, please specify: _____
6. Have you recently noticed any bladder or bowel problems? Yes No
If yes, please specify: _____
7. Do you have pain, swelling or redness in other joints? Yes No
If yes, please specify: _____
8. Do you have any skin rashes? Yes No
If yes, please specify: _____
9. Do you have eye discomfort, watery eyes, eye pain with light? Yes No
If yes, please specify: _____
10. Do you have weakness in your legs? Yes No
If yes, please specify: _____
11. Do you have balance problems? Yes No
If yes, please specify: _____
12. Have you had a recent fever (not including flu or cold)? Yes No
If yes, please specify: _____
13. Have you had a recent infection? Yes No
If yes, please specify: _____
14. Do you get pain in your legs that is caused by walking and relieved by resting? Yes No
If yes, please specify: _____
15. Is your back stiff in the morning for longer than half an hour? Yes No
If yes, please specify: _____
16. Are you currently taking any medication? Yes No
If yes, please specify: _____

A1.7 Physical activity readiness questionnaire (PARQ)

Yes No

Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

Do you feel pain in your chest when you do physical activity?

In the past month, have you had chest pain when you were not doing physical activity?

Do you lose your balance because of dizziness or do you ever lose consciousness?

Do you have a bone or joint problem that could be made worse by a change in physical activity?

Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

Do you know of any other reason why you should not do physical activity?

A1.8 Baseline assessment sheet

Questionnaires

1. ACC LBP questionnaire
2. Pain and global perceived effect scales
3. Tampa
4. Pain related self-statement instrument
5. Patient specific functional status
6. Roland Morris Disability Questionnaire
7. Pain self-efficacy scale
8. DASS
9. Treatment credibility scale (completed at end of first treatment session)

Physical examination

Measure	Score
Backward bending range (deg)	
Forward bending range (cm)	start: end:
Left side-bending rang (cm)	start: end:
Right side-bending range (cm)	start: end:
Left straight leg raise range (deg)	
Right straight leg raise range (deg)	
Neurological examination (if indicated)	

Interview

1. Prior to this episode of LBP were you working? Yes No
Specify: 1. 2. 3. 4. 5. 6. 7. 8.
 FT/FD FT/SD PT/FD PT/SD NW/E NW/E/R NW/U/R NW/U
(FT=full time; FD=full duties; SD= suitable duties; PT=part time; NW=not working;
E=employed; R=retraining; U=unemployed)
2. Are you currently working? Yes No
Specify: 1. 2. 3. 4. 5. 6. 7. 8.
 FT/FD FT/SD PT/FD PT/SD NW/E NW/E/R NW/U/R NW/U
3. Do you currently smoke? Yes No
If yes how much _____
4. Are you currently taking pain killers for your LBP? Yes No
5. Do you use alcohol to relieve your LBP? Yes No
6. Have you taken pain killers for your LBP in the past 6 weeks? Yes No
7. Was the onset of LBP sudden? Yes No
8. How many appointments with a health care provider have you had in the past 6 weeks for your back? _____
9. Please describe other treatment you have received for your back pain.

10. No of previous episodes of LBP - _____
11. Previous sick leave due to LBP Yes No

Baseline assessment sheet (cont)

12. Since this episode of low back pain began, how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain (sciatica)? _____ number of days
13. Since this episode of low back pain began, how many days did low back pain or leg pain (sciatica) keep you from going to work? _____ number of days
14. Previous LBP surgery Yes No
15. Do you currently undertake moderate exercise for greater than 30 minutes at least three times per week? Yes No

	Light exercise	Moderate exercise	Hard/vigorous exercise
sports	walking slowly	walking briskly	running
	cycling stationary	cycling for pleasure	cycling fast /racing
work	office work	digging	wood chopping
household activities	wash dishes, vacuuming, dusting	scrubbing floor on hands & knees	carrying boxes or furniture

16. Prior to this episode of LBP did you undertake moderate exercise for greater than 30 minutes at least three times per week? Yes No
17. Marital status _____
18. In general, would you say that your health is:
Excellent very good good fair poor
19. How TRUE or FALSE is each of the following statements for you?
(Circle one number on each line)

	definitely false	mostly true	don't know	mostly false	definitely false
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

20. To help us locate you should you move house please provide a contact address and phone number of a close friend/relative who would know where you have moved to.

Name of friend/relative: _____

Relationship: _____

Contact details for friend

Phone: _____

Fax: _____

Email: _____

Address: _____

A1.9 Follow up assessment sheet
(6 weeks, 3 months, 12 months)

Questionnaires

1. Pain and global perceived effect questionnaire
2. Patient specific functional status
3. Roland Morris Disability Questionnaire
4. DASS
5. Treatment evaluation scale (12 months only)

Physical examination

Measure	Score
Backward bending range (deg)	
Forward bending range (cm)	start: end:
Left side-bending rang (cm)	start: end:
Right side-bending range (cm)	start: end:
Left straight leg raise range (deg)	
Right straight leg raise range (deg)	

Interview

1. Prior to this episode of LBP were you working? Yes No
Specify: 1. 2. 3. 4. 5. 6. 7. 8.
 FT/FD FT/SD PT/FD PT/SD NW/E NW/E/R NW/U/R NW/U
(FT=full time; FD=full duties; SD= suitable duties; PT=part time; NW=not working;
E=employed; R=retraining; U=unemployed)
2. Are you currently working? Yes No
Specify: 1. 2. 3. 4. 5. 6. 7. 8.
 FT/FD FT/SD PT/FD PT/SD NW/E NW/E/R NW/U/R NW/U
3. Are you currently taking pain killers for your LBP? Yes No
4. Have you taken pain killers for your LBP in the past 6 weeks? Yes No
5. How many appointments with a health care provider have you had in the past 6 weeks for your back? _____
6. Please describe other treatment you have received for your back pain _____
7. _____
8. Please describe any side effects from the trial treatment _____
9. Since the last assessment, how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain (sciatica)?
_____ number of days
10. Since the last assessment, how many days did low back pain or leg pain (sciatica) keep you from going to work? _____ number of days
11. To help us locate you should you move house please provide a contact details of a close friend/relative who would know where you have moved to.
Name of friend: _____
Relationship: _____
Phone/fax/email: _____
Address: _____

A1.10 Total lumbar and pelvic extension range of motion

Description

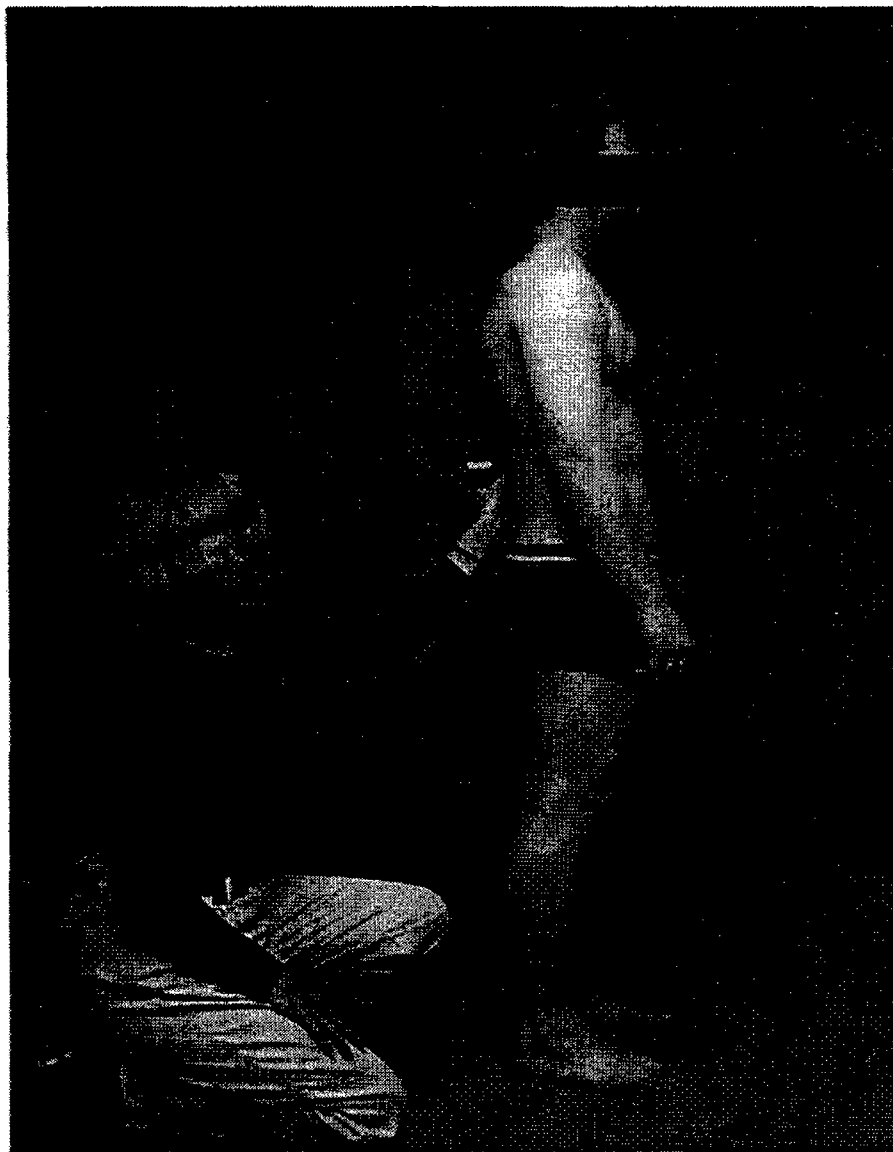
Measurement of total lumbar extension range of motion using a single inclinometer.

Instruments required

Analogue or digital inclinometer, felt tip pen to mark anatomical landmarks, pen and paper to record results.

Starting position of subject

Bare feet, feet hip width apart, knees straight with the weight borne evenly on the two legs, looking straight ahead, arms hanging at the sides relaxed. If there is severe muscle spasm the patient is asked to get as close to the starting position as possible. The subject's low back and upper buttocks should be exposed.



Starting position for measurement of lumbar spine extension using a single inclinometer. Foot, knee and arm position are standardised. The inclinometer is positioned at T12-S1 level.

Starting position of examiner

The examiner is positioned to the side of the patient.

Procedure

Horizontal marks are made on the skin in the midline at S2 and T12-L1. The S2 spinous process is assumed to lie midway between the inferior aspects of the posterior superior iliac spines. T12-L1 is identified by counting up the spinous processes, checking that the iliac crests approximate to the L4-5 level (Standard Waddell skin markings).

The inclinometer is first zeroed against a vertical surface and a recording made at T12-L1 with the subject in the erect standing position. The patient is asked to arch backwards as far as possible looking up to the ceiling while the examiner supports the patient with one hand on their shoulder to maintain their balance. The second recording is then made in the extended position and a measure of total extension is made by subtracting the initial score from the second.

Common errors to avoid

Misreading the inclinometer.

Variations of the test

Superior landmarks of T12/L1 interspace, L1 or a point 15cm above the line joining the PSIS have also been used. It is possible to measure isolated pelvic and lumbar extension range as it is for flexion, however these extension measures have poor reliability. A double inclinometer method has also been advocated for measuring lumbar extension, however, it provides unreliable measures of active extension range of motion in standing. In contrast if extension range is measured in prone, with the patient passively positioned into extension using a motorised bed, acceptable reliability is possible (ICC = 0.83).

Reliability

Waddell and colleagues have shown that the method described here provides highly reliable estimates of total lumbar extension range (ICC = 0.86) for normal and low back patients when using the Cybex EDI digital inclinometer.

A1.11 Forward bending range of motion

Description:

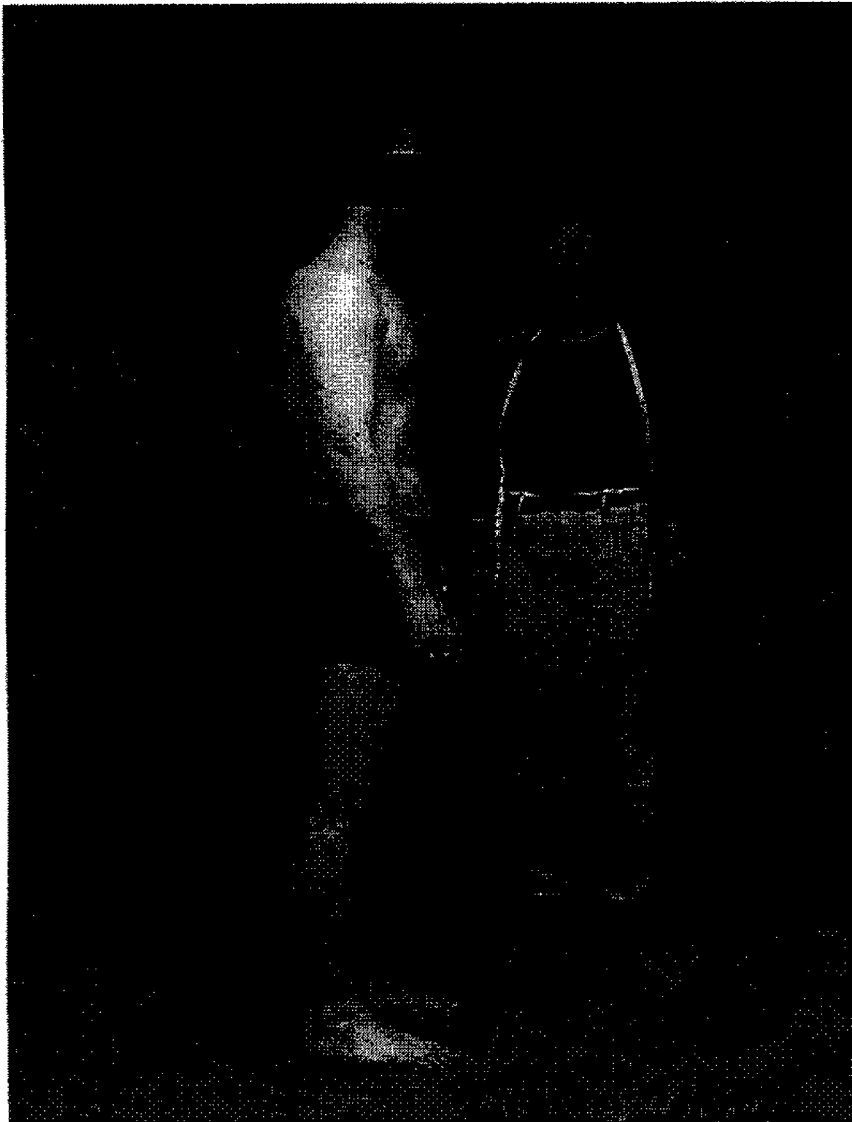
Measurement of the degree of forward bending (fingertip-to-floor method) using a tape measure.

Instruments required

Tape measure, stool for flexible subjects to stand on if they are not at end of range when fingertips touch the floor.

Starting position of subject

Bare feet, feet hip width apart, knees straight with the weight borne evenly on the two legs, looking straight ahead, arms hanging at the sides relaxed. If there is severe muscle spasm the patient is asked to get as close to the position as possible. The subject's low back and upper buttocks should be exposed.



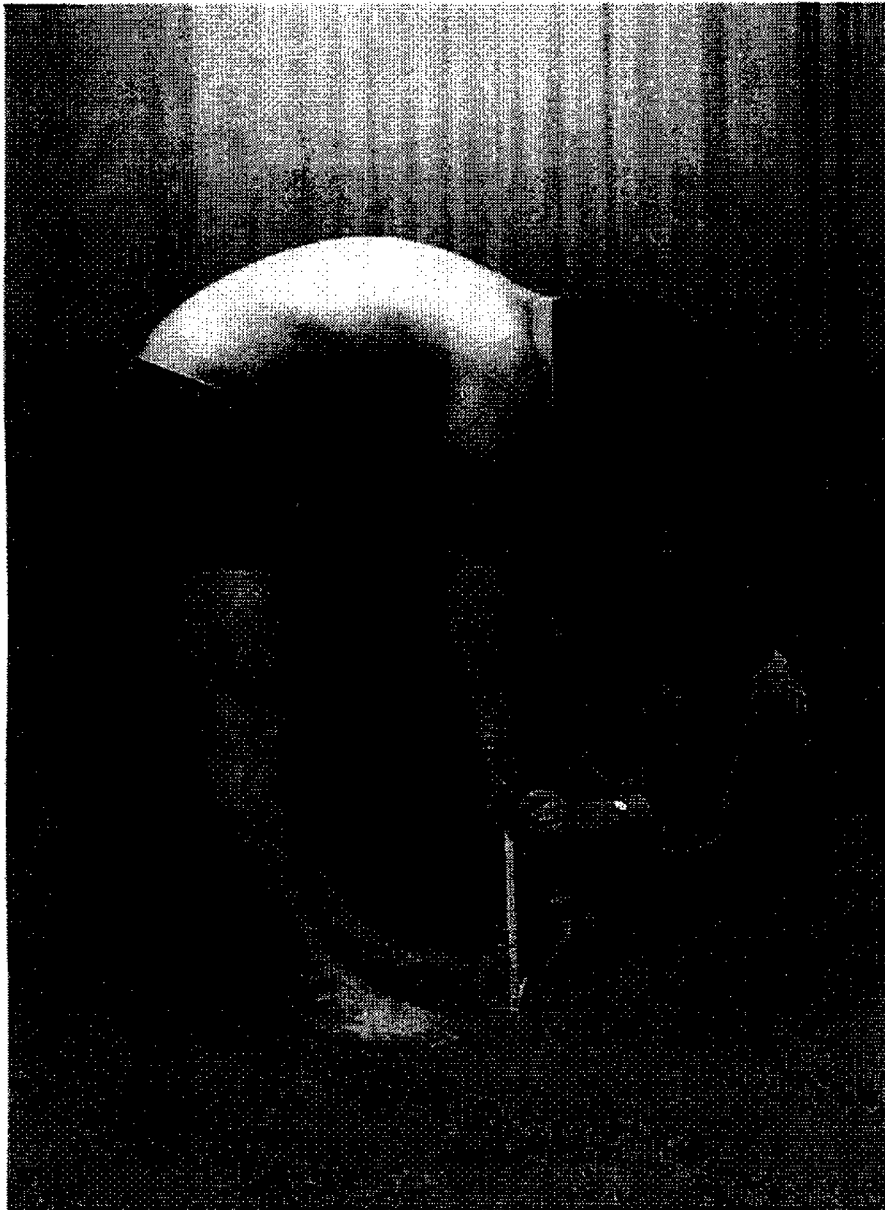
Starting position for measurement of forward bending using fingertip-to-floor method. The patient's foot, knee, arm and head position are standardised.

Starting position of examiner

The examiner is seated on a stool or kneels in front of the subject.

Procedure

Two measures need to be taken. The first measure is the distance between the subject's long finger and the floor while the subject is standing upright with their hands placed on their upperlegs. Then the subject is instructed to bend forward as far as possible and attempt to touch the floor with the fingertips. The therapist then measures the distance between the subject's right long finger and the floor.



Measurement of forward bending using a tape measure. The vertical distance from the tip of the middle finger to the floor is measured.

Common errors to avoid

Uncontrolled foot position, knee position or head position or unclear or inconsistent instructions to patients as to whether they should bend forward to onset of symptoms or end of range.

Variations of the test

The test is more commonly performed without the use of a stool because most subjects with low back pain are not able to reach the floor. In the case of a subject who is very flexible it may be necessary to ask them to stand on a stool for testing. If the subject reaches beyond the stool record this as a negative distance eg 3cm beyond the surface of the stool = -3.0cm.

A1.12 Side-bending range of motion

Description

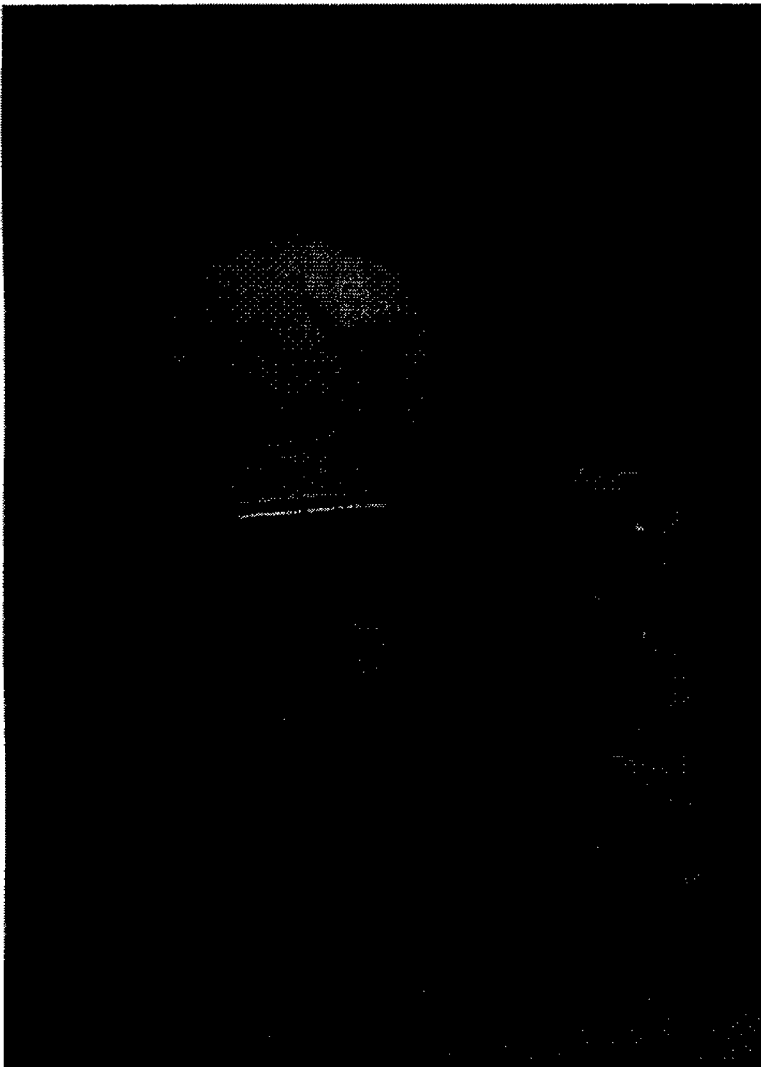
Measurement of trunk side-bending range of motion (fingertip-to-floor method) using a tape measure

Instruments required

Tape measure.

Starting position of subject

Bare feet, feet hip width apart, knees straight with the weight borne evenly on the two legs, looking straight ahead, arms hanging at the sides relaxed. If there is severe muscle spasm the patient is asked to get as close to the starting position as possible. The subject's low back and upper buttocks should be exposed.



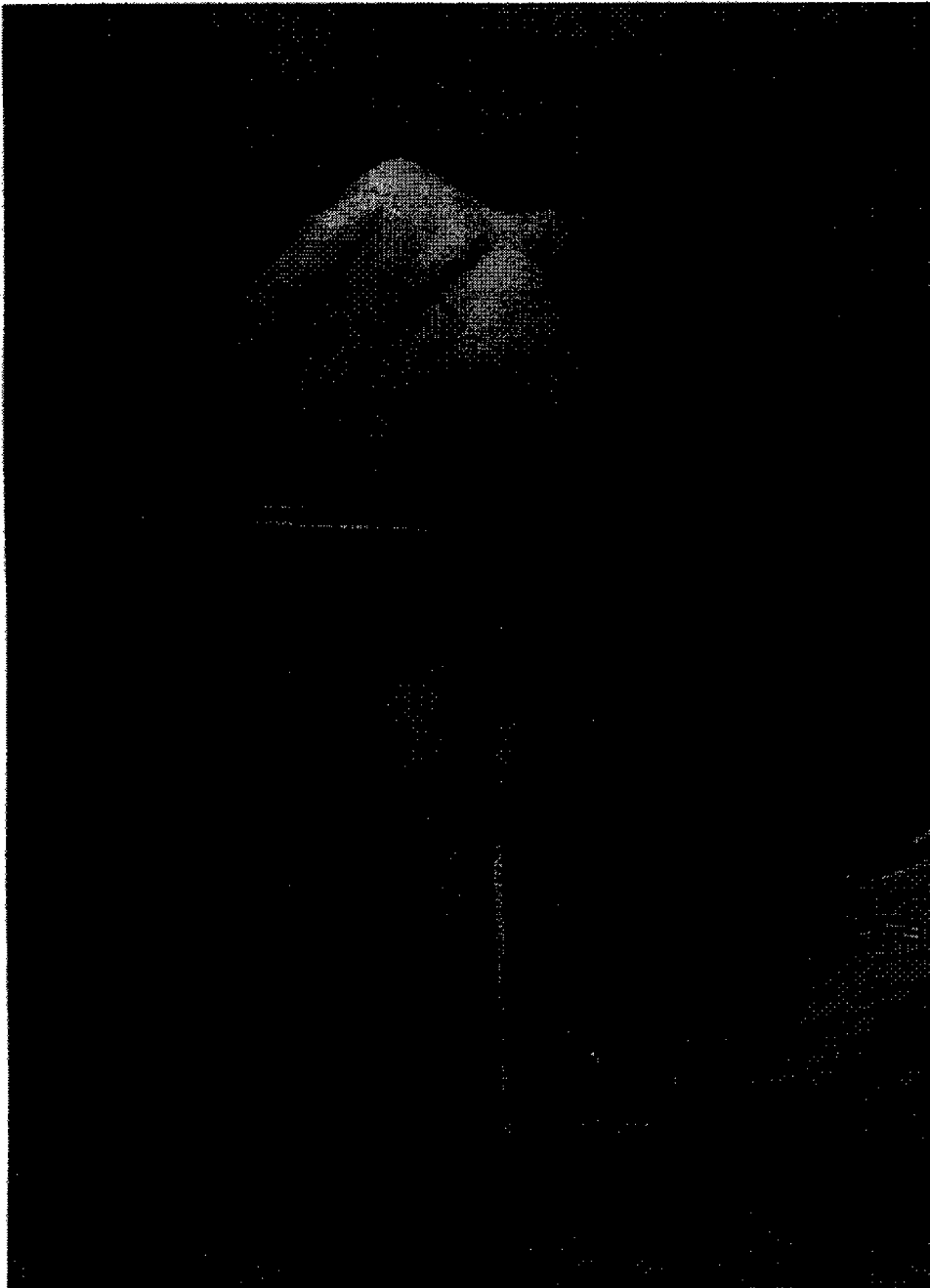
Starting position for measurement of side-bending range of motion. Position of feet is standardised.

Starting position of examiner

The examiner stands to the side of the patient.

Procedure

Two measures need to be taken. The first measure is the distance between the subject's long finger and the floor while the subject is standing upright with the arms at the sides. Then the patient is instructed to lean over to the side as far as possible keeping the fingers in contact with the leg making sure that the feet remain stationary and that the trunk does not rotate or flex. The distance from the middle finger to the floor is then measured in cm.



Measurement of side-bending range of motion using a tape measure to record distance form fingertip to floor.

Common errors to avoid

Allowing compensatory movements

A1.13 Single straight leg raise test

Description

Measurement of passive single straight leg raising using a single inclinometer.

Instruments required

Analogue or digital inclinometer

Starting position of subject

The subject is positioned in the standard Waddell supine position ie lying relaxed flat on their back, head lying on the couch without a pillow, arms at the sides with hips and knees as extended as possible without tension. The subject should not look up to watch what is happening.



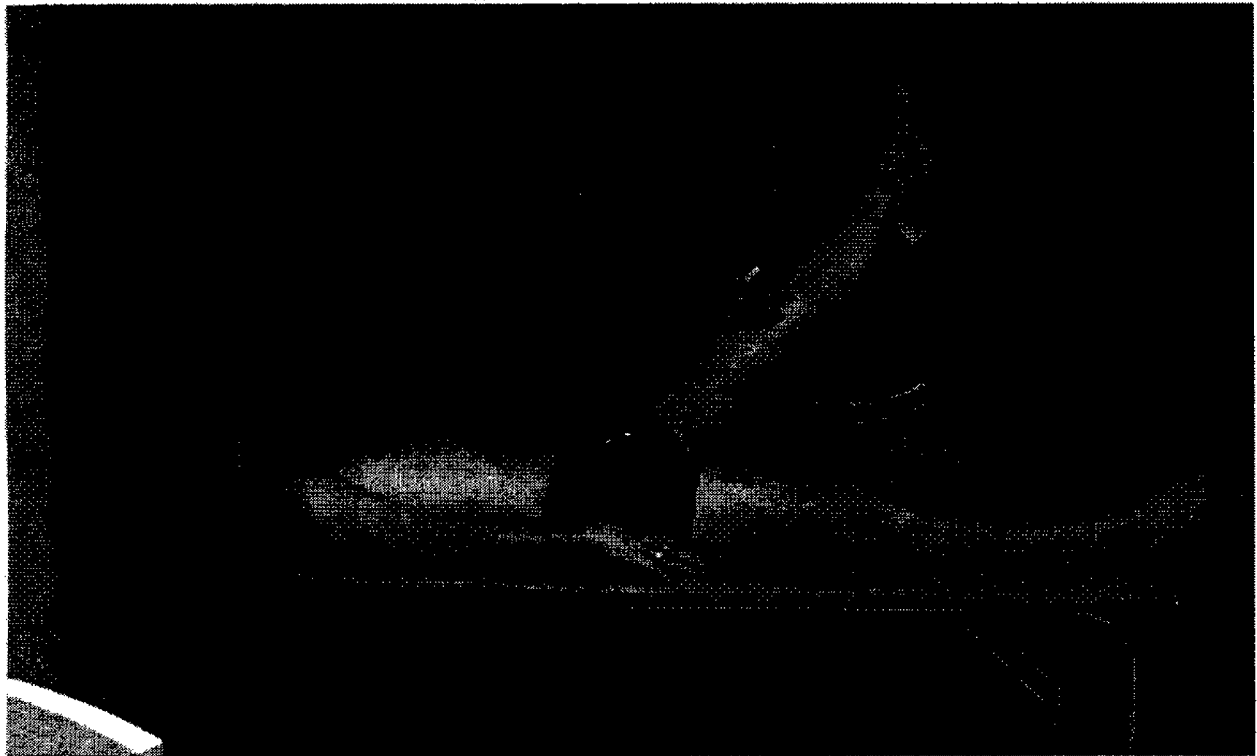
Starting position for measurement of straight leg raise using an inclinometer. The inclinometer is positioned over the tibial crest, distal to the tibial tubercle. The inclinometer is zeroed in this position.

Starting position of examiner

Standing at the side of the examining table adjacent to the extremity being measured.

Procedure

The foot is held with one hand making sure that the hip is in neutral rotation. The inclinometer is positioned with the other hand on the tibial crest just below the tibial tubercle and set at zero. The leg is then raised passively by the examiner, whose other hand continues to hold the patient's knee fully extended. The leg is raised to the maximum tolerated SLR (not the onset of pain) and the maximum reading is recorded.



Measurement of straight leg raise using an inclinometer. The leg is held in neutral rotation. Extension of the knee is maintained by the examiner by pressure from the hand. A reading is taken at maximum tolerated SLR range.

Common errors to avoid

Failure to standardise patient starting position, failure to maintain hip in neutral rotation and abduction/adduction, failure to control knee extension and allowing patient to lift the head or move the trunk or limbs to watch test performance. Failure to zero inclinometer, misreading analogue inclinometer.

A1.14 ACC Low Back Pain Questionnaire

These questions and statements apply if you have aches or pains, such as back, shoulder or neck pain. Please read and answer each question carefully. Do not take too long to answer the questions. However, it is important that you answer every question. There is always a response for your particular situation.

1. What year were you born? 19_____
 2. Are you: male female
 3. Were you born in Australia? yes no
 4. Where do you have pain? Place a tick (✓) for all the appropriate sites. 2x
 neck shoulders upper back lower back leg
 5. How long have you had your current pain problem? Tick (✓) one. □
 0-1 weeks [1] 1-2 weeks [2] 3-4 weeks [3] 4-5 weeks [4] 6-8 weeks [5]
 9-11 weeks [6] 3-6 months [7] 6-9 months [8] 9-12 months [9] over 1 year [10]
 6. How would you rate the pain that you have had during the past week? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
No pain *Pain as bad as it could be*
 7. In the past three months, on average, how bad was your pain? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
No pain *Pain as bad as it could be*
 8. How often would you say that you have experienced pain episodes, on average, during the past 3 months? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
Never *Always*
 9. Based on all the things you do to cope, or deal with your pain, on an average day, how much are you able to decrease it? Circle one. 10x
0 1 2 3 4 5 6 7 8 9 10
Can't decrease it at all *Can decrease it completely*
 10. How tense or anxious have you felt in the past week? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
Absolutely calm and relaxed *As tense and anxious as I've ever felt*
 11. How much have you been bothered by feeling depressed in the past week? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
Not at all *Extremely*
 12. In your view, how large is the risk that your current pain may become persistent? Circle one. □
0 1 2 3 4 5 6 7 8 9 10
No risk *Very large risk*
- Here are some of the things which other people have told us about their back pain. For each statement please circle one number from 0 to 10 to say how much physical activities, such as bending, lifting, walking or driving would affect your back.
13. Physical activity makes my pain worse. □
0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*
 14. An increase in pain is an indication that I should stop what I am doing until the pain decreases. □
0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

Here is a list of 5 activities. Please circle the one number which best describes your current ability to participate in each of these activities.

15. I can do light work for an hour. 10x
 0 1 2 3 4 5 6 7 8 9 10
Can't do it because *Can do it of pain problem without pain being a problem*

16. I can walk for an hour. 10x
 0 1 2 3 4 5 6 7 8 9 10
Can't do it because *Can do it of pain problem without pain being a problem*

17. I can do ordinary household chores. 10x
 0 1 2 3 4 5 6 7 8 9 10
Can't do it because *Can do it of pain problem without pain being a problem*

18. I can go shopping. 10x
 0 1 2 3 4 5 6 7 8 9 10
Can't do it because *Can do it of pain problem without pain being a problem*

19. I can sleep at night. 10x
 0 1 2 3 4 5 6 7 8 9 10
Can't do it because *Can do it of pain problem without pain being a problem*

You only need to fill in the next few questions if you are performing paid employment.

20. How many days of work have you missed because of pain during the past 18 months? Tick (✓) one.
 0 days [1] 1-2 days [2] 3-7 days [3] 8-14 days [4] 15-30 days [5]
 1 month [6] 2 months [7] 3-6 months [8] 6-12 months [9] over 1 year [10]

21. Is your work heavy or monotonous? Circle the best alternative. 10x
 0 1 2 3 4 5 6 7 8 9 10
Not at all *Extremely*

22. In your estimation, what are the chances that you will be working in 6 months? Circle one. 10x
 0 1 2 3 4 5 6 7 8 9 10
No chance *Very large chance*

23. If you take into consideration your work routines, management, salary, promotion possibilities and work mates, how satisfied are you with your job? Circle one. 10x
 0 1 2 3 4 5 6 7 8 9 10
Not at all satisfied *Completely satisfied*

24. I should not do my normal work with my present pain. 10x
 0 1 2 3 4 5 6 7 8 9 10
Completely disagree *Completely agree*

A1.15 Pain and Global Perceived Effect Scales

Global perceived effect scale

Assessor to read and fill in:

*"Compared to when this episode first started, how would you describe your back **these days**"?*

-5	-4	-3	-2	-1	0	1	2	3	4	5
----	----	----	----	----	---	---	---	---	---	---

vastly
worse

unchanged

completely
recovered

Average pain over the past week

*"I would like you to rate your pain on a scale from 0 to 10 where 0 is no pain and 10 is the worst pain possible. Please give me a number to describe your **average pain over the past week.**"*

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

no pain

worst pain
possible

A1.16 TAMPA questionnaire

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 1 to 4 to signify whether you agree or disagree with the statement.

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
1. I'm afraid that I might injure myself if I exercise.	1	2	3	4
2. If I were to try to overcome it, my pain would increase.	1	2	3	4
3. My body is telling me I have something dangerously wrong.	1	2	3	4
4. My pain would probably be relieved if I were to exercise.	1	2	3	4
5. People aren't taking my medical condition seriously.	1	2	3	4
6. My accident has put my body at risk for the rest of my life.	1	2	3	4
7. Pain always means I have injured my body.	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous.	1	2	3	4
9. I am afraid that I might injure myself accidentally.	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body.	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active.	1	2	3	4
13. Pain lets me know when to stop exercising so that I do not injure myself.	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active.	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured.	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous.	1	2	3	4
17. No one should have to exercise when he/she is in pain.	1	2	3	4

A1.17 Pain Related Self Statements Questionnaire

Most of the time, we have an internal conversation with ourselves. We encourage ourselves, for example, to do certain things, we blame ourselves if we have made a mistake, and we reward ourselves for our accomplishments. When we are in pain, we also say certain things to ourselves that are different from what we say when we are feeling good. Below, are listed typical thoughts of people in pain. Please read each of the statements, and then mark how often you have this thought when your pain is severe. Please circle the appropriate number on the scale ranging from 0 = almost never to 5 = almost always.

	ALMOST NEVER					ALMOST ALWAYS	
	0	1	2	3	4	5	
1. If I stay calm and relax, things will be better	0	1	2	3	4	5	
2. I cannot stand this pain any longer	0	1	2	3	4	5	
3. I can do something about my pain	0	1	2	3	4	5	
4. No matter what I do my pain doesn't change	0	1	2	3	4	5	
5. I need to relax	0	1	2	3	4	5	
6. I'll manage	0	1	2	3	4	5	
7. I need to take some pain medication	0	1	2	3	4	5	
8. I will soon be better again	0	1	2	3	4	5	
9. This will never end	0	1	2	3	4	5	
10. I am a hopeless case	0	1	2	3	4	5	
11. There are worse things than my pain	0	1	2	3	4	5	
12. I'll cope with it	0	1	2	3	4	5	
13. When will it get worse again?	0	1	2	3	4	5	
14. This pain is killing me	0	1	2	3	4	5	
15. I can't go on anymore	0	1	2	3	4	5	
16. This pain is driving my crazy	0	1	2	3	4	5	
17. Distraction helps best	0	1	2	3	4	5	
18. I can help myself	0	1	2	3	4	5	

A1.19 Roland Morris Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **today**. As you read the list, think of yourself **today**. When you read a sentence that describes you today, fill the box to the left of the sentence. If the sentence does not describe you, then leave the box blank and go on to the next one. Remember, only mark the sentence if you are sure that it describes you **today**.

- 1. I stay at home most of the time because of my back.
- 2. I change positions 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 a 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 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 stockings) 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, I am more irritable and bad tempered with people than usual.
- 23. Because of my back, I go upstairs more slowly than usual.
- 24. I stay in bed most of the time because of my back.

A1.20 Pain Self-Efficacy Questionnaire

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle one of the numbers on the scale under each item, where "0" = not at all confident and "6" = completely confident.

For example

0	1	2	3	4	5	6
Not at all						Completely
confident						confident

Remember, this questionnaire is **not** asking whether or not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain**.

1. I can enjoy things, despite the pain

0	1	2	3	4	5	6
Not at all						Completely
confident						confident

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain

0	1	2	3	4	5	6
Not at all						Completely
confident						confident

3. I can socialise with my friends or family members as often as I used to do, despite the pain

0	1	2	3	4	5	6
Not at all						Completely
confident						confident

4. I can cope with my pain in most situations

0	1	2	3	4	5	6
Not at all						Completely
confident						confident

5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work)

0	1	2	3	4	5	6
Not at all confident						Completely confident

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain

0	1	2	3	4	5	6
Not at all confident						Completely confident

7. I can cope with my pain without medication

0	1	2	3	4	5	6
Not at all confident						Completely confident

8. I can still accomplish most of my goals in life, despite the pain

0	1	2	3	4	5	6
Not at all confident						Completely confident

9. I can live a normal lifestyle, despite the pain

0	1	2	3	4	5	6
Not at all confident						Completely confident

10. I can gradually become more active, despite the pain

0	1	2	3	4	5	6
Not at all confident						Completely confident

A1.21

DASS 21

Please read each statement and circle number 0,1,2 or 3 which indicates how much the statement applied to you over *the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

- 0 Did not apply to me at all
- 1 Applied to me to some degree, or some of the time
- 2 Applied to me to a considerable degree, or a good part of time
- 3 Applied to me very much, or most of the time

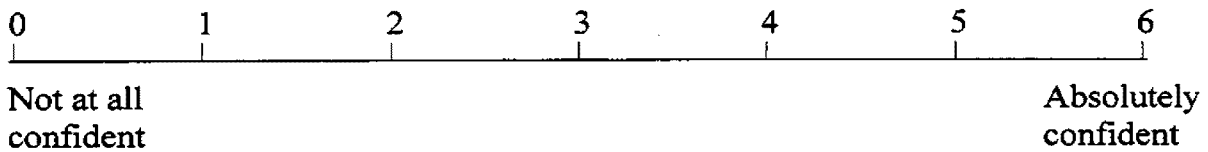
1	I found it hard to wind down.	0	1	2	3
2	I was aware of dryness of my mouth.	0	1	2	3
3	I couldn't seem to experience any positive feeling at all.	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things.	0	1	2	3
6	I tended to over-react to situations.	0	1	2	3
7	I experienced trembling (eg, in the hands).	0	1	2	3
8	I felt that I was using a lot of nervous energy.	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself.	0	1	2	3
10	I felt that I had nothing to look forward to.	0	1	2	3
11	I found myself getting agitated.	0	1	2	3
12	I found it difficult to relax.	0	1	2	3
13	I felt down-hearted and blue.	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing.	0	1	2	3
15	I felt close to panic.	0	1	2	3
16	I was unable to become enthusiastic about anything.	0	1	2	3
17	I felt that I wasn't worth much a person.	0	1	2	3
18	I felt that I was rather touchy.	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat).	0	1	2	3
20	I felt scared without any good reason.	0	1	2	3
21	I felt that life was meaningless.	0	1	2	3

A1.22 Treatment Credibility Scale

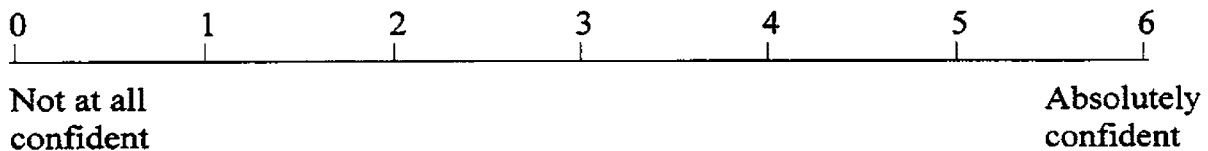
(To be completed after first treatment)

Please answer each of the questions by circling a number. Each number represents a possible answer. For instance in the first question "0" indicates that you are not at all confident that the treatment can help you, "1" that you have little confidence only, "2" some confidence, "3" moderately confident and so on.

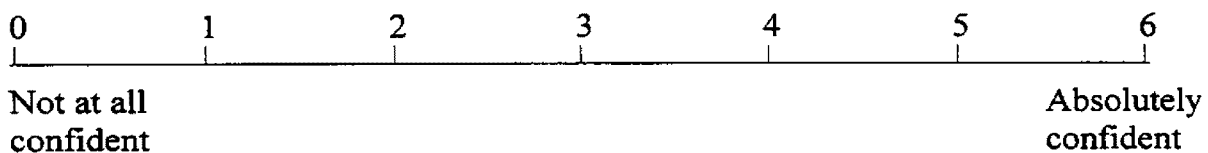
1. How confident do you feel that this treatment can relieve your pain?



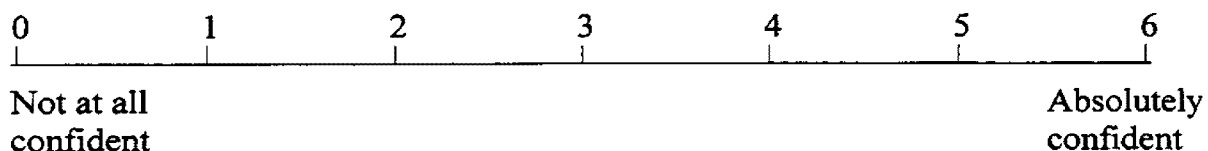
2. How confident do you feel that this treatment will help you manage your pain?



3. How confident would you be in recommending this treatment to a friend who suffered from similar complaints?



4. How logical does this type of treatment seem to you?



A1.24 Treatment Allocation Questionnaire

For the assessor to fill in after the assessment:

My guess is that the subject has been receiving (tick one box):

- Exercise and advice
- SWD + US and advice
- Exercise and ventilation
- SWD + US and ventilation

A1.25 Treatment appointment timesheet

Name: _____ **Trial no:** _____

date of appointment	total treatment time	1-1	talk
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			

Comments:

A1.26

Schedule exercise home program

Name: _____ Trial no: _____ Week: _____

Exercises	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1.							
2.							
3.							
4.							
5.							
6.							
7.							

APPENDIX 2

Standardised Physical Assessment

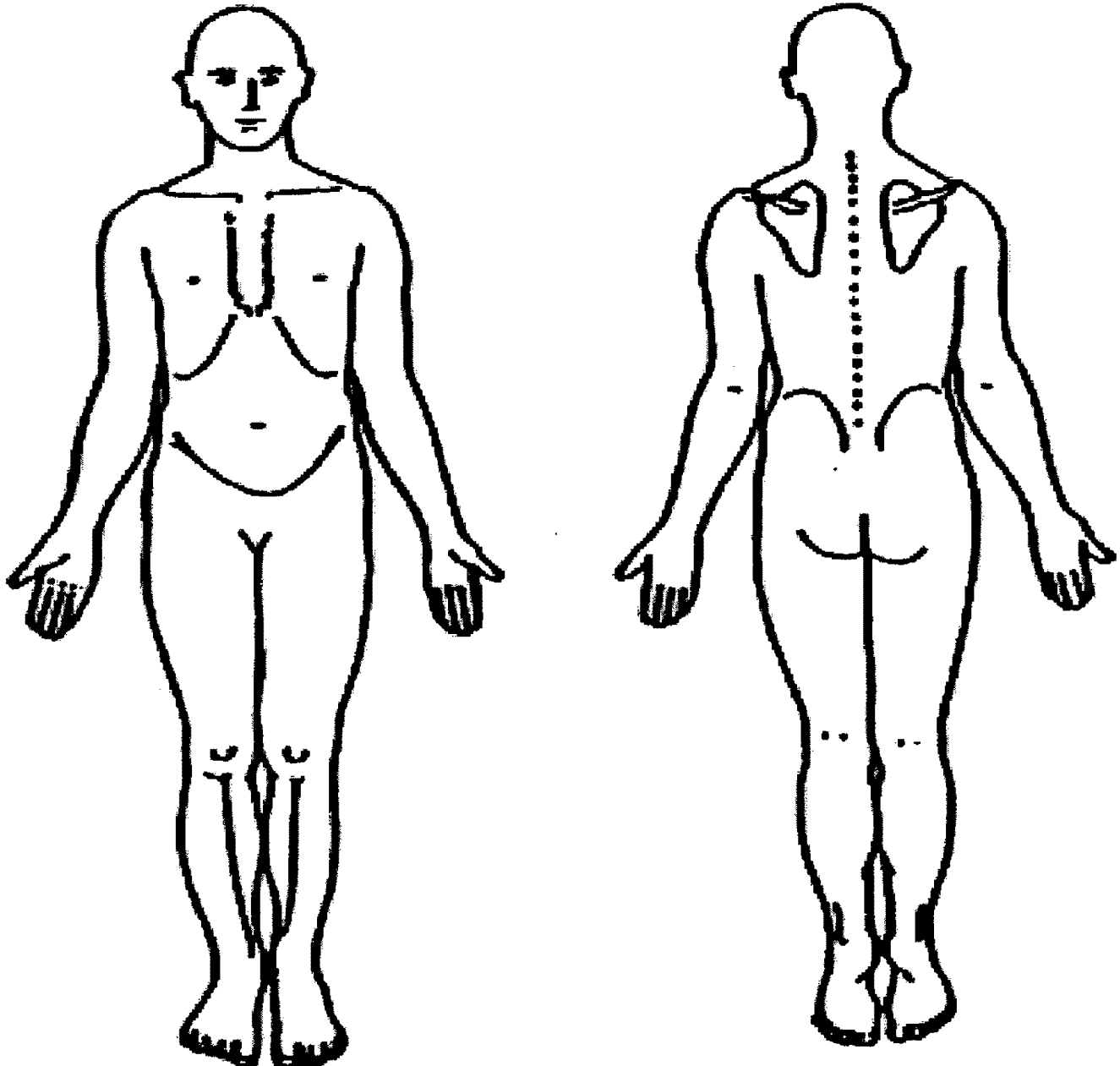
PHYSICAL THERAPY ASSESSMENT

Name: _____ DOB: _____

MRN: _____ Date: _____

Referrer: _____

- **Body Chart (Include areas, frequency, quality, VAS):**



VAS: _____

No pain

Pain as bad as
it could be

Status:

i. Working: Full time; Part time (hours -)
 Does not work

ii. W/C Third party

iii. Litigation pending

iv. Source of income

v. Return to work attempts

- **Current history** (include medical reports, results of investigations, etc):

- **Past history:**

SCREENING

- **Inspect PARQ, Screening Questionnaire and if necessary (i-iii).**

i. General health: _____

ii. Medication (include dosage): _____

iii. Operations: _____

- **Social history**

Domestic status: _____

Support networks: _____

- **Tolerances (minutes):**

Functional goals:

1 _____
2 _____
3 _____
4 _____
5 _____

Typical day

- **Functional status** (also consider Patient Specific Functional Status and the Roland Morris disability questionnaire)

	activity	current capacity	desired
Self care	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
Housework/ Recreation	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
Work	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>
	<hr/>	<hr/>	<hr/>

Patients' understanding of their LBP:

i. Cause?

ii. What will help?

iii. What will exacerbate?

iv. Self management.

v. What does an increase in LBP mean?

Physical examination

All groups:

- **Postural observations**

- **Spinal mobility (Schober's)**

- i. Flexion _____
- ii. Extension _____
- iii. Lateral flexion _____
- iv. Rotation _____

- **Gait**

- **Neural tension tests**

- i. SLR _____
- ii. Slump _____

Exercise groups only:

- **Muscle tightness**

- i. Hip flexor _____
- ii. Hamstrings _____
- iii. Adductor _____
- iv. Glut _____
- v. Calf _____

vi. Lattissimus dorsi stretch _____

- **Strength (lumbar stabilisation)**

- i. Lumbar stabilisation in supine _____

- ii. Lumbar stabilisation with SLR:

 - unilateral _____

 - bilateral _____

- iii. Side lying with double leg raise _____

- **Test (optional):**

- i. 6 minute walk test

- ii. Functional tests

- iii. Cardiovascular tests

APPENDIX 3

Treatment Manual for Subacute Low Back Pain Trial

INDEX

COGNITIVE-BEHAVIOURAL PRINCIPLES.....	174
EXERCISE	190
SHAM EXERCISE	196
ADVICE	199
SHAM ADVICE	201

Cognitive-Behavioural Principles¹

One of the problems confronting people with sub-acute low back pain is the question of activity versus rest. Should they rest (wait for the pain to settle) and only engage in activities which do not aggravate pain (commonly known as 'let pain be your guide')? Or should they try to ignore their pain, having been advised by their doctor and physiotherapist that there is nothing seriously wrong with their back ('no red flags'), and try to gradually resume normal activities, including exercises?

The weight of current expert opinion, supported by studies like those of Indahl (1995), Lindstrom et al. (1994) and Linton et al (1993), is that providing there are no 'red flags' present (indicative of major pathology) people with sub-acute low back pain should be encouraged to resume normal activities as soon as possible. The evidence from these studies suggests that those who follow this approach tend to suffer less disability and distress, return to work sooner and use health care services less than those who are treated in more traditional ways (often described as 'let pain be your guide', that is, if it hurts stop doing it).

It is not difficult to imagine that when a patient is experiencing pain which has persisted for more than 6-8 weeks that they may be starting to become concerned about what is happening. This concern could well be increased if they feel that no one has been able to give them a clear explanation of the pain or to significantly improve it. They may well fear that by continuing to do things despite the pain they are risking causing further damage or prolonging their condition. Fear of pain may also develop – either because of its possible implications or a somewhat natural aversion to the experience of pain.

At the same time a person in this position is also likely to be getting all sorts of advice on what to do about their pain. This advice may be from their doctor, physiotherapist, chiropractor, family and friends, even people at work. It would be surprising if this advice was consistent. Some may be urging further investigations or possible lines of treatment while others may be recommending a 'take it easy' approach, with activity avoidance and resting as key strategies. In this setting it is also likely that many people in persisting pain will have their normal household chores taken over by others in an attempt to ease their burden and to enable them to recover. While this help will normally be well-meaning it could have the unintended consequence of effectively reinforcing disability – both in the pain sufferer's mind and in the minds of those around them. As a result the person in pain could well become increasingly inactive and passive, while waiting for someone to 'fix' the problem.

We also know that often when people stop doing things which they normally enjoy or give their life meaning (like working, socialising, playing sport, participating in family activities) their mood is likely to become increasingly despondent and frustrated. In time, many will become quite depressed. When this low mood is coupled with the other aspects of the picture (the fear of pain or re-injury, the failure of treatments to help, the increasing disability) there is a strong risk of the person

losing confidence and starting to become increasingly helpless. As a result, the risk of developing all the common features of chronic disabling pain (depressed mood, inactivity, disturbed sleep, reliance on passive treatments like drugs, and withdrawal from most normal activities including work) becomes greatly heightened. Treatment outcomes with people once they reach this state are often very poor.

For those whose low back pain does not settle in the 8-12 week post-onset period there is clearly a high risk of their slipping into the chronic disabling pain category. This is particularly true of those who develop the features outlined above. It is hoped that by intervening before the patient gets to this stage that their progression to chronic disability will be reversed (even if their pain cannot be relieved). The few studies available which have examined this proposition have generally reported positive results (e.g. Indahl, Lindstrom, Linton), but it is important to note that they were not effective in preventing all patients from developing into chronic cases. Some cases will, therefore, require further and more intensive interventions (e.g. Vlaeyen et al., 1995; Williams et al., 1996, 1999). For the rest, fortunately, it is expected that relatively light interventions, properly targeted and conducted, will be enough to reverse their progression towards chronic disability.

It has been shown (eg. Malmivaara et al., 1997) that simply prescribing exercises is not enough. Patients have to gradually resume more normal activities despite their pain. Exercises may assist patients in achieving this goal (eg. Lindstrom et al., 1994). To overcome the natural anxieties that these patients often have about such tasks and the reinforcement they often receive for inactivity the treating physiotherapist needs to incorporate a number of what are called 'cognitive-behavioural' principles in their work with such patients. Each of the studies referred to earlier (Indahl, Lindstrom and Linton) have employed many of these principles in the interactions with their patients, although the Lindstrom and Linton studies were more explicit about it than Indahl.

These cognitive-behavioural principles were derived from laboratory studies of how people (and other animals) learn as well as from trials of clinical applications. The important point to keep in mind as you read these principles is how you could utilise them in your work with patients in the program. An article written for physiotherapists on the use of these principles is attached to provide an additional illustration.

Basic Principles

1. People learn most effectively by doing

Observing others perform (or model) an activity can also aid learning (the activity or task). Providing information, simply telling someone what to do, is much less effective as a method of training. Prof. Wilbert Fordyce, the pioneer of behavioural treatments for chronic pain once made this point very clearly when he said “information is to behaviour change as spaghetti is to a brick”. The history of the ‘Back School’ approach to back pain is a good example of how advice (by itself) on back care is of limited use.

2. Shaping

If the task (i.e. behaviour or exercise) is new to the patient, a gradual process called ‘shaping’ can help them to acquire (or learn) the new behaviour. This involves starting at whatever level the person can manage or whatever version of the behaviour (eg. an exercise) s/he can manage and then practising the behaviour repeatedly, gradually getting closer and closer to the desired goal behaviour. Thus, a perfect performance is not required or expected initially. Rather, the patient should start with a rough approximation (or whatever s/he can manage) and then gradually refine it until they can perform the desired or expected task.

3. Reinforcement

All behaviour is maintained by its consequences (or what follows the behaviour). If a behaviour is being maintained, the consequences are referred to as ‘reinforcers’. In common language they can be thought of as rewards. Reinforcers are usually something the person desires or wants to achieve (few people are likely to work for something they don’t want). Reinforcers do not have to follow a behaviour every time in order to maintain it, just often enough. So you don’t have to feel good or win a prize every time you complete an exercise, just often enough for you.

Equally, not all behaviours need to be reinforced individually to be maintained – it can be enough that the same type of behaviour (or a similar behaviour) has been reinforced, or is reinforced. Thus, if a behaviour from a certain class of behaviours is reinforced, other behaviours in that class will also be maintained even without direct reinforcement themselves. For example, if an exercise performed by a patient is reinforced (praised) by the therapist (or just feels good to do) it is possible that the patient will go on to perform other similar exercises without having to be praised by the therapist in every instance.

Furthermore, reinforcers don’t have to be external events (like food or praise from others), they can also be internal, like the satisfaction of having achieved something or having done something you are proud of, like achieving a goal.

Reinforcers often tend to be very individual things, so what one person values as a reinforcer may not suit another person. For example, some people find praise by others (such as their physiotherapist or a family member) helpful in maintaining their performance of an exercise. Others may prefer to see their achievements recognised in the form of a chart showing how much they have improved since they first started.

3.1 Consistency

Reinforcement for an activity is most effective when it is consistently applied. That means the same activity or task is reinforced in a consistent manner (rather than a competing, or contradictory activity). Thus, in a health care setting, this would mean that not only the therapist should reinforce (praise/encourage) the patient's performance of an exercise, say, but also all other health care providers involved with that patient (doctor, nurse, psychologist, etc) should do so as well. Ideally, so should the patient and his/her family, employer etc.

When this doesn't happen, for example, when one person encourages rest or avoidance of any activity which might aggravate pain while another is encouraging more activities, it is not hard to imagine that the patient will become confused – and probably won't follow the advice.

When a patient is required, as part of their treatment plan, to play an active role (whether it is exercising, taking tablets or following a diet), all those involved in working with the patient must agree to support the single approach. When they don't the patient is unlikely to adhere to the plan. The same principle applies when only one health provider is involved – consistency in reinforcement is critical.

3.2 Self-reinforcement

People can also learn to reinforce themselves for their achievements. Another way of thinking about this is taking credit for your achievements. A good example of people doing this is when a tennis player or a footballer punches the air in excitement when s/he hits a winner or scores a goal. They are recognising their achievement. In the long run it can be very helpful for maintenance of a behaviour (such as an exercise) if the person concerned can reinforce themselves for their achievements. Some people can have trouble doing this – for example, they may feel they are just 'big-noting' themselves. Some people will also feel that their achievement is not that great – they may say that they used to be able to do much better than that. Strictly speaking, this can be true, but does it help and did they have a pain condition when they did it before? These are examples of what we call maladaptive cognitions or thoughts which can effectively undermine performance. These sorts of thinking styles can result in failure to progress and will usually need to be addressed, but we will return to them shortly.

3.3 Selecting reinforcers (and goals)

In order to use reinforcers to promote performance or learning it is important to work out what sorts of things the person is likely to find reinforcing. It can help to devise a sort of menu from which the person can select something according to their wishes. Some variety can also help to prevent the reinforcers losing their potency (they can become boring or less meaningful with too much repetition). Reinforcers should also be feasible or attainable. Naturally, the person (or patient in

a clinical setting) must play an active role in identifying possible reinforcers for themselves. The therapist can make suggestions of what others have found useful – as a guide only. Typical examples would include, self-praise, small treats (food, drink, a night off studying, an outing, etc.), keeping a record or chart of progress, and so on.

The same principle applies to setting goals. Goals, of course, can also be reinforcers – we get a sense of achievement when we reach them and that can keep us motivated to do more. Of course goals are normally things we are trying to reach for some purpose and not just an aid to motivation. But as with reinforcers generally, goals should be things that are meaningful to us, things we want. Otherwise we are unlikely to try very hard to achieve them. Ideally, it helps to make goals as clear or specific as possible – then we know what we are seeking and when we get there. So rather than say “I’d like to be fit” (what is that and when would we know we’d achieved it?), it can be more useful to define it more precisely, like “I’d like to be able to use the stairs to my office every day without having to sit down to recover”. If we could do that we would be reasonably fit, but we’ve defined it in terms of something we can measure our performance against and we will know when we have reached it. By setting a goal precisely it can also help us to work out a way to achieve it. Thus, getting ‘fit’ could mean anything and doesn’t really help us work out how to get there. In contrast, climbing stairs is obvious and we can work out a plan to achieve it (eg. stop for a rest at the top of each flight to begin with and then at the top of every second flight, and so on)

3.4 Timing of reinforcers

It is also usually more effective if the reinforcer(s) follows the behaviour (task or exercise) as soon as possible afterwards. So immediate feedback (after a performance) usually works better than delayed feedback. If people feel that it will be a long while before their efforts bear fruit they can be tempted to give up quite easily. Of course, many things we achieve in life do take a long time (eg. a university degree can take 4-6 years), but we manage to keep going by achieving small goals (reinforcers) along the way. These can be in the form of feedback from others on how well we are going or small milestones we set for ourselves.

3.5 Short-term reinforcers

Develop a list of short-term reinforcers. These might include: keeping a chart of your progress and ticking (checking) it each time you complete a stage; a brief statement to yourself that you’ve done well; or reminding yourself that you’ve made more progress towards your ultimate goal. To make it more fun you could also do things like: allowing yourself to eat some snack food that you wouldn’t normally have or allowing yourself to watch a certain program on TV that night or calling an old and distant friend whom you haven’t seen for sometime.

3.6 Long-term reinforcers

Long-term reinforcers will usually be the goal(s) you are trying to achieve (being able to walk the dog, returning to work/study; resuming sport, etc.). In the end, no one is likely to work for long at something they don’t really want to achieve. Thus, the long-term goal(s) of any exercise program should be clarified early with the patient. Are they just seeking pain relief, to get fitter, or are they wanting to resume ceased activities, etc.? This is a critical point in planning an exercise program. Of

course, as with all reinforcers, these goals should be realistic or attainable (in these situations there is no point in aiming at achieving goals which are very unlikely – the risk of failure is too great). So don't plan on becoming an astronaut at this stage.

None of us needs reminding that few people sustain an exercise program for long, regardless of whether we have pain or not. If you do have persisting pain there may even be less motivation to continue to exercise – unless you have a good reason (ie. something you really want to achieve and you believe the exercises will help you to achieve that goal).

If the ultimate goal (reinforcer) is likely to take some time to achieve, it can also help to have some larger than usual reinforcers to maintain your motivation (ie. to keep you at the task). Depending on your means these might be things like a night out; buying a new article of clothing or something you've been putting off getting; even a trip or weekend away).

3.7 Using reinforcers

It is also important that when a reinforcer is provided that the person reminds themselves what it is for (eg. 'this is for completing my exercise program today'). This helps to strengthen the link between the performance of the task or exercise and the reinforcer. It also signifies success – an important consideration when you are in pain.

Initially, it is usually helpful to make the reinforcers or goals easy to achieve. In other words, success can encourage success. The converse, of course, is that if a person tries to achieve something and repeatedly fails they are likely to become discouraged and stop trying. In someone at risk of developing chronic disabling pain this is not what we want. So when starting something like an exercise program with someone in pain it is important that the first goals or tasks are fairly easy to achieve. As the person starts to regularly achieve this goal then the task can be made slightly more difficult (or more repetitions may be required). When that level is regularly achieved then the task can be made more difficult again. At the same time the earning of reinforcers can be made more difficult, to encourage harder work. Completion of a task or an exercise is likely to become a reinforcer in itself, but it can be augmented by an external reinforcer like those mentioned above.

To give a concrete example of how a physiotherapist might apply this principle, you would show the person roughly what you would like them to do then ask them to do it as best they could. When they do it (and not before – remember you should only reinforce a behaviour after it has occurred) then you should praise them very lavishly (within reason). The next time they do it praise again, no matter how poorly they do it – you are really just praising them for trying. Keep this up (providing they are at least doing something) until you see some progress. When this level is being achieved reliably you should then ask them to do a little more – and only praise them when this is achieved. And so on. Soon they should set their own goals and they should start to reinforce themselves for achieving them. You should explain the use of reinforcers to them and praise them for using them as well. By now you should see that we are also using reinforcers to promote shaping (praising closer and closer approximations of what we are trying to get the patient to do).

3.8 Feedback as a reinforcer

Another way of thinking about reinforcers is that they are a form of feedback. They tell you when you have achieved your goal. There is good evidence that when patients in chronic pain get feedback on their exercise improvements they tend to achieve higher levels of exercise (eg. Cairns and Pasino, 1977; Fordyce, Caldwell and Hongadorom, 1979).

3.9 Using quotas and pacing to aid reinforcement

Linked to the idea of feedback as a reinforcer is the use of quotas in exercise programs. Traditionally, people with persisting back pain have been advised to exercise as long as it is comfortable and stop if their pain increases. The trouble with this approach is that it can result in the person focussing too much on the experience of pain. In turn this can mean that s/he starts to avoid activities which aggravate their pain. But if most activities aggravate their pain this approach will lead to generalised inactivity – the very thing that we are trying to prevent. There is also evidence that when people with back pain do exercise regularly (i.e. they keep going despite the pain) they can actually end up with less pain (eg. Waling, Sundelin, Ahgren and Jarvholm, 2000). The trick is to find a way of persisting with the exercises (or whatever activity), gradually doing more, but without significantly aggravating the pain – which can lead to feelings of defeat and cessation of the activity.

[Waling, K., Sundelin, G., Ahgren, C., and Jarvholm, B. (2000). Perceived pain before and after three exercise programs – a controlled clinical trial of women with work-related trapezius myalgia. *Pain*, 85, 201-208.]

Fordyce (1976) pioneered a method of achieving this using the concepts of quotas and pacing. By setting quotas for exercises (eg. 5 repetitions of one exercise and, say, 7 of another) the patient has an external goal to aim for (which can help to take their mind off their pain). Quotas also allow the patient to know when they have achieved the short-term goal (ie. the feedback is immediate – a good reinforcement principle), and they give us a benchmark of what they can do (allowing for planning the next increment).

Pacing (i) Pacing up activities, means working at a level (eg. an exercise quota) that can be achieved and, when that is being achieved reliably, doing a bit more until that is achieved reliably and then doing a bit more, and so on.

(ii) Pacing can also involve taking regular breaks in activities. Thus, one could exercise for a period (or number of repetitions) that one can tolerate, then take a break for a few minutes (perhaps doing something else in that time, like relaxing or stretching or standing up and walking about), then resuming the task or exercise for the same tolerance period before stopping again, and so on.

To work out the initial tolerance level we normally ask people to try the activity/task/exercise for as long as they can do it comfortably (but before their pain is really stirred-up). This time/ distance/ or number of repetitions is recorded (eg. 5 minutes for sitting, 50 metres for walking, etc) and then repeated at least 2-4 times and then averaged to give us a reasonable baseline or starting point.

To make the first quota of the exercise even easier to achieve (and remember that the initial goals/reinforcers should be easy to achieve to promote encouragement) it can also help to set the task at a little below the baseline average. For example, Fordyce (1976) suggests using a figure of 20% below the baseline average (i.e. 80% of the baseline average). Thus, if the average sitting tolerance at baseline was 5 minutes, then the starting sitting quota would be 80% of 5 minutes – that is, 4 minutes. Once the quota is set it is important the patient works to it and doesn't stop earlier if their pain is worse that day (so they do it despite the extra pain). If this starts to become difficult and they keep stopping short of their quota then the quota should be re-set.

The amount by which the quota is raised each time and the timing of the rise is something that is usually negotiated between the patient and the therapist. Patients may be keen to raise the level as fast as possible, but this risks overdoing and unnecessarily aggravating their pain (something we are trying to minimise).

Equally, some patients will be very avoidant and pain-focussed. They usually don't want to move up until their pain is relieved (which may not be a realistic option). In both these cases the physiotherapist needs to take a middle line. They should advise the 'overdoer' to keep to a realistic pacing up of quota levels (say, increasing by only so many repetitions every 2nd day). In the case of the 'underdoer' or 'avoider' they should encourage them to try a small increment, perhaps reminding them of the purpose of the exercises and restating that they will not come to any harm by doing these exercises. It may also be necessary to explore the patient's concerns if they are particularly hesitant. In these cases, however, you should be aware of a possible trap you might fall into - whereby you could end up reinforcing inactivity.

Three points to make here:

(i) Try not to push the patient – if you do they may become reliant on you to move them along. But when you are not present they could easily stop. The motivation must come from the patient – they must want to achieve their stated goals (which you should have already worked out with them). They should also agree that the exercises are a feasible way for them to achieve these goals (you may have to put time into explaining this clearly).

(ii) Patients must learn to reassure themselves. It is appropriate for the physiotherapist to explain and educate the patient about their pain, what it signifies and the prognosis, etc. This will usually entail a degree of reassurance that s/he is basically well, that there is nothing seriously (dangerously) wrong with their back (they won't end up in a wheel chair because of this problem).

However, once these issues have been addressed but you find the patient is starting to repeatedly seek reassurance about the same issues it can be a sign of a problem developing. Each time you try to allay their concerns they could well say that it makes sense and they are satisfied with your explanation and even feel

better about it now. But if they come back worried about the same issue again and again your repeated attempts to reassure them could well be starting to actually reinforce their worries rather than resolve them – exactly the opposite of what you intended. Remember, while you are taking up time listening to their worries and trying to reassure them, they are not exercising, just talking and getting attention from you for doing it.

Certainly, appropriate explanations, answering questions and reassurance are important initial steps and may be *briefly* repeated from time to time, but the patients must learn to do it for themselves as well. Thus, when the same questions you answered last time you saw the patient get raised again you should try to deflect it back to the patient. Get them to do the work, not just depend on you to do it for them.

Thus you might say something like: “that sounds like what we discussed last time I saw you; is that right?” (always check with the patient that your perception is accurate). If the answer is “yes” then you might follow that up with something like: “Well, what did I say about that the last time?” (in other words, try to get the patient to recall your earlier advice – you might also need to remind them that they said they were satisfied with that advice). Of course, if the patient thinks there might be a new angle or aspect to it you will have to judge if that is so, or decide if it really is basically their original concern. If they say they can’t recall what you said last time you could repeat it, but then ask them to repeat it back to you so they demonstrate they understood it (ie. not just say they did).

Then you need to point out to them that they should now be able to remind themselves of this advice and the next time they start to worry about it they should be able to deal with it as well as you (or anyone else) could.

In some cases they might say that they have a new symptom (eg. pain in different site). In these cases you might be concerned that something new has developed (is it red flag?). This is what the patient is probably concerned about. However, before getting concerned and recommending further investigations it is worth checking your original assessment of their symptoms and complaints. It is often the case that they actually have reported this ‘new’ symptom before, but have been overlooking it lately (or it has been less evident lately). In this case you can readily point this out. It is relevant to remember that many patients with persisting pain do start to focus more than usual on different sensations in their bodies. If they are already concerned that you or the doctor has overlooked something or that they really do have a serious illness, then their report of a ‘new’ symptom could easily be a reflection of these beliefs and associated somatic focussing rather than a sign of developing disease or disease flare. Remember that when most of us start an exercise program we are activating muscles and joints we haven’t used very much lately, so some extra aches and pains are always likely. Of course, you must use your clinical judgement in these cases, but your initial assessment notes will often be an important place to start your re-assessment of the patient’s complaints.

(iii) Shift the focus back onto the task (exercise) and reinforce performance

Rather than reinforce talking about fears/concerns (without any evidence of the patient doing anything about it themselves) it is important to as soon as possible shift your focus and attention back to the exercise program. Reinforce with praise and attention the patient's attempts at that, reminding them of how that will ultimately help them to achieve their goals. At the same time, remind them to reinforce themselves for their performance achievements (despite their fears and pain).

Finally, fading out your role as a reinforcer. If we are trying to encourage self-reliance in our patients we need to avoid their becoming dependent on us for encouragement. Instead, they should be encouraging (or reinforcing) themselves and perhaps finding ways of getting it from their own environment (eg. family). Thus, as your patient is starting to make progress with their exercise program you should begin to praise them less (letting them know beforehand that this does not imply that you are losing interest in them, just trying to encourage them to take responsibility for looking after their own health). Occasional feedback to the patient is important but it doesn't need to be nearly as frequent as in the initial stages of a program. You can help to prompt it in the patient by making remarks like: "You must be very pleased with how well you are doing?"

4. Using association effects (reminders)

While reinforcers provide the motivation for continued performance, they don't necessarily tell us when a given activity will be reinforced. Most of our actions are strongly influenced by learning when (under what circumstances or in what situation) our actions will be reinforced.

For example, when you are driving and you see that the traffic lights change to red, you will usually put your foot on the brake to stop the car. That action is reinforced by successful avoidance of a possible collision with another car (or other obvious consequences). What triggered your stopping was not the motivation to avoid an accident, but rather the sight of the red light. The red light tells us that stopping is the right thing to do at that time (providing we wish to avoid a collision or a fine, etc). However, if the light had been green, stopping would have been the wrong thing to do. The green light tells us that if we keep moving we will not only get where we want to go, but also we will avoid someone running into our tail.

A moment's reflection will reveal that there are many such examples through our normal day where our behaviour is changed upon a signal or a change in situation. The same applies to our routines through the day. In fact, when we try to change the time or place of when/where we normally do something we can feel uncomfortable. Take cleaning your teeth – usually we do it in the bathroom, but try doing it in the kitchen and it will feel somehow 'not right', even though logically it should make no difference (the water is the same and the drains go to the same place). The main difference is that we are not used to cleaning our teeth in the kitchen. That is, we don't associate the kitchen with cleaning our teeth. But we do associate the

bathroom with that activity, and when we see the bathroom after a meal or before bed we usually think about cleaning our teeth.

How could we apply these ideas to an exercise programme for our patients?

We are more likely to practise an exercise programme if we can tie it (associate the exercises) with specific times or places. These might be straight after getting out of bed in the morning or after getting home at the end of the day, or even during tea/coffee breaks through the day, for example. We could also improve our memory of when to exercise by using little reminders (eg. a note in the diary, on the fridge, or even a sticker on a wrist watch).

If we simply tell someone they should exercise and we apply all the reinforcement principles outlined earlier to encourage them to do it (and to keep doing it) we will probably be successful. After all, most patients seem to manage to get through life without health professional telling them how to spend every 5-minutes. So most of them will work out a convenient time to do their exercises and, over time, they will get used to doing them at these times (and maybe even feel 'not right' if they don't do them then).

However, some will be helped if you give them some guidance on finding a suitable time to do the exercises. If this is a new activity (which is most likely) the patient will have to make a change to their normal routine - they will already be doing something (even if only lying down) at these times. They will need to think about how they spend their days and look for possible times that could be suitable. As they will already be doing something at these times, they will need to make doing the exercises a higher priority than the activity they will replace (or move the existing activity to another time).

It is strongly advised that the patient should make a specific plan for when they will do the exercises (and commit themselves to it) before they leave the clinic. It is important that they do not leave the clinic saying that they will think about it and 'see how they go'. If there are conflicting issues it is important that the patient identifies these beforehand and works out possible solutions. If the patient comes back for review and says they haven't been doing their exercises as they haven't found a suitable time, it tells you something about their motivation and lifestyle. If they are serious about achieving the goals they seek with the treatment or exercise programme then they will need to make it a higher priority and work out ways of dealing with any obstacles.

Remember to avoid the trap that awaits all health professionals in this situation – *don't do it for them* – the patient must take the leading role in sorting these issues out, even if it takes longer than you might. Otherwise, they may never learn to deal with such problems.

5. Overcoming fear-avoidance responses through exposure

You may be aware that a key element in the psychological treatment of a phobia (or strong fear of something) is to arrange for the person with the phobia to repeatedly get into the presence of what they fear. For example, if a person fears crowds, the treatment would involve getting the person to repeatedly go into somewhere like a crowded shopping centre until it didn't bother them. It has been found that this is one of the most effective treatments for a phobia and the effect lasts. However, if the phobia or a version of it recurs the person now knows how to deal with it. This approach is called exposure training (and sometimes desensitization – making someone less sensitive or less reactive to something they fear).

Naturally, the task of getting someone with a phobia to actually confront what they are afraid of can be quite difficult and stressful for that person (as well as the psychologist). So some preparation is usually required and certain skills may also need to be learnt by the patient before they will be ready or prepared to try confronting situations they would much rather avoid. This may involve discussion with the patient to reassure them about the safety of the task as well as skills like relaxation techniques and cognitive coping strategies (eg. reminding themselves that they will be all right, that nothing really bad will happen, and that they have coped with these situations before, etc).

It is not difficult to see how such an approach could be applicable for people with persisting pain who are avoiding activities due to fear of aggravating their pain or of causing more damage.

Steps to take

- (i) **Identify what might be limiting progress with activities/exercises.** Is it fear or anxiety about getting more pain or causing more damage? Remember, many patients have been told to stop if their pain increases – to let pain be their guide (this could also be the view of the patient's spouse – so his/her views should be sought too). Another possibility is that the patient might have a poor understanding of what the pain might mean – s/he could be imagining rather serious possibilities when, in fact, the reality is much more benign.
- (ii) **Clarify likely basis of pain (in a reassuring way).** This should be as factual as possible (given the obvious limits on current knowledge), but put in terms the patient can understand. For example, Indahl et al. (1995) advised patients that they should think of low back pain as a sign that the blood circulation in the back muscles was inadequate and this could lead to stiffness and pain. It was also explained that this restricted circulation was often due to inflammation in part of the intervertebral disc which caused a reflex action (tension) in the paraspinal muscles. The patients were also told that pain or the anticipation of pain could also result in guarding of the back and increased muscle tension which in turn could lead to more pain (via the same restriction in circulation). Regardless of what was thought to be the particular cause of a patient's back pain, all patients were told that their back problems

are mainly due to heightened stabilisation of the back by lumbar paraspinal muscles (ie. excessive tension in these muscles holding the back rigid).

Avoid vague statements that can easily be misinterpreted, such as “it is just degeneration” (the patient might feel their back is crumbling away).

This explanation should also address the fears or concerns you identified in Step (i). If they have scans which have been interpreted as “negative” or not showing anything significant, point out that this is actually positive – it means there is nothing seriously wrong with their back – they are OK. They are really no different to most people in the community at their age. Most of us experience back pain sooner or later, but it doesn’t last in most cases and it doesn’t need to stop us getting on with our lives.

Again, ask the patient to repeat back to you what they have understood you to have said, just to ensure that you have been interpreted correctly. Suggest that the patient tells their spouse the good news too, especially in cases where the spouse has a poor understanding of the problem.

- (iii) **Encourage resumption of feared activities.** Starting at a level they think they can manage, but building on this gradually in a paced manner. Remember, continued avoidance of these activities must be reversed.

You might ask what they would find helpful or reassuring. It is unlikely that words from you or their doctor will be enough. Most people gain more confidence by actually doing what they are afraid of, finding that they can do it and discovering that they are OK afterwards. Point this out to them. Think of similar examples that are not to do with pain. For example, learning to drive a car, use a computer, raise a child, travel overseas. No matter how much others tell us about these things, we only start to feel confident about doing them when we have actually done them ourselves.

- (iv) **Monitor and reinforce progress. Seek to extend the activities.** Remember the sections on reinforcement principles above (especially self-reinforcement). Also, the exercises and initial activities should not be the only goal, just the first step. The patient should be encouraged to extend these (gradually) until they have resumed most normal activities in the various areas of their lives (work, home, socially, etc.). It is also useful to remind them to apply these principles (of minimising avoidance, maintenance of activities and self-confidence, and reinforcement, etc.) whenever they find themselves having these sorts of problems in the future.

6. Thoughts/Beliefs/Expectations

All of us are influenced by the ways in which we see (or perceive) the world, those around us and even our own behaviour. These perceptions may or may not be accurate, but they can affect how we feel and behave. Thus, if we believe that a bit of pain in the lower back might suggest we could end up in a wheel chair if we are not careful then we are likely to be very cautious (guarded) in how we move, what we are prepared to do, etc. This, in turn, is likely to have secondary effects on our

gait, exercises and other activities we are prepared to engage in. Hence, ignoring a patient's beliefs and expectations about their pain, what it means and its appropriate treatment could easily risk their non-adherence to an exercise program. On the other hand, if we inquire about these issues then we may be able to correct any inaccurate views and reassure the patient about the best course of action. However, recall the point made earlier - that repeated requests for reassurance are a warning sign to you that the patient may be at risk if becoming dependent on you and failing to take prime responsibility for managing their pain – see the comments on dealing with this.

It is critical to managing a patient's back pain that their thoughts and beliefs about their pain be sought and discussed by the treating therapist. We cannot assume that the patient will have a good understanding of their pain and its management, no matter how capable or intelligent the patient may appear.

Possible questions to ask could include things like:

“What is your understanding of what has caused your back pain?”

or “What do you think is going on in your back when you have this pain?”

or “Do you ever wonder that when you do something and your pain gets worse that you might have damaged something?”

Such questions should elicit some of their beliefs or expectations which you can then discuss in the light of your assessment and the other information available on their back pain. Of course, this could lead to further concerns being raised and you can then address those too.

Care in checking the patient's understanding or perceptions of what you have told them is also critical as it is easy for professionals (of all disciplines) to assume that patients understand health issues as well as they do. When checking a patient's beliefs it is recommended that you should avoid asking for ‘yes’ or ‘no’ answers. For example, after having explained something to a patient if you asked “do you understand?” It is likely that the patient, especially one who is lacking in confidence or feels unassertive, would say “yes” simply to avoid sounding stupid or dumb. Rather, you should try to get the patient to repeat back to you what you have just said. This could be put like:

“Now, just to make sure that you have understood what I have said about your back, tell me what I have said”. And, of course, correct this response as necessary, and most importantly, tell the patient “that's right”. They might also like to write it down if they are having trouble remembering.

6.1 Things to avoid

When someone has persisting non-specific back pain, especially in the first few weeks after onset, they can be very susceptible to attending to any information that might indicate there is something seriously wrong with them. Such information could easily give rise to heightened anxiety or apprehension – fears which can easily obstruct advice to exercise. It is critical therefore, that care is taken in how a therapist responds to the patient's account of the onset of the pain, their description of symptoms and their pain behaviours, as well as any reports of imaging. The box on the following page describes some commonly reported statements by therapists and patients.

Anxiety-inducing responses by therapist could include statements like:	Possible interpretations by patient:
"Let pain be your guide"	The pain means I'm doing too much
"If it hurts stop"	I could be damaging myself
"Be careful"	If I'm not careful, I'll make it worse
"Avoid any activities that aggravate your pain"	They might make matters worse
"These scans indicate a fair bit of degeneration".....	I'm falling apart
"These scans show there's a disc bulging"	It must be about to burst
"These scans look pretty terrible".....	There must be something terribly wrong
"There is some instability in your spine".....	My back could snap in two
"If the exercises hurt let me know, you must be doing them incorrectly"	The exercises should take my pain away.
If they don't it's my fault.	

It usually helps to prepare for encounters like these if you have practised saying the sorts of things you would like to say in these situations, either alone in front of a mirror or with colleagues. These examples also highlight the importance of checking with the patient that they have understood what you told them.

6.2 Things to try

If the patient is concerned about possible awful things happening to him/her when they exercise (damaging spine, etc), ask them to clarify as much as possible exactly what they are concerned about. Has anyone suggested anything to him/her (either inadvertently or intentionally) eg. possibility of needing surgery otherwise they might end up in a wheel chair one day? Equally, have they read or heard something (newspapers, TV, or even someone they know) which made them wonder about their back?

If they can't be specific, then ask about what is the worst thing they could imagine happening to them if they exercise while in pain.

Once you have this sort of information, you will need to discuss with the patient how likely (or unlikely) these things are. Typically, you will try to reassure them that they are very unlikely. However, some patients will still say, "yes, I know it is unlikely, but it would be terrible if it happened and so I don't want to risk it". Of course, you can never say that something terrible will never happen, regardless of how unlikely they are. It is also true that some things that happen to people can be very unpleasant and even tragic. So, there is a grain of truth in what these patients say. So, what are the options for dealing with this situation?

1. Agree with them and say maybe it is better that they just take it easy and see how they go. (*OK, but this does raise the risk of avoidance of activities which, in turn, could lead to greater disability and worse outcomes in the long run – in this group who are still seeking help at 8-12 weeks post onset*)
2. Having emphasised that the thing they fear is extremely unlikely (and could just as easily happen to you), explore exactly how terrible it might be. Yes, people do have spinal cord injuries and become quadraplegic, but are their lives over? Look at the Para-Olympics – many of the competitors there seem to manage quite well, and are often more active than those with no physical impairments.

In other words, even if the worst thing happened would it really be so terrible, or would they just have to find a way to manage – as they have done through their lives already when something has gone wrong? Equally, if they spend their lives worrying about what might happen or not doing useful things about their back pain in case something terrible could possibly happen as a result, where might they end up? Could it be that they might actually be increasing the risk of something awful happening by not resuming normal activities and exercises?

In this way, you will not only be addressing the rarity of the thing they fear, but also getting them to see that what they fear may not be so bad anyway. Even if the worst thing did happen they would still find a way to manage and to get on with their lives, just as thousands of others have done when seriously injured. Most of us will know of examples of people who have overcome great adversity. Reminding the patient of these people or asking them if they know of anyone like that could be useful (they might still say something like ‘that’s all right for them, but I know I couldn’t do it’ – but, you could point out that neither did most of those people before they were injured).

References

1. Nicholas M, Tonkin L. Persisting pain: using cognitive-behavioural principles for activity-based pain management. In Refshauge KM and Gass E (eds) *Musculoskeletal Physiotherapy: Clinical Science and Practice*. 2nd edition. Oxford: Elsevier (In press).

Exercise

NB Please read in conjunction with the previous Cognitive Behavioural Therapy section

Key points

- It is not necessary to provide 1:1 contact throughout treatment sessions, please follow normal clinical practice. We anticipate direct personal contact for 50% of treatment session.
- The physical activity program must focus on improving the patient's ability to perform their 5 functional goals.
- The program will be tailored to the patient's needs. Each patient will get aerobic training, functional tasks, activities to build speed, endurance and co-ordination, stretches, and trunk and limb strengthening exercises.
- Physiological principles for exercise prescription are less important than the CBT principles. If the two approaches conflict, follow the CBT approach.
- Patients must be involved in goal setting and monitoring of activity program
- All patients must have a home activity program
- Patients will be encouraged to continue activity program for at least 6 weeks after program finishes. In final two weeks use the briefer post program exercise monitoring charts so that they will have experience using these.

Treating physiotherapists will receive the following baseline questionnaires: Physical activity readiness questionnaire, Red flags screening questionnaire, Tampa, Roland Morris, Patient-specific functional scale. These measures are provided because it is recognised that most physiotherapists would collect this information prior to treatment and this will save asking the patient the same questions again. Physiotherapists must collect all other information they need to administer the allocated treatment. We have provided an assessment guideline to use.

The treating physiotherapist will ask the patient to identify up to 5 important activities that they are unable to do or have difficulty performing as a result of their low back pain and to describe the extent to which they can currently perform them. The patient will then be asked to describe the work, activities of daily living and leisure activities that they wish to return to. The physiotherapist considers both of these pieces of information to identify the functions that are presumably impaired and need training. They then perform functional capacity testing to:

1. Set a baseline for the graded exercise program
2. Provide a basis for positive reinforcement of the patient's gained function
3. Confirm that a function is indeed impaired

Point 3 is actually quite difficult because there is no intact side to provide a normal value and there is little published data on normative values. In most situations the physio will have to consider the demands of the patient's lifestyle and then make an

educated guess as to whether the function needs improvement. Examples of baseline functional tests are shown on page 21.

Specific program

The program includes aerobic training, functional tasks, activities to build speed, endurance and co-ordination, stretches, and trunk and limb strengthening exercises. All patients need to perform aerobic training and the mode of aerobic training selected (eg walking, bike) must be able to be continued in the home program. The exercise program should be compatible with their functional goals and their current abilities. However for some patients the activities may need to be either upgraded or downgraded. Examples of various levels of functional exercises are given on page 21. The individualized program can also be adapted to include different activities more relevant to the patients' functional goals. The physiotherapist should use their own clinical judgment to select these additional activities

The physio will then design a program that gradually increases the complexity of the activity until eventually the patient is able to perform the goal ADL activity. The complexity of the activity can be increased by increasing the load, increasing the number of repetitions, increasing speed of movement, incorporating changes in direction, increasing balance requirements, increasing the height of a step, performance of concurrent tasks and linked tasks. Again this concept is illustrated on page 24. Use baseline testing to establish where to start the patient in the series. In each case the patient should record their accomplishments.

An important element of the program is that patients need to be involved in setting goals and also complete their activity charts so that they can monitor their progress. This concept is described in the CBT manual. The physiotherapist will select the exercises to perform and implement them considering the CBT principles outlined in the CBT manual. Where prescription of exercise considering physiological principles conflicts with a CBT principle please follow the CBT approach. For example if you decide to prescribe a walking program and the patients baseline walking tolerance is 20 metres then you would start them training at 80% of 20 metres rather than follow the American College of Sports Medicine's (ACSM) guidelines and get them to walk/run for 20-30 minutes three times per week at 60-90% of max heart-rate.

Examples of activity tests

The following are tests for a range of activities. You can also refer the ACSM guidelines for aerobic fitness testing protocols.

Walking

- **Fifty-foot walk**
Subjects walk 25 feet, turn around, and walk back to the starting position, once as fast as they can and once at their preferred walking speed. They are timed during the performance of these walks.¹
- **Five-minute walk**
Subjects are requested to walk as far as they can in 5 minutes.¹
- **Step-ups**
Step up and down onto shallow step, record number of step-ups. Progress onto deeper step and increase number of steps.²
- **Jogging on bouncer**
Stand on bouncer and lift alternate feet slowly. Increase speed until jogging on the bouncer.²
- **Skipping rope exercise**
Place a rope stretched out on the floor. Step over it from side to side. Record number of steps. Repeat above and increase speed. Skip using the rope. Try not to land heavily on the heels.²
- **Shuttle walking**
Walk between markers on the floor. Record number of times they walk up and down. Increase their speed.²
- **Balance**
Ability to walk along a 20 foot 2x4 board with less than 6 errors total. Tested in normal stride (forward/backward), heel to toe (forward/backward) and sideways (forward/backward).⁴
- **Stand on tiptoe with arms elevated**
Rated as cannot manage, with some difficulty, without difficulty.³

Climbing/stairs test & activities

- **Sit and stand**
Sit on chair with arms crossed and stand up straight. Sit down again and repeat as often as possible. Record number of times you can stand up. Repeat the above with a medicine ball.
- **Stair climbing**
Number of steps able to be ascended and descended, 100 maximum.⁴
- **Step ladder climbing**
Ascend and descend 3-4 steps of step ladder for 10 repetitions⁴
- **Alternate knee raising**
Stand straight. Lift right knee to touch left hand and repeat lifting opposite knee. Record number of lifts. Repeat the above, lifting knee higher to touch left elbow. Increase speed of the exercise.²
- **Climb onto a 25-cm stool**
Rated as cannot manage, with some difficulty, without difficulty.³
- **Jump from a 25-cm stool**
Rated as cannot manage, with some difficulty, without difficulty.³

- Timed up-and-go

The subject starts from the seated position, stands up, and walks forward to a line 3m away, turns, walks back to the chair, and sits down. Subjects are timed as they perform the task.¹

- Repeated sit-to-stand

The subject is asked to rise to standing and return to sitting as quickly as possible five times. The time taken for the subject to perform this task was measured with a stopwatch.¹

Lifting/pushing/pulling tests & activities

- Arm raising

The subjects stands with the arms by their side, raising alternate arms above their head. Record number of times they raise their arms.²

- Free arm weights

The subjects lies on their back with their arms by their side, lifting right arm to left shoulder. Repeat with left arm. Repeat above with weight. Increase and record weight for progression. This exercise should be done slowly.²

- Medicine ball lifts

The subject lies flat on their back with their knees bent. They lift a small medicine ball up from their chest until their arms are straight and lower. Record number of lifts. Repeat above with heavier ball and increase repetitions.²

- Press ups

Subject stands with shoulders facing the wall with feet approximately 2 feet from the wall. Subject leans towards the wall and then pushes away keeping their back straight. Record number.²

- Floor to waist lift

- Waist to overhead lift

- Dynamic push/pull.

Ability to push/pull vehicle loaded with 100kg of weights. Rated as cannot manage, with some difficulty, without difficulty.³

- Horizontal lift

Lift milk crate from waist level shelf, move horizontally 4 feet put crate down again. Repeat five times. Scored as maximum safe lifted weight.⁴

- Front carry

Lift milk crate off floor or waist height bench, carry milk crate 25 feet forward and then return back to floor or bench. Recorded as maximum safe lift.⁴

- Right-handed or left-handed carry

Lift container with handle (eg tool chest) off waist height bench, carry milk crate 25 feet forward and then return back to bench. Recorded as maximum safe lift.⁴

- Static push/pull

Average of static force held 3 seconds⁴

- Dynamic push/pull.⁴

Push weighted trolley 30 feet and then reverse and pull 30 feet. Scored as maximum weight safely moved.⁴

- Loaded reach

Subjects stand next to a wall on which a meter rule was mounted at shoulder height. They then reached forward at shoulder height, holding a weight that did not exceed 5% of body weight or 4.5kg. The maximum reach distance was recorded in cm.¹

- Unloaded reach
- As above except subjects do not hold a weight.¹
- Lateral pull down at gym station
 - Bench press at gym station
 - Pectoral strengthening at gym station

References

1. Simmonds MJ, Olson SL, Jones S, Hussein T, Lee CE, Novy D *et al.* Psychometric characteristics and clinical usefulness of physical performance tests in patients with low back pain. *Spine* 1998;23:2412-21.
2. Frost H, Lamb SE, Klaber Moffett JA, Fairbank JC, Moser JS. A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial. *Pain* 1998;75:273-9.
3. Lindstrom I, Ohlund C, Eek C, Wallin L, Peterson LE, Fordyce WE *et al.* The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioral approach. *Phys Ther* 1992;72:279-90.
4. Isernhagen SJ (ed). *Work injury: management and prevention*. Rockville: Aspen Publishers, 1988.

Examples of varying the complexity of functional tasks

Functional task #1: Walking

- Increasing speed

Standing, stepping, walking on the spot, walking slowly, walking briskly, jogging, running

- Direction changes

Walking smoothly in a straight line, shuttle walking, timed up and go, repeated sit-to-stand

- Inclines

Level walking, step up shallow steps, climb flights of stairs, climb step ladder

- Balance

Walking on level floor, stand on tiptoes with arms elevated, stand on minitramp and lift alternate feet slowly- increase speed until jogging, wobbleboard, walking along 2x4 board

- Load

Walking without load, walking carrying a load in one hand, walking carrying a load in front with both hands, pushing a loaded trolley

- Increasing speed lateral movements

Sideways stepping, sideways steps -raising arms, star jumps

- Skipping

Step over rope from side to side, hop from side to side, skip using rope

Functional task #2: Lifting/pushing/pulling

- Press up against wall, modified press-up, full press-up
- Arm raising, arm raising with weights, overhead manipulation
- Lift from floor to waist, lift from waist to shoulder, horizontal lift,
- Unloaded reach, loaded reach
- Bench press at gym station increase reps and/or weight
- Pectoral strengthening at gym station increase reps and/or weight
- Lat pull down at gym station increase reps and/or weight
- Pushing an unloaded trolley, pushing an unloaded trolley through shuttles, pushing an unloaded trolley with stop and starts, increase the speed of pushing trolley (repeat with load)

Sham Exercise

(Detuned ultrasound and shortwave diathermy)

Overview

To control for the therapist's attention during the exercise session, detuned pulsed ultrasound (U/S) and detuned pulsed shortwave (SWD) will be delivered. The US will be for 5 minutes and the SWD for 20 minutes. It is not necessary to be with the patient for the whole 20 minutes of SWD, do what you would do for active SWD.

The therapist must deliver the therapy in a credible manner and with equal enthusiasm as for the exercise intervention. We expect that patients will respond to this treatment and the size of the effect may be quite surprising. If we are honest we can all recall examples where we have forgotten to switch on the ultrasound and have gotten good results.

Key points

- Try to replicate the normal clinical routine for delivering active pulsed UAS and SWD.
- Always refer to the treatment as pulsed U/S and pulsed SWD **NEVER** placebo.
- Do not provide advice during U/S & SWD treatment sessions. If the patient requests advice first either try to deflect the conversation back to the treatment being delivered or provide placebo advice (see placebo advice section).
- Do not apply the principles of cognitive behaviour therapy used for the active exercise intervention.
- It is not necessary to provide 1:1 contact throughout treatment sessions, please follow normal clinical practice. We anticipate direct personal contact for 50% of treatment session.

While many of the steps are redundant, eg checking for contraindications, if this is not done you will increase the potential for unblinding. The approach we will use is based upon the Australian Physiotherapy Association Clinical Standards for the use of Electrophysical Agents.

1. Take a history

Treating physiotherapists will receive the following baseline questionnaires:

- PARQ/Screening questionnaire
- Tampa
- Roland Morris
- Patient-specific functional status measure

These measures are provided because it is recognised that most physiotherapists would collect this information prior to treatment and this will save asking the patient the same questions again.

2. Explain the benefits of the treatment

Brief version:

The ultrasound and shortwave will help reduce your back pain. During the treatments you may feel a slight warmth.

Longer version if more info is requested.

The ultrasound and shortwave have similar clinical benefits but affect different tissues. The ultrasound is a sound or vibration that is absorbed into the soft tissues such as muscle and ligaments but not the bone. The ultrasound is mainly absorbed in the superficial tissues and we need to use a gel to transmit it. It is the same as used on pregnant mums. The SWD is an electromagnetic field that can penetrate to the deepest tissues in your back and also the bone. The benefit of using both treatments is that we can affect all the tissues in your back: the soft and hard tissues and also the superficial and deeper tissues.

The treatments have an anti-inflammatory effect by helping the body break down and disperse the painful chemicals produced following an injury. They also assist tissue repair and healing. Both treatments reduces the nerve's ability to conduct pain signals and so they have an analgesic effect. Lastly if there is any muscle spasm in the area they can help relax the muscle.

Do you have any questions?

3. Check for contraindications

During the history check for the following:

- Circulatory insufficiency
- Bleeding disorders
- Metal in the area
- Acute inflammation/infection
- Inability to detect
- Severe cardiac or renal disease
- Cardiac pacemaker
- Malignancy
- Tuberculosis
- Osteomyelitis
- Pregnancy

Inspect the area to note the following:

- Open wounds
- Skin disorders

Conduct a hot/cold skin test

4. Provide standard warnings

When receiving the ultrasound treatment, it will first feel quite cool because of the gel and the steel head of the machine. After a little while it may feel like warm. This is normal. We are using a pulsed mode to allow the heat to disperse. If it gets any warmer than a mild warm feeling please let me know and I will turn down the intensity or the pulse ratio.

Do not move or touch any of the equipment during treatment.

When receiving the SWD treatment, you will first feel nothing and then it may warm up. We are using a pulsed mode to allow the heat to disperse. If it gets any warmer than a mild warm feeling please let me know and I will turn down the intensity or the pulse ratio.

Do not move or touch any of the equipment during treatment.

5. Reassess after the treatment

Prior to administering the treatment you should measure something that can be used to assess the effect of SWD/US treatment. Potential measures would be: straight leg raise, range of motion, lumbar spine range of motion, resting pain. If there is an improvement following treatment please respond in the typical manner. You also need to reassess prior to the follow-up treatment to see if treatment gains were maintained and also to see the effect of treatment on activities of daily living etc. Again if improvement is noted reinforce this as you would for delivery of an active treatment.

Advice

(Based upon Indahl's advice protocol.¹)

Overview

“Based upon my examination you do not have anything seriously wrong with your back. The problem is a simple sprain of the disc or ligament and with time this will heal. A sprain of the disc or ligaments in your back produces inflammation and this will cause muscle spasm in your back muscles. The muscle spasm will diminish circulation to the muscles and lead to stiffness and pain and the pain can be quite severe. The muscle cramping in your back is much the same as the cramp you may get in your calf and just as it helps to move your foot to get rid of the cramp so movement of your back will help. When patients have LBP, pain or anticipation of pain can make them want to hold their back still but this is the worst thing to do because it will lead to increased muscle spasm and subsequently increased pain”.

“It is now at least 6 weeks from the onset of your LBP and it is quite safe to start returning to your normal activities. Light activity will not further injure the disc, ligaments or any other structure that could be involved in the process, and it is a general medical observation that light activity actually enhances the repair process. Being overly careful and avoiding activity is the worst thing you can do and will delay recovery. What you need to do is to start with light activity and set your own goals for increasing your activity levels until you have returned to your normal activities”.

“A lot of people are scared and worried by their LBP, this is natural. However in most cases this fear is unjustified and the fear will probably make your pain worse. Emotional stress will tend to make your LBP worse because it will increase muscle tension and so LBP. Again this does not mean you have re-injured your back. Unfortunately it can set up a vicious cycle where emotional stress leads to muscle spasm and so pain which leads to more stress and muscle spasm and so on”.

“You should try to bend and move your back as much as possible. For example when you are walking or moving around you should not hold yourself stiffly but rather try to be as flexible as possible. Keeping your back still is not helpful. The only exception is lifting. There are three rules to remember for lifting:

- (i) Avoid bending and twisting when lifting
- (ii) When lifting very heavy objects, lift correctly with the back as vertical as possible, make use of the thighs and keep the load close to the body
- (iii) Carrying involves static work for the back muscles, therefore any excess carrying should be avoided”.

“If you experience LBP this is a sign that circulation to the muscles is inadequate and you can help this by mobilising your back with stretching and light activity. If you experience acute stabbing pain in the back, this does not mean you have re-

injured your back it is usually an acute muscle spasm and you should treat this with stretching and light activity”.

“A lot of patients with LBP that has persisted for over 6 weeks are afraid that they will never recover. This is not true. The majority of patients (insert %?) do recover. You can increase your chances of making a good recovery by changing how you view your LBP. LBP patients who take on the sick role eg by resting, taking time off work and allowing others to do their work and chores are less likely to recover. As I said before being overly careful and avoiding activity is the worst thing you can do and will delay recovery. The best thing you can do is to mobilise the back by light activity and set your own goals for returning to your work and chores”.

“In short, there is generally no reason to be afraid of your back. Do not be overcautious, but try to be as flexible as possible. Try to stop worrying about doing ‘something wrong’ with your back, but instead use it”.

Practical implementation of the principles and guidelines will be demonstrated by the physiotherapist. Explain the nature of LBP and clarify any misconceptions.

References

1. Indahl A, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered. A randomized clinical trial. *Spine* 1995;20:473-7.

Sham Advice

Overview

To control for the therapist's attention during the advice sessions, 'ventilation' or support sessions will be provided.

The therapist will provide the subject with an opportunity to talk about their LBP and the therapist will respond to them in a warm and empathic manner, and display genuine interest in subject (patient). However, no advice about LBP will be given.

Keypoints

The therapist should inform the subject at the first (and subsequent) sessions that these sessions were aimed at providing them with an opportunity to discuss the problems of living with LBP.

It should be pointed out that many people with such conditions reported that they felt alone or unusual and that other people often didn't seem to understand them or what they were going through, especially if these other people didn't have LBP.

It is then suggested that these sessions were aimed at providing them with an opportunity to discuss a number of issues concerning their back pain.

It should be said that while the therapist may not be able to answer some questions about back pain, it can be helpful to have an opportunity to talk through some of these issues with an professional therapist.

The general principle is that the therapist avoids giving specific information or advice about back pain. Thus, recommendations for a specific exercise or posture must be avoided. Equally, information on a likely cause of pain should be avoided.

When such questions are asked the therapist should be prepared to deal with them directly and without sounding evasive. For example, if asked "do you think I should be resting more?" the therapist could say something like, "well, as you know we can't really give you specific advice on this, but what do you find helpful?" In other words, the therapist tries to deflect the question back to the patient to answer. The therapist should neither agree nor disagree with the answer – just say something along the lines of "well it sound as if you're happy with that approach for now" or "it seems you're not quite sure what to do, but what might be your options?" Then, "well have you thought of trying one of those?"

Clearly, if the patient was considering something the therapist considered dangerous the patient should be advised to discuss it with their treating doctor as the therapist could say they were concerned about that particular proposal.

The three sessions can be given a form of structure to promote the sense that they are planned and purposeful. Thus, the initial 10-15 minutes can be focused on the patient's experiences with their back since the last sessions. Then anything coming out of that could be discussed further (eg. if the patient has been concerned about reactions by work-mates or friends to their back pain then these matters could be discussed, again in an interested and empathic manner, but not with the intention of advising the patient on a particular course of action). Alternatively, if nothing particular comes out of the initial discussion, the therapist can move on to 'a suggested topic for today'.

These suggested topics might include:

1. Impact of back pain on daily activities/chores, hobbies, sports, etc.
2. Reactions of family, friends, work-mates to their back pain.
3. Experiences of dealings with medical practitioners and other health care providers in relation to their pain.
4. Possible impact of other events on their back pain (eg, stresses, family, activities, weather, work, travelling, household chores, work demands).

To end the sessions, the therapist should try to do this as politely as possible. Remember, the therapist is trying to sound as interested in and empathic with the patient as possible. Thus, the end of the session could be introduced along the lines of: "well, <I guess or I'm sorry but> that's all we have time for today. In our next session I would like to look at xxxx".