PHYSIOTHERAPY AND LOW BACK PAIN - PART 1: OUTCOMES RESEARCH IN THE QUEST FOR EVIDENCE

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ABSTRACT: *Low back pain (LBP) is one of the most common and costly conditions treated by physiotherapists and is acknowledged as a major health problem. Much published research on LBP is of poor design and optimal outcome measures are not selected for LBP patients. Effective and cost-effective interventions for LBP, particularly chronic LBP, need to be identified using appropriate, valid, reliable and responsive measures of outcome. These outcome measures should reflect the biopsychosocial model necessary for evaluating the broad impact of LBP, in particular chronic LBP, on a patient's life. Outcomes research is a feasible and affordable analysis of clinical practice as it occurs, and provides an opportunity to evaluate the effectiveness of interventions for LBP. This is in contrast to a randomised, controlled trial (RCT) that evaluates efficacy under controlled conditions that often do not reflect clinical practice. Using a battery of outcome measures appropriate for measuring change in the LBP population, outcomes research has the potential to identify effective and cost-effective interventions, promote and influence further research, and contribute to the demand for evidence-based practice.*

KEY WORDS: LOW BACK PAIN, OUTCOMES RESEARCH, EVIDENCE-BASED PRACTICE, OUTCOME MEASURES, BIOPSYCHOSOCIAL MODEL, EFFECTIVENESS, EFFICACY

INTRODUCTION

Low back pain (LBP) is the most common diagnosis for which patients are treated in outpatient physiotherapy settings (Jette and Davis 1991), and 70%-80% of people in Western society have at least one episode of LBP in a lifetime (Biering-Sorensen 1983). It is a well-known major health problem that causes the greatest disability in patients under the age of 45 years (Deyo 1983), as well as the greatest disability in role function (Jette and Jette 1996). With high prevalence and recurrence rates (Croft et al 1997; Taimela et al 1997), it has enormous implications for health-care. Furthermore, there appears to be an associated increase in chronic incapacity and up to 35% of those with LBP develop a chronic problem (Taimela et al 1997), which further adds to the burden of providers and purchasers of health-care. Thus LBP, in particular chronic/recurrent low back pain (CLBP), is a growing problem that places increasing demands on health budgets and has raised questions about the validity of current treatments (Waddell 1998).

Much of the published research on therapies for LBP is flawed by poor design and suboptimal outcome measures (Hoffmann et al 1994). Outcomes research has emerged from a growing concern about which medical treatments work best and for whom (Andersson & Weinstein 1994), and it is a focus of attention which the physiotherapy profession needs to acknowledge and address. Outcomes research is an analysis of clinical practice as it actually occurs for the purpose of determining effectiveness of clinical methods (Domholdt 2000). This research is affordable, highly feasible in the clinical situation and has the potential to improve the quality of research into the clinical management of LBP. It would appear to be a valuable tool in determining the best use of limited resources for the management of a condition that places enormous demands on health-care budgets. Applied in the clinical situation, outcomes research has the potential to play a role in evaluating whether beneficial outcomes are due to physiotherapeutic interventions (Bardin 1998), or to time, chance or coincidental occurrences (Twomey 1990). Furthermore, the results and conclusions from outcomes research are likely to contribute to further research questions, the formulation of hypotheses and the planning of randomised, controlled trials (RCT's) currently regarded as the gold standard of evidence and the only 'scientific' way of providing evidence of effective intervention and management (Mawson 2002).

OUTCOMES RESEARCH AND EVIDENCE-BASED PRACTICE

Although RCTs are regarded as the most robust form of evidence (Sackett et al. 1996), it has been suggested that they are not a universally attainable or even desirable gold standard of evidence in physiotherapy (Bithell 2000). They may also not be suitable for rehabilitation (Mawson 2002), which is highly relevant in the approach to management of CLBP (Bardin 1998 and 2000b). The Research Committee (Victorian Branch) of the Australian Physiotherapy Association (1999) recently advocated that

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the use of evidence concerning efficacy derived under the restricted, experimental conditions of a RCT requires clinical skill, judgement and experience for application to individual patients. Because of the large number of variables that can impact on a clinical intervention, the RCT may not always be the best methodology for evaluating the efficacy of many of the modalities and multimodalities used in clinical practice (Moore and Petty 2001). It has been suggested that within the chronological growth of the health professions, evidence-based practice is still in it's infancy (Moore and Petty 2001). The RCT is at the top of the hierarchy of evidence, which ranges from clinical experience up to systematic review of RCTs (Fig.1). It has further been suggested that there is a paradox regarding the RCT. It is recognised as the best way to assess whether an intervention works, but is arguably the worst way to assess who will benefit from it (Mant 1999).

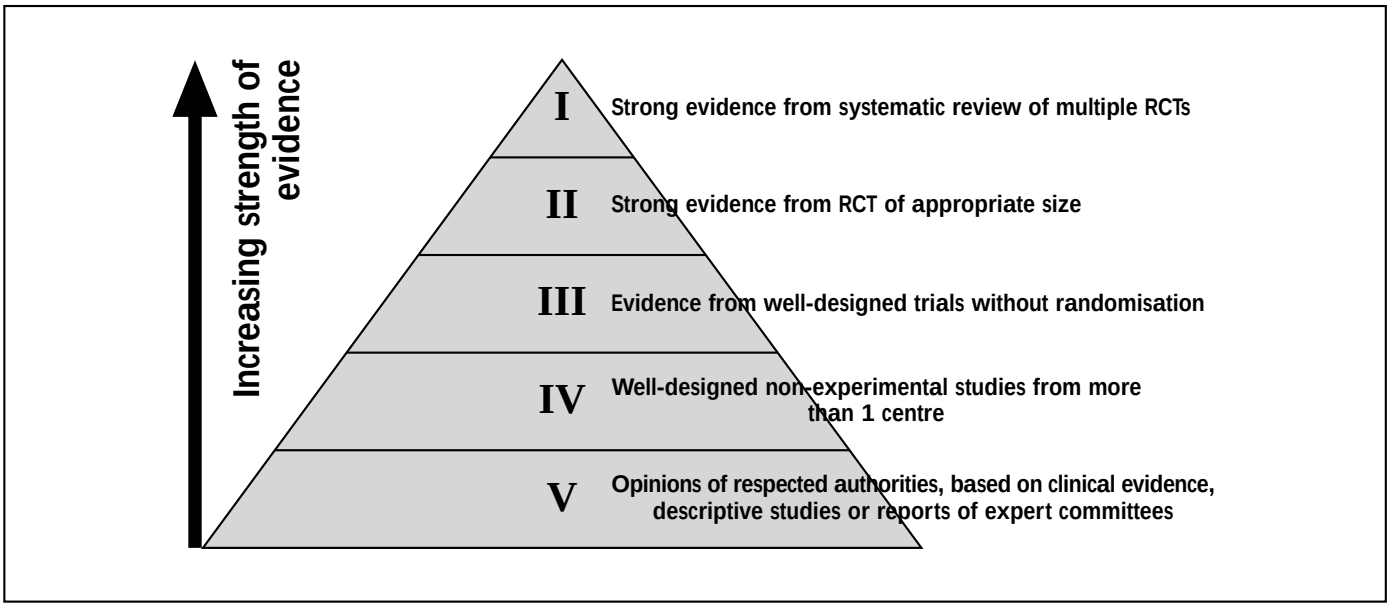
Few RCTs exist in the evaluation of orthopaedic procedures as ethical and practical issues limit the possibility of randomisation. Outcomes research is an alternative clinical investigation where the balance of rigour and relevance is more easily attained. Liang et al (1994) defined outcomes research as research on the management of patients that asks what treatment is effective, and for whom, in more realistic settings than ones used in RCTs. Outcomes research provides a feasible analysis of clinical practice as it occurs (Bardin 2000a). Domholdt (2000) suggests that research questions should arise from problems experienced in the clinical practice of physiotherapy. Outcomes research can be conducted in everyday clinical physiotherapy settings and, prospectively planned, is well suited to raise and explore various aspects of clinical research that can contribute to the body of evidence from grade V to III levels (Fig. 1).

In the quest for credibility of the value of treatment for LBP, the role of outcomes research should be considered, possibly as a forerunner to develop research questions, to test hypotheses and to refine aspects of the research process. Preliminary research using the outcomes research model should have the potential to improve the quality of research implemented in RCTs, which are often difficult and expensive to conduct. In spite of difficulties in the application of the evidence of efficacy (Australian Physiotherapy Association, Victorian Branch 1999) and of to whom to apply treatment, the RCT is likely to continue to be acknowledged as the highest level of evidence. For this reason it is of cardinal importance that future protocols for this rigorous research are based on appropriate preliminary research, of which outcomes research is one example. It would appear that outcomes research has a significant role to play in our endeavours to refine the quality of scientific inquiry into the effective management of LBP.

MEASURING THE OUTCOME AND ASSESSING EFFECTIVENESS

Physiotherapists need to adopt outcome measures that will document effectiveness of interventions and guide clinical decisions and management. In outcomes research effectiveness is the usefulness of a particular treatment to the individual(s) receiving it, under typical clinical conditions usually determined by nonexperimental methods (Domholdt 2000). In contrast, clinical efficacy is the biological effect of treatment under carefully controlled conditions, usually determined by RCT. Measuring the effectiveness of our treatments is vital to the survival of the physiotherapy profession and to satisfy the demands for evidence-based practice. It is only possible if we measure change by careful documentation of the outcome of care provided in clinical practice. Although it has been suggested that evidence-based physiotherapy is possibly seeking the unattainable (Clemence 1998), the pursuit of best evidence is of paramount importance to our future credibility. It is not optional if the profession is to compete in the health-care arena for the provision of evidence-based treatments

Figure 1: Hierarchy of evidence ranging from clinical experience up to systematic review of RCTs. A broad contribution from levels V - III is possible through outcomes research. (Modified from Moore and Petty 2001)



for LBP. Outcomes research using appropriate outcome measures in a typical clinical setting is attainable, affordable and should provide a measure of evidence. It will undoubtedly emphasise accountability for standards of care and selection of treatment intervention, and is likely to promote and influence further research.

What is an outcome measure?

Broadly speaking, an outcome measure quantifies a change in the patient's status over time (Kane 1994), and makes it possible to examine the end results of health-care and the effects of the health care process on the well-being of either individual patients or whole populations (Andersson and Weinstein 1994). It has also been described as a measure of change, the difference from one point in time (usually before an intervention) to another point in time (usually following an intervention) (Kendall 1997). Mayo et al (1994) further specify a physiotherapy outcome measure as a test or scale, administered and interpreted by physiotherapists, that has been shown to measure accurately a particular attribute of interest to patients and therapists and is expected to be influenced by the intervention.

Purpose of outcome measures

The physiotherapy profession is being challenged to record the outcome of care provided to patients. The purpose of using outcome measures is an attempt to define closely the subjective and objective information we usually record, but in a more robust manner (Hammond 2000). This can be achieved by the use of appropriate and valid outcome measures which, by providing reliable documentation, will guide clinical decisions, treatment planning and prove effectiveness of interventions in a clinical setting (Bardin 1998).

Measuring outcomes enables the clinician to determine:

- The impact of an overall treatment on an individual
- The impact of a specific treatment approach on an individual
- The overall impact of care on all clients within a programme
- Productivity - i.e. the relationship between resources used and treatment outcomes is assessed in order to evaluate the effectiveness and efficiency of the service provided

It has been suggested that, in order to assess progress in patient management, important outcomes to measure are those of pain relief and disability (Liebenson and Yeomans 1997). Reduction in LBP, improvement in function and prevention of disability are core aspects of physiotherapy management of LBP. It is important for the credibility of our management approach to LBP that we measure the effect of our treatments on these outcomes.

Selection of outcome measures

Outcome measures should be clinically appropriate, functionally relevant, valid, reliable and responsive to clinical change (Schoppink et al 1996; Bardin 1997; Bardin 1998). Pain scales useful in the clinical situation, for example, are the Numerical Rating Scale, Visual Analogue Scale and McGill Pain Questionnaires (MPQ) (long- and short-forms) (Jensen et al 1986; Melzack 1975). The Roland Morris Disability Questionnaire (Roland and Morris 1983), Aberdeen Back Pain Scale (Ruta et al 1994) and Oswestry Disability Questionnaire (Fairbank et al 1980) for pain and functional impairment/disability, and the condition-specific functional status questionnaire for lumbar spinal stenosis (Stucki et al 1996) are examples of questionnaires measuring the broad biopsychosocial impact of interventions for LBP. Bouter et al (1998) suggest that researchers identify the factors to be measured and measure them with high-quality, standardised parameters with explicit instructions for administration and scoring. This will enable practitioners to make comparisons about the health status of patients at the end of their intervention. Several authors suggest that outcome measures need to be inexpensive and time-efficient to minimize the burden to health professionals and patients (Liebenson and Yeomans 1997; Deyo et al 1998; Wright et al 1998), while Hammond (2000) is of the opinion that in order to be acceptable to patients they should be comfortable and painless. **A spectrum of outcomes measures reflecting the biopsychosocial model will be reviewed in Physiotherapy and low back pain: Parts II and III.**

OUTCOMES RESEARCH IN THE ASSESSMENT OF THE QUALITY OF HEALTH CARE

Outcomes research is a focus of attention on the assessment of health-care quality that the physiotherapy profession needs to acknowledge and address. It has emerged from a growing concern about which medical treatments work best and for whom (Andersson and Weinstein 1994), and will assist analysis of the relative effectiveness and cost-effectiveness of different interventions for LBP. Furthermore it should facilitate physiotherapists to identify subgroups to be treated (Bardin 1998 and 2000c; O'Sullivan 2000), and to provide purchasers of health-care with evidence of effectiveness (Chesson et al 1996; Watson 1999).

Health-care consumers want evidence of effectiveness when choosing what to purchase. In the context of cost containment, there is a need to analyse the relative effectiveness of different interventions especially for recurrent/chronic LBP (Bardin 1998 and 2000b).

Outcomes research will facilitate the practice of outcomes management which relies on an analysis of outcomes to examine the cost and quality of health-care. These two inter-related issues are of great interest to clinicians as well as to government health departments, insurance departments, insurance companies and consumers. Outcomes management offers great potential for identifying client needs, improving outcomes, utilising evidence-based treatments and allocating scarce resources (Hazard 1995; Mayer et al 1995; Bardin 1998), and is considered a crucial component in promoting quality without sacrificing cost.

Outcomes research, as defined by Liang et al (1994), focuses on investigating what treatments are effective in realistic clinical settings (in contrast to RCTs) and for which groups of patients. These researchers suggest that the emphasis should be on the patient's assessment of pain, function, quality of life and satisfaction with the results of the intervention. Outcomes research can be described as research that evaluates the broad biopsychosocial impact of

treatments implemented in typical clinical settings (Keller et al 1994; Bradham 1994; Bardin 2000a). This is in sharp contrast to a clinical efficacy study where the biological effect of treatment is monitored under the carefully controlled conditions possible with laboratory research. A recent study by Bardin (1998 and 2000b) is an example of outcomes research. This research included inter alia patients' assessments, as suggested by Liang et al (1994), to evaluate the effectiveness of a spinal rehabilitation programme utilising patient education and group exercises for the treatment of selected patients with chronic/recurrent LBP. Results from this study showed significant reduction in pain and handicap, as well as significant improvement in function and flexibility following patient participation over a one-month period. Importantly, these improvements in outcomes were significantly maintained at the three and six month follow-ups and there was an exceptionally high (91%) level of patient satisfaction with this cost-effective approach to the management of CLBP. Domholdt (2000) suggests that in outcomes research practitioners and researchers supplement measures of pathology and impairment with person-level measures of functional limitation, disability or handicap. This type of research is feasible in most clinical situations and is necessary to determine a valid approach to the management of LBP, particularly CLBP. In a study on the outcome of 438 patients treated surgically for lumbar spinal stenosis, the authors acknowledged that the most important shortcoming of their study was that the initial levels of the patients' pain, depression and disability were not known (Olavi et al 1997). This acknowledged shortcoming illustrates that prospectively planned documentation of outcomes is essential if we are to gather even lower levels of evidence, without which the higher levels may not achieve an appropriate focus of inquiry.

Outcomes research is a feasible, affordable analysis of the outcome of health-care that utilises measures reflecting the biopsychosocial model necessary for evaluating the impact of LBP, in particular CLBP, on a patient's life. Outcome measures that reflect the biopsychosocial model are important to evaluate change in LBP patients (Bardin 1998; Cherkin 1998; Deyo et al 1998) as objective outcome measures related to the biological component have been found to be only weakly correlated with patient behaviour or symptoms. Health related quality of life measures, which assess multiple dimensions of life, are thought to be an inexpensive, valuable source of quantitative data for quality assurance and research of the CLBP patient.

The physiotherapy profession should respond positively to the challenge of analysing the quality of our care for acute and chronic LBP patients. Outcomes research is feasible and affordable. It should be enthusiastically embraced as an opportunity to demonstrate our scientific foundations, to promote quality of care and to provide a necessary and valuable contribution to our quest for evidence-based practice.

CONCLUSION

The high prevalence, recurrence rates and enormous cost to society of LBP, particularly CLBP, places a responsibility on the physiotherapy profession to provide evidence for management approaches to LBP patients and for effectiveness of interventions. In the quest for evidence, physiotherapists can utilise outcomes research - an analysis of clinical practice that focuses on patients' assessments of pain, function, quality of life and satisfaction with the results of the intervention. Prospectively planned documentation of outcomes using valid, reliable and responsive outcome measures is necessary to provide evidence of effectiveness, and to contribute to further research in the field of LBP. These outcome measures should be clinically appropriate, functionally relevant and reflect the broad biopsychosocial impact occurring in the LBP patient as a result of this disabling condition. The RCT, conducted under controlled conditions, is the highest form of evidence, however treatment under these conditions often does not reflect clinical practice and the application of evidence may be difficult. The role of outcomes research to assess health-care, to evaluate effectiveness and cost-effectiveness, and to promote further research and scientific inquiry should be considered. It is a feasible and affordable option to complement RCTs in the demand for evidence-based practice. Outcomes research of LBP is an important aspect of clinical practice that will assist the physiotherapy profession to meet the demand for evidence-based practice, to demonstrate our scientific foundations and to validate that this profession has now come of age.

REFERENCES

Andersson GBJ, Weinstein JN 1994 Outcomes related to low back pain. Spine 19: 2026S - 2027S

Australian Physiotherapy Association, Victorian Branch Research Committee and invited contributors 1999. Evidence-based practice. Australian Journal of Physiotherapy 45: 167- 171

Bardin LD 1997 Outcome measurements in spinal rehabilitation - a case report. Proceedings of International congress of South African Society of Physiotherapy, Cape Town, South Africa, April 1997

Bardin LD 1998 A study to evaluate the effectiveness of a total back care programme for group rehabilitation of selected patients with chronic low back pain. MSc thesis, University of Stellenbosch, South Africa

Bardin LD 2000a Outcomes research of a spinal rehabilitation programme for chronic/ recurrent low back pain. Proceedings of the South African Spine Society Congress, Cape Town, June 2000

Bardin LD 2000b A Spinal Rehabilitation Programme for selected patients with recurrent/chronic low back pain: a one year prospective study. Proceedings of the 7th Scientific Conference of the International Federation of Orthopaedic Manipulative Therapists, Perth, Australia, November 2000

Bardin LD 2000c Spinal rehabilitation of chronic low back pain using patient education and group exercise therapy. Course manual, pre-conference course, 7th Scientific Conference of the International Federation of Orthopaedic Manipulative Therapists, Perth, Australia, November 2000

Biering-Sorensen F 1983 A prospective study of low back pain patients in a general population: I. Occurrence, recurrence and aetiology.

Scandinavian Journal of Rehabilitation Medicine 15: 71-79

Bithell C 2000 Evidence-based physiotherapy. Physiotherapy 86: 58 - 60

Bouter LM, van Tulder M, Koes B 1998. Methodologic Issues in Low Back Pain Research in Primary Care. Spine 23: 2014 - 2019

Bradham DD 1994 Outcomes research in orthopaedics: history, perspectives, concepts and future. Arthroscopy 10: 493 - 501

Cherkin DC 1998 Primary Care Research on Low Back Pain. Spine 23: 1997-2002

Chesson R, Macleod M, Massie S 1996 Outcome measures used in therapy departments in Scotland. Physiotherapy 82: 673-679

Clemence ML 1998 Evidence-based physiotherapy: seeking the unattainable? British Journal of Therapy and Rehabilitation 5: 257-260

Croft PR, Papageorgiou AC, McNally R 1997 Low back pain: Healthcare needs assessment. Radcliffe Medical Press, Oxford

Deyo RA 1983 Conservative therapy for low back pain: distinguishing useful from useless therapy. Journal of the American Medical Association 250: 1057-1062

Deyo RA, Battie M, Beurskens AJHM, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G 1998 Outcome Measures for Low Back Pain Research: a proposal for standardised use. Spine 23: 2003-2013

Domholdt E 2000 Physical Therapy Research. WB Saunders, Philadelphia

Fairbank J, Couper J, Davies JB, O'Brien JP 1980 The Oswestry low back pain questionnaire. Physiotherapy 66: 271-273

Hammond R 2000 Evaluation of physiotherapy by measuring outcome. Physiotherapy 86: 170-172

Hazard RG 1995 Spine update: functional restoration. Spine 20: 2345-2348

Hoffmann RM, Turner JA, Cherkin DC, Deyo RA, Herron LD 1994 Therapeutic trials for low back pain. Spine 19: 2068S - 2075S

Jensen MP, Karoly P, Braver S 1986 The measurement of clinical pain intensity: a comparison of six methods. Pain 27: 117-126

Jette AM, Davis KD 1991 A comparison of hospital-based and private outpatient physical therapy practices. Physical Therapy 74: 366-375
Jette DU, Jette AM 1996 Physical therapy and health outcomes in patients with spinal impairments. Physical Therapy 76: 930-945

Kane R 1994 Looking for physical therapy outcomes. Physical Therapy 74: 425-429

Keller RB, Rudicel SA, Liang MH 1994 Outcomes research in orthopaedics. Instructional course lectures 43: 599 - 611

Kendall N 1997 Developing outcome assessments: A step-by-step approach. New Zealand Journal of Physiotherapy, December 11-17

Liang MH, Andersson GBJ, Bombardier MD, Cherkin DC, Deyo MD 1994 Strategies for outcomes research in spinal disorders. Spine 19: 2037S-2040S

Liebenson C, Yeomans S 1997 Outcomes assessment in musculoskeletal medicine. Manual Therapy 2: 67 - 74

Mant D 1999 Can randomised trials inform clinical decisions about patients? Lancet 353: 743-746

Mawson S 2002 Teler versus MAS: validating TELER indicator definitions for use in the measurement of physiotherapy outcomes in acute stroke rehabilitation. Physiotherapy 88: 67-76

Mayer TG, Polatin P, Smith B 1995 Contemporary concepts in spine care: spine rehabilitation- secondary and tertiary non-operative care. Spine 20: 2060-2066

Mayo N, Cole B, Dowler J, Gowland C, Finch E 1994 Uses of outcome measures in physiotherapy: Survey of current practice. Canadian Journal of Rehabilitation 81:82

Melzack R 1975 The McGill Pain Questionnaire: major properties and scoring methods. Pain 277-299

Moore A and Petty N 2001 Evidence-based practice - getting a grip and finding a balance. Manual Therapy 6: 195-196

Olavi A, Arto H, Veli T, Tapani S, Olavi S 1997 Surgical outcome of 438 patients treated surgically for lumbar spinal stenosis. Spine 22: 2278-2282

O'Sullivan PB 2000 Lumbar segmental 'instability': clinical presentation and specific stabilising exercise management. Manual Therapy 5: 2-12

Roland M, Morris R 1983 A study of the natural history of low back pain: I Development of a reliable and sensitive measure of disability in low back pain. Spine 1983: 141-144
Ruta DA, Garratt AM, Wardlaw D, Russell IT 1994 Developing a valid and reliable measure of health outcome for patients with low back pain. Spine 19: 1887-1896

Sackett DL, Rosenberg WMC, Gray JAM, Haynes BR, Richardson WS 1996 Evidence based medicine: what it is and what it isn't. British Medical Journal 312: 71-72

Schoppink LEM, Van Tulder HW, Koes BW, Behrskens SAJHM, De Bie RA 1996 Reliability and validity of the Dutch adaptation of the Quebec Back Disability Scale. Physical Therapy 76: 268 - 275

Stucki G, Daltroy L, Liang M, Lipson S, Fossel A, Katz JN 1996 Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. Spine 21: 796-803

Taimela S, Kujala UM, Salminem JJ, Viljanen T 1997 The prevalence of low back pain among children and adolescents: A nationwide, cohort-based questionnaire survey in Finland. Spine 22: 1132-1136

Twomey L 1990 A growing commitment to research and evaluation. Australian Journal of Physiotherapy 36:83.

Waddell G 1998 The Back Pain Revolution, Churchill Livingstone, London.

Watson PJ 1999 Psychosocial Assessment. Physiotherapy 85: 530-535

Wright J, Cross J, Lamb S 1998 Physiotherapy outcome measures for rehabilitation of elderly people. Physiotherapy 84: 216-221