Physiotherapy Interventions for Low Back Pain

- Subgrouping Patients with Improved Efficacy

Raymond Tsang
SPT, QMH
FHKCOP
24 April 2010

Background

- **Low back pain (LBP) is a common condition encountered by orthopaedic surgeons, pain specialists, physiatrists and physiotherapists in acute orthopaedic wards and out-patient clinics**
- **LBP is the "most frequently reported acute condition second only to common cold/influenza-like illness" in Hong Kong (Population Health Survey 2003/04)**

Table 1: People aged 15 and above reported that they had low back pain in one month before enumeration by sex, age group and occupation

	Number ('000)	Rate*
Sex		
Male	550.8	21.4
Female	998.9	32.1
Age group		
15-24	137.5	15.3
25-34	242.5	26.3
35-44	353.9	27.2
45-54	393.0	34.5
55-64	177.4	27.9
65 and above	245.4	31.1
Occupation#		
Managers and administrators	70.0	29.9
Professionals/Associated professionals	115.3	27.2
Clerks	199.8	30.0
Service workers or shop sales workers	163.9	22.9
Craft and related workers	42.2	22.6
Plant and machine operators and assemblers	74.6	30.9
Non-skilled workers	130.2	30.4
Retirees	237.1	30.7
Unemployed	67.4	23.8
Full-time students	64.0	11.4
Home-makers	351.8	33.6
Unknown/missing	32.6	26.8

Notes :* Rate per 100 population in the respective sex / age group / occupation.
Statistics for skilled agricultural and fishery workers were not released due to small sample size which is subject to large sampling errors.
Source: Population Health Survey 2003/04.

(Population Health Survey 2003/04, HKSAR)

Classification

According to duration of onset of LBP

- **Acute – < 6 weeks**
- **Subacute – 6 to <12 weeks**
- **Chronic - 12 weeks or more**

Classification

According to identifiable causes

- **Non-specific LBP (majority)**
- **Specific LBP**
  - **Fracture, infection, cauda equina syndrome, tumours (serious pathologies)**
  - **Spinal stenosis, spondylolisthesis, spondylolysis, disc prolapse, inflammatory disorders …**

Impact

In developed countries, LBP as

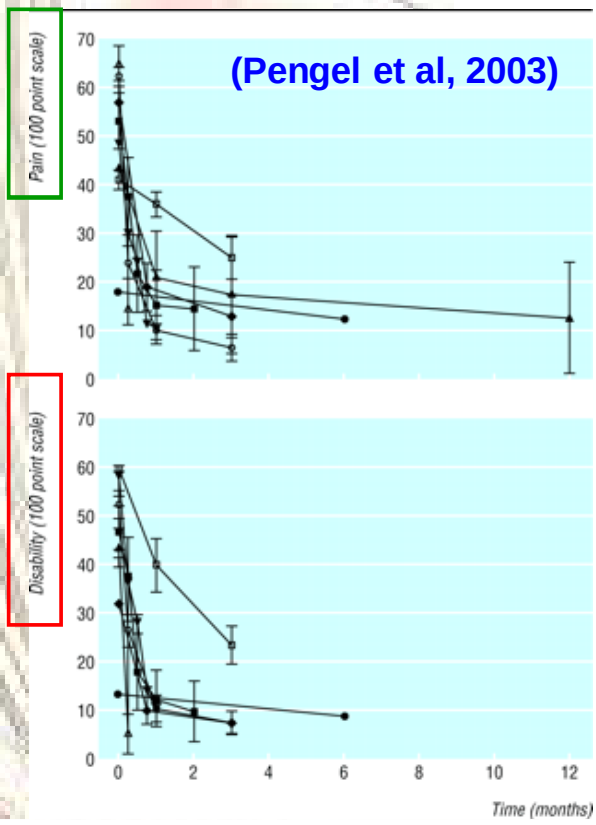
- **most frequent occupational problem with an estimated 2-5% of people having chronic LBP**
- **most frequent activity-limiting complaint in young & middle aged**
- **second leading cause of sick leave**

(Hoy et al, 2010)

Prognosis

- Acute LBP has good prognosis
- Pooled mean reduction of 58% of initial scores in pain and disability within one month

(Pengel et al, 2003)



Prognosis

- However, 1/4 to 1/3 people with acute LBP still have symptoms 6-12 months after a consultation (Hayden et al, 2010)
- Recurrence is common – approximately 60% people experience relapses of pain and 30% have repeated episodes of work absence (Hestbaek et al, 2003)

Interventions

- Non-operative interventions for non-specific LBP
  - Advice to stay active
  - Exercise therapy
  - Analgesia (paracetamol, NSAIDs, muscle relaxants)
  - Epidural steroids
  - Spinal manipulation
  - Back schools

(van Tulder et al, 2006)

Interventions

- Non-operative interventions for non-specific LBP
  - Behavioural therapy
  - Traction
  - Massage therapy
  - TENS

(van Tulder et al, 2006)

- Operative interventions for some specific LBP

Evidence Review

Assendelft WJJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low-back pain. *Cochrane Database of Systematic Reviews* 2004, Issue 1.

- **Main Results:** Thirty-nine RCTs were identified. Meta-regression models were developed for acute or chronic pain and short-term and long-term pain and function. For patients with acute low-back pain, spinal manipulative therapy was superior only to sham therapy (10-mm difference [95% CI, 2 to 17 mm] on a 100-mm visual analogue scale) or therapies judged to be ineffective or even harmful.

Evidence Review

Assendelft WJJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low-back pain. *Cochrane Database of Systematic Reviews* 2004, Issue 1.

- **Main Results:** Spinal manipulative therapy had no statistically or clinically significant advantage over general practitioner care, analgesics, physical therapy, exercises, or back school. Results for patients with chronic low-back pain were similar.
- **Authors' Conclusion:** There is no evidence that spinal manipulative therapy is superior to other standard treatments for patients with acute or chronic low-back pain.

Evidence Review

Hayden J, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 3.

- **Main Results:** Sixty-one randomized controlled trials (6390 participants) met inclusion criteria: acute (11), subacute (6) and chronic (43) low-back pain (1 unclear). Evidence was found of effectiveness in chronic populations relative to comparisons at all follow-up periods; pooled mean improvement was 7.3 points (95% CI, 3.7 to 10.9) for pain (out of 100), 2.5 points (1.0 to 3.9) for function (out of 100) at earliest follow-up.

Evidence Review

Hayden J, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 3.

- **Main Results:** In studies investigating patients (i.e. presenting to healthcare providers) mean improvement was 13.3 points (5.5 to 21.1) for pain, 6.9 (2.2 to 11.7) for function, representing significantly greater improvement over studies where participants included those recruited from a general population (e.g. with advertisements).

Evidence Review

Hayden J, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 3.

- **Main Results:** **There is some evidence of effectiveness of graded-activity exercise program in subacute low-back pain in occupational settings, though the evidence for other types of exercise therapy in other populations is inconsistent. There was evidence of equal effectiveness relative to comparisons in acute populations [pain: 0.03 points (95% CI, -1.3 to 1.4)].**

Evidence Review

Hayden J, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 3.

- **Authors' Conclusion:** **Exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic low-back pain, particularly in healthcare populations. In subacute low-back pain there is some evidence that a graded activity program improves absenteeism outcomes, though evidence for other types of exercise is unclear. In acute low-back pain, exercise therapy is as effective as either no treatment or other conservative treatments.**

Lack of Evidence

- Lack of evidence of some common non-operative interventions (e.g. exercise therapy) can partly be explained by
  - Lack of high-quality RCTs (i.e. poor methodological quality of trials)
  - the "false assumption that sufferers of LBP are a homogeneous group" (Ford et al, 2007, p.33)

Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

- To specify a theoretical framework for exercise therapy for designing intervention and selecting appropriate treatment efficacy measures;
- To overcome blinding problems;
- To evaluate role of patient-provider interactions

Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

- **To assure quality of treatment, and use of exercise interventions that reference existing exercise guidelines;**
- **To use subgroup analyses to identify subgroups of patients most likely to benefit;**

Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

- **To report detailed description of study population, exercise protocol, and measure of patient compliance;**
- **To further categorize exercise interventions in terms of concept, mode, intensity, duration, frequency, and length**

Subgrouping

- **"If patients could be subdivided into groups based on the nature of physical, psychological, and/or organizational barriers to recovery, matching them to appropriate interventions may improve outcomes and reduce overall costs."**
  (Helmhout et al, 2008)
- **Identification of subgroups that are responders to specific treatment**

Treatment Effect Modifiers

- **"Characteristics that identify subgroups of patients who respond differently to a specific intervention"**
  (Hancock et al, 2009)
- **3 stages of developing treatment-based subgroups (Kamper et al, 2010):**
  - **Hypothesis generation**
  - **Hypothesis testing**
  - **Replication and generalization**

Hypothesis Generation

- Aim: identify a small number of variables (treatment effect modifiers) to define a subgroup and a plausible reason as to why this subgroup would respond to a particular treatment
- Methods: variables may be identified via: previous research; biological rationale; clinical lore

Hypothesis Testing

- Aim: evaluate whether subgroups patients defined by the candidate variable respond differently to a particular treatment
- Methods: randomized controlled trial with attention to: pre-specified analyses; adequate power; limited number of comparisons; appropriate analysis (interaction tests)

Replication & Generalization

- **Aim: Confirm the results found in the previous stage (replication) and test the extent to which they will hold outside the conditions of the original RCT (generalization)**
- **Methods: Repeat of RCT as above. Replication: similar – patients, setting, therapists, interventions.**

  Generalization: slightly different – patients, setting, therapists, interventions.

An Example – Manipulative Therapy

Hypothesis Generation

SPINE Volume 27, Number 24, pp 2835–2843

A Clinical Prediction Rule for Classifying Patients with Low Back Pain Who Demonstrate Short-Term Improvement With Spinal Manipulation

Timothy Flynn, PT, PhD,*‡ Julie Fritz, PT, PhD,† Julie Whitman, PT, DSc,‡ Robert Wainner, PT, PhD,*‡ Jake Magel, PT, DSc,‡ Daniel Rendeiro, PT, DSc,‡ Barbara Butler, PT,‡ Matthew Garber, PT, DSc,‡ and Stephen Allison, PT, PhD*

(Flynn et al, 2002)

An Example – Manipulative Therapy

Hypothesis Generation

- Study design – prospective cohort study of patients with nonradicular LBP
- Subjects – 71 subjects completing study, 41% were female; mean age=37.6 ± 10.6y; mean baseline ODI score=42.4 ± 11.7
- Assessment – history & physical examination (special tests for SIJ dysfunction), NPRS, pain diagram, Modified ODI, FABQ

(Flynn et al, 2002)

An Example – Manipulative Therapy

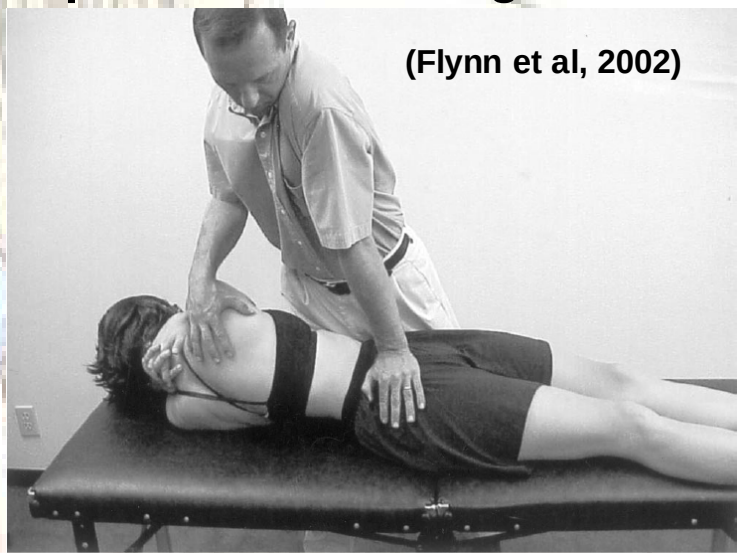
Hypothesis Generation

- Treatment – passive trunk rotation with posterior & inferior quick thrust through ASIS

Other Rx:

•Supine pelvic tilt exercises 10X; 3-4 sessions per day

•Maintain usual activity



(Flynn et al, 2002)

An Example – Manipulative Therapy

Hypothesis Generation

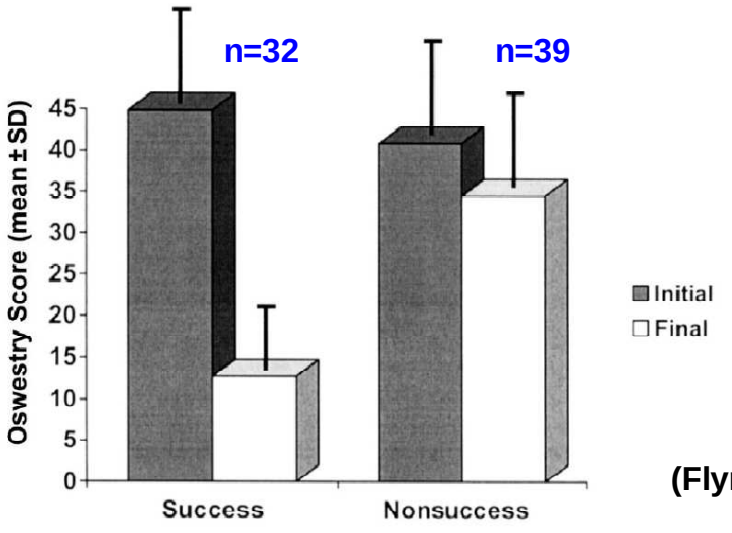
- Treatment – a maximum of 3 sessions within 2 weeks
- Treatment success - >50% reduction of baseline ODI score
- Treatment non-success - ≤50% reduction of baseline ODI score

(Flynn et al, 2002)

An Example – Manipulative Therapy

Hypothesis Generation

- Results



(Flynn et al, 2002)

Figure 2. Initial and final Oswestry scores for the success and nonsuccess groups. The mean percent change in the success group was 73.2 ± 15.8%. For the nonsuccess group, the mean percent change was 14.6 ± 18.2%.

An Example – Manipulative Therapy

Hypothesis Generation

- **Results – 5 variables among 11 potential predictors able to predict treatment success in logistic regression:**
  - **Duration of symptoms <16 days**
  - **At least one hip with >35^0 internal rotation**
  - **Hypomobility with lumbar spring testing**
  - **FABQ work subscale score <19**
  - **No symptoms distal to knee**

(Flynn et al, 2002)

- **Presence of ≥4 variables increased likelihood of success with manipulation from 45% to 95% (+ve LR=24.4, 95% CI 4.6 to 139.4)**

An Example – Manipulative Therapy

Hypothesis Testing

A Clinical Prediction Rule To Identify Patients with Low Back Pain Most Likely To Benefit from Spinal Manipulation: A Validation Study

Maj John D. Childs, PhD, PT; Julie M. Fritz, PhD, PT; Timothy W. Flynn, PhD, PT; James J. Irrgang, PhD, PT; Maj Kevin K. Johnson, PT; Maj Guy R. Majkowski, PT; and Anthony Delitto, PhD, PT

Ann Intern Med. 2004;141:920-928.

(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

- **Study design – multicentre RCT of patients with nonradicular LBP with ITT analysis**
- **Subjects – 131 subjects completing study, 42% were female; mean age=33.9 ± 10.9y; mean baseline ODI score=41.2 ± 10.4**
- **Randomization**
  - **spinal manipulation + exercise (n=70)**
  - **exercise only (n=61)**

(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

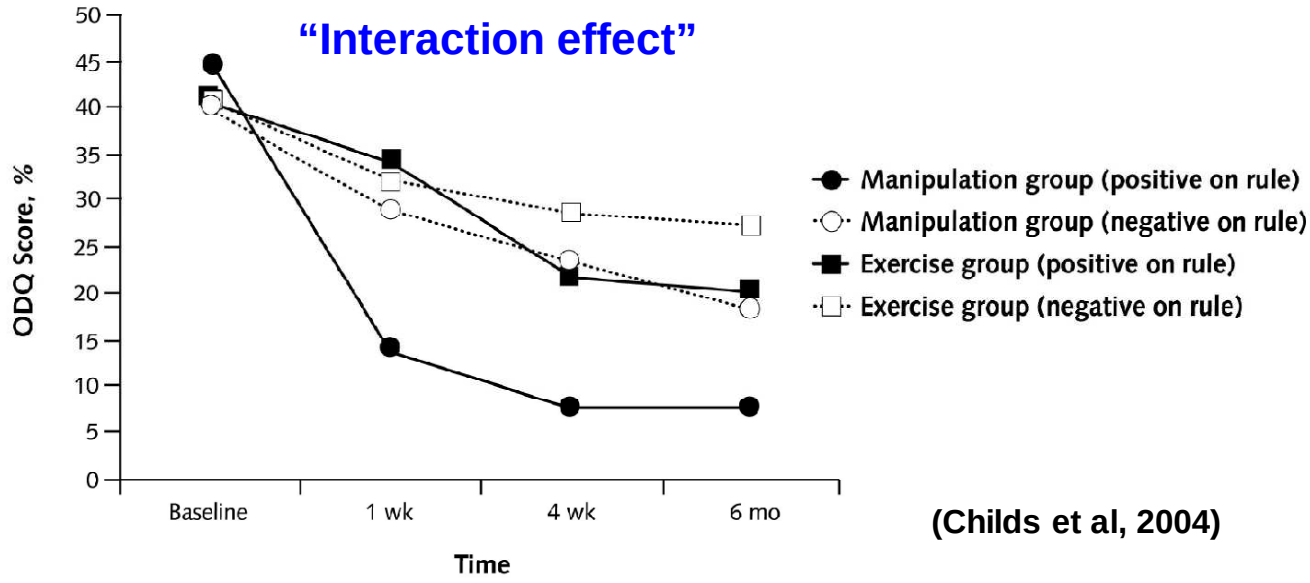
- **Treatment – patients in both groups attended physical therapy 2x in first week and then 1x per week for next 3 weeks, with a total of 5 sessions**
  - **Manipulation group – high-velocity thrust spinal manipulation (same technique used in Flynn et al's study) & ROM exercise**
  - **Exercise group – low-stress aerobic and lumbar spine strengthening programme**

(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

- **Results**



(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

- **Implication – patients were more likely to benefit from spinal manipulation if they met the clinical prediction rule**

(Childs et al, 2004)

Replication & Generalization

- **Studies pending**

Evolution of Treatment-based Subgrouping

4 major subgroups (Hebert et al, 2008)

- **Specific exercise**
  - **Extension**
  - **Flexion**
- **Stabilization**
- **Manipulation**
- **Traction**

Table 1
Subgroups of patients with low back pain with subgroup criteria and treatment approaches

Subgroup	Subgroup criteria	Treatment approach
Specific exercise: extension **(Browder et al, 2007)**	Symptoms distal to the buttock Symptoms centralize with lumbar extension Symptoms peripheralize with lumbar flexion Directional preference for extension	End-range extension exercises Mobilization to promote extension **(PA)** Avoidance of flexion activities
Specific exercise: flexion	Older age (>50 y) Directional preference for flexion Imaging evidence of lumbar spine stenosis	End-range flexion exercises Mobilization or manipulation of the spine and/or lower extremities Exercise to address impairments of strength or flexibility Body weight–supported ambulation

Table 1
Subgroups of patients with low back pain with subgroup criteria and treatment approaches

Stabilization **(Hick et al, 2005)**	Younger age (<40 y) Average straight-leg raise (>91°) Aberrant movement present Positive prone-instability test	Exercises to strengthen large spinal muscles (erector spinae, oblique abdominals) Exercises to promote contraction of deep spinal muscles (multifidus, transversus abdominus)
Manipulation **(Childs et al, 2004; Flynn et al, 2002)**	No symptoms distal to knee Duration of symptoms <16 d Lumbar hypomobility Fear-Avoidance Beliefs Questionnaire for Work <19 Hip internal rotation range of motion >35°	Manipulation techniques for the lumbo-pelvic region Active lumbar range-of-motion exercises

39

Table 1
Subgroups of patients with low back pain with subgroup criteria and treatment approaches

Traction **(Fritz et al, 2007)**	Symptoms extend distal to the buttock(s) Signs of nerve root compression Peripheralization with extension movement; or positive contralateral straight-leg raise test	Prone mechanical traction Extension-specific exercises

40

Evolution of Treatment-based Subgrouping

- Clinical prediction rules for “specific exercise”, “stabilization” and “traction” subgroups would require further hypothesis testing, replication and generalization
- Clinical prediction rules for “manipulation” subgroup would require further replication and generalization

→ to establish sufficient certainty to recommend the incorporation of these prediction rules into clinical practice

Take Home Messages

- Growing evidence exists to support the efficacy of subgrouping patients with non-specific LBP to match with appropriate treatment according to clinical prediction rules to achieve better clinical outcomes
- Future studies should be emphasized to complete the 3 stages of developing treatment-based subgroups

References

- Browder DA, Childs JD, Cleland JA, Fritz JM (2007) Effectiveness of an extension-oriented treatment approach in a subgroup of subjects with low back pain: a randomized clinical trial. *Physical Therapy* 87: 1608-1618.
- Child MJD, Fritz JM, Flynn TW, Irrgang JJ, Johnson MKK, Majkowski MGR, Delitto A (2004) A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Annals of Internal Medicine* 141: 920-928.
- Flynn T, Fritz J, Whitman J, Wainner R, Magel J, Rendeiro D, Butler B, Garber M, Allison S (2002) A clinical prediction rule for classifying patients with low back pain who demonstrate short-term improvement with spinal manipulation. *Spine* 27: 2835-2843.

References

- Ford J, Story I, O'Sullivan P, McMeeken J (2007) Classification systems for low back pain: a review of the methodology for development and validation. *Physical Therapy Reviews* 12: 33-42.
- Fritz JM, Lindsay W, Matheson JW, Brennan GP, Hunter SJ, Moffit SD, Swalberg A, Rodriquez B (2007) Is there a subgroup of patients with low back pain likely to benefit from mechanical traction. Results of a randomized clinical trial and subgrouping analysis. *Spine* 32: E793-E800.
- Hancock M, Herbert RD, Maher CG (2009) A guide to interpretation of studies investigating subgroups of responders to physical therapy interventions. *Physical Therapy* 89: 698-704.
- Hebert J, Koppenhaver S, Fritz J, Parent E (2008) Clinical prediction for success of interventions for managing low back pain. *Clinics in Sports Medicine* 27: 463-479.

References

- Helmhout PH, Staal JB, Maher CG, Petersen T, Rainville J, Shaw WS (2008) Exercise therapy and low back pain: insights and proposals to improve the design, conduct, and reporting of clinical trials. *Spine* 33: 1782-1788.
- Hestbaek L, Leboeuf-Yde C, Manniche C (2003) Low back pain: what is the long-term course? A review of studies of general patient populations. *European Spine Journal* 12: 149-165.
- Hicks GE, Fritz JM, Delitto A, McGill SM (2005) Preliminary development of a clinical prediction rule for determining which patients with low back pain will respond to a stabilization exercise program. *Archives of Physical Medicine and Rehabilitation* 86: 1753-1762.
- Hoy D, March L, Brooks P, Woolf A, Blyth F, Vos T, Buchbinder R (2010) Measuring global burden of low back pain. *Best Practice & Research Clinical Rheumatology* 24: 155-165.

References

- Kamper SJ, Maher CG, Hancock MJ, Koes BW, Croft PR, Hay E (2010) Treatment-based subgroups of low back pain: a guide to appraisal of research studies and a summary of current evidence. *Best Practice & Research Clinical Rheumatology* 24: 181-191.
- Pengel LHM, Herbert RD, Maher CG, Refshauge KM. Acute low back pain: systematic review of its prognosis. *BMJ* 2003; 327: 323.
- Population Health Survey 2003/04. Department of Health and Department of Community Medicine, University of Hong Kong.
- Van Tulder M, Becker A, Bekkering T, Breen, del Real MTG, Hutchinson A, Koes B, Laerum E, Malmivaara A (2006) European guidelines for the management of acute nonspecific low back pain in primary care. *European Spine Journal* 15(Suppl. 2): S169-191.