

**Osteopathic Treatment of Low Back Pain.**  
**A Systematic Review of Randomized Controlled Trials**

by  
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## Approval Page

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## Abstract

**Osteopathic Treatment of Low Back Pain. A Systematic Review of Randomized Controlled Trials.** Angela Bierent-Vass, 2010: Thesis, Post-graduate School of Osteopathic Clinical Research, A.T. Still University of Health Sciences./M.Sc./Osteopathic Clinical Research.

**Background:** Low back pain is one of the most common health problems. It is a disabling disorder that greatly affects western societies. It is a burden for the individual patient and in addition there are costs for society because of loss of work and medical expenses. Patients with low back pain are finding it increasingly difficult to make sense of the growing list of treatment approaches. Osteopathic treatment is one of them. Because of this it is important to investigate treatment approaches and to gain high-evidence research for the osteopathic approach.

**Objective:** The objective of this systematic review is to determine the effectiveness of osteopathic treatment as a complementary treatment for low back pain. This can be done in two steps. The first one is to evaluate the clinical problem, especially the therapeutic approaches. The second one is to investigate the osteopathic approach.

**Methods:** A specific electronic search for the clinical problem is performed in MEDLINE, Guideline Clearing House, Cochrane Library, and grey literature. Data extraction focuses on definition, epidemiology, etiology, diagnosis and therapy. According to the osteopathic literature, computerized bibliographic searches of MEDLINE, Cochrane Library, EMBASE, OVID, EBSCO, PsycINFO, Science Direct, Pedro, Physiotherapy Choice, OSTMED DR, Osteopathic Research and German Academy for Osteopathy were supplemented by manual searches and expert inquiries.

11 trials were included because they were randomized controlled trials of osteopathic treatment according to the definition of the American Osteopathic Association that involved assessment of low back pain in ambulatory settings. In these studies osteopathic treatment is compared with a different treatment or no treatment. Duration follow-up and relevant outcome measures were defined. Methodological quality and risk of bias are analyzed to determined, if they are sufficient. Comparison is done by stratifying duration of pain, radiation pattern or circumstances of low back pain.

**Results:** There is a consistent definition of low back pain. A classification of specific and non-specific low back pain has been made. About 85 % of patients have non-specific low back pain. Classifying the patients according to diagnostic triage is recommended. There is just a small number of therapeutic interventions, which can be recommended, often with side effects.

There is high evidence that osteopathic treatment is better than conventional treatment and no treatment for chronic low back pain, but not better than sham treatment. There is high evidence that osteopathic treatment is better or similar to standard therapies and moderate evidence that it is better than physiotherapy for sub-acute low back pain. There is high evidence that osteopathic treatment is better than sham and conventional treatment and moderate evidence that it is better than no treatment for pregnant women with low back pain. There is moderate evidence that osteopathic treatment is better than no treatment for women post partum with low back pain. There is high evidence that osteopathic treatment is not better after 12 months but better in the first few weeks than chemonucleolysis in patients with disc herniation.

**Conclusion:** There is no “gold standard”, and more research must be done on therapeutic approaches having benefits for patients. This, and the fact that the rate of patient visits in primary care is high, might be a good base for osteopathic treatment. But the public is not yet familiar with osteopathic medicine. The guidelines do not even mention osteopathic treatment, and no Cochrane review exists so far. The review of osteopathic literature shows that osteopathic treatment has evident benefits for patients with low back pain of different duration and causes. More high-quality studies must be done to find a way into the guidelines. A Cochrane review might be a good first step to reach this aim.

## **Glossary:**

ACP	American College of Physicians
AOA	American Osteopathic Association
APS	American Pain Society
ATSU	Andrew Taylor Still University
AWMF	Association of the Scientific Medical Societies in Germany
BÄK	Bundesärztekammer
CBRG	Cochrane Back Research Group
CDSR	Cochrane Database of Systematic Reviews
CLBP	Chronic Low Back Pain
CLIP Practice	Clinic on Low Back Pain in Interdisciplinary Practice
CT	Computer Tomography
e. g.	for example
GDP	Gross Domestic Product
GP	General Practitioner
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	Haemophilus Influentia Virus
HVLA	High Velocity Low Amplitude
Hz	Herz
IDA	Interdisziplinärer Abgleich
i. e.	in example
KBV	Kassenärztliche Bundesvereinigung
KCOM	Kirksville College of Osteopathic Medicine
LBP	Low Back Pain
MRI	Magnet Resonance Imaging
MQIC	Michigan Quality Improvement Consortium
NCCPC	National Collaborating Centre of Primary Care
NICE	National Institute for Health and Clinical Excellence

NSAID	Nonsteroidal anti-inflammatory Drugs
NVL	Nationale Versorgungsleitlinie
OMT	Osteopathic Manipulative Treatment
RCT	Randomized Controlled Trial
SR	Systematic Review
SWD	Short Wave Diathermy
TENS	Transcutaneous Electrical Nerve Stimulation
UK	United Kingdom
U.S.	United States of America
WOHO	World Osteopathic Health Organisation

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# **Chapter 1: Introduction**

Low back pain is a disabling disorder that greatly affects western society; it is a burden for the individual patient and an additional cost for society because of loss of work and medical expenses. (Assendelft, Morton, Yu, Suttorp & Shekelle, 2004) Therefore, adequate treatment of low back pain is an important issue for patients, treating clinicians, and healthcare policy makers. Osteopathic manipulative treatment significantly reduces low back pain. The level of pain reduction is greater than expected from placebo effect alone and persists for at least three months. (Licciardone, Brimhall & King, 2005) The goal in this review is to update and improve the previous systematic review, following guidelines for systematic reviews developed by the Cochrane Back Review Group (van Tulder, Furlan, Bombardier & Bouter, 2003). Relevant clinical variables should be incorporated and combined to estimate the effectiveness of osteopathic therapy for low back pain. By presenting the most current information on this issue, support may be provided for individual and collective treatment decisions.

## ***1.1 Background***

### ***1.1.1 Incidence***

Low back pain is being described in the medical literature as a common condition. It is the second leading cause of office visits to primary care physicians and the most common reason for office visits to occupational medicine physicians, orthopedic surgeons and neurosurgeons in the US. It seems that there is an increase in patient visits due to this problem. During 2003/2004 there were more than twice as many patient visits annually for low back pain than reported in the 1990 National Ambulatory Medical Care Survey (Licciardone, 2008). Back pain also remains a major reason for all physician office visits. There were almost 15 million office visits for low back pain in 1990, ranking this problem fifth as a reason for all physician visits (Hart, Deyo & Cherkin, 1995).

Deyo, Mirza and Martin reviewed and analyzed data from the 2002 National Health Interview survey. They summarized published data from the survey on the prevalence of back pain and compared it with earlier surveys. Low back pain lasting at

least a whole day in the past 3 months was reported by 26.4 % of respondents. About one fourth of U.S. adults report low back pain in the past 3 months (Deyo, Mirza & Martin, 2006).

It is often claimed that up to 90 % of low back pain episodes resolve spontaneously within 1 month. In order to investigate the long-term course of incident and prevalent cases of low back pain, a systematic review was undertaken. The results showed that the reported population of patients who still experienced pain after 12 months was 62 % on average, the percentage of patients sick-listed 6 months after inclusion into the study was 16 %, the percentage who experienced relapses of pain was 60 % and the percentage who had relapses of work absence was 33 %. The results of the review show that low back pain does not resolve itself when ignored (Hestebaek, Leboueuf-Yde & Manniche, 2003).

The results of a 4-year follow-up study in the UK showed that the overall prevalence of chronic low back pain increased from 45.5 % at baseline to 53.8 % at follow-up. Seventy-nine percent of those with chronic pain at baseline still had it at follow-up. The average annual incidence was 8.3 % and the average annual recovery rate was 5.4 %. Chronic pain is a common, persistent problem in the community with relatively high incidence and low recovery rates (Elliott, Smith, Hannaford, Smith, & Chambers, 2002).

In Germany the “Bundes-Gesundheitssurvey 1998” (German national health survey) showed that back pain is the most common pain in women and men of all ages. Statistically 39 % in women and 31 % in men mentioned back pain in the last seven days. It shows that it is a more common problem in Germany compared to international dates. Compared to cervical and thoracic region, low back pain is the most common in percentage (Gesundheit in Deutschland, Gesundheitsberichterstattung des Bundes, Robert Koch-Institute, 2006). Following infections of the upper respiratory tract, back pain ranks second among the leading causes for patient visits to primary care in Germany. Among men back pain is the most (14 %), and among women the second most (11 %) frequent reason for sick leave (Fink & Haidinger, 2007).

Research of low back pain in different industrialized countries demonstrates that it is one of the most common health problems that can lead to long-term disability.

### ***1.1.2 Costs***

Low back pain is also very costly. Low back pain is associated with significant economic, societal, and health impact. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States have reached \$ 90,7 billion for the year 1998. On average, individuals with back pain incurred health care expenditures about 60 % higher than individuals without back pain (\$ 3,498 versus \$ 2,178). In the United States, it was estimated that the cost of treatment in the first year after failed back surgery for pain was approximately \$ 18,883 in 1997. The major share of these costs is associated with disability compensation, lost productivity, and lost tax revenue. Disability secondary to low back pain is enormous (Manchikanti, Boswell, Singh, Benyamin, Fellows & Abdi, 2009).

In addition, indirect costs related to days lost from work are substantial, with approximately 2 % of the U.S. work force compensated for back injuries each year (Andersson, 1999).

In a German study which used a bottom-up approach to estimate costs for back pain in German general adult population based on a large cross-sectional survey, the average annual costs per person with back pain is estimated at € 1,322. These costs are divided among direct (46 %) and indirect costs (54 %) almost evenly. An extrapolation of results to the German adult population between 18 and 75 years of age led to an estimated € 48,96 billion for direct and indirect back pain-related expenditures, tantamount to 2.2 % of the German GDP (Wenig, Schmidt, Kohlmann & Schweikert, 2008).

### ***1.1.3 Overview: Medical treatment approaches of low back pain***

Patients with chronic low back pain are finding it increasingly difficult to make sense of the growing list of treatment approaches. This difficulty is shared by all interested stakeholders, clinicians and third-party payers. All share a common goal and wish to use limited healthcare resources to support those interventions most likely to result in clinically meaningful improvements in symptoms and functional capacity. But the inventory of the available, advertised and commonly used treatment options is enormous. Haldeman and Dagenais present a list of treatments. They found over 60 pharmaceutical products that are currently being offered to patients with chronic low back pain. There are 32 different manual therapies, 20 different exercise programs, 26

different passive physical modalities, 9 educational and psychological therapies, over 20 different injection therapies, a growing list of procedures commonly included under the umbrella of minimally invasive interventions, some traditional and newer surgical approaches, a variety of extensive lifestyle products, including braces, beds, chairs, etc. (Haldeman & Dagenais, 2007).

#### ***1.1.4 Overview: Research of osteopathic treatment of low back pain***

There are few trials studying the subject of manual therapy for patients with low back pain. The results are inconsistent. Sometimes, reviews do not distinguish between osteopathic approach and other approaches (Ernst & Canter, 2006). There are also clinical trials investigating osteopathic treatments. Degenhardt, Darmani, Johnson, Towns, Rhodes & Trinh (2007) reported on a significant positive change in pain biomarkers. Licciardone, Brimhall & King (2005) published a ground breaking systematic review and meta-analysis of randomized controlled trials and found that OMT can significantly reduce low back pain. Since this systematic review is restricted to RCTs using the term OMT for osteopathic therapy and to reviewed literature written in English, a reasonable amount of evidence may not have been included as for instance reports from European authors. There are additional trials in the UK and Germany, e.g.:

- A prospective study of patients with chronic back pain randomized to group exercise, physiotherapy or osteopathy (Chown, Whittamore, Rush, Allan, Stott & Arder, 2007)
- The effectiveness of a holistic osteopathic treatment in sub-acute low back pain. A randomized controlled trial (Heinze 2006)

A report urges general practitioners (GPs) to refer patients for manual therapies, such as osteopathy, early. The key concept to understanding osteopathic principles is somatic dysfunction. Williams states that it is proposed that somatic dysfunction is the new paradigm for non-specific back pain (Williams, 1997).

In the UK, it is - after general practitioners - the three professional groups of chiropractors, osteopaths and physiotherapists who see most low back pain patients. Patients with low back pain account for approximately half their workloads (Pincus, Forster, Vogel, Santos, Breen & Underwood, 2007).

## ***1.2 Objective***

The objective of this review is to determine the effectiveness of osteopathic treatment for low back pain.

In this thesis a systematic review of randomized controlled trials of low back pain should be carried out with special emphasis on aspects potentially impacting the osteopathic therapy of patients with low back pain. The methodology of the systematic review of randomized controlled trials of low back pain will, as much as possible, be geared to the principles of the Cochrane collaboration (Higgins & Green, 2008).

Two systematic reviews should be performed. The aims are:

### ***1.2.1 Objective review 1:***

In the systematic review 1, the literature concerning the clinical problem is to be evaluated, and the evidence concerning different therapeutic approaches to low back pain scrutinized.

### ***1.2.2 Objective review 2:***

The objective is to evaluate the evidence of osteopathic approaches to low back pain through search in medical and osteopathic databases.

## Chapter 2: Methods

### 2.1 Systematic Review 1: The Clinical Problem

#### 2.1.1 Developing a search strategy

Search in the leading electronic databases, e.g. the COCHRANE LIBRARY (CDSR) and MEDLINE with special focus on:

- The epidemiological and clinical background
- The evidence of common therapeutic approaches

This literature review is not a sensitive search, but a specific search, primarily for guidelines, Cochrane reviews (therapy), systematic reviews and meta-analyses (latest studies on therapy), since the amount of data published on low back pain in recent years is extremely large.

Guidelines:

In this thesis, guidelines published since 2004 were selected by electronic search in MEDLINE, Guideline Clearing House, grey literature (Google).

Cochrane Reviews (therapy):

Regarding the therapy of LBP, systematic reviews of the Cochrane Library database were also evaluated.

Systematic reviews (therapy):

To incorporate the latest knowledge regarding therapy, the most recent studies of the past 2 years published in MEDLINE were included in the evaluation.

#### 2.1.2 Search (key words)

Table 1: Search for guidelines:

Database	Search Term	Limits
MEDLINE	Low back pain [MESH]	Last 5 years, guidelines
Guideline Clearing House	Low back pain	No limits
Grey literature (Google)	Low back pain	No limits
Grey literature (Google)	Versorgungsleitlinie AND Rückenschmerz	No limit

Search in the Cochrane Library:

ATSU – KCOM Library – The Cochrane Library

Search: “low back pain”

Search in MEDLINE for latest findings regarding the therapy of LBP:

Search 1: self-management OR remain active OR behavioral therapy OR NSAID OR opioids OR tricyclic antidepressants OR muscle relaxants OR gabapentin OR capsaicin OR exercise OR acupuncture OR massage OR spinal manipulation OR epidural injection OR laser therapy OR multidisciplinary rehabilitation OR superficial heat/cold OR TENS, Limits: Randomized Controlled Trial, Review, published in the last 2 years

Search 2: “low back pain” Limits: Randomized Controlled Trial, Review, published in the last 2 years

Search: 1 AND 2, Limits: Randomized Controlled Trial, Review, published in the last 2 years:

Search: 1 AND 2, Limits: Review, published in the last 2 years

Table 2: Search for studies concerning therapy of low back pain:

Database	Search Term	Limits
Cochrane Library	Low back pain	No
Medline	“Low back pain” [MESH] AND 16 therapies with OR	Review, published in the last 2 years

### 2.1.3 Grading the quality of evidence and strength of recommendations

The Cochrane Handbook of Systematic Reviews of Interventions and the Cochrane Back Research Group (CBRG) Editorial Board recommend that review authors go beyond the reporting of the results of quantitative analyses and rate the quality of the evidence for each important patient-centered outcome. To help readers use this new approach, the CBRG has adopted the GRADE approach for back and neck pain reviews. The quality of the evidence on a specific outcome is based on 5 domains: limitations of the study design, inconsistency, indirectness (inability to generalize), and imprecision (insufficient or imprecise data) of results and publication bias across all studies that measure that particular outcome.



The most important step is to choose which outcomes are relevant for inclusion in the GRADE Evidence Profile. This is based on the choice of “primary outcome measures” selected by establishing inclusion criteria: outcome measures. Only RCTs included in the primary analysis of the review should be included in the GRADE Evidence Profile.

The overall “quality of the evidence” for each outcome is the result of the combination of the assessments in all domains. The GRADE Working Group recommends 4 levels of evidence:

High quality evidence = at least 75 % of the RCTs with no limitations of study design have consistent findings, direct and precise data and no known or suspected publication biases.

Moderate quality evidence = 1 of the domains is not met.

Low quality evidence = 2 of the domains are not met.

Very low evidence = 3 of the domains are not met. (Furlan, Pennick, Bombardier & van Tulder, 2009)

## ***2.2 Systematic Review 2: Osteopathic Literature***

### ***2.2.1 Eligibility – Inclusion/Exclusion Criteria***

#### ***2.2.1.1 Inclusion criteria:***

Study design:

Included are randomized controlled trials of osteopathic treatment for low back pain, finished and available by June 2010.

Participants:

Setting: Studies with patients from primary (ambulatory) care

Duration of complaints: All patients with low back pain were included, regardless of duration. By analyzing the data, patients will be categorized as acute, sub-acute and chronic.

Radiation pattern: All patients with back pain were included, regardless of radiation pattern. By analyzing the data, if necessary, patients will be categorized according to different patterns.

Circumstances: Patients with all circumstances, e.g. age are included. They will be also categorized by analyzing the data.

Interventions:

Osteopathic treatment for low back pain is to be compared with a different treatment or control.

The term OMT refers to the following:

Osteopathic Manipulative Treatment as defined by AOA: “The therapeutic application of manually guided forces by an osteopathic physician (US usage) to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction.”

OMT employs a variety of techniques, the most important being: articulatory treatment, balanced ligamentous tension, counterstrain, cranial treatment, myofascial

release, functional method, HVLA, muscle energy technique, soft tissue technique and visceral manipulation (American Osteopathic Association, 2009)

A report states that the key concept to understanding osteopathic principles is somatic dysfunction. This is a disorder of function, rather than pathology, of the musculoskeletal and related systems. Its characteristic features are asymmetry of anatomical landmarks, asymmetry of joint movement, tissue texture changes, and tenderness (Williams, 1997).

Control-group:

Only truly randomized studies can be included.

The treatment group can be compared to no treatment, sham, other treatment that showed evidence, or conventional general practitioner care.

Outcome measures:

Studies that measured at least one clinically relevant outcome measure are included.

The outcomes were measured at follow-up treatment (efficacy studies) up to more than one year later (effectiveness studies).

The following outcome measures are primarily reported:

1. Level of pain in the individual patients (expressed on visual analogue or similar scales)
2. Disability: Functional status of the individual patient (expressed on a back pain-specific scale, e.g. Roland-Morries Disability Questionnaire, Oswestry Disability Index)
3. Quality of life: e.g. SF 36

#### ***2.1.1.2 Exclusion criteria:***

The terms "manipulative treatment" or "spinal manipulation" are insufficient criteria if therapy is not performed according to the principles of osteopathy, i.e. when done by physiotherapists or chiropractors. (See discussion of methods.)

Pooling osteopathic treatment and treatment with analgesics prescription is an insufficient category because, as seen in a Cochrane review, most initial visits to primary care providers for low back pain result in an analgesic prescription (Roelofs, Deyo, Koes, Scholten & van Tulder, 2008).

Pooling osteopathic treatment and treatment with therapies regarded as not to be recommended to patients with low back pain is an insufficient category.

Physiological variables, such as spinal flexibility and number of degrees of straight leg raising can not be used in the assessment of results since, as shown in review 1, diagnosis section, in low back pain research this kind of outcome correlates poorly with the clinical status of the patient (American Osteopathic Association, 2009).

### ***2.2.2 Search methods for identification of studies***

For underpinning this systematic review the searcher tries to include all available evidence. Therefore the search strategy should relate directly to the research question and should be based on the inclusion criteria with respect to study design, participants, interventions and outcomes. The search strategy should not be limited by language.

#### ***2.2.2.1 Searched databases***

The following databases are searched:  
MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL) and Cochrane Back Review Group Trials Register, EMBASE, OVID, EBSCO, PsycINFO, Science direct, Pedro, Physiotherapy Choices, OSTMED DR, Osteopathic Research, German Academy of Osteopathy, “grey literature”

#### ***2.2.2.2 Search strategy***

Search at **MEDLINE**:

1.

Search 1: “Low Back Pain”[Mesh]

Search 2: "Low Back Pain

Search 3: #1 OR #2

Search 4: "Manipulation, Osteopathic"[Mesh]

Search 5: "Osteopathic Medicine"[Mesh]

Search 6: "Osteopathic Medicine" OR "Osteopathic Manipulative Treatment" OR "OMT"  
OR "Osteopathy" OR "Osteopathic Therapy" OR "Osteopathic Spinal Manipulation"

Search 7: #4 OR #5 OR #6

Search 8: #3 AND #7

Search 9: #3 AND #7 Limits: Randomized Controlled Trial, Review

2:

Search 1: Low Back Pain [MESH] OR Low Back Pain

Search 2: "Osteopath Med Prim Care" AND "osteopath\*" AND #1

3:

Search 1: "articulatory treatment" OR "balanced ligamentous tension" OR "counterstrain"  
OR "cranial treatment" OR "myofascial release" OR "functional method" OR "high  
velocity/low amplitude technique" OR "muscle energy technique" OR "soft tissue  
technique" OR "visceral manipulation"

Search 2: Low Back Pain [MESH] OR Low Back Pain

Search 3: #1 AND #2 Limits: Randomized Controlled Trial, Review

Search at **Cochrane Library**:

Search 1: low back pain AND osteopath\*

Search 2: "lumbago" AND "osteopath\*"

Search 3: "ache" AND "osteopath\*"

Search 4: "sciatica" AND "osteopath\*"

Search at **EMBASE** (via Medipilot of Bayerische Staatsbibliothek Munich):

Search 1: "back pain" (keyword) AND "osteopath\*" (keyword)

Search 2: "low back pain" (keyword) AND "low back pain" (Mesh) AND "osteopath\*" (keyword)

Search at **OVID**:

Search 1: "low back pain" AND "osteopath\*"

Search 2: “lumbago” AND “osteopath\*”

Search 3: “ache” AND “osteopath\*”

Search 4: “sciatica” AND “osteopath”

Search at **EBSCO**:

Journal of the American Osteopathic Association (JAOA):

Search: Low back pain

Search at **MANTIS**:

Search: “back pain” OR “low back pain” OR “lumbago” OR “ache” OR “sciatica” AND “osteopath\*” AND “random\*”

Search strategy for **CINAHL**:

Search 1: Osteopath\*

Search 2: Manipulation, Osteopathic

Search 3: Medicine, Osteopathic

Search 4: #1 OR #2 OR #3

Search 5: Low Back Pain

Search 6: #4 AND #5

Search at **PsycINFO**:

Search:

Low back pain (all fields) AND osteopath\* (all fields)

Ache (all fields) AND osteopath\* (all fields)

Lumbago (all fields) AND osteopath\* (all fields)

Sciatica (all fields) AND osteopath\* (all fields)

Search at **Pedro**:

Search: Osteopath\* (Title/Abstract) AND pain AND lumbar spine, sacro-iliac joint or pelvis

Search at **Physiotherapy Choices**:

Search: Back, pelvis AND pain AND osteopath\*

Search at **OSTMED DR**:

Search: Keyword 1: Low back pain, Title: Osteopath\*, Keyword 2: random\*

Search at **Science direct**:

Search: IJOM AND low back pain:

Science direct:

Search: Journal of Osteopathic Medicine AND low back pain:

Science direct:

Search: Osteopathic Family Physician AND low back pain:

Search at **Osteopathic research**:

Search: Low back pain AND random\*

Search at the German Academy of Osteopathy (**AFO**):

Search: Low back pain AND osteopath\* AND random\*

Search at Research at **”grey literature“**:

Websites of schools

Contacting experts in UK, France, Italy, Australia

### ***2.2.3 Study selection and data extraction***

In a first step of selection, the inclusion criteria should be applied to select the potentially relevant trials from the titles, abstracts and keywords of the references retrieved by the literature search.

After the initial search by screening titles, abstracts and keywords, the full text of the article must be retrieved and screened to determine the final selection of the trials to be included in the review. The methodological quality must be assessed by using a risk of bias tool.

### 2.2.4 Methodological quality assessment

In this review the risk of bias should be assessed by using the criteria, adapted from the Cochrane Handbook of Reviews of Interventions. (Higgins & Green, 2008) Of these criteria, 11 have already been used in 26 (65 %) and 10 have been used in 7 (18 %) systematic reviews within the Cochrane Back Review Group. These criteria are also considered important by others who study non-pharmacological interventions.

These criteria refer to characteristics of the study that might be related to selection bias (criteria 1, 2, 9), performance bias (criteria 3, 4, 10, 11), attrition bias (criteria 6, 7), and detection bias (criteria 5, 12). It is recommended that the studies are rated as having “low risk of bias” when at least 6 of 12 criteria have been met and the study has no serious flaws (e.g. high drop-out rate in a group). Studies with serious flaws, or those in which fewer than 6 of the criteria are met, should be rated as having a “high risk of bias”, see Table 3. (Furlan et al., 2009)

Table 3: *Sources of Risk of Bias (Furlan et al., 2009)*

1	Was the method of randomization adequate?	Yes/No/Unsure
2	Was the treatment allocation concealed?	Yes/No/Unsure
3	Was the patient blinded to the intervention?	Yes/No/Unsure
4	Was the care provider blinded to the intervention?	Yes/No/Unsure
5	Was the outcome assessor blinded to the intervention?	Yes/No/Unsure
6	Was the drop-out rate described and acceptable?	Yes/No/Unsure
7	Were all randomized participants analyzed in the group to which they were allocated?	Yes/No/Unsure
8	Are reports of the study free of suggestion of selective outcome reporting?	Yes/No/Unsure
9	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes/No/Unsure
10	Were co-interventions avoided or similar?	Yes/No/Unsure
11	Was the compliance acceptable in all groups?	Yes/No/Unsure
12	Was the timing of the outcome assessment similar in all groups?	Yes/No/Unsure

In the Cochrane handbook for systematic reviews one can also find a table of criteria for a judgment of “yes” for the sources of risk of bias mentioned in Table 4: (Higgins & Green, 2008)



Table 4: Criteria for a judgment

1	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.
2	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
3	This item should be scored “yes” if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
4	This item should be scored “yes” if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.
5	<p>Adequacy of blinding should be assessed for the primary outcomes. This item should be scored “yes” if the success of blinding was tested among the outcome assessors and it was successful or:</p> <ul style="list-style-type: none"> <li>– For patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate For outcome assessors if participant blinding is scored “yes”.</li> <li>– For outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination</li> <li>– For outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome</li> <li>– For outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item “4” (caregivers) is scored “yes”</li> <li>– For outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data.</li> </ul>
6	The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described

	and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20 % for short-term follow-up and 30 % for long-term follow-up and does not lead to substantial bias a “yes” is scored. (N.B. these percentages are arbitrary, not supported by literature).
7	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
8	In order to receive a “yes”, the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
9	In order to receive a “yes”, groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
10	This item should be scored “yes” if there were no co-interventions or they were similar between the index and control groups.
11	The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.
12	Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

For interventions such as osteopathic manipulative treatment a true double-blinding is not feasible. So this criterion must be sorted out.

### **2.2.5 Data analysis**

The characteristics of participants, types of interventions, and the exact outcome values should be clearly articulated for each group of study results.

#### **Data extraction for analysis**

There are no strict guidelines for the use of risk of bias assessment in systematic reviews. It will be done as described:

1. The risk of bias will be used as an additional inclusion criterion for studies in the review. Only studies that adequately fulfill six of the 11 validity criteria and have no serious flaws are included.

2. A stratified analysis will be performed in which the results are presented separately for different strata of studies. (Furlan et al., 2009)

Data describing study characteristics that include characteristics of participants, interventions, comparisons, outcomes, analyses, results and study sponsorship would be extracted and presented in the summary of findings.

There must be a decision whether it is clinically relevant to combine the results from a group of studies. For example, studies of participants with different types of treatment, different comparison groups, or different clinical characteristics. If there is a high heterogeneity, results of every sub-group can be presented separately.

A meta-analysis should only be conducted with trials measuring a specific outcome at similar follow-up, reporting sufficient data. The primary analysis of the review should only be based on the results from RCTs. (Higgins & Green, 2008)

## Chapter 3: Results

### 3.1 *Systematic review 1: The clinical problem*

#### 3.1.1 *Search results*

##### 3.1.1.1 *Results of the search of guidelines*

Results of search in MEDLINE: 20

Thereof not a guideline: 3

Thereof not sufficiently applicable to the subject since only partial areas were covered:  
13

Included in other guidelines: 1

Hits: 3

Additional results of search in Guideline Clearing House: 42 related guidelines

Thereof not or only in partial areas applicable to the subject: 37

Applicable to the subject but too old: 3

Included in other guidelines: 1

Hits: 2

Additional results of search in grey literature (Google):

Guidelines found: 8

Applicable to the subject but too old: 2

Applicable only to partial areas: 1

Included in other guidelines (European guidelines for low back pain): 5

Hits: 1

Result of search: Versorgungsleitlinie Kreuzschmerz

Guidelines found: 1

Relevant guidelines: 7

Table 5: Search for guidelines:

Database	Search Results	Included Guidelines
MEDLINE	20	3
Guideline Clearing House	42	2
Grey literature (Google)	9	2

Table 6: Summary of relevant guidelines:

Guideline	Guideline
Bundesärztekammer (BÄK), Kassenärztliche Vereinigung (KBV), Arbeitsgemeinschaft der wissenschaftlichen Medizinischen Fachgesellschaften (AWMF), 2010, Nationale Versorgungsleitlinie (NVL) Kreuzschmerz	Chou, Qaseem, Snow, Casey, Cross,... & Shekelle, 2007, American College of Physicians (ACP) and American Pain Society (APS) Guidelines
Airaksinen, Brox, Cedraschi, Hildebrandt, Klaber-Moffett,... & Kovacs, 2006, European guidelines for chronic low back pain	Savignon, Kunze, Watson, Underwood, Ritchie, Cotterell,... & Walsh, 2009, National Collaborating Centre of Primary Care (NCCPC) Guideline
Van Tulder, Becker, Beddering, Breen, Real, ... & Hutchinson, 2006, European guidelines for the management of acute non-specific low back pain in primary care	Rossignol, Poitras, Dionne, tousignant, Truchon,... & Arsenault, 2001, CLIP Practice Guideline
Michigan Quality Improvement Consortium Guideline, 2008, Management of acute low back pain	

All included guidelines were available online.

Assessment of quality:

### 1. Nationale Versorgungsleitlinie (NVL) Kreuzschmerz:

The generation of these guidelines was supervised, among others, by the AWMF and therefore meets the following criteria:

The Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (Association of the scientific medical societies in Germany) AWMF developed a classification grid for guidelines.

The guidelines of the scientific medical societies in Germany can be categorized in 3 development stages. For short-term guideline generation, the expert group is sufficient. Medium-term and permanent solution should be based on the techniques of development stages 2 or 3.

1st stage = expert group:

A representative group of experts from the medical society/societies consents informally on a recommendation to be approved by the Board of the society/societies.

2nd stage = Guideline with formal evidence research or formally found consensus:

Guidelines are developed from formally (evidence level) assessed propositions of the scientific literature or discussed and approved using one of the tried and tested formal consensus procedures, with representative involvement of all subject fields:

- \* Nominal group process or
- \* Consensus conference or
- \* Delphi conference

3rd stage = Guideline including all elements of systematic development:

The guideline development process of development stage 2 is extended to include the following 5 components:

- \* Logic analysis
- \* Formal consensus procedure (representative)
- \* "Evidence-based medicine"
- \* Decision analysis
- \* "Outcome" analysis

IDA = Interdisciplinary development:

"+ IDA" (= InterDisziplinärer Abgleich, interdisciplinary comparison) is added to the development stage

Representation of evidence for the recommendation of therapies:

- ↑↑ Positive statement, well proven
- ↑ Positive statement, proven
- ↔ Conflicting, limited evidence
- ↓ Negative statement, well proven

## **2. American College of Physicians (ACP) and American Pain Society (APS)**

### **Guidelines:**

The literature search for this guideline included studies from MEDLINE (1966 through November 2006), the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, and EMBASE. The literature search included all

English-language articles reporting on randomized controlled trials of non-pregnant adults (age >18 years) with low back pain (alone or with leg pain) of any duration that evaluated a target medication and reported at least 1 of the following outcomes: back-specific function, generic health status, pain, work disability, or patient satisfaction. The American College of Physicians (ACP) and the American Pain Society (APS) convened a multidisciplinary panel of experts to develop the key questions and scope used to guide the evidence report, review its results, and formulate recommendations. The background papers by Chou and colleagues provide details about the methods used for the systematic evidence review.

This guideline grades its recommendations by using the ACP's clinical practice guidelines grading system, adapted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) work group. The evidence in this guideline was first evaluated by the ACP/APS panel by using a system adopted from the U.S. Preventive Services Task Force for grading strength of evidence, estimating magnitude of benefits, and assigning summary ratings. The evidence was independently reviewed by the ACP's Clinical Efficacy Assessment Subcommittee. This guideline considered interventions to have "proven" benefits only when they were supported by at least fair-quality evidence and were associated with at least moderate benefits (or small benefits but no significant harms, costs, or burdens).

Description of evidence for recommendation of therapies: The GRADE system:

1 of 4 levels: very low, low, moderate, and high

### **3. NCCPC Guideline**

Low back pain: early management of persistent non-specific low back pain, full guideline, May 2009

National Collaborating Centre of Primary Care (NCCPC):

The methods are in accordance with those set out by the Institute in 'The guidelines manual'. April 2006. London: National Institute for Health and Clinical Excellence (NICE). Available from: [www.nice.org.uk/guidelinesmanual](http://www.nice.org.uk/guidelinesmanual). An initial scoping search for published guidelines, systematic reviews, economic evaluations and ongoing research was carried out on the following databases or websites: National Library for Health

(NLH) Guidelines Finder, National Guidelines Clearinghouse, Scottish Intercollegiate Guidelines Network (SIGN), Guidelines International Network (GIN), Canadian Medical Association (CMA) Infobase (Canadian guidelines), National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines (Australian Guidelines), New Zealand Guidelines Group, BMJ Clinical Evidence, Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA), NHS Economic Evaluations Database (NHSEED), National Research Register and Current Controlled Trials Low back pain: early management of persistent non-specific low back pain  
Description of evidence for recommendations of therapies:  
High evidence, moderate evidence, insufficient/conflicting evidence, no evidence

#### **4. European Guidelines for Chronic LBP:**

European Guidelines for the Management Of Chronic Non-specific Low Back Pain.

The guideline group on chronic, non-specific low back pain was developed within the framework of the COST ACTION B13 ‘Low back pain: guidelines for its management’, issued by the European Commission, Research Directorate-General, Department of Policy, Co-ordination and Strategy. The guidelines Working Group (WG) consisted of experts in the field of low back pain research. Members were invited to participate, to represent a range of relevant professions. The core group 4 consisted of three women and eight men from various disciplines, representing 9 countries. None of the 11 members believed they had any conflict of interest. The guidelines were reviewed by the members of the Management Committee of COST B13, in Palma de Mallorca on 23rd October 2004. The full guidelines are available at: [www.backpaineurope.org](http://www.backpaineurope.org)

#### Literature search

The recommendations for treatment are based on a systematic review of systematic reviews and randomized clinical trials on chronic low back pain (CLBP). The following databases were searched for systematic reviews published before November 2002: Cochrane, Medline, Health Star, Embase, Pascal, Psychoinfo, Biosis, Lilacs and



IME (Indice Medico Espanol). Where a Cochrane review was found for a given procedure, this formed the basis for putting together the recommendations for that procedure.

Additional RCTs (i.e. those possibly not included in the previously identified systematic reviews) were identified from electronic searches that covered a time period from January 1995 up to November 2002.

Other “additional studies” (both SRs and RCTs) were identified from the working group’s personal knowledge of the literature, especially for papers published after November 2002.

The methodological quality of a systematic review (SR) identified by the search was assessed using the Oxman & Guyatt index (Oxman and Guyatt 1991). SRs were rated from 0 to 7: SRs rating as 4 (or lower) were those for which it was difficult to rule out major flaws (= low quality); SRs with a rating of 5 or higher were considered to be “high quality”. Additional relevant RCTs, not previously included in the latest systematic reviews, were also assessed for their methodological quality, using criteria related to the internal validity of the trial (van Tulder et al 1997). One point was awarded for each condition that was fulfilled. If a trial achieved a score of 5 or more out of 10, it was considered “high quality”.

Checklist for methodological quality of therapy studies

- 1) Adequate method of randomization
- 2) Concealment of treatment allocation
- 3) Withdrawal/drop-out rate described and acceptable
- 4) Co-interventions avoided or equal
- 5) Blinding of patients
- 6) Blinding of observer
- 7) Blinding of care provider
- 8) Intention-to-treat analysis
- 9) Compliance
- 10) Similarity of baseline characteristics

The evidence levels for the treatments were classified as follows:

Level A (Strong Evidence): Generally consistent\* findings provided by (a systematic review of) multiple high quality randomized controlled trials (RCTs); Level B (Moderate Evidence): Generally consistent findings provided by (a systematic review of) multiple low quality RCTs; Level C (Limited or Conflicting Evidence): One RCT (either high or low quality) or inconsistent findings from (a systematic review of) multiple RCTs; Level D (No Evidence): No RCTs

## **5. European Guidelines for Acute LBP.**

European Guidelines for the Management of Acute Nonspecific Low Back Pain in Primary Care

Guidelines working group

The guidelines were developed within the framework of the COST ACTION B13 ‘Low back pain: guidelines for its management’, issued by the European Commission, Research Directorate-General, Department of Policy, Co-ordination and Strategy. The guidelines working group consisted of experts in the field of low back pain research in primary care who have been involved in the development of national guidelines for low back pain in their countries. Members were invited to participate, taking into account that all relevant health professions should be represented. All countries that had already issued national guidelines were represented.

To ensure an evidence-based approach, the recommendations were based on Cochrane reviews (and on other systematic reviews if a Cochrane review was not available), additional trials published after the Cochrane reviews, and existing national guidelines. The authors of this guideline had no financial conflict of interest and were not involved in quality assessment or discussion of their own papers.

The systematic reviews were identified using the results of validated search strategies in the Cochrane Library, Medline, Embase, and, if relevant, other electronic databases, performed for Clinical Evidence, a monthly updated directory of evidence on the effects of common clinical interventions, published by the BMJ Publishing Group ([www.evidence.org](http://www.evidence.org)).

A grading system was used for the strength of the evidence. This grading system is simple and easy to apply, and shows a large degree of consistency between the grading

of therapeutic and preventive, prognostic and diagnostic studies. The system is based on the original ratings of the AHCPR Guidelines (1994) and levels of evidence recommended in the method guidelines of the Cochrane Back Review group. The strength of the recommendations was not graded. Several of the existing systematic reviews have included non-English language literature, usually publications in French, German, and Dutch language and sometimes also Danish, Norwegian, Finnish and Swedish. All existing national guidelines included studies published in their own language. Consequently, the non-English literature is covered for countries that already have developed guidelines. The group additionally included the Spanish literature, because this evidence was not covered by existing reviews and guidelines.

Recommendations are classified in:

Level A: strong evidence, level B: moderate evidence, level C: limited/conflicting evidence, level D: no evidence

## **6. CLIP Practice Guidelines**

Clinic on Low-Back Pain in Interdisciplinary Practice (CLIP) guidelines:

The clinical practice guideline for low back pain was developed in 2005 and 2006 with the support of the Robert-Sauvé Research Institute in Workplace Health and Safety (“Institut de Recherche Robert-Sauvé en santé et sécurité du travail”) and with the collaboration of five organizations representing primary healthcare professionals. Although this guideline is based on an extensive review of the best available scientific evidence and the assessment of the knowledge in all areas of low back pain management, it is built around the know-how of practicing clinicians, thereby combining evidence-based practice with the participants’ clinical experience.

The evidence of treatment is classified in:

Strong, moderate, poor and lack of evidence

## **7. MQIC Guideline, Management of acute low back pain**

Michigan Quality Improvement Consortium Guideline, Management of acute low back pain:

Southfield (MI): Michigan Quality Improvement Consortium; 2008 Mar. 1p.

Guideline availability: Michigan Quality Improvement Consortium Web site:  
[www.mqic.org](http://www.mqic.org)

The type of supporting evidence is provided for the most significant recommendations. This guideline is based on several sources, including the ICSI Adult Low Back Pain Guideline, Institute for Clinical Systems Improvement, 2006. Guideline Developers are the Michigan Quality Improvement Consortium – Professional Association. The composition of the group that authored the guideline are physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community health and Michigan Peer Review Organization.

Levels of evidence for the most significant recommendations:

- |  |                              |
|--|------------------------------|
| A. Randomized controlled trials        | high evidence                |
| B. Controlled trials, no randomization | moderate evidence            |
| C. Observational studies               | conflicting/limited evidence |
| D. Option of expert panel              | no evidence                  |

Besides the guidelines quoted herein, there is a considerable number of further well elaborated guidelines such as the European guidelines for prevention in low back pain (Burton, Balague, Cardon, Eriksen, Henrotin,... & Lahad, 2004) New Zealand Acute Low Back Pain Guide (Accident compensation Commission, 1999) Acute low back problems in adults. Clinical practice guidelines No.14 (Bigos, Bowyer & Braem, 1994) RCGP: Clinical guidelines for the management of acute low back pain (Royal College of General Practitioners, 1999) Evidence-based guidelines for the management of acute low back pain (Bogduk, 2010) Clinical guidelines for the management of low back pain in primary care (Koes, van Tulder, Ostelo, Kim,... & Wadell, 2001) Clinical practice guidelines of the Finnish Medical Association Duodecim (Malmivaara, Kotilainen & Laasonen, 1999) Their findings and recommendations, however, are contained in the quoted guidelines.

### ***3.1.1.2 Results of search for reviews of therapy for low back pain***

Search in the Cochrane Library:

In total 38 hits.

19 systematic reviews met the subject and are included in this review

Search in MEDLINE regarding latest findings on the therapy of low back pain:

Search 1: 16668 hits

Search 2: 434 hits

Search 1 AND 2, Limits: Randomized Controlled Trial, Review, published in the last 2 years 219 results

Search 1 AND 2, Limits: Review, published in the last 2 years: 97 results

Table 7: *Result of studies concerning therapy of low back pain:*

Database	Search Results	Included Studies
Cochrane library	38	19
MEDLINE	97	9

### ***3.1.2 Definition and classification***

Low back pain is defined as acute or chronic pain in the lumbar or sacral region, which may be associated with musculo-ligamentous sprains and strains, intervertebral disc displacement, and other conditions. (Pubmed MESH Term, 2009). The ICD 10 of WHO defines low back pain in the following sub-graphs:

M54.4 lumbago with sciatica, M54.5, low back pain, lion pain, low back strain, lumbago NOS (ICD 10 G Version 2007, World Health Organization, 2007)

Osteopaths share this concept: “Pain localized between the twelfth rib and the inferior glutei folds, with or without leg pain.” (Licciardone, 2008, p 4)

The European Guidelines for non-specific CLBP define low back pain as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain. They refer to a simple and practical classification, which has gained international acceptance. This classification groups low back pain into three categories – the so-called “diagnostic triage”:

Specific spinal pathology

Nerve root pain/radicular pain

Non-specific low back pain (Araksinen et al., 2004)

The guidelines of APA/ACP also contain the division into 3 categories and use the term non-specific low back pain: pain occurring primarily in the back with no signs of a serious underlying condition (such as cancer, infection, or cauda equine syndrome), spinal stenosis or radiculopathy, or another specific spinal cause (such as vertebral compression fracture or ankylosing spondylitis). Degenerative changes or lumbar imaging are usually considered non-specific, as they correlate poorly with symptoms (Chou et al., 2007).

The NCCPC Low back pain: early management of persistent non-specific low back pain full guideline has adopted this view: Non-specific low back pain is tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain. Several structures in the back, including joints, discs and connective tissues, may contribute to symptoms. The diagnosis of non-specific low back pain is dependent on the clinician being satisfied that there is not a specific cause for their patient's pain. The lower back is commonly defined as the area bounded by the bottom of the rib cage and the buttock creases. Some people with non-specific low back pain may also feel pain in their upper legs, but the low back pain usually predominates. Several structures, including the joints, discs and connective tissues, may contribute to symptoms (Savignon et al., 2009)

The Canadian CLIP Practice Guideline also differentiates between three types of low back pain. As a synonym to non-specific low back pain, it speaks of simple back pain. The other types are back pain with neurological involvement and back pain with suspected serious spinal pathology.

Both the European Guidelines and the Canadian CLIP Practice Guideline use the term "red flags" for the third group. Red flags are warning signs that should lead the clinician to investigate for a serious pathology in need of immediate diagnosis. These are mainly lumbar complications from a serious trauma or a disease such as cancer (Rossignol et al., 2007).

The National Institute for Health and Clinical Excellence (NICE) and NCCPC clinical guidelines low back pain refer to the diagnosis and therapeutic approaches for non-specific low back pain, which they define as tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain. Several structures in the back, including the joints, discs and connective tissues, may contribute to symptoms. This is set in contrast to specific causes of low back pain: malignancy, infection, fracture and ankylosing spondylitis and other inflammatory disorders (Savignon et al., 2009).

The NVL Kreuzschmerz also differentiates between non-specific and specific low back pain, depending on whether causes, such as infection, tumor, osteoporosis, fracture, herniated disc etc. can be identified (NVL Kreuzschmerz, 2010)

The guidelines of APA/ACP suggest the following definitions relating to the duration of low back pain:

Acute low back pain: Low back pain present for fewer than 4 weeks, sometimes grouped with sub-acute low back pain as symptoms present for fewer than 3 months.

Chronic low back pain: Low back pain present for more than 3 months (Chou et al., 2007)

This is a classification that is shared by most guidelines (van Tulder et al., 2006, Rossignol et al., 2007, NVL Kreuzschmerz, 2010). Only the NCCPC guidelines define persistent or recurrent low back pain as non-specific low back pain that has lasted for more than 6 weeks, but for less than 12 months (Savignon et al., 2009).

The European Guidelines for the management of acute non-specific low back pain in primary care and NVL Kreuzschmerz also use the term recurrent low back pain, defining it as a new episode after a symptom-free period of 6 months, but not an exacerbation of chronic low back pain. (van Tulder et al., 2006, NVL Kreuzschmerz, 2010)

There is less information about chronic back pain in the literature, partly because of a lack of agreement about definition. Chronic back pain is sometimes defined as back pain that lasts for longer than 7 – 12 weeks. Others define it as pain that lasts beyond the expected period of healing, and acknowledge that chronic pain may not have well-

defined underlying pathological causes. Others classify frequently recurring back pain as chronic pain since it intermittently affects an individual over a long period (Andersson, 1999).

The APA/ACP Guidelines offer a summarization of definitions for symptoms associated with low back pain:

Acute low back pain: Low back pain present for fewer than 4 weeks, sometimes grouped with sub-acute low back pain as symptoms present for fewer than 3 months.

Cauda equina syndrome: Compression on nerve roots from the lower cord segments, usually due to a massive, centrally herniated disc, which can result in urinary retention or incontinence from loss of sphincter function, bilateral motor weakness of the lower extremities, and saddle anesthesia.

Chronic low back pain: Low back pain present for more than 3 months.

Herniated disc: Herniation of the nucleus pulposus of an intervertebral disc through its fibrous outer covering, which can result in compression of adjacent nerve roots or other structures.

Neurogenic claudication: Symptoms of leg pain (and occasionally weakness) on walking or standing, relieved by sitting or spinal flexion, associated with spinal stenosis.

Non-specific low back pain: Pain occurring primarily in the back with no signs of a serious underlying condition (such as cancer, infection, or cauda equina syndrome), spinal stenosis or radiculopathy, or another specific spinal cause (such as vertebral compression fracture or ankylosing spondylitis). Degenerative changes on lumbar imaging are usually considered non-specific, as they correlate poorly with symptoms.

Radiculopathy: Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.

Sciatica: Pain radiating down the leg below the knee in the distribution of the sciatic nerve, suggesting nerve root compromise due to mechanical pressure or inflammation. Sciatica is the most common symptom of lumbar radiculopathy.

Spinal stenosis: Narrowing of the spinal canal that may result in bony constriction of the cauda equine and the emerging nerve roots (Chou et al., 2007).

Usually surgeons tend to reject the global definition of non-specific chronic low back pain and attempt to identify sub-groups in the chronic LBP group of patients with



presumed, and in part clinically defined, symptoms elicited by a degenerated segment, often described as segmental pain, often the sequel of a disc herniation (Airaksinen et al., 2004). In Table 8 you can find a summary of definition and classification.

Table 8: *Summary of definition and classification:*

<p><b><u>Definition:</u></b>  Low back pain: Pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain (Airaksinen et al., 2004).</p>
<p><b><u>Classification:</u></b>  The “diagnostic triage”  1. Specific spinal pathology  2. Nerve root pain/radicular pain  3. Nonspecific low back pain (Chou et al., 2007)</p>
<p><b><u>Definition of non-specific low back pain:</u></b>  Non-specific low back pain is tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain. Several structures in the back, including the joints, discus and connective tissues, may contribute to symptoms (Savignon et al., 2009).</p>
<p><b><u>Definition according to duration:</u></b>  Acute low back pain: Low back pain present for fewer than 4 weeks  Sub-acute low back pain: Low back pain present for fewer than 3 months  Chronic low back pain: Low back pain present for more than 3 months (Chou et al., 2007)  Recurrent low back pain: A new episode after a symptom-free period of 6 months, but not an exacerbation of chronic low back pain (Airaksinen et al., 2004)</p>

### 3.1.3 Etiology

LBP symptoms, pathologies and radiological findings differ greatly. Pain is not attributable to specific pathology or neurological encroachment in about 85 % of people (Deyo, Rainville & Kent, 1992).

In a minority of patients presenting themselves for initial evaluation in a primary care setting, low back pain is caused by a specific disorder, such as cancer (0.7 %), compression fracture (4 %), or spinal infection (0.01 %), ankylosing spondylitis (0.3 - 5 %), spinal stenosis (3 – 4 %), cauda equine syndrome (prevalence 0.04 %) and symptomatic herniated disc (3 – 4 %) (Chou et al., 2007). A remarkable number of

patients complain about pain in the back and the leg following failed back surgery. It was estimated that 37,500 new patients suffer failed back surgery syndrome annually in the US.

It seems that the prevalence of lumbar radiculopathy has never been examined. It may be concluded that specific causes of low back pain are rare (< 15 % of all back pain) (Airaksinen et al., 2004).

The most frequently reported risk factors are heavy physical work, frequent bending, twisting, lifting, pulling and pushing, repetitive work, static postures and vibrations, psychosocial risk factors including stress, distress, anxiety, depression, cognitive dysfunction, pain behavior, job dissatisfaction and mental stress at work (van Tulder et al., 2006). In a literature review, Waddell et al identified the obstacles having a major impact on the ability to return to usual activities. They are:

- Clinical: intensity of pain, perceived disability, perception of health in general, symptoms (with no signs) of radiating pain below the knee, history of prolonged back pain
- Psychosocial: psychological distress, depression, fears and beliefs, catastrophizing, somatization
- Work-related: satisfaction at work, patient's projection with regard to returning to work, financial incentives, absence from any type of work (Waddell & Burton, 2000)

Table 9: *Summary of etiology:*

<p><b><u>Specific causes are rare:</u></b> Pain is not attributable to specific pathology or neurological encroachment in about 85 % of people (Airaksinen et al., 2004).</p>
<p><b><u>Specific disorder:</u></b> Cancer (0.7 %), compression fracture (4 %), spinal infection (0.01 %), ankylosing spondylitis (0.3-5 %), herniated disc (3-4 %), spinal stenosis (3-4 %), cauda equine syndrome (prevalence 0.04 %) (Chou et al., 2007). It appears that the prevalence of lumbar radiculopathy has never been examined (Airaksinen et al., 2004).</p>
<p><b><u>Risk factors:</u></b> Heavy physical work, frequent bending, twisting, lifting, pulling and pushing, repetitive work, static postures and vibrations, psychosocial risk factors including stress, distress, anxiety, depression, cognitive dysfunction, pain behavior, job dissatisfaction and mental stress at work (van Tulder et al., 2006).</p>

### **3.1.4 Epidemiology**

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months and 7.6 % reported at least 1 episode of severe acute low back pain within a 1-year period.

There is generally a favorable prognosis of acute low back pain with or without sciatica, including a high probability for substantial improvement in the first month, however, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity.

In the U.S. more than 85 % of patients who present themselves to primary care have low back pain that cannot reliably be attributed to a specific disease or spinal abnormality (non-specific low back pain) (Chou et al., 2007).

According to the NCCPC guideline, low back pain affects probably around one-third of the UK adult population each year. Of these, around 20 % (1 in 15 of the population) will consult their GP about their back pain (Mac Farlane, Jones, & Hannaford, 2006). This results in 2.6 million people, in the UK, seeking advice about back pain from their GP each year (Savignon et al., 2009).

One year after a first episode of back pain, 62 % of people still have pain and 16 % of those initially unable to work are not working after one year. Typically, pain and disability improve rapidly during the first month (58 % reduction from initial scores for both pain and disability) with little further improvement being observed after three months. Estimates for the adult population burden of chronic back pain include 11% for disabling back pain in the previous three months, 23 % for low back pain lasting more than three months and 18 % for at least moderately troublesome pain in the previous month (Savignon et al., 2009).

The European Guidelines for non-specific CLBP provide the following results from their systematic review:

None of the reviews identified by them gave specific prevalence for acute, recurrent, chronic or non-specific low back pain. They also address the issue that the high number of patients with recurrent pain makes it difficult to distinguish between acute and

chronic pain. There is also a lack of standards for severity, location, and co-morbid conditions (Airaksinen et al., 2004).

One systematic review identified 56 population prevalence studies of low back pain. Thirty studies were of acceptable quality. Point prevalence of low back pain ranged from 12 – 33 %, 1-year prevalence from 22 – 65 % and lifetime prevalence from 11 – 84 % (Walker, 2000).

The authors of the European Guidelines for non-specific CLBP summarize that after an initial episode of LBP, 44 – 78 % of patients suffer relapses of pain, and 26 – 37 % have relapses of work absence. They found little scientific evidence on the prevalence of chronic non-specific low back pain and concluded that the best estimates suggest that the prevalence is approximately 23 %, with 11 – 12 % of the population being disabled by low back pain (Airaksinen et al., 2004).

The annual prevalence of chronic low back pain ranges from 15 % to 45 %, with a point prevalence of 30 %. The studies evaluating chronic low back pain estimated the average age related prevalence of persistent low back pain to be approximately 15 % in adults and 27 % in the elderly (Manchikanti et al, 2009). It is estimated that among the working population (age 20 to 64), more than 26 million Americans have frequent low back pain, whereas among Americans aged 65 and older, almost 60 million have frequent low back pain. Another study evaluated pain associated with disability and graded them into Grade I to Grade IV. Based on this, 11 % of the patients had Grade III and Grade IV pain levels with high pain intensity and significant disability. In an extensive review of the international literature on the incidence of disabling low back pain, it is also reported that the problem of low back pain was even greater in Canada, Great Britain, Netherlands, and Sweden, in comparison to the United States and Germany (Manchikanti et al., 2009). In a review of world prevalence data, Volinn suggested that there were lower rates of prevalence in developing countries than in developed countries, but did not determine whether differences reflect demographic, cultural or research method factors (Volinn, 1997). It is estimated that 28 % of the U.S. industrial population will experience disabling low back pain at some time and 8 % of the entire working population will be disabled in any given year, contributing to 40 % of all lost work days. Remarkably, studies have shown increasing prevalence of chronic pain, specifically low back pain. A

study reported the rising prevalence of chronic low back pain following an evaluation of North Carolina households conducted in 1992 and repeated in 2006. The results showed an increasing prevalence of chronic impairing low back pain over the 14-year interval from 3.9 % (95 % CI, 3.4 % – 4.4 %) in 1992 to 10.2 % (95 % CI, 9.3 % – 11.0 %) in 2006. The overall prevalence of low back pain increased by 162 % (an annual increase of 11.6), across all demographic groups.

The duration of back pain and its chronicity have been topics of controversy. It is widely believed that most of the episodes will be short-lived with 80 % to 90 % of attacks resolving in about 6 weeks, irrespective of the administration or type of treatment, with only 5 % to 10 % of patients developing persistent back pain. However, this widely held belief has been frequently questioned as the condition tends to relapse and most patients will experience multiple episodes and long lasting back pain is common (Manchikanti et al, 2009). However, it is reported that the recurrence of low back pain was found to be much less common than previous estimates, ranging from 24 % using 12 months as the definition of recurrence, to 33 % using pain at follow-up as the definition of recurrence. Even then, this is higher than the conventionally believed proportion of 4 % to 10 %. A report showed a prevalence of back pain among the elderly within the community ranging from 13 % to 49 %; within the medical practice setting, the range was from 24 % to 51 %; and in the long-term care setting, the prevalence was 40 %, with an overall prevalence of 27 %. They suggested that the prevalence of low back pain in the elderly is not known with certainty and is not comparable with that in the younger population. The prevalence of LBP in children is low (1 %-6 %) but increases rapidly (18 % – 50 %) in the adolescent population (Manchikanti et al., 2009). The prevalence of LBP peaks around the end of the sixth decade of life. In a prospective study in United Kingdom, the age distribution of LBP was unimodal, with the peak prevalence occurring in those aged 45 to 59 years old. This is similar to USA epidemiological data describing the peak point prevalence, period prevalence and lifetime prevalence all within ages 55 to 64 years (Kent & Keating, 2005)

In the USA, for people aged 45 years or less, LBP is the most frequent cause of activity limitation. Also about one in 10 Australian adults have had activity limitation as a result of LBP in the past six months severe enough to result in significant time off from

usual activities. These data are very similar to the 6-month LBP intensity and activity limitation data of a Canadian adult sample (Kent & Keating, 2005).

In a sample from North Carolina USA, 61 % of recent-onset (<12 weeks) LBP sufferers sought care during their most recent episode. Those seeking care were likely to have more intense pain, leg pain, or a pain onset at work, than those who did not seek care (Carey, Evans, Hadler, Lieberman, Kalsbeek,... & Jackman, 1996).

Licciardone (2008) scanned patient visits attributed to LBP in the National Ambulatory Medical Care Survey (NAMCS) during 2003-2004. There were 61.7 million LBP patient visits and 42.4 million primary LBP patient visits. 55 % of LBP patient visits were received by primary care physicians (Licciardone, 2008).

The most common clinicians consulted for back pain in North America are chiropractors, general medical practitioners and orthopedists. In Australia, the most common clinicians consulted for LBP are chiropractors, general medical practitioners, massage therapists, and physiotherapists (Kent & Keating, 2005). In Table 10 there is a summary of the epidemiologically facts.

Table 10: *Summary of epidemiology:*

<p><b><u>A common problem:</u></b>          Approximately one quarter of U.S. adults reported having low back pain in the past 3 months.          Up to one third of patients are reporting persistent back pain 1 year after an acute episode.          In the U.S. more than 85 % of patients can be attributed to non-specific low back pain (Chou et al., 2007)          Around one-third of the UK adults are affected by low back pain each year.          One year after a first episode, 62 % of people still have pain and 16 % of those initially unable to work are not working after one year (Savignon et al., 2009).</p>
<p><b><u>Prevalence:</u></b>          Point prevalence of low back pain ranged from 12 – 33 %,          1-year prevalence form 22 – 65 % and          lifetime prevalence from 11 – 84 % (Walker, 2000).</p>
<p><b><u>Patient significance:</u></b>          11 % of the U.S. patients have high pain intensity and significant disability (Manchikanti et al., 2009)</p>
<p><b><u>Chronicity:</u></b>          Studies have shown increasing prevalence of chronic low back pain. It is widely believed that most of the episodes will be short-lived with 80 % to 90 % of attacks resolving in about 6 weeks. But a review reported that the recurrence of low back pain was ranging from 24 % to 33 % (Manchikanti et al., 2009).</p>
<p><b><u>Age:</u></b>          It is estimated that among the working population, more than 26 million Americans have frequent low back pain ,whereas among Americans aged 65 and older, almost 60 million have frequent low back pain (Manchikanti et al., 2009).          Prevalence of LBP in children is low (1 % - 6 %) but increases rapidly (18 % - 59 %) in adolescents.          In UK the peak prevalence occurring in those aged 45 to 59 years old. This is similar to U.S. epidemiological data with the peak point prevalence within ages 55 to 64 years.          In the USA, for people aged 45 or less, LBP is the most frequent cause of activity limitation (Kent &amp; Keating, 2005).</p>
<p><b><u>Care visits:</u></b>          Low back pain is the fifth most common reason for all physician visits in the US.          55 % of LBP patient visits were received by primary care physicians. (Licciardone, 2008)</p>

### 3.1.5 *Diagnostics*

APA/ACP suggests categorizing patients under the “diagnostic triage“, according to their case history and physical examination. Diagnostic triage into 1 of the 3 categories helps guide subsequent decision making (Chou et al., 2007).

The priority in the examination procedure is recommended to follow this line of clinical reasoning. The first priority is to make sure that the problem is of musculoskeletal origin and to rule out non-spinal pathology. The next step is to exclude the presence of serious spinal pathology. The next priority is to decide whether the patient has nerve root pain. If that is not the case, the pain is classified as non-specific low back pain (van Tulder et al., 2006).

This requires that the patient’s case history be recorded in detail and the patient physically examined extensively. In the guideline of APA/ACP, the authors present and assess tests and facts from the patient’s case history that are linked to specific lumbar spine defects such as herniated disc, lumbar spinal stenosis, vertebral compression fracture or ankylosing spondylitis, but also the possibility of low back pain due to problems of non-spinal origin such as cancer or infection. Psychosocial factors and emotional distress are mentioned as further factors (Chou et al., 2007).

The European Guidelines for the management of chronic non-specific low back pain also emphasize the use of diagnostic triage to exclude specific spinal pathology and nerve root pain. They also stress the assessment of prognostic factors (yellow flags), which include work-related factors, psychosocial distress, depressive mood, severity of pain and functional impact, prior episodes of LBP, extreme symptom reporting and patient expectations (Airaksinen et al., 2004).

The Canadian CLIP Practise Guideline agrees that this categorization makes sense and offers a helpful differentiation of characteristics regarding case history and examination.

The following characteristics are listed for simple back pain:

- Lumbar or lumbosacral pain with no neurological involvement
- ”Mechanical pain”, varying over time and with physical activity
- General health of patient is good



The second category is back pain with neurological involvement. It is used to characterize patients showing one or several symptoms or signs of possible neurological involvement, such as:

Symptoms:

- Pain radiating below the knee, which is as intense or more intense than the back pain
- Pain often radiating to the foot or toes
- Numbness or paresthesia in the painful area

Signs:

- Positive sign for radicular irritation as tested, for example, by straight leg raising
- Motor, sensitivity or reflex signs supporting nerve root involvement

The third category is back pain with suspected serious spinal pathology, showing the following general characteristics:

- Violent trauma
- Constant, progressive, non-mechanical pain
- Thoracic or abdominal pain
- Pain at night that is not eased by a prone position
- History of or suspected cancer, HIV or other pathologies that can cause back pain
- Chronic corticosteroid consumption
- Unexplained weight loss, chills or fever
- Significant and persistent limitation of lumbar flexion
- Loss of feeling in the perineum, recent onset of urinary incontinence (Rossignol et al., 2007)

The most common recommendation published throughout the world in clinical practice guidelines concerns initial patient triage (Koes et al., 2001). The main sought after goal is the identification of red flags requiring immediate medical or surgical attention. In practice, such complications are rare but systematic questioning and examination is required in order to detect them.

Neurological signs and symptoms in the patient with back pain with no red flags often resolve themselves without recourse to surgery. A referral for a specialized consultation should not be required until the clinician has observed a functional deficit that is persistent or deteriorating after four weeks (Rossignol et al., 2007).

The Nationale Versorgungsleitlinie Kreuzschmerz (2010) recommends refraining from further diagnostic measures if the case history and clinical examination do not suggest a risk of critical development or other serious pathologies. The complaint should at this stage be classified as non-specific LBP. If, despite medical measures, pain persists for longer than 4 weeks, psychosocial risk factors should be recorded already in the primary care setting. If pain persists further (> 12 weeks), extended somatic diagnostic measures and a comprehensive diagnosis of psychosocial influencing factors should be performed. If warning signs are detected, further laboratory or imaging examinations should be performed and/or the patient be referred to specialized medical treatment (NVL Kreuzschmerz, 2010).

The authors of the APA/ACP guideline recommend to refrain from routine radiography imaging on patients with non-specific low back pain because there is no evidence that routine radiography in patients with non-specific low back pain is associated with a greater improvement in patient outcomes, and unnecessary exposition to ionizing radiation should be avoided.

By contrast, prompt work-up with MRI or CT is recommended in patients who have severe or progressive neurologic deficits or are suspected of having a serious underlying condition. Delayed diagnosis and treatment are associated with poorer outcomes. MRI is generally preferred over CT. MRI or CT are also recommended for patients with persisting low back pain and signs or symptoms of radiculopathy or spinal stenosis if they are potential candidates for surgery or epidural steroid injection (Chou et al., 2007).

The European Guidelines agree to this view regarding non-specific chronic LBP. They also recommend radiographic imaging only for cases where a specific cause is strongly suspected. MRI is recommended for diagnosing patients with radicular symptoms (Airaksinen et al., 2004).

The NCCPC guidelines of low back pain also recommend not offering x-ray of the lumbar spine. They recommend to only offering MRI for non-specific low back pain in the context of a referral for an opinion on spinal fusion or if one of the following diagnoses is suspected: spinal malignancy, infection, fracture, cauda equine syndrome, ankylosing spondylitis or another inflammatory disorder (Savignon et al., 2009).

The authors of the NVL Kreuzschmerz express similar views. In cases of acute non-specific LBP, radiographic imaging should be performed for the suspected causes only if there are specific warning signs (“red flags“). In cases of LBP showing no improvement or even deterioration after 6 weeks of therapy according to the guidelines, a diagnostic imaging technique should be used once. The same is recommended for patients with chronic non-specific LBP (>12 weeks), however only if psychosocial chronification factors can be ruled out (NVL Kreuzschmerz, 2010).

The NCCPC guideline evaluates the following recommendation: Keep diagnosis under review. Do not offer x-ray of the lumbar spine for the management of non-specific low back pain. Consider MRI (magnetic resonance imaging) when a diagnosis of spinal malignancy, infection, fracture, cauda equine syndrome or ankylosing spondylitis or other inflammatory disorders are suspected. Only offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion (Savignon et al., 2009).

The Canadian CLIP Practice Guideline is also in line with this recommendation. X-ray is advised particularly for patients over 55 years of age to exclude spinal pathology. Specialized imaging tests (CT and MRI) should be reserved for cases in which surgery is being considered or where there is a strong suspicion of systemic disease.

The authors point out a specific problem:

Unnecessary use of these highly sensitive examinations will produce numerous false positive results, which can create a labeling effect for the clinician and his patient that can in itself contribute to a less favorable prognosis (Rossignol et al., 2007).

Lumbar intervertebral discs, facet joints, sacroiliacal joint, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the lumbar spine with resulting symptoms of low back pain and lower extremity pain. The diagnostic blocks applied in the precision diagnosis of chronic low back pain include

lumbar facet joint nerve blocks, lumbar provocation discography, and sacroiliac joint blocks. Manchikanti et al explored the indicated evidence for accuracy of diagnostic facet joint nerve blocks as very low in the diagnosis of lumbar facet joint pain. The evidence for lumbar provocation discography and sacroiliac joint injections is low (Manchikanti et al, 2009).

Rubinstein and van Tulder presented a best-evidence review of diagnostic procedures for neck and low back pain. They say the real challenge to the clinician is to distinguish serious spinal pathology or nerve-root pain from non-specific low back pain. Systematic reviews were identified which evaluated evidence for diagnostic procedures in the following categories: history, physical examination, and special studies, including diagnostic procedures. With regard to the physical examination, the straight-leg raise is the only sign consistently reported to be sensitive for sciatica due to disc herniation, but is limited by its low specificity. The diagnostic accuracy of other neurological signs and tests is unclear. For plain spinal radiography there is strong evidence that it accurately identifies sciatica due to disc herniation, as well as serious pathology, but is not advisable for non-specific low back pain. (Rubinstein & van Tulder, 2008) In Table 11 there is a summary of diagnostic facts.

Table 11: *Summary of diagnostics:*

<p><b><u>Diagnostic triage:</u></b> Diagnostic triage into 1 of the 3 categories helps guide subsequent decision making: Step 1: make sure that the problem is of musculoskeletal origin and to rule out non-spinal pathology (i.e. cancer, infection) Step 2: Exclude the presence of serious spinal pathology (i.e. herniated disc, vertebral compression fracture) Step 3: Decide whether the patient has nerve root pain If that is not the case, the pain is classified as non-specific low back pain (van Tulder et al., 2009)</p>
<p><b><u>Prognostic factors:</u></b> Assessment of prognostic factors like work related factors, psychosocial distress, depressive mood, severity of pain and functional impact, prior episodes of LBP, patient expectations (Airaksinen et al., 2004)</p>
<p><b><u>X-ray and MRI or CT:</u></b> There is no evidence to recommend radiographic imaging for the management of non-specific low back pain. A prompt work-up with MRI or CT is recommended in patients who have severe or progressive neurological deficits or are suspected of having a serious underlying condition. MRI or CT is also recommended to assess patient with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis if there are potential candidates for surgery or epidural steroid injection (Chou et al., 2007).</p>
<p><b><u>Diagnostic blocks:</u></b> These are applied in the precision diagnosis of chronic low back pain and include lumbar facet joint nerve blocks, lumbar provocation discography, and sacroiliac joint blocks. The evidence for accuracy of diagnostic facet joint nerve blocks is very low in the diagnosis of lumbar facet joint pain. The evidence for lumbar provocation discography and sacroiliac joint injections is low (Manchikanti et al., 2009).</p>

### **3.1.6 Therapy**

As was elaborated in the chapters Definition and Diagnostics, the guidelines used, and the system reviews as well, refer to the treatment of non-specific low back pain, as all forms of specific low back pain require a different therapeutic approach, depending on the specific cause. Therefore, the forms of therapy suggested in this topic are intended for the treatment of acute, sub-acute or chronic non-specific low back pain.

The following forms of therapy are described in Table 12:

*Table 12: Summary of recommended therapeutic approaches:*

General advice on self-management	Opioids
Exercise therapy	Muscle relaxants
Back school	Antidepressants
Cognitive behavioral therapy	Herbal medicine
Individual patient education	Manual therapy
Interdisciplinary rehabilitation (multidisciplinary therapy)	Other non-pharmacological therapies
Acetaminophen (Paracetamol)	Invasive procedures
Nonsteroidal anti-inflammatory drugs (NSAID)	Surgery

#### General advice on self-management

Butler et al reviewed web sites with regard to information they can provide to patients with back pain. He published his results in “The Back Book“. Among the key messages the following were noted:

- reassure the patient about the generally positive prognosis of back pain
- reassure the patient that serious spinal problems are rare and that the signs for such problems are not present
- reassure the patient regarding returning to continuing usual activities, including work, even in the presence of symptoms
- avoid labeling the patient by putting an exaggerated emphasis on a specific spinal problem and its impact (Rossignol et al., 2007)

In Table 13 you can find a overview of research findings according to this subject.

Table 13: *Comparison of general advice on self-management:*

Guidelines	Year	Title	Comments/Results
Chou et al.	2007	ACP and APS Guideline	General advice on self-management should include recommendations to remain active. This is more effective than resting in bed.
Savigny et al.	2009	NCCPC Guideline	Information on the nature of the problem. Encourage the person to be physically active and continue with normal activities as far as possible.
Rossignol et al.	2007	CLIP Practice Guideline	To remain as active as possible is the most widely respected clinical and scientific recommendation in the world today. Patients advised to continue daily activities including work and avoiding bed rest recover more quickly than patients who are advised to be guided by pain in resuming activity.
Airaksinen et al.	2006	European guidelines for chronic LBP	Promote self-management: advise people to be physically active, to carry on with normal activities as far as possible
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Individual information and consultation, measures to increase activity
Michigan Quality Improvement Consortium	2008	Management of acute low back pain	Stay active and continue ordinary activity within the limits permitted by pain. Avoid bed rest. Early return to work is associated with less disability.
Cochrane systematic review	Year	Title	Comments/Results
Hilde, Hagen, Jamtvedt & Winnem	2006	Advice to stay active as a single treatment for low-back pain and sciatica.	Bed rest is ineffective. There was strong evidence against bed rest. If there is such strong evidence against bed rest, the corollary is that patients should stay active instead.

## Exercise therapy

A supervised exercise program or formal home exercise regimen, ranging from programs aimed at general physical fitness or aerobic exercise to programs aimed at muscle strengthening, flexibility, stretching, or different combinations of these elements (Chou et al., 2007)

Table 14: *Comparison of exercise therapy:*

Guidelines:	Year	Title	Comments/Results
Savigny et al.	2009	NCCPC Guideline	Advise people with low back pain to exercise. Consider offering a structured exercise program tailored to the person.
Chou et al.	2007	ACP an APS Guideline	Supervised exercise therapy and home exercise regimens are not effective for acute low back pain, and the optimal time to start exercise therapy after the onset of symptoms is unclear. For patients with chronic LBP in meta-regression analyses, exercise programs that incorporate individual tailoring, supervision, stretching, and strengthening are associated with the best outcomes.
Airaksinen et al.	2006	European Guidelines chronic LBP	Advise to supervised exercise therapy
Rossignol et al.	2007	CLIP Practice guideline	Recommendation to exercise for short-term pain reduction for acute and sub-acute pain For chronic low back pain exercises are also recommended.
Michigan Quality Improvement Consortium	2008	Management of acute low back pain	Recommended for adults with low back pain or back-related leg symptoms for < 6 weeks: Safe back exercises and Mc Kenzie exercises are helpful for pain radiating below the knee.
Cochrane systematical review:	Year	Title	Comments/Results
Hayden, Tulder, Malmivaara & Koes	2005	Exercise therapy for treatment of non-specific low back pain	Exercise therapy is slightly effective at decreasing pain and improving function for chronic low back pain. In patients with sub-acute low back pain there is some evidence that a graded activity program improves absenteeism outcomes. For patients with acute low back pain it is as effective as either no treatment or other conservative treatments.



Medline review:	Year	Title	Comments/Results
Choi, Verbeek, Tam & Jiang	2010	Exercises for prevention of recurrences of low back pain	There is moderate quality evidence that post-treatment exercise programmes can prevent recurrences of back pain but conflicting evidence was found for treatment exercise.

### Back school

Back school is an intervention consisting of an education and a skills program, including exercise therapy in which all lessons are given to groups of patients and supervised by a paramedical therapist or medical specialist (Chou et al., 2007).

Table 15: *Comparison of back school:*

Guidelines:	Year	Title	Comments/Results
Airaksinen et al.	2006	European guidelines for chronic LBP	Consider back schools where information given is consistent with evidence-based recommendations for short-term (<6 weeks) pain relief and improvements in functional status. We do not recommend back schools as a treatment for chronic low back pain when aiming at long-term effects (>12 months).
Rossignol et al.	2007	CLIP Practice Guideline	Back school is recommended for chronic low back pain
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Back school is recommended for chronic low back pain
Cochrane systematic review:	Year	Title	Comments/Results
Heymans, van Tulder, Esmail, Bombardier & Koes	2004	Back schools for non-specific low back pain	There is moderate evidence suggesting that back schools are more effective for pain and function than other conservative treatments if patients are from the general public, primary or secondary care. There is conflicting evidence whether back schools are more effective than placebo or waiting list controls for pain, function and return-to-work. There is moderate evidence suggesting that back schools, in an occupational setting, reduce pain and improve function and return-to work status.

## Cognitive behavioral therapy

A range of therapies based on psychological models of human cognition, learning and behavior (Savignon et al., 2009). Progressive relaxation: A technique which involves the deliberate tensing and relaxation of muscles, in order to facilitate the recognition and release of muscle tension (Chou et al., 2007).

Table 16: *Comparison of cognitive behavioral therapy:*

Guidelines:	Year	Title	Comments/Results
Savigny et al.	2009	NCCPC Guideline	Consider referral for a combined physical and psychological treatment programme for people who have received at least one less intensive treatment and have high disability and/or significant psychological distress. Combined physical and psychological treatment programmes should include a cognitive behavioral approach.
Airaksinen et al.	2006	European guidelines for chronic LBP	The use of a cognitive-behavioral approach, in which graded exercises are performed, using exercise quotas, appears to be advisable. We recommend cognitive-behavioral treatment for patients with chronic low back pain.
Chou et al.	2007	ACP and APS Guideline	For sub-acute low back pain functional restoration with a cognitive-behavioral component reduces work absenteeism due to low back pain in occupational settings. For chronic low back pain, cognitive-behavioral therapy or progressive relaxation varies from fair to good.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	For patients with non-specific chronic LBP cognitive-behavioral therapy or progressive relaxation is recommended.
Cochrane systematic review:	Year	Title	Comments/Results
Ostelo, van Tulder, Vlaeyen, Linton, Morley & Assendelft	2005	Behavioral treatment for chronic low back pain	A combined respondent-cognitive therapy and a progressive relaxation therapy alone are more effective than waiting list control for short-term pain relief. No significant differences could be detected when the various types of cognitive-behavioral treatments were compared among each other. No significant differences could be detected in short-term and long-term effectiveness when behavioral components are added to usual treatment programs for chronic low-back pain (i.e. physiotherapy, back education, or various forms of medical treatment) or exercises.

## Individual patient education

This means brief individualized educational interventions: Individualized assessment and education about low back pain problems without supervised exercise therapy or other specific interventions. As they are defined here, brief educational interventions differ from back schools because they do not involve group education or supervised exercise (Chou et al., 2007).

Table 17: *Comparison of individual patient education:*

Guidelines:	Year	Title	Comments/Results
Airaksinen et al.	2006	European Guidelines of chronic LBP	We recommend brief educational interventions. We do not give recommendations on the specific type of brief educational intervention to be undertaken (face-to-face, Internet-based, one-to-one, group education, discussion groups, etc.).
Chou et al.	2007	ACP and APS Guideline	Brief individualized educational interventions (defined as a detailed clinical examination and advice, typically lasting several hours over 1 to 2 sessions) can reduce sick leave in workers with sub-acute low back pain.
Savigny et al.	2009	NCCPC Guideline	Include an educational component as part of other interventions, but do not offer stand-alone formal education programmes.
Cochrane systematic review:	Year	Title	Comments/Results
Engers, Jellema, Wensing, van der Windt, grol & van Tulder	2008	Individual patient education for low back pain	People with low-back pain who received an in-person patient education session lasting at least two hours in addition to their usual care had better outcomes than people who only received usual care. Shorter education sessions, or providing written information by itself without an in-person education session, did not seem to be effective. People with chronic low-back pain were less likely to benefit from patient education than people with acute pain.
Brox, Storheim, Grotle, Indahl & Eriksen	2008	Systematic review of back schools, brief education, and fear-avoidance training for chronic LBP	Consistent recommendations are given for brief education in the clinical setting, and fear-avoidance training should be considered as an alternative to spinal fusion.

### Interdisciplinary rehabilitation (multidisciplinary therapy)

It is defined as an intervention that includes a physician consultation coordinated with a psychological, physical therapy, social, or vocational intervention. It combines and coordinates physical, vocational, and behavioral components and is provided by multiple health care professionals with different clinical backgrounds. The intensity and content of interdisciplinary therapy varies widely. Intensive interdisciplinary rehabilitation may not be available in all settings, and costs for similarly effective interventions can vary substantially (Chou et al., 2007).

Table 18: *Comparison of interdisciplinary rehabilitation:*

Guidelines:	Year	Title	Comments/Results
Chou et al.	2009	ACP and APS Guideline	For sub-acute low back pain, intensive interdisciplinary rehabilitation is moderately effective, although the level of supporting evidence for different therapies varies from fair to good. There is insufficient evidence to recommend the use of decision tools or other methods for tailoring therapy in primary care, although initial data are promising.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Patients with chronic non-specific low back pain should be treated with multimodal curing or rehabilitation programmes if less intense evidence-based therapies have not been sufficiently effective.
Airaksinen et al.	2006	European guidelines for chronic LBP	We recommend multidisciplinary bio-psychosocial rehabilitation with functional restoration for patients with chronic low back pain who have failed mono-disciplinary treatment options.
Savignon et al.	2009	NCCPC Guideline	Consider referral for a combined physical and psychological treatment programme, comprising around 100 hours over a maximum of 8 weeks, for people who have received at least one less intensive treatment and have high disability and/or significant psychological distress.
Cochrane	Year	Title	Comments/Results
Karjalainen, Malmivaara, van Tulder, Roine, Jauhiainen, ... & Hurri	2003	Multidisciplinary bio-psychosocial rehabilitation for sub-acute low back pain among working age adults.	Multidisciplinary bio-psychosocial rehabilitation programs (including workplace visits) seem to offer some benefit for adults with sub-acute low back pain, but further research on effectiveness and cost-effectiveness is needed. For chronic low back pain physical rehabilitation can also include psychological, behavioral and educational interventions. This is available as outpatient rehabilitation, or in pain clinics and rehabilitation centers.

### Acetaminophen (paracetamol)

The upper limit of U.S. Food and Drug Administration-[FDA] approved dosing of acetaminophen is 4g/d in healthy adults. Higher doses are associated with asymptomatic elevations of aminotransferase levels. Limitation of doses must be respected (Chou et al., 2007).

Table 19: *Comparison of acetaminophen:*

Guidelines:	Year	Title	Comments/Results
Chou et al.	2007	ACP and APS Guideline	Acetaminophen is a reasonable first-line option for treatment of acute or chronic low back pain because of a more favorable safety profile and low cost.
Savigny et al.	2009	NCCPC Guideline	Advise the person to take regular paracetamol as the first medication option.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	For light to moderate acute LBP, paracetamol can be prescribed up to a maximum daily dosage of 3 g. For sub-acute and chronic LBP, paracetamol can only be used upon a comprehensive account of drug prescription history, and only for a short time in a dosage that is as low as possible.
Michigan Quality Improvement Consortium	2008	Management of acute low back pain	Medication treatment depending on pain severity with acetaminophen
Cochrane systematic review:	Year	Title	Comments/Results
Davies, Maher & Hancock	2008	A systematic review of paracetamol for non-specific low back pain	There is insufficient evidence to assess the efficacy of paracetamol in patients with low back pain. There is a clear need for large, high quality RCTs to provide reliable evidence of effectiveness.

### Nonsteroidal anti-inflammatory drugs (NSAID)

Clinicians should assess cardiovascular and gastrointestinal risk factors before prescribing NSAIDs and recommend the lowest effective doses for the shortest periods necessary. Clinicians should also remain alert for new evidence about which NSAIDs are safest and consider strategies for minimizing adverse events in higher-risk patients who are prescribed NSAIDs (such as co-administration with a proton-pump inhibitor) (Chou et al., 2007).

There is evidence for up to 1.2 g ibuprofen, 100 mg diclofenac or 750 mg naproxen per day. If the effect is less than satisfactory, the dose may be increased up to 2.4 g ibuprofen, 150 mg diclofenac or 1.25 g naproxen provided possible side effects are taken into account and precautions taken where necessary. (NVL Kreuzschmerz, 2010)

At Table 20 is a comparison of the findings to this subject.

Table 20: Comparison of nonsteroidal anti-inflammatory drugs:

Guidelines:	Year	Title	Comments/Results
Savigny et al.	2009	NCCPC Guideline	Offer non-steroidal anti-inflammatory drugs (NSAIDs). Give due consideration to the risk of side effects of NSAIDs, especially in older people and other people with increased risk of experiencing side effects. When offering treatment with an oral NSAID/COX-2 (cyclooxygenase 2) inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor. In either case, for people over 45 these should be co-prescribed with a PPI, choosing the one with the lowest acquisition cost.
Airaksinen et al.	2006	European Guidelines for chronic LBP	Most studies examined the effectiveness for up to 3-month periods of time. There is strong evidence that NSAIDs are effective for the relief of chronic low back pain. We recommend NSAIDs for pain relief in patients with chronic low back pain. Because of the side-effects, NSAIDs should only be used for exacerbations or short-term periods (up to 3 months)
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	For acute and chronic LBP, tNSARs should be used for pain relief in limited dosage and for as short as possible. In patients with gastrointestinal risks, a proton pump inhibitor should be co-prescribed as a precaution. There is recommendation against parenteral administration of tNSARs. Provided warning instructions are taken into account, COX-2 inhibitors can be used for acute or chronic non-specific low back pain where there is a contraindication or intolerance of tNSARs.
Chou et al.	2007	ACP and APS Guideline	Non-selective NSAIDs are effective, but they are associated with well-known gastrointestinal and renovascular risks. In addition, there is an association between exposure to cyclooxygenase-2–selective or most nonselective NSAIDs and increased risk for myocardial infarction. There is insufficient evidence to recommend for or against analgesic doses of aspirin in patients with low back pain.
Cochrane	Year	Title	Comments/Results
Roelofs et al.	2008	Non-steroidal anti-inflammatory drugs for low back pain	NSAIDs are slightly effective for short-term symptomatic relief in patients with acute and chronic low-back pain without sciatica. In patients with acute sciatica, no difference in effect between NSAIDs and placebo was found. NSAIDs are not more effective than other drugs (paracetamol/acetaminophen, narcotic analgesics, and muscle relaxants). The new COX-2 NSAIDs do not seem to be more effective than traditional NSAIDs, but are associated with fewer side effects, particularly stomach ulcers. Some COX-2 NSAIDs are associated with increased cardiovascular risk.

## Opioids

Because of substantial risks, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy. Failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation (Chou et al., 2007).

Table 21: *Comparison of opioids:*

Guidelines	Year	Title	Comments/Results
Chou et al.	2007	ACP and APS Guideline	Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled with acetaminophen and NSAIDs. Evidence is insufficient to recommend one opioid over another.
Savignon et al.	2009	NCCPC Guideline	Consider offering strong opioids for short-term use to people in severe pain. Consider referral for specialist assessment for people who may require prolonged use of strong opioids. Give due consideration to the risk of opioid dependence and side effects for both strong and weak opioids.
Airaksinen et al.	2006	European Guidelines for chronic LBP	We recommend the use of weak opioids (e.g. tramadol) in patients with non-specific chronic low back pain who do not respond to other treatment modalities. Due to the risk of addiction, slow-release opioids are preferable to immediate-release opioids, and should be given regularly (around the clock) rather than as needed.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	If a patient does not respond to analgetics, weak opioids (e.g. tramadol, tilidin/naloxon) can be used for non-specific LBP. Re-evaluation: after 4 weeks maximum with acute non-specific LBP, after 3 months maximum with chronic LBP. Therapy to be continued only when successful. Because of the risk of addiction, slow-release opioids should be preferred over immediate-release opioids. They should be administered according to a fixed time schedule (“around the clock”). Transdermal opioids should not be used for acute or sub-acute non-specific LBP.



Cochrane systematic review:	Year	Title	Comments/Results
Deshpande, Furlan, Mailis-Gagnon, atlas & Turk	2007	Opioids for chronic low back pain	<p>On average, those receiving tramadol, an atypical weak opioid, reported more pain relief and less difficulty performing their daily activities in the short-term than those who received a placebo. Those receiving an opioid, either morphine or a morphine-derivative, reported little or no difference in terms of pain relief in the short-term compared with those who received a NSAID (naproxen). In general, there was little or no difference between the two groups in their ability to perform daily activities.</p> <p>The trials that do exist suggest that a weak opioid reduces pain but has minimal effect on function. Side effects were more common with opioids but not life-threatening. The results of these trials should be regarded with caution and may not be appropriate in all clinical settings.</p>
Michigan Quality Improvement Consortium Medline review: Nicholson	2008	Management of acute low back pain	Opiate analgesics have not been shown to be more effective than NSAIDs in acute low back pain.
	Year	Title	Comments/Results
	2009	Benefits of extended-release opioid analgesic formulations in the treatment of chronic pain	Opioids offer more consistent and improved night-time pain control, less need to awaken at night to take another dose of pain medication, and less clock-watching by patients in chronic non-cancer pain. Tramadol possesses a unique mechanism of action, making it a viable opioid of first choice for patients suffering from a variety of chronic non-cancer pain, such as low back pain.

## Muscle relaxants

The Glossary term skeletal muscle relaxants refers to a diverse group of medications, some with unclear mechanisms of action, grouped together because they carry FDA-approved indications for treatment of musculoskeletal conditions or spasticity (Chou et al., 2007).

Table 22: *Comparison of muscle relaxants:*

Guidelines:	Year	Title	Comments/Results
Chou et al.	2007	ACP and APS Guideline	Although the antispasticity drug tizanidine has been well studied for low back pain, there is little evidence for the efficacy of baclofen or dantrolene, the other FDA-approved drugs for the treatment of spasticity. Other medications in the skeletal muscle relaxant class are an option for short-term relief of acute low back pain, but all are associated with central nervous system adverse effects (primarily sedation). There is no compelling evidence that skeletal muscle relaxants differ in efficacy or safety. Because skeletal muscle relaxants are not pharmacologically related, however, risk–benefit profiles could in theory vary substantially. For example, carisoprodol is metabolized to meprobamate (a medication associated with risks for abuse and overdose), dantrolene carries a black box warning for potentially fatal hepatotoxicity, and both tizanidine and chlorzoxazone are associated with hepatotoxicity that is generally reversible and usually not serious.
Airaksinen et al.	2006	European Guidelines for chronic LBP	Consider the use of muscle relaxants (benzodiazepines) for short-term pain relief in chronic LBP, but use them with caution due to their side effects (drowsiness, dizziness, addiction, allergic side-effects, reversible reduction of liver function, gastrointestinal events). As they do not appear to exert their effect by reducing muscle spasm, other pain relieving drugs with fewer serious side-effects should be considered first.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Muscle relaxants should be used with caution due to their side effects such as drowsiness or addiction (especially tetrazepam), due to their allergic side effects, reversible reduction of liver function and gastrointestinal complications. They should be used no longer than 2 weeks continuously for acute, sub-acute or chronic low

back pain. Although benzodiazepines showed pain-relieving effects in low back pain, their use should be avoided because the addictive potential of this group of drugs is very high.

Muscle relaxants have not been shown to be more effective than NSAIDs.

Michigan Quality Improvement Consortium

2008 Management of acute low back pain

Cochrane systematic review:	Year	Title	Comments/Results
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van Tulder et al.	2003	Muscle relaxants for non-specific LBP.	Muscle relaxants are effective for short-term symptomatic relief in patients with acute and chronic low back pain. However, the incidence of drowsiness, dizziness and other side effects is high. Muscle relaxants must be used with caution and it must be left to the discretion of the physician to weigh the pros and cons. Large high quality trials are needed that directly compare muscle relaxants to analgesics or NSAIDs and future studies should focus on reducing the incidence and severity of side effects.
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Medline review:	Year	Title	Comments/Results
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See & Ginzburg	2008	Choosing a skeletal muscle relaxant	Systematic reviews and meta-analyses support using skeletal muscle relaxants for short-term relief of acute low back pain when NSAIDs or acetaminophen are not effective or tolerated. Comparison studies have not shown any skeletal muscle relaxant to be superior to another. Adverse effects, particularly dizziness and drowsiness, are consistently reported with all skeletal muscle relaxants.
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## Antidepressants

Table 23: *Comparison of antidepressants:*

Guidelines:	Year	Title	Comments/Results
Chou et al.	2007	ACP and APS Guideline	Tricyclic antidepressants are an option for pain relief in patients with chronic low back pain and no contraindications to this class of medication. Antidepressants in the selective serotonin reuptake inhibitor class and trazodone have not been shown to be effective for low back pain, and serotonin–norepinephrine reuptake inhibitors (duloxetine and venlafaxine) have not yet been evaluated for low back pain. Clinicians should bear in mind, however, that depression is common in patients with chronic low back pain and should be assessed and treated appropriately.
Savignon et al.	2009	NCCPC Guideline	Consider offering tricyclic antidepressants if other medications provide insufficient pain relief. Start at a low dosage and increase up to the maximum antidepressant dosage until therapeutic effect is achieved or unacceptable side effects prevent further increase. Do not offer selective serotonin reuptake inhibitors (SSRIs) for treating pain.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Noradrenergic or noradrenergic-serotonergic antidepressants can be considered as co-medication for patients with chronic low back pain. Contraindications and possible side effects must be observed. Antidepressants of the SSNRI type should not be used as normal medication for LBP.
Airaksinen et al.	2006	European Guidelines for chronic LBP	Consider the use of noradrenergic or noradrenergic-serotonergic antidepressants as co-medication for pain relief in patients with chronic low back pain without renal disease, glaucoma, pregnancy, chronic obstructive pulmonary disease and cardiac failure.
Cochrane systematic review:	Year	Title	Comments/Results
Kassis	2008	Antidepressants to treat non-specific low back pain	Although antidepressants have been shown to be superior to placebo in some forms of chronic pain, they do not reduce pain or improve functional status or depression in patients with non-specific LBP.

## Herbal medicine

Table 24: *Comparison of herbal medicine:*

<b>Guidelines:</b>	<b>Year</b>	<b>Title</b>	<b>Comments/Results</b>
Airaksinen et al.	2006	European Guidelines for chronic LBP	There is strong evidence that capsicum pain plaster is more effective than placebo for short term (3 weeks) treatment.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Herbal medication cannot be recommended for pain therapy with acute or chronic non-specific LBP. Externally applied medication may be used for adjuvant therapy, at best.
Chou et al.	2007	ACP and APS Guideline	Herbal therapies, such as devil's claw, willow bark, and capsicum, seem to be safe options for acute exacerbations of chronic low back pain, but benefits range from small to moderate. In addition, many of the published trials were led by the same investigator, which could limit applicability of findings to other settings.
<b>Cochrane systematic review:</b>	<b>Year</b>	<b>Title</b>	<b>Comments/Results</b>
Gagnier, van Tulder, Berman & Bombardier	2006	Herbal medicine for low back pain	Devil's Claw, Willow Bark and Cayenne plaster were reviewed. Although there are good results with all of these three herbal medicines in short-term trials, with strong evidence for a particular form of one of the herbal medicines, there is no evidence yet that any of these substances are safe and useful for long term use.
<b>Medline review:</b>	<b>Year</b>	<b>Title</b>	<b>Comments/Results</b>
Vlachojannis, Cameron & Chrubasik	2009	A systematic review of the effectiveness of willow bark for musculoskeletal pain	The review provides moderate evidence of effectiveness for the use of ethanolic willow bark extract in LBP.

## Manual therapy

The manual therapies reviewed were spinal manipulation (a low-amplitude high-velocity movement at the limit of joint range taking the joint beyond the passive range of movement), spinal mobilization (joint movement within the normal range of motion) and massage (manual manipulation/mobilization of soft tissues). Collectively these are all manual therapy; that is the use of the therapist's hands to deliver some, or all of the intervention. Mobilization and massage are performed by a wide variety of practitioners. Manipulation can be performed by chiropractors or osteopaths, and by doctors or physiotherapists who have undergone specialist post-graduate training in manipulation (Savignon et al., 2009).

Table 25: *Comparison of manual therapy:*

Guidelines:	Year	Title	Comments/Results
Airaksinen et al.	2006	European Guidelines for chronic LBP	There is strong evidence that manipulation and GP care/analgesics are similarly effective in the treatment of CLBP (level A). Consider a short course of spinal manipulation/mobilization as a treatment option for CLBP. We cannot recommend massage therapy as a treatment for chronic low back pain
Savignon et al.	2009	NCCPC Guideline	Consider offering a course of manual therapy including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Manipulation/mobilization may be used to treat acute or chronic non-specific LBP. Massage should not be used to treat acute non-specific LBP. It may be used for sub-acute/chronic non-specific LBP in combination with exercise.
Chou et al.	2007	ACP and APS Guideline	For acute low back pain (duration <4 weeks), spinal manipulation administered by providers with appropriate training is associated with small to moderate short-term benefits. The evidence is insufficient to conclude that benefits of manipulation vary according to the profession of the manipulator (chiropractor vs. other

clinician trained in manipulation) or according to presence or absence of radiating pain.

Cochrane systematic review:	Year	Title	Comments/Results
Assendelft, et al.	2004	Spinal manipulative therapy for low back pain	There is no evidence that spinal manipulative therapy is superior to other standard treatments for patients with acute or chronic low-back pain.
Furlan, Imamura, Dryden & Irvin	2008	Massage for low back pain.	Massage might be beneficial for patients with sub-acute and chronic non-specific LBP, especially when combined with exercises and education.
Medline review:	Year	Title	Comments/Results
Lawrence, Meeker, Branson, Bronfort, cates,... & Haas	2008	Chiropractic management of LBP and low back-related leg complaints: a literature synthesis	As much or more evidence exists for the use of spinal manipulation to reduce symptoms and improve function in patients with chronic LBP as for use in acute or sub-acute LBP. There was less evidence for patients with LBP and radiating leg pain, sciatica, or radiculopathy.

### Other non-pharmacological therapies

Other non-pharmacological therapies in this context are therapies in which the patient has little active involvement with the treatment. The most common treatments were suggested by the stakeholder group and a final list was developed by the Guideline Development Group based upon those treatments that are commonly used in the National Health Service. This is not exhaustive as treatments frequently come onto the market with little or no testing and may not be commonly available on the National Health Service. The main treatments considered were commonly used electrotherapies, lumbar supports and spinal traction including motorized mechanical traction and autotraction. Autotraction is performed by utilizing the patient's own body weight (for example by suspension via the lower limb) or through movement (Savignon et al., 2009).

The European Guidelines included to the mentioned therapies shortwave diathermy and thermotherapy/heat.

Interferential therapy: The superficial application of a medium-frequency alternating current modulated to produce low frequencies up to 150 Hz. It is thought to

increase blood flow to tissues and provide pain relief and is considered more comfortable for patients than transcutaneous electrical nerve stimulation.

Low-level laser therapy: The superficial application of lasers at wavelengths between 632 and 904 nm to the skin in order to apply electromagnetic energy to soft tissue. Optimal treatment parameters (wavelength, dosage, dose-intensity, and type of laser) are uncertain.

Massage: Soft tissue manipulation using the hands or a mechanical device through a variety of specific methods. The pressure and intensity used in different massage techniques vary widely.

Shortwave diathermy: Therapeutic elevation of the temperature of deep tissues by application of short-wave electromagnetic radiation with a frequency range from 10-100 MHz.

Spa therapy: A therapy involving several interventions, including mineral water bathing, usually with heated water, typically while staying at a spa resort.

Transcutaneous electrical nerve stimulation (TENS): Use of a small, battery-operated device to provide continuous electrical impulses via surface electrodes, with the goal of providing symptomatic relief by modifying pain perception (Chou et al., 2007).

At Table 26 the mentioned non-pharmacological therapies are compared.



Table 26: *Comparison of other non-pharmacological therapies:*

Guidelines:	Year	Title	Comments/Results
Savignon et al.	2009	NCCPC Guideline	Do not offer laser therapy, interferential therapy, therapeutic ultrasound, transcutaneous electrical nerve stimulation (TENS), lumbar supports, lumbar traction.
Airaksinen et al.	2006	European Guidelines for chronic LBP	We cannot recommend interferential therapy, laser therapy, shortwave diathermy, therapeutic ultrasound, thermotherapy/heat, lumbar traction, TENS as a treatment for chronic low back pain. We cannot recommend wearing a lumbar support for the treatment of nonspecific chronic low back pain.
Chou et al.	2007	ACP and APS Guideline	There is insufficient evidence to recommend transcutaneous stimulation, interferential therapy, low-level laser therapy, shortwave diathermy, or ultrasound for chronic low back pain.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	For acute and chronic non-specific LBP interferential therapy, therapeutic ultrasound, laser therapy, lumbar traction, shortwave, diathermy, are not recommended. Thermography: heat can be used at patients with acute non-specific LBP
Cochrane	Year	Title	Comments/Results
Khadilkar, Odebiyi, Brosseau & Wells	2008	Transcutaneous electrical nerve stimulation (TENS) versus placebo	The evidence from a small number of trials does not support the use of TENS in the routine management of chronic LBP.
Yousefi-Nooraie, et al.	2007	Low level laser therapy for non-specific LBP	There are insufficient data to draw firm conclusions on the clinical effect of LLLT for LBP.
French, Cameron, Walker, Reggars & Esterman	2006	Superficial heat or cold for low back pain	There is moderate evidence that heat wrap therapy reduces pain and disability for patients with back pain that lasts for less than three months. There is still not enough evidence about the effect of the application of cold for low-back pain of any duration, or for heat for back pain that lasts longer than three months
Clarke, et al.	2007	Traction for low back pain with or without sciatica	We conclude that traction as a single treatment for LBP is probably not effective
Medline review:	Year	Title	Comments/Results
Van Duijvenbode, Jellema, van Poppel & van Tulder	2008	Lumbar supports for prevention and treatment of low back pain	There is moderate evidence that lumbar supports are not more effective than no intervention or training in prevention. It remains unclear whether lumbar supports are effective for treating low back pain.

## Invasive procedures

These include therapies like acupuncture, injections and nerve root blocks, epidural corticosteroids and spinal nerve root blocks with steroids, facet injections, intradiscal injections, intramuscular injections of botulinum toxin, sacroiliac joint injections, sclerosant injections (prolotherapy), trigger point injections, neuroreflexotherapy, percutaneous electrical nerve stimulation (PENS), radiofrequency (RF) and electrothermal denervation procedures, RF facet denervation, IRFT and IDET, RF lesioning of dorsal root ganglion, spinal cord stimulation (Airaksinen et al., 2004).

Table 27: *Comparison of invasive procedures:*

Guidelines:	Year	Title	Comments/Results
Savignon et al.	2009	NCCPC Guideline	Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks. Neuroreflexotherapy cannot be recommended. Do not offer injections of therapeutic substances into the back for non-specific low back pain. Searches were carried out to identify any form of injection for the lower back, however only data on facet joint, prolotherapy and intradiscal injections was identified. The Guideline Development Group agreed that there was a lack of evidence to recommend the use of these treatments and agreed by consensus injections were of no benefit for this population.
Airaksinen et al.	2006	European Guidelines for chronic LBP	We cannot recommend acupuncture for the treatment of chronic low back pain. We cannot recommend the use of epidural corticosteroids, intraarticular injections of steroids or facet nerve blocks, botulinum toxin, sacroiliac joint injections with corticosteroids, injection of sclerosants (prolotherapy), trigger point injections, RF facet denervation, intradiscal radiofrequency, electrothermal coagulation, radiofrequency denervation of the rami communicans, RF lesioning of the dorsal root ganglion, spinal cord stimulation, in patients with non-radicular non-specific low back pain. Consider NRT for patients with moderate or severe low back pain. Consider PENS for symptomatic pain reduction in patients with chronic non-specific low back pain.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Invasive therapies should not be used on patients with non-specific low back pain.

Cochrane systematic reviews:	Year	Title	Comments/Results
Furlan, van Tulder, Cherkov, Tsukayama, Lao, ... & Koes	2005	Acupuncture and dry-needling for low back pain	When acupuncture is added to other conventional therapies, it relieves pain and improves function better than the conventional therapies alone. However, effects are only small. Dry-needling appears to be a useful adjunct to other therapies.
Yuan, Purepong, Kerr, Park, Bradbury & Mc Donough	2008	Effectiveness of acupuncture for low back pain: a systematic review	There is strong evidence that acupuncture can be a useful supplement to other forms of conventional therapy for non-specific LBP, but the effectiveness compared with other forms of conventional therapies still requires further investigation.
Boxem, Staal, deBie, Vet, Zundert & van Kleef	2008	Injection therapy for sub-acute and chronic low back pain	There is no strong evidence for or against the use of any type of injection therapy in sub-acute and chronic low-back pain. However, it cannot be ruled out that specific sub-groups of patients may respond to a specific type of injection therapy.
Dagenais, Yelland, Del Ma & Schoene	2007	Prolotherapy injections for chronic low back pain.	When used alone, prolotherapy is not an effective treatment for chronic low-back pain. When combined with spinal manipulation, exercise, and other co-interventions, prolotherapy may improve chronic low-back pain and disability.
Medline reviews:	Year	Title	Comments/Results
Buenaventura, Datta, Abdi & Smith	2009	Systematic review of therapeutic lumbar transforaminal epidural steroid injections	The indicated evidence for transforaminal lumbar epidural steroid injections is Level II-1 for short-term relief and Level II-2 for long-term improvement in the management of lumbar nerve root and low back pain (USPSTF classification).
Rabionovitch, Peliowski & Furlan	2009	Influence of lumbar epidural injection volume on pain relief for radicular leg pain and/or low back pain	The results suggest a positive correlation between larger volumes of fluid injected in the epidural space and greater relief of radicular leg pain and/or low back pain.
Datta, Lee, falco, Bryce & Hayek	2009	Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions	The level of evidence for therapeutic lumbar facet joint interventions is Level II-1 or II-2 for lumbar facet joint nerve blocks, Level II-2 or II-3 (limited) evidence for radiofrequency neurotomy, and Level III (limited) evidence for intraarticular injections (USPSTF classification).

## Surgery

The rationale for the use of surgery in chronic low back pain is the assumption that spinal segments demonstrating degenerative changes on imaging can lead to mechanical pain.

The surgical procedures are usually aimed at obtaining a solid fusion between two or more vertebral segments. This can be performed with a posterior, anterior, or combined approach. The surgeon can also use different types of commercially available instrumentation (spacers, cages, screws, hooks and rods), and supplemental bone from the same patient or others, or, more recently, synthetic bone and growth factors, to promote bone formation and the achievement of solid fusion (arthrodesis). As in other fields of medicine, in recent years there has been a trend towards minimally invasive spine surgery. Another type of surgery that is potentially indicated in degenerative disc disease, and hence worthy of consideration, is disc replacement surgery (Airaksinen et al., 2004). In Table 28 is a comparison of findings according to surgery.

Table 28: *Comparison of surgery:*

Guidelines:	Year	Title	Comments/Results
Savignon et al.	2009	NCCPC Guideline	We cannot recommend fusion surgery for chronic LBP unless 2 years of all other recommended conservative treatments have failed and combined programs of cognitive intervention and exercises are not available in the given geographical area. Considering the high complication rates of surgery, as well as the costs to society and suffering for patients with failed back surgery, we strongly recommend that only carefully selected patients with severe pain (and with maximum 2 affected levels) should be considered for this procedure.
Chou et al.	2007	ACP and APS Guideline	In considering referral for possible surgery or other invasive interventions, other published guidelines suggest referring patients with non-specific low back pain after a minimum of 3 months to 2 years of failed non-surgical interventions. Although specific suggestions about timing of referral are somewhat arbitrary, one factor to consider is that trials of surgery for non-specific low back pain included only patients with at least 1 year of symptoms.
Airaksinen et al.	2006	European Guidelines for chronic LBP	We cannot recommend fusion surgery for chronic LBP unless 2 years of all other recommended conservative treatments have failed and combined programs of cognitive intervention and exercises are not available in the given geographical area. Considering the high complication rates of surgery, as well as the costs to society and suffering for patients with failed back surgery, we strongly recommend that only carefully selected patients with severe pain (and with maximum 2 affected levels) should be considered for this procedure.
BÄK, KBV, AWMF	2010	NVL Kreuzschmerz	Few studies are available for the evidence of surgical treatment of chronic LBP with no radicular component. These deal with fusion surgery or disc replacement surgery. Indication of surgery is conditional on the proof of disc or spinal channel pathology, besides the typical clinical symptoms. Radiological changes alone do not normally constitute proof of specificity.
Medline review:	Year	Title	Comments/Results
Singh, Manchikanti, Benyamin, Helm & Hirsch	2009	Percutaneous lumbar laser disc decompression: a systematic review of current evidence	This systematic review illustrates Level II-2 (USPSTF) evidence for percutaneous laser disc decompression which is equivalent to automated percutaneous lumbar disc decompression.

**Summary:** Recommendations for treatment of acute, sub-acute and chronic non-specific low back pain. Evidence of treatment is classified according to the GRADE-system:

Table 29: *Summary of recommendations for therapy:*

Problem	Treatment	Evidence
Acute, sub-acute and chronic low back pain	Self-management – remain active	High evidence
Acute and sub-acute low back pain	Exercise therapy	Low evidence
Chronic low back pain	Exercise therapy	High evidence
Acute and sub-acute and chronic low back pain	Back school	High to moderate evidence
Chronic low back pain	Cognitive behavioral therapy	High evidence
Acute and sub-acute and chronic low back pain	Individual patient education	High evidence (But not standard programs)
Sub-acute low back pain	Interdisciplinary rehabilitation	High to moderate evidence
Chronic low back pain	Interdisciplinary rehabilitation	High evidence
Acute, sub-acute and chronic low back pain	Acetaminophen (Paracetamol)	High to moderate evidence (Side effects!)
Acute, sub-acute and chronic low back pain	Non-steroidal anti-inflammatory drugs (NSAID)	High evidence (Side effects!)
Acute, sub-acute and chronic low back pain	Opioids	High evidence, if NSAIDs are not successful (Side effects!)
Acute, sub-acute and chronic low back pain	Muscle relaxants	Low evidence (Very short-term relief possible, side effects!)
Chronic low back pain	Antidepressants	High to moderate evidence (Side effects!)
Acute, sub-acute and chronic low back pain	Herbal medicine	Moderate evidence for short-term use
Acute, sub-acute and chronic low back pain	Spinal manipulation	High to moderate evidence
Acute, sub-acute and chronic low back pain	Massage	Low evidence
Acute, sub-acute and chronic low back pain	Other non-pharmacological therapies	Very low evidence (Heat for acute LBP: moderate evidence)
Chronic low back pain	Acupuncture	Recommendations differ from high to low evidence
Acute, sub-acute and chronic low back pain	Injection therapies	Low to very low evidence
Acute, sub-acute and chronic low back pain	Surgery	Very low evidence (Unless 2 years of other treatment)

## ***3.2 Systematic review 2: Osteopathic literature***

### ***3.2.1 Characteristics of studies***

#### ***3.2.1.1 Results of study selection***

**MEDLINE** search 1:

22 results were found.

Abstract analysis:

12 studies did not meet the subject or were not RCTs.

9 studies (8 RCTs and 1 systematic review) selected.

MEDLINE search 2:

40 results were found.

1 additional study

Abstract analysis:

Study is not finished, no additional study

MEDLINE Search 3:

3 results were found.

1 study met the subject.

Abstract analysis:

1 additional study

**Cochrane Library:**

22 trials and 1 systematic review were found.

Abstract analysis:

13 met the subject

6 RCTs are additional to previous search.

**Embase:**

82 (back pain) + 6 (sciatica) results

16 results met the subject.

No additional studies to previous search

**EBSCO:**

Journal of the Osteopathic Medical Association (JAMA)

148 results were found.

32 results met the subject.

No additional studies to previous search

**MANTIS:**

30 results were found.

9 results met the subject.

No additional studies to previous search

**PsycINFO:**

10 results

4 results met the subject.

Abstract analysis:

No additional studies to previous search

**Pedro:**

11 results were found and met the subject.

Abstract analysis:

No additional studies to previous search

**Physiotherapy Choices:**

17 results were found and met the subject.

Abstract analysis:

No additional studies to previous search



**Science direct:**

IJOM

92 results

1 additional study met the subject.

Abstract analysis:

No randomization, no additional study

Journal of Osteopathic Medicine

33 results

1 additional RCT met the subject.

Abstract analysis:

Study not investigating low back pain, no additional study

Osteopathic Family Physician

7 results

Abstract analysis:

No additional RCT

**OSTMED DR:**

81 results were found.

Abstract analysis:

No additional studies to previous search

**Osteopathic Research:**

26 results

Abstract analysis:

No additional RCT found

**German Academy of Osteopathy (AFO):**

6 results

Abstract analysis:

3 additional RCTs found

Checking websites of osteopathic schools and

Contacting experts in UK, France, Italy, Australia and Canada:

7 results

No additional RCT found

Table 30: *Results of study selection:*

Data Base	Result of located Studies	Studies met Subject	Excluded (by abstract reading or previously found)	Selected Studies
MEDLINE search 1	22	22	12	9
MEDLINE Search 2	40	1	1	0
MEDLINE Search 3	3	1	0	1
Cochrane Database	23	13	7	6
EMBASE	88	16	16	0
EBSCO	148	32	32	0
Mantis	30	9	9	0
Psyc INFO	10	4	4	0
Pedro	11	11	11	0
Physiotherapy choices	17	17	17	0
Science direct	132	9	9	0
OSTMED DR	81	81	81	0
Osteopathic Research	26	26	26	0
German Academy of Osteopathy	6	6	3	3
Checking websites and contacting experts	7	7	7	0

**Total account of relevant studies out of the initial search:**

**1 systematic review and 18 trials**

### 3.2.1.2 Characteristics of studies after first step of search

The characteristics of findings after first step are showed at Table 31.

Table 31: *Summary of findings after first step of search:*

Population	Comparison	Outcome	Follow-up*
Sub-acute low back pain	1 OMT with standard physiotherapy (Andersson, Lucente, Davis, Kappler, Lipton & Leurgans, 1999) 1 osteopathic treatment and physiotherapy with physiotherapy (Heinze, 2006) 1 osteopathic spinal manipulation and “usual care” with “usual care” (Williams, Wilkinson, Russell, Edwards, Hibbs, ... & Linck, 2003)	Pain, disability, rage of motion  Pain (disability)  Pain (disability)	Intermediate  Intermediate  Short-term and intermediate
Chronic low back pain	1 OMT with “usual care” (Kirk, Underwood, Chapell, Martins. Mendez & Thomas, 2005) 1 OMT with short-wave diathermy and placebo (SWD) (Gibson, Grahame, harkness, Woo, Blagave & Hills, 1985)  3 OMT with sham (2) or sham and no treatment (1) (Adorjan-Schaumann, Hörhahn, Wille & Wolff, 1999, Licciardone, Stoll, Fulda, Russo, Siu, ... & Winn, 2003, Mandara, Fusaro, Musicco & Bado, 2008 ) 1 osteopathy with group exercise or physiotherapy (Chown, et al., 2008)	Disability Pain (disability)  Pain and disability  Disability	Intermediate Intermediate  Intermediate (Mandara) (Adorjan)  Short-term and long-term
Low back pain with any duration	1 OMT with “usual care” (MacDonald & Bell, 1990)	Disability and recovery	Intermediate
Back pain in pregnancy	1 OMT with sham or obstetric care (Licciardone, Buchanan, Hensel, King, Fulda & Stott, 2009) 1 OMT with no treatment (v.d.Linde & Peters, 2006)	Pain and disability  Pain	Intermediate  Short-term

Sub-acute back pain post partum	1 Osteopathic treatment with no treatment (Recknagel, 2007)	Pain	Intermediate
Back pain during menstruation	1 OMT with no treatment or both (Boesler, Warner, Alpers, Finnerty & Kilmore, 1993)	EMG and blood-marker	Immediately
Back pain as an menopausal symptom	1 Osteopathic techniques with sham (Cleary & Fox, 1994)	Reduction of symptoms and blood-marker	Intermediate
Symptomatic lumbar disc herniation	1 OMT with chemonucleolysis (Burton, Tillotson & Cleary, 2000)	Pain and disability	Short-term and long-term
Chronic back pain and no back pain	2 OMT with no treatment to patients with and without pain (Degenhardt, et al., 2007, Ellenstad, Nagle, Boesler & Kilmore, 1990)	1 pain-biomarker 1 EMG-level	1 next days 1 after treatment
1 Systematic review: 6 trials are included. 5 of them met the including criteria of this review and are part of the summary above (Licciardone, et al., 2005)			

\*Definition of follow-up periods:

Short-term: closest to 4 weeks

Intermediate: closest to 6 months

Long-term: closest to 1 year (Furlan, 2009)

### ***3.2.1.3 Characteristics of studies after second step of search***

#### **Characteristics of excluded studies:**

In a second step of search the full text articles of all included studies were retrieved and scanned. For their characteristics, 5 studies had to be dropped.

Characteristics of excluded studies:

A systematic review was excluded. It contained 6 studies, 5 of which met the including criteria, were integrated in this review and are part of it (Licciardone et al., 2003).

A study of assessing the effects of osteopathic treatment for low back pain by evaluation of pain biomarkers was made with high quality, but it was not an RCT but a prospective, blinded assessment. (Degenhardt et al., 2007)

Another study assessed the benefit of osteopathic treatment for low back pain but focussed mostly on menopausal problems. The outcome of the study focussed on low back pain was very low. It only compared 8 treatment volunteers to volunteers in a control group (Clearly & Fox, 1994).

A fourth study was dropped because there were only 12 volunteers, 8 of them in a waiting list, and only 4 volunteers were randomized. The study focused on a very close group of participants. It evaluated women, aged from 22 to 36 years, with menstrual cramping (Boesler, et al., 1993).

A 5th study was dropped because it was not possible to obtain the necessary facts for analysis and comparison (Mandara et al., 2008).

### **Risk of bias**

In a next step, the risk of bias for every remaining study was evaluated.

Table 32: *Summary of risks of bias:*

	Adequate Randomization?	Allocation Concealment?	Patient blinded to Intervention?	Outcome Assessor blinded?	Drop-out rate described?	Participant analyzed in their Groups?	All Outcome Data addressed?	Similarity of Baseline Characteristics?	Co-interventions avoided or similar?	Compliance acceptable?	Timing Outcome Assessments similar?
Adorjan 1999	Y	U	Y	N	Y	Y	Y	Y	Y		
Andersson 1999	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Burton 2000	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Chown 2007	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Ellenstadt 1990	U	U	N	U	U	Y	Y	U	N		
Gibson 1985	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Heinze 2006	Y	Y	N	U	Y	Y	Y	Y	Y		
Kirk 2005	Y	Y	N	U	Y	U	U	U	U		
Licciardone 2003	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Licciardone 2009	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Von der Linde 2006	Y	U	N	N	Y	Y	Y	Y	Y		
Mac Donald 1989	U	U	N	U	U	Y	Y	Y	Y		
Recknagel 2007	Y	U	N	N	Y	Y	Y	Y	Y		
Williams 2003	Y	Y	N	Y	Y	Y	Y	Y	Y		

Legend: Y = yes, N = no, U = unsure

The therapist clearly cannot be blinded in studies where osteopathic treatment is applied. So this criterion was dropped.

As Furlan et al recommended in the updated guideline for systematic reviews, the risk of bias can be used as an additional inclusion criterion, Ellenstadt et al, Kirk et al and Mac Donald et al, have to be excluded. (Ellenstadt et al., 1990) (Kirk et al., 2005) (Mac Donald et al., 1989)

## **Flow diagram**

The flow of findings, inclusion and exclusion of studies is showed in Figure 1.

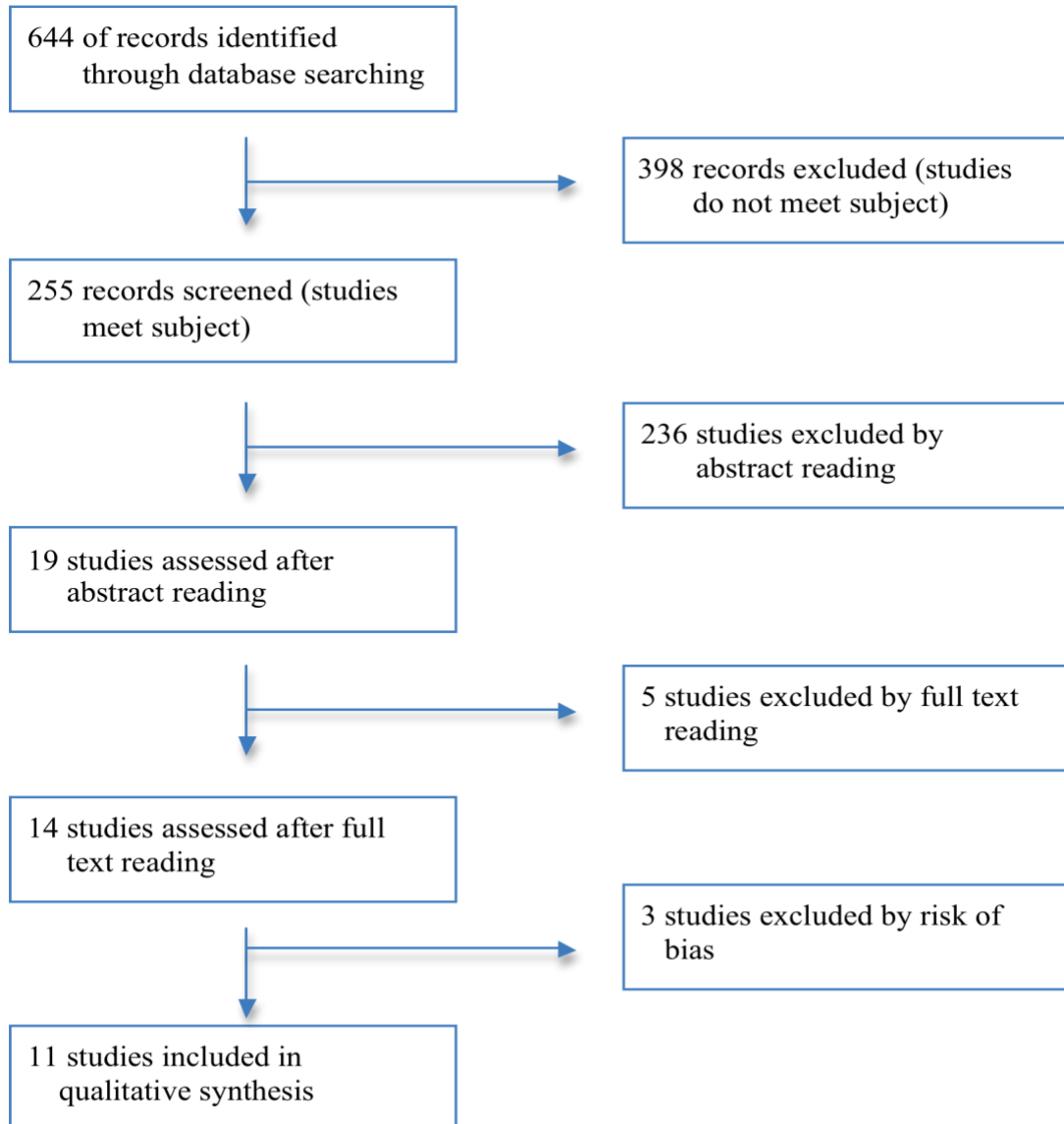


Figure 1: Flow diagram:

### **Characteristics of included studies**

In Table 33 – 35 the included studies are presented, subdivided to chronic and sub-acute low back pain and low back pain in special cases.

Table 33: *Comparison of the selected osteopathic RCTs for chronic low back pain:*

Author	Adorjan et al., 1999	Chown et al., 2007	Gibson et al., 1985	Licciardone et.al., 2003
Study design	RCT	RCT	RCT	RCT
Treatment group	Osteopathic treatment	Osteopathy	Spinal manipulation by an osteopath	OMT
Control group	Sham (osteop. treatment)	a) group exercise b) physiotherapy	a) shortwave diathermy (SWD) b) placebo (detuned SWD)	a) sham treatment b) no intervention
Patients assessed for eligibility	82	499	Not stated	199
Number of subjects	57 (29/28)	239 (79/80/80)	109 (41/34/34)	91 (2:1:1)
Number of therapists	4	1 osteopath several physiotherapists	1 osteopath 1 physiotherapist	Third- or fourth-year medical students
Primary outcome	Quality of life, Pain	Disability	Pain	Health status Pain Disability
Secondary outcome	Pain, disability, osteopathic findings, compliance	No secondary outcome	Spinal tenderness Quality of life	Back-specific patient satisfaction work disability
Assessment instruments	Questionnaire: Roland & Morries Pain VAS Questionnaire SF36	Questionnaire: Oswestry Disability Index EuroQal-5D Shuttle walking test, patients subjective responses	Pain VAS Examination Questionnaire: Macrae and Wright	Questionnaire: SF-36 Roland-Morris disability Pain VAS Likert scale for satisfaction and work disability
Number of osteopathic/control treatments	5/5	5/5/5	4/12	7/7
Treatment period	Every 15 days	Within a 3-monthly period	Treatment weekly Control 3 x in a week	1 week, 2 weeks then monthly
Follow up	75 days	6 weeks after discharge and after 12 months	12 weeks	1 month 3 months 6 months
Result/conclusion	Osteopathic	All 3 treatments	Improvement:	a) OMT and



	treatment was statistically significant better to sham in case of all outcomes	indicated reductions at 6-week follow-up. Group exercise: -4.1 (-1.4 to -8.6) Physiother.: -4.1 (-1.4 to -6.9) Osteopathy: -5.0 (-1.6 to -8.4) Limited evidence from final FU suggested that the decline in ODI has sustained	62 % with osteopathy 50 % with SWD 67 % with placebo No significant difference	sham both appear to provide some benefits when used in addition to usual care for chronic LBP b) As compared with no-intervention, OMT showed greater improvements in pain, functioning and satisfaction.
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Table 34: Comparison of the selected osteopathic RCTs for sub-acute low back pain:

Author	Andersson et al., 1999	Heinze, 2006	Williams et al., 2003
Study design	RCT	RCT	RCT
Treatment group	OMT	Osteopathic treatment and physiotherapy	Osteopathic spinal manipulation and GP
Control group	Standard therapies	Physiotherapy	GP
Patients assessed for eligibility	1193	69	2000
Number of subjects	178 (83/72)	60 (28/32)	125 (53/72) (for LBP)
Number of therapists	3 osteopaths, several physicians	1 osteopath. 3 physiotherapists	1 osteopath and several general physicians
Primary outcome	Pain, disability	Pain	Pain
Secondary outcome	N	Disability	Quality of life
Assessment instruments	Questionnaire: Oswestry, Roland & Morries, Pain VAS, Range of motion, straight-leg rising	Pain Numeric Rating Scale Questionnaire: Roland & Morries	Extended Aberdeen Spine Pain Scale Questionnaire. SF 12, Eruo Qol Mc Gill pain questionnaire
Number of osteopathic /control treatments	Four weekly, then intervals of two weeks	6	Interventions of 1-2 weeks during 2 months
Treatment period	Not stated	6 weeks	2 months
Follow-up	12 weeks	12 weeks	2 months 6 months
Result/conclusion	OMT and standard medical care have similar clinical results. The use of medication is greater with standard care.	2.5-fold improvement of treatment group according to pain Statistically significant improvement of disability	Outcomes improved significantly more in osteopathy group

Table 35: Comparison of the selected osteopathic RCTs for low back pain in special cases:

Case	Pregnancy (3rd trimester)	Pregnancy	Post partum	Disc herniation
Author	Licciardone et al., 2009	v.d. Linde & Peters, 2006	Recknagel & Ross, 2007	Burton et al., 2000
Study design	RCT	RCT (waiting list)	RCT (waiting list)	RCT
Treatment group	Obstetric and OMT	Osteopathic treatment	Osteopathic treatment	OMT
Control group	a) Obstetric and sham (ultrasound) b) Obstetric	No treatment	No treatment	Chemoneucleolysis
Patients assessed for eligibility	863	Not stated	Not stated	
Number of subjects	144 (49/48/49)	60 (30/30)	40 (20/20)	40 (20/20)
Number of therapists	Several specialists	2	2	1 Osteopath 1 Surgeon
Primary outcome	Pain and disability (function)	Pain	Pain, quality of life	Pain, disability
Secondary outcome	No	Disability	No	Distress
Assessment instruments	Pain VAS Questionnaire: Roland Morris	Pain VAS Quebec Back Pain Disability Scale	Pain VAS Questionnaire: Oswestry pain	Pain 7 point rating scales Questionnaire: Roland Disability Distress and Risk Assessm. Method
Number of osteopathic/control treatments	7/7/7	4/4	4/4	Average of 11 treatments in OMT group
Treatment period	During 3trimesters	4 weeks	8 weeks	Not stated
Follow up	2-3 months	5 weeks	9 and 16 weeks	2 weeks, 6 weeks and 12 months
Result/conclusion	Back pain decreased in the treatment group, remained unchanged in obstetric + sham group and increased in the obstetric group	Pain: 68 % improvement in treatment group, no improvement in control group Disability: 28 % improvement in treatment group, 20 % worse in control group	Pain: 70 % improvement in treatment group, 3.4 % improvement in control group Quality of life: 62 % improvement in treatment group, little worse in control group	After 12 months, there was no statistically significant difference between the treatments, but OMT produced a statistically significant greater improvement for pain and disability in the first few weeks.

### ***3.2.2 Effects of osteopathic treatment***

#### ***3.2.2.1 Feasibility of statistical pooling***

As stated in the method section, statistical pooling is only considered if subgroups of studies were clinically homogeneous and the authors provided sufficient information on study characteristics, outcome measures and study results. After reviewing the study characteristics of the studies included, they seemed to be insufficiently clinically homogeneous to perform statistical pooling. Consequently, instead of statistical pooling, we had to perform a best-evidence synthesis for the subgroups of the studies. To estimate the evidence it is useful to assess the quality according to the GRADE system. The studies are scanned in terms of design, limitations (i.e. risk of bias), inconsistency, indirectness and imprecision. Every case reduced the evidence by one level.

#### ***3.2.2.2 Effects of osteopathic treatment of chronic low back pain***

Three studies compared the effects of osteopathic treatment to sham/placebo treatment (Adorjan-Schaumann et al., 1999, Gibson et al., 1985, Licciardone et al., 2003). All studies have follow-up periods of 3 months. One study has follow-up periods of 1, 3 and 6 months (Licciardone, 2003). 2 of them were rated as high-quality studies. (Gibson et al., 1985, Licciardone et al., 2003) One of them was rated as a moderate-quality study in terms of risk of bias towards usual care for low back pain, but sham treatment has the same result. (Gibson et al., 1985, Licciardone et al., 2003) The study of Licciardone et al has a serious limitation. Patients were not treated by fully educated specialists but by students of osteopathy. The study of Gibson et al shows also a serious limiting fact. The treatment was done by an osteopath, but he just used spinal manipulation as a single technique. By looking at the definition of osteopathic treatment, the exclusive use of spinal manipulation might be considered an insufficient approach. A study of Adorjan showed only moderate limitations, but is unpublished and “academically under-graduated” (Adorjan-Schaumann et al., 1999). This fact of imprecision rates the study down to a low quality of evidence. In summary, two studies (Gibson et al., 1985, Licciardone et al., 2003) show some benefit when OMT is used for low back pain compared to sham, but have some limitation due to imprecision. The study of Adorjan et

al. (1999) shows a significant benefit of osteopathic treatment for low back pain compared to sham but has a limitation of imprecision. Because of serious limitations and imprecision, the quality of evidence of this comparison is low.

Two studies (one of them with 2 control treatments) compared the effects of osteopathic treatment with other conventional treatment. In addition there are 3 comparisons (Chown et al., 2007, Gibson et al., 1985). Both studies were rated as high-quality studies. All three comparisons show significantly that osteopathic treatment leads to improvement in disability and reduction of pain compared with other treatments with follow-up times of 6 weeks, 12 weeks and 12 months. But there is a factor of imprecision because the one study only measures disability, and the other only pain. As there is just one study for every outcome, the evidence is moderate.

One study compared OMT to no intervention (Licciardone et al., 2003). This high-quality study shows significantly that OMT compared with no intervention showed greater improvements in pain, functioning and satisfaction after 1, 3 and 6 months.

But having only one study is an issue of imprecision according to the GRADE evidence profile. So the evidence is moderate.

Table 36: *GRADE quality of evidence for chronic low back pain:*

Quality assessment							Summary of findings				Quality
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	No of patients		Effect		
							OMT	Control	Relative	Absolute	
Chronic low back pain, osteopathic treatment and sham, pain intensity (VAS)											
3	RCT	serious limitations <sup>1</sup>	no serious inconsistency	no serious indirectness	serious imprecision <sup>2</sup>	none	116	85	-	-	low
Chronic low back pain, osteopathic treatment and other treatment, pain intensity (VAS)											
1	RCT	no serious limitations	no serious inconsistency	no serious indirectness	serious imprecision <sup>3</sup>	none	41	34	-	-	moderate
Chronic low back pain, osteopathic treatment and other treatment, functional status											
1	RCT	no serious limitations	no serious inconsistency	no serious indirectness	serious imprecision <sup>3</sup>	none	79	160	-	-	moderate
Chronic low back pain, osteopathic treatment and no treatment, pain intensity (VAS)											
1	RCT	no serious limitations	no serious inconsistency	no serious indirectness	serious imprecision <sup>3</sup>	none	45	23	-	-	moderate

<sup>1</sup> limitations in conducting therapy or assessment

<sup>2</sup> study unpublished and under-graduated

<sup>3</sup> only one study

### ***3.2.2.3 Effects of osteopathic treatment of sub-acute low back pain***

Two studies compared the effects of osteopathic treatment of sub-acute low back pain with standard therapies (Andersson et al., 1999, Williams et al., 2003). Both studies are rated as high-quality studies. The follow-up period of one of the studies is 3 months (Andersson et al., 1999) and of the other study, follow-up periods are 2 and 6 months (Williams et al., 2003). One study shows significantly that pain and quality of life improved more in the osteopathy group. (Williams et al., 2003) The other study shows significantly that osteopathic treatment and medical care have similar clinical results, but the use of medication is lower with OMT. (Andersson et al., 1999) There is high evidence

that osteopathic treatment brings improvement in pain and quality of life compared to standard therapy after 2, 3 and 6 months.

One study compared the effects of osteopathic treatment of sub-acute low back pain with physiotherapy (Heinze, 2006). The follow-up period is 3 months. The study is rated as a moderate-quality study in terms of risk of bias limitations, but is unpublished and “academically under-graduated”. This fact of imprecision leads to a low evidence. But the result supports the result of the two studies mentioned above. The result shows a 2.5-fold improvement of the osteopathic treatment group according to pain and disability.

Table 37: *GRADE quality of evidence for sub-acute low back pain:*

Quality assessment							Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	No of patients		Effect		Quality
							OMT	Control	Relative	Absolute	
Sub-acute low back pain, osteopathic treatment with standard therapy, pain intensity (VAS)											
2	RCT	no limitations	no inconsistency	no indirectness	no imprecision	non	136	144	95 % CI	-	high
Sub-acute low back pain, osteopathic treatment with physiotherapy, pain intensity (VAS)											
1	RCT	serious limitation <sup>1</sup>	no inconsistency	no indirectness	Serious imprecision <sup>2 3</sup>	Non	28	32	95 % CI	-3.5 -- 1.5	low

<sup>1</sup> limitations due to risk of bias

<sup>2</sup> study unpublished and under-graduated

<sup>3</sup> only one study

### ***3.2.2.4 Effects of osteopathic treatment of patients with low back pain in special cases***

Two studies estimated the effect of osteopathic treatment for pregnant women with low back pain (Licciardone et al., 2009, v.d.Linde & Peters, 2006). Licciardone et al. (2009) included women being in the third trimester of pregnancy. They compared OMT and obstetrics to a) obstetrics and sham-ultrasound and b) obstetrics. The follow-up period was 2-3 months. The study is rated as a high-quality study. But there is just one study result for the different control groups. This is a fact of imprecision and so the

evidence is moderate. The other study compared osteopathic treatment with no treatment. The follow-up period was 5 weeks. The study is rated as a moderate-quality study for limitations due to risk of bias, but is unpublished and “academically under-graduated” There is also just this study for this case. This is a fact of imprecision, so this study has low evidence.

A study compared the effect of osteopathic treatment for women with low back pain post partum to no treatment. (Recknagel & Ross, 2007) The follow-up period was 9 and 16 weeks. This study shows significantly that osteopathic treatment brought improvement in pain and quality of life. The study is rated as a moderate-quality study in terms of risk of bias limitations but is unpublished and “academically under-graduated”. Furthermore, it is only one study evaluating the subject. This fact of imprecision rates the study down to low evidence.

A study compared the effect of osteopathic treatment to chemonucleolysis in patients with disc herniation. (Burton et al., 2000) The follow-up periods are 2 weeks, 6 weeks and 12 months. The study is rated as a high-quality study. The results showed no statistically significant improvement over 12 months but a significant improvement for pain and disability in the first few weeks. There is just one study investigating this case. This is a fact of imprecision so the result has moderate evidence.

Table 38: *GRADE quality of evidence for low back pain in special cases:*

Quality assessment							Summary of findings				
							No of patients		Effect		Quality
No of studies	De-sign	Limi-tations	Inconsi-stency	Indirect-ness	Impre-cision	Other conside-rations	OMT	Control	Relative	Absolute	
Low back pain in pregnant women, osteopathic treatment to other treatment, pain intensity (VAS)											
1	RCT	no limita-tions	no inconsi-stency	no indirect-ness	serious impre-cision <sup>3</sup>	non	49	49	95 % CI	0.31 – 1.14	moderate
Low back pain in pregnant women, osteopathic treatment to other treatment combined with sham, pain intensity (VAS)											
1	RCT	no limita-tions	no inconsi-stency	no indirect-ness	serious impre-cision <sup>3</sup>	non	49	48	95 % CI	-0.06 – 0.76	moderate
Low back pain in pregnant women, osteopathic treatment to no treatment, pain intensity (VAS)											
1	RCT	serious limita-tions <sup>1</sup>	no inconsi-stency	no indirect-ness	serious impre-cision <sup>2 3</sup>	non	30	30	95 % CI	-	low
Low back pain post partum, osteopathic treatment to no treatment, pain intensity (VAS)											
1	RCT	serious limita-tions <sup>1</sup>	no inconsi-stency	no indirect-ness	serious impre-cision <sup>2 3</sup>	non	20	20	95 % CI	-	Low
Low back pain with disc herniation, osteopathic treatment to chemonucleolysis, disability											
1	RCT	no limita-tions	no inconsi-stency	no indirect-ness	serious impre-cision <sup>3</sup>	non	20	20	95 % CI	-	Moderate

<sup>1</sup> limitations due to risk of bias

<sup>2</sup> study unpublished and under-graduated

<sup>3</sup> only one study



## Chapter 4: Discussion

### *4.1 Systematic review 1: The clinical problem*

#### *4.1.1 Methods*

The systematic review relating to the clinical problem was made with the objective of obtaining an overview of the current state of knowledge regarding definition, etiology, epidemiology, diagnosis and therapy of low back pain. Since the focus was not on finding current literature for a comparative assessment, the approach of specific literature search was chosen.

To obtain an overview, the search was focused on guidelines regarding the subject low back pain. The field of possible therapies was reviewed in more detail as the subject of the thesis is osteopathy as a possible therapy for low back pain. Therefore, Cochrane reviews and recent reviews in MEDLINE on this subject were examined.

The search for studies focused on Medline, the Cochrane Library and, for guidelines, also on Guideline Clearinghouse and grey literature.

The evaluation of the guidelines and reviews regarding definition, etiology, epidemiology, diagnosis and therapy was partly done by personal review, and partly by means of the literature administration program "Reference Manager".

#### Guidelines:

As has been shown, LBP is a very frequent disorder. It is therefore not surprising that an extremely large volume of studies on all aspects of this subject can be found during research in MEDLINE alone.

As LBP plays a major role in many countries, numerous working groups were formed worldwide who evaluated published studies and developed guidelines to examine the background and provide recommendations for clinical practice.

A case-control study involving parallel benchmarking audits to compare the safety, efficacy and cost-effectiveness of recommendations in guidelines to manage acute low back pain brought the following results: If patients were managed by medical

practitioners according to the guidelines, medical care resulted in a significantly lower cost of treatment, a significantly greater reduction in pain, sustained at both 6 and 12 months, significantly fewer patients requiring continuing care at 3, 6 and 12 months, a significantly greater proportion of patients fully recovered at 12 months and significantly greater proportions of patients rating their treatment as extremely helpful and offering positive, unsolicited comments about their treatment (McGuirk, King, Govind, Lowry & Bogduk, 2001). This result underpins the justification to base the evaluation of the recommendations for the therapy of low back pain largely on the guidelines.

Restriction to guidelines from 2004 onwards:

Bouwmeester et al. (2009) have evaluated that the quality of low back pain guidelines has improved. In a systematic review of clinical guidelines for the management of acute and chronic low back pain in primary care, the recommendations were compared. In general, the quality was satisfactory. The assessed guidelines had best scores on clarity and presentation. Compared to the quality assessment performed in 2004, the average quality of guidelines has improved (Bouwmeester, van Enst & van Tulder, 2009). I therefore decided to include guidelines from 2004 to 2010 in my systematic review 1.

Research for systematic reviews of therapeutic approach to low back pain:

In terms of systematic reviews concerning therapeutic approach, the Cochrane reviews are considered to show the highest quality, so including them in this study was an obvious choice. So as not to overlook any newer findings, the latest systematic reviews of therapy for low back pain were searched in MEDLINE and evaluated in addition. Studies on 16 different forms of therapy were analyzed, which were also included in the guidelines and the Cochrane reviews.

Research relating to these newest therapy studies were restricted to the last 2 years since a large proportion of the guidelines used (Chou et al., 2007, Savignon et al., 2009, Versorgungsleitlinie Kreuzschmerz, 2010) have 2009/2010 as publishing dates, and it can be assumed that they have included all major studies up until 2008 in their extensive search.

### **4.1.2 Results**

#### **Definition:**

In the Definition chapter, the first important task was to elaborate a general definition of low back pain. This could be done with success because low back pain is defined as a MESH term and, moreover, the high-quality guidelines, in which important national teams had cooperated, have published largely uniform definitions.

An important aspect was to delimit specific low back pain against non-specific low back pain. As shown in that chapter, approx. 85 % of all cases are cases of low back pain.

#### **Etiology:**

The Etiology chapter showed primarily that only a small number of patients suffering from specific low back pain, i.e. low back pain that can be attributed to specific causes. These causes are shown as it is essential for the individual patient that such causes are identified.

Non-specific low back pain has no such clear, tangible cause. It can be assumed that its origin lies with excessive physical and/or psychic stress.

#### **Epidemiology:**

Numerous factors showed that low back pain is a vast medical, psychological and socio-economic field. On the one hand, there is an incredibly large number of individual patient histories to be considered. The patients concerned suffer from pain and limitations in their lives, a sizeable number over several years. On the other hand, the huge direct cost for the healthcare systems becomes apparent, along with the indirect cost to be borne by society due to patients' absence from work.

#### **Diagnostics:**

The development of the diagnostic triage provides a system enabling diagnosis of the individual patient with the aid of a classification grid. At first, specific disorders outside the musculoskeletal system are ruled out; then specific spinal pathologies are

evaluated and patients referred to corresponding further diagnostic measures and treatments. Patients not covered by these first two categories are then considered as patients suffering from non-specific low back pain.

### **Therapy:**

The previous chapters of the systematic review 1 have shown that approx. 85 % of all cases of low back pain are non-specific. The Therapy chapter follows the lines of the included guidelines by evaluating exclusively therapies for patients with non-specific low back pain. The included reviews also describe treatments for this group of patients. This explains, for example, the high evidence of therapeutically approaches involving psycho-emotional coaching and exercise, compared with a very low evidence of invasive procedures and surgery. If the study were dealing with patients suffering from vertebral disc herniation, for example, the result could be expected to be the other way round.

A rather recent system for the classification of evidence to recommend treatment is the GRADE system. It comprises 4 grades of evidence. All the other guidelines included use systems for the classification of evidence comprising 4 grades of evidence. It was therefore possible to interpret their classifications according to the GRADE system and create a summarization of the recommendations for treatment of non-specific low back pain. An increasing number of more recent systematic reviews have also been using the GRADE system. The Cochrane Collaboration recommends its use. This is a positive development since it can help to make therapeutic recommendations more comparable and reliable worldwide.

As the results show, there are only few therapeutic interventions that can be recommended without the risk of side effects, which can be rather severe. It is difficult to assess what the usually applied primary care for non-specific low back pain looks like, whether there is in fact any such thing. Somerville et al published a systematic review, finding out that treatment received by patients with non-specific low back pain was varied and often not in line with back pain guidelines, particularly with respect to opioid

prescription and x-ray examination (Somerville, Hay, Lewis, Barber, van der Windt,... & Hill, 2008).

#### **4.1.3 Conclusion**

The main conclusions according to results are:

- There is a consistent definition of low back pain.
- The classification of specific and non-specific low back pain has been made.
- There is just a small number of patients with specific low back pain.
- Low back pain is not just a big medical, psychological and socio-economic problem but also a fateful experience for a multitude of persons.
- Diagnostic triage seems to be very practicable.
- Guidelines and reviews focused on patients with non-specific low back pain. This fact has consequences in results. We have highly evident recommendations for exercises and a psychological approach, and low evidence for recommendations to surgery. In cases with specific causes, these results might be different.
- The GRADE system helped a lot to classify the evidence.
- There is just a small amount of therapeutic interventions which can be recommended, often with side effects. So we can ask:

IS THERE A USUALLY APPLIED TREATMENT FOR NON-SPECIFIC LOW  
BACK PAIN?

## ***4.2 Systematic review: Osteopathic literature***

### ***4.2.1 Methods***

#### ***4.2.1.1 Discussion of inclusion criteria:***

Study design:

To work out a systematic review with high methodological quality, I used the checklist of the Cochrane collaboration. To include studies with strong evidence, it is necessary to accept randomized clinical trials only.

Participants:

As I knew from my first research familiarizing myself with the subject, it was not to be expected that a large number of studies would be found. Since I considered the possibility of modifying the analysis of the data by means of stratification, no limitations were made regarding duration, radiation patterns and circumstances.

Interventions:

Interventions turned out to be the most problematic aspect of inclusion criteria. Despite the first results of the WOHO, there are no clear criteria and standards defining how osteopathic treatment is to be performed. To me, the guidelines of AOA (2009) offered a possibility to come to a certain degree of standardization however these standards are not binding for osteopathic practitioners worldwide. As can be seen from the guidelines, a wide spectrum of performance is possible in osteopathy. A study by Johnson and Kurtz, which involved a national mail survey of 3000 randomly selected osteopathic physicians in the US, showed that approaches differ widely. Responders in the US were more likely to use direct techniques than indirect ones. Female and older osteopathic physicians were more likely to use indirect techniques, whereas male and younger physicians preferred direct techniques. OMT specialists used a broader range of techniques than other osteopathic physicians. The authors also mentioned that research on the quality and effectiveness of various OMT techniques must be done (Johnson & Kurtz, 2002). Looking at the curricula of the British School of Osteopathy, it appears that the structural osteopathic approach is very predominant compared to the cranial or visceral

approach. (Authors visit at BSO) Looking at the German studies found, it appears that the use of indirect, cranial and visceral techniques is very common.

In this review all studies were included which met the definition of the AOA (2009) guidelines for OMT as the most practicable procedure.

Control-group:

Treatment in the control group was variable. No treatment, sham treatment or conventional general practitioner care. If a different therapeutic treatment was used, it was necessary that this therapy showed acceptable evidence from review 1.

Outcome measures:

Because this is a review exploring a clinical subject, the measured outcomes must be clinically relevant. They must be suitable to measure effectiveness or efficacy of the osteopathic treatment. In a review of low back pain, it appears only logical that pain should be the most important parameter. However, disability is also an important factor in the evaluation of improvement of patients with low back pain. In terms of effectiveness of osteopathic treatment, it is also a point of interest to investigate the quality of life, i.e. consequences to participation, range of motion, functional impairments, and compromised activities of daily living.

#### ***4.2.1.2 Discussion of exclusion criteria:***

Spinal manipulation as a single approach:

The Agency for Health Care Policy and Research in the United States concluded that spinal manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms. Nevertheless, because most studies of spinal manipulation involve chiropractic or physical therapy, it is unclear if such studies adequately reflect the efficacy of OMT for low back pain. Although the professional bodies that represent osteopaths, chiropractors, and physiotherapists in the United Kingdom developed a spinal manipulation package consisting of three common manual elements for the UK Back Pain Exercise and Manipulation (UK BEAM) trial, there are no data on the comparability of profession-specific outcomes. It is well known that OMT comprises a diversity of techniques. These OMT techniques are not adequately represented by the UK BEAM trial package. Because differences in professional background and training lend themselves to diverse manipulation approaches, clinicians

have been warned about generalizing the findings of systematic reviews to practice (American Osteopathic Association, 2009).

Pooling osteopathic therapy with analgesic prescription:

Although general practitioners may suggest other therapy for back pain in addition to prescribing medication, empirical evidence shows that 80 % of initial visits to primary care providers for back pain result in an analgesic prescription. (Assendelft et al., 2008) Consequently, these two categories can be considered too similar to pool.

Data analysis:

To extract data for analysis, Furlan offered a practicable procedure. First the author used the assessment of risk of bias as an additional inclusion criterion.

As the inclusion criteria were very varied, the data obtained is very heterogeneous. However, the data could be sufficiently analyzed by using a stratified analysis. Data were presented separately in different strata of studies.

Due to the pronounced heterogeneity of the data, statistical pooling and the performance of a meta-analysis were not carried out.

#### **4.2.2 Results**

After extensive research, 18 studies and 1 systematic review were found, most of them at MEDLINE and in the Cochrane Database. Research in other databases offered no additional studies except the Database of the German Academy of Osteopathy. Studies found there had a moderate or high methodological quality but all of them are unpublished. The authors did under-graduated research. This must be considered as a limitation of the evidence of the results. But these studies support the results of the other published high-quality studies.

The author found studies investigating effects of osteopathic treatment of patients with acute low back pain. All studies had to be excluded for low methodological quality or too much bias. So it was not possible to present a result in this case.



#### ***4.2.2.1 Summary of evidence***

There is moderate evidence that osteopathic treatment is better than conventional treatment for pain and for disability, and there is moderate evidence that osteopathic treatment is better than no treatment for pain in patients with chronic low back pain.

There is low evidence that osteopathic treatment is not better than sham treatment in reduction of pain.

There is high evidence that osteopathic treatment is better than, or similar to (but with less use of analgesics) standard therapies for patients with sub-acute low back pain.

There is low evidence that osteopathic treatment is better than physiotherapy.

There is moderate evidence that osteopathic treatment is better than sham and other conventional treatment for pregnant women with low back pain. There is low evidence that osteopathic treatment is better than no treatment for pregnant women with low back pain.

There is low evidence that osteopathic treatment is better than no treatment for women post partum with low back pain.

There is moderate evidence that osteopathic treatment is not better than chemonucleolysis in patients with disc herniation after 12 months, but better in the first few weeks.

#### ***4.2.2.2 Limitations***

Search of studies:

A limitation in this review is the possibility of publication bias. The author attempted to minimize it through an extensive database search without language restriction. A seek of unpublished studies was also done. But only 4 German studies were brought to the author's attention. One additional Italian study had to be excluded because it was not possible to obtain enough information from the authors.

Selection and assessment of studies:

A limitation due to the possibility of selection bias is also to be considered. The author sought and scanned a large amount of information to find out the methodologically strongest way to select and assess the studies found. This was possible by following the recommendations of the Cochrane Collaboration. But to gain a high methodological quality in the selection and assessment of studies, it is necessary that more than one investigator scans the data.

#### **4.2.3 Conclusion**

For patients, clinicians and osteopaths the findings of this review should be considered. There is no evidence that osteopathy is worse than other conservative treatment, sham treatment or no treatment. The result shows that osteopathic treatment is at least equal to but in most cases better than the compared approaches. No harms were found.

The limitations for this conclusion must be considered.

Compared to the large amount of research for low back pain, the amount of methodological high-evidence studies investigating this subject is very low. More studies of high quality must be made to underpin this result.

### ***4.3 Comprehensive discussion***

The therapies used so far are not necessarily successful, least of all in chronic LBP. In a study of reviews of conservative treatment for chronic LBP, Furlan et al. (2001) summarized the results of 109 systematic reviews. The interventions included medication (analgesics, antidepressants, epidural and facet injections, muscle relaxants, NSAIDs, and opioids), education/behavioral (back schools, bed rest, cognitive/behavior, couple therapy, multidisciplinary teams), and physical treatments (acupuncture, exercise, laser, orthoses, spinal manipulation, TENS, traction). The summaries produced mostly negative or conflicting findings. They concluded that the only interventions associated with positive patient outcomes were muscle relaxants, opioids, and interventions provided by multidisciplinary teams (Furlan, Clarke, Esmail, Sinclair, Irvin & Bombardier, 2001). This shows that there is no such thing as a “gold standard” for the therapy of chronic LBP. Research into further inexpensive, low-impact methods such as osteopathy is therefore justified.

The rate of patient visits for low back pain in primary care is very high, so osteopathy might be offered at that stage (Licciardone, 2008).

Surprisingly, in the US osteopathic physicians were more likely than allopathic physicians to provide medical care during LBP patient visits. NSAIDs and narcotic analgesics were ordered mostly. (Licciardone, 2008)

Despite an initial lack of acceptance by mainstream medicine, and amidst projections of a serious oversupply of physicians, the osteopathic profession continues to grow, successfully competing for shrinking health care resources and attracting the attention of insurers and those in managed care. However, a telephone survey of 800 health maintenance organization beneficiaries suggested that the public is not yet familiar with osteopathic medicine (Lesho, 1999). As we saw in review 1, the recent guidelines have not even included osteopathic treatment in the comparative analyses of therapeutic approaches. Also, there is still no Cochrane review of osteopathic treatment for low back pain, so there are still no evidence-related assertions of the effectiveness of osteopathic treatment for patients with low back pain. On the other hand, it may be deducted from

review 2 that osteopathic treatment has been successful for low back pain of different duration and in different cases. The challenge of the next years must be to underpin the evidence of the osteopathic approach for low back pain with more high-quality studies, which are to be published. This will enable osteopathic treatment to be included in guidelines and assessed, so that it can be suggested as a therapeutic approach for low back pain on the basis of proven effectiveness.

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## **Chapter 6: Appendix**

Abstracts of included osteopathic studies

## **Osteopathic treatment of chronic low back pain. A randomized controlled trial**

Adorjàn-Schaumann K, Höhrhan G, Wille H, Wolff A.

Abstract (German):

**Studienziel:** Prüfung der Hypothese, ob die osteopathische Behandlung im Hinblick auf die therapeutische Wirksamkeit in der Lage ist, auf die funktionelle Beeinträchtigung und die Schmerzen der an chronischer Lumbalgie leidenden Patienten einen spezifischen Effekt zu erzielen.

**Studiendesign:** Kontrollierte, randomisierte, einfachblinde, prospektive Interventionsstudie.

**Setting:** Vier Osteopathen, ausgebildet am COE München, Dauer der Studienarbeit von Februar '97 bis Juni '99

**Patienten und Methoden:** Randomisierte Aufteilung der 57 Patienten in 29 Patienten der Gruppe A (Verum-Gruppe) und 28 Patienten der Gruppe B (Sham-Gruppe). Neben Intention to treat -Analyse Durchführung einer explorativen Studie an allen 28 Patienten der Sham- Gruppe.

**Behandlungen:** 5 Behandlungen im Abstand von 15 Tagen. Auswertung durch diverse Fragebögen: 1. lumbalgiespezifisch 2. Schmerzskalen 3. krankheitsübergreifend primäre und sekundäre Zielparameter:

Lebensqualität (Roland & Morris) Schmerz / Gesundheitszustand / Osteopathische Untersuchungen / Therapieverträglichkeit.

**Resultate:** Osteopathische Behandlung gegenüber der Sham-Behandlung zeigte eine statistisch signifikante Verbesserung hinsichtlich primärer und sekundärer Zielparameter und erzielt einen klinisch relevanten spezifischen Effekt.

**Fazit:** Osteopathie zeigt sich als eine sehr effiziente Behandlungsmethode ohne große Nebenwirkungen für Patienten mit chronischer Lumbalgie.



**A comparison of osteopathic spinal manipulation with standard care for patients with low back pain.**

Andersson GB, Lucente T, Davis AM, Kappler RE, Lipton JA, Leurgans S.

**BACKGROUND:** The effect of osteopathic manual therapy (i.e., spinal manipulation) in patients with chronic and subchronic back pain is largely unknown, and its use in such patients is controversial. Nevertheless, manual therapy is a frequently used method of treatment in this group of patients.

**METHODS:** We performed a randomized, controlled trial that involved patients who had had back pain for at least three weeks but less than six months. We screened 1193 patients; 178 were found to be eligible and were randomly assigned to treatment groups; 23 of these patients subsequently dropped out of the study. The patients were treated either with one or more standard medical therapies (72 patients) or with osteopathic manual therapy (83 patients). We used a variety of outcome measures, including scores on the Roland-Morris and Oswestry questionnaires, a visual-analogue pain scale, and measurements of range of motion and straight-leg raising, to assess the results of treatment over a 12-week period.

**RESULTS:** Patients in both groups improved during the 12 weeks. There was no statistically significant difference between the two groups in any of the primary outcome measures. The osteopathic-treatment group required significantly less medication (analgesics, antiinflammatory agents, and muscle relaxants) ( $P < 0.001$ ) and used less physical therapy (0.2 percent vs. 2.6 percent,  $P < 0.05$ ). More than 90 percent of the patients in both groups were satisfied with their care.

**CONCLUSIONS:** Osteopathic manual care and standard medical care had similar clinical results in patients with subacute low back pain. However, the use of medication was greater with standard care.

Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial.

**Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation.**

Burton AK, Tillotson KM, Cleary J.

This single-blind randomised clinical trial compared osteopathic manipulative treatment with chemonucleolysis (used as a control of known efficacy) for symptomatic lumbar disc herniation. Forty patients with sciatica due to this diagnosis (confirmed by imaging) were treated either by chemonucleolysis or manipulation. Outcomes (leg pain, back pain and self-reported disability) were measured at 2 weeks, 6 weeks and 12 months. The mean values for all outcomes improved in both groups. By 12 months, there was no statistically significant difference in outcome between the treatments, but manipulation produced a statistically significant greater improvement for back pain and disability in the first few weeks. A similar number from both groups required additional orthopaedic intervention; there were no serious complications. Crude cost analysis suggested an overall financial advantage from manipulation. Because osteopathic manipulation produced a 12-month outcome that was equivalent to chemonucleolysis, it can be considered as an option for the treatment of symptomatic lumbar disc herniation, at least in the absence of clear indications for surgery. Further study into the value of manipulation at a more acute stage is warranted.

## **A prospective study of patients with chronic back pain randomised to group exercise, physiotherapy or osteopathy**

Marjorie Chown, Lynne Whittamore, Mark Rush, Sally Allan,  
David Stott, Mark Archer

**Objective:** To investigate the difference in outcome between patients treated with group exercise, physiotherapy or osteopathy.

**Design:** Prospective study of patients referred at random to one of three treatments, with follow-up 6 weeks after discharge and after 12 months.

**Setting:** National Health Service physiotherapy department at St Albans City Hospital, part of the West Hertfordshire Musculoskeletal Therapy Service.

**Participants:** Two hundred and thirty-nine patients aged 18–65 years recruited from referrals to the physiotherapy department with chronic low back pain.

**Interventions:** Eligible patients were randomised to group exercises led by a physiotherapist, one-to-one predominantly manipulative physiotherapy, or osteopathy.

**Main outcomes:** Oswestry Disability Index (ODI), EuroQol-5D, shuttle walking test and patients' subjective responses to pain and treatment.

**Results:** All three treatments indicated comparable reductions in mean (95% confidence intervals) ODI at 6-week follow-up: group exercise,  $-4.5$  ( $-0.9$  to  $-8.0$ ); physiotherapy,  $-4.1$  ( $-1.4$  to  $-6.9$ ); and osteopathy,  $-5.0$  ( $-1.6$  to  $-8.4$ ). Attendance rates were significantly lower among the group exercise patients. One-to-one therapies provided evidence of greater patient satisfaction.

**Conclusion:** The study supports the use of a variety of approaches for the treatment of chronic low back pain. Particular attention needs to be given to the problems of attracting enough participants for group sessions, as these can be difficult to schedule in ways that are convenient for different participants.

**Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain.**

Gibson T, Grahame R, Harkness J, Woo P, Blagrove P, Hills R.

The effectiveness of spinal manipulation carried out by a non-medical qualified osteopath was compared with that of short-wave diathermy (SWD) and a placebo (detuned SWD) in 109 patients with low back pain. More than half the subjects in each of the 3 treatment groups benefited immediately from therapy. Significant improvements were observed in the 3 groups at the end of 2 weeks' treatment, and these were still apparent at 12 weeks. The outcome of treatment was unrelated to the initial severity or duration of pain or to the trend of pain towards deterioration or improvement. It is, therefore, unlikely that the results simply reflect the natural history of low back pain. Benefits obtained with osteopathy and SWD in this study may have been achieved through a placebo effect.

## **The effectiveness of a holistic osteopathic treatment in subacute low back pain. A randomized controlled trial.**

Heinze G.

**Background:** Back pain is one of the most common health problems which lead to long term disability. The most common is unspecific back pain without identifiable anatomical and neurophysiologic cause. The majority of the symptoms manifest themselves in the lower back (LBP=Low Back Pain). Different traditional treatment options exist. Results however are only partially proven in the literature.

**Objective:** How effective – with regards to pain reduction and the activities of daily life – are osteopathic treatments with patients with sub acute low back pain?

**Study Design:** A randomized, controlled clinical study.

**Setting:** Patients were recruited from orthopedic, surgical, accident surgical and general medical practices.

**Patients:** 60 participants (age on average 43 years), who suffered between 4 weeks and 6 months with lower back pain, were assigned by external randomization into two groups: Group of investigation (osteopathic treatment and physiotherapy) with 28 participants, control group (physiotherapy) with 32 participants. 2 study participants from the control group did not complete the study.

**Intervention:** Within 6 weeks all participants received six physiotherapy treatments. The participants of the group of investigation kept in this time 2 to 3 additional osteopathic treatments. All treatments were implemented finding-oriented and adhered according to the holistic principles of the osteopathic philosophy.

**Primary Target Parameter:** Principal target parameter was the improvement of current pain, measured by means of numeric rating scale (NRS). To record the level of the experienced disability in everyday life the Roland and Morris disability questionnaire (RM) was used.

**Result:** In the direct comparison between intervention group and control group current pain arose with the parameter an aprox. 2.5-fold improvement and a statistical significance in favor of the intervention group ( $p < 0.001$ , 95% CI=3.5 to 1.5). In the temporal course (beginning of treatment / 6 weeks after end of treatment) current pain on the NRS improved in the intervention group on average from 4.3 to 1.8 (improvement 66%,  $p < 0.001$ , 95% CI=3.5 to 5.1) in the control group against it improved the averages of the NRS only from 6.0 to 4.2 (improvement 30%,  $p < 0.001$ , 95% CI=1.0 to 2.6).

**Conclusion:** The clear result confirm present osteopathic studies with regard to sub acute lower back pain and show that the Osteopathy is a suitable therapy from and can explain this clinical picture. In the area of pain, as well as in the area of the disabilities a clinically relevant improvement could be achieved. Indeed, improvements of the symptoms appeared in the control group with physiotherapy only but they did not nearly reach the values of the intervention group. Further studies in this area taking into account permanence should still confirm this result.

## **Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial.**

Licciardone JC, Stoll ST, Fulda KG, Russo DP, Siu J, Winn W, Swift J Jr.

**STUDY DESIGN:** A randomized controlled trial was conducted.

**OBJECTIVE:** To determine the efficacy of osteopathic manipulative treatment as a complementary treatment for chronic nonspecific low back pain.

**SUMMARY OF BACKGROUND DATA:** Osteopathic manipulative treatment may be useful for acute or subacute low back pain. However, its role in chronic low back pain is unclear.

**METHODS:** This trial was conducted in a university-based clinic from 2000 through 2001. Of the 199 subjects who responded to recruitment procedures, 91 met the eligibility criteria. They were randomized, with 82 patients completing the 1-month follow-up evaluation, 71 completing the 3-month evaluation, and 66 completing the 6-month evaluation. The subjects were randomized to osteopathic manipulative treatment, sham manipulation, or a no-intervention control group, and they were allowed to continue their usual care for low back pain. The main outcomes included the SF-36 Health Survey, a 10-cm visual analog scale for overall back pain, the Roland-Morris Disability Questionnaire, lost work or school days because of back pain, and satisfaction with back care.

**RESULTS:** As compared with the no-intervention control subjects, the patients who received osteopathic manipulative treatment reported greater improvements in back pain, greater satisfaction with back care throughout the trial, better physical functioning and mental health at 1 month, and fewer cotreatments at 6 months. The subjects who received sham manipulation also reported greater improvements in back pain and physical functioning and greater satisfaction than the no-intervention control subjects. There were no significant benefits with osteopathic manipulative treatment, as compared with sham manipulation.

**CONCLUSIONS:** Osteopathic manipulative treatment and sham manipulation both appear to provide some benefits when used in addition to usual care for the treatment of chronic nonspecific low back pain. It remains unclear whether the benefits of osteopathic manipulative treatment can be attributed to the manipulative techniques themselves or whether they are related to other aspects of osteopathic manipulative treatment, such as range of motion activities or time spent interacting with patients, which may represent placebo effects.

**Osteopathic manipulative treatment of back pain and related symptoms during pregnancy: a randomized controlled trial.**

Licciardone JC, Buchanan S, Hensel KL, King HH, Fulda KG, Stoll ST.

**OBJECTIVE:** To study osteopathic manipulative treatment of back pain and related symptoms during the third trimester of pregnancy.

**STUDY DESIGN:** A randomized, placebo-controlled trial was conducted to compare usual obstetric care and osteopathic manipulative treatment, usual obstetric care and sham ultrasound treatment, and usual obstetric care only. Outcomes included average pain levels and the Roland-Morris Disability Questionnaire to assess back-specific functioning.

**RESULTS:** Intention-to-treat analyses included 144 subjects. The Roland-Morris Disability Questionnaire scores worsened during pregnancy; however, back-specific functioning deteriorated significantly less in the usual obstetric care and osteopathic manipulative treatment group (effect size, 0.72; 95% confidence interval, 0.31-1.14;  $P = .001$  vs usual obstetric care only; and effect size, 0.35; 95% confidence interval, -0.06 to 0.76;  $P = .09$  vs usual obstetric care and sham ultrasound treatment). During pregnancy, back pain decreased in the usual obstetric care and osteopathic manipulative treatment group, remained unchanged in the usual obstetric care and sham ultrasound treatment group, and increased in the usual obstetric care only group, although no between-group difference achieved statistical significance.

**CONCLUSION:** Osteopathic manipulative treatment slows or halts the deterioration of back-specific functioning during the third trimester of pregnancy.

## **Osteopathic treatment of women with low back pain during pregnancy. A randomized controlled trial.**

Von der Linde M., Peters R.

**Objective:** The main objective of this study was to assess the effectiveness whether osteopathic treatment influences the pain-symptomatology of women with pregnancy related pain in the pelvic and/or lumbar area.

**Design:** Randomized controlled trial based on the classical “waiting list design”.

**Setting:** The study was accomplished by two osteopaths, qualified at the “Still Academy”, in their practice in Überlingen and Mülheim.

**Patients:** In the trial participated sixty pregnant women with a pain-symptomatology in the pelvic and/or lumbar area (on average 30 years old, on average in the 25th week of pregnancy). The pain symptomatology had to occur in the time of pregnancy and had to be present for at least one week (VAS>3). 30 women were allocated to an intervention group and 30 to a control group by randomization. During the trial three patients of the control group dropped out.

**Intervention:** The intervention group received four osteopathic treatments in weekly intervals. The patients of the control group did not receive any treatment during that time. They received osteopathic treatment after 5 weeks, which was not relevant for the trial. The osteopathic dysfunctions in the cranial, visceral and parietal system, found on the day of treatment, were diagnosed and treated individually.

**Main outcome parameters:** The primary parameter was the greatest pain intensity within the last 3 days, measured with a visual analogue scale (VAS). The secondary parameter was the interference of every day activities through back pain, measured by the Quebec Back Pain Disability Scale.

**Results:** In the intervention group the pain intensity, measured by VAS, was on the average reduced from with pain in the pelvic and/or lumbar area 6,5 to 2,1, which corresponds to an improvement of 68% ( $p<0.0005$ , 95% CI=3.5 to 5.2). In the control group no improvement occurred during that time ( $p=0.404$ , 95% CI=-1.0 to 0.4). From this a statistic significance is calculated ( $p<0.0005$ ). The Quebec Back Pain Disability Scale was improved by 11 points in the intervention group and thus by 28% ( $p=0.001$ , 95% CI=4.9 to 17.3), whereas the control group worsened here by 20% ( $p<0.0005$ , 95% CI=-12.9 to -4.6).

**Conclusion:** Four osteopathic treatments, over a period of five weeks, could cause a clinically relevant influence on the pain-symptomatology and on the interference of daily life of pregnant women with pain in the pelvic and/or lumbar area. This result encourages implementing further studies on this problem. For further studies it seems to be useful to document the sustainability of the effect about the remaining process of the pregnancy.



## **Study on the effectiveness of osteopathic treatment for women with persistent post partum back pain. A randomized controlled trial**

Recknagel C., Roß J.

**Background:** With persistent unspecific backache post partum the so called epidemiological statistics showing the frequency of this problem in previous publications vary between 9% and 50%. Up until now there are no scientific findings that show any significant success with conservative treatment methods for this problem.

**Objective:** The aim of the study was to investigate whether osteopathic treatments had an effect on women with post partum persistent unspecific back pain.

**Design:** Randomized controlled trial in the „Waiting list design”. Follow up six weeks after completion of treatment.

**Setting:** The study was carried out by two osteopaths in their clinics in Kassel. The patients were recruited from several midwife clinics and on recommendation from the own clinics.

**Patients:** In total 40 women (on average 34,5 years old) with unspecific backache post partum took part in the study, whereby the backache had to be present at least three months but not longer than 24 months and in connection with pregnancy or birth. 20 patients for the treatment group and 20 for the control group were chosen randomly.

**Intervention:** The treatment group received four osteopathic treatments over an eight week period. The women in the control group remained untreated during this period.

**Mean outcome measure:** The main target parameters were firstly the subjective pain felt, quantified by the Visual Analogue Scale (VAS), secondly the strength of the pain and the effect thereof on the daily life of the patient measured with the Oswestry Pain Questionnaire (OPQ).

**Results:** 39 participants completed the study, 20 in the treatment group and 19 in the control group. In a direct comparison between osteopathy and control group there was a statistic significance in the pain intensity as well as the OPQ ( $p < 0.001$ , 95% CI = -33.8 to -57.6 compared to  $p < 0.001$ , 95% CI = -11.6 to -23.8). In the treatment group the intensity of the pain was reduced to the VAS average of 68.3 to 20.6, which means an improvement of 70% ( $p < 0.001$ , 95% CI = -36.5 to -58.8). The control group on the other hand only improved minimally from 3.4% ( $p = 0.383$ , 95% CI = -6.7 to 2.7). Similar results were shown in the restrictions to daily life. The measurements from the Oswestry Pain Questionnaire (OPQ) improved with the osteopathy group on average by 17,4 points, which is 62% ( $p < 0.001$ , 95% CI = -11.6 to -23.8), the control group showed a deterioration of 0.4 points. The eventual affect of external factors on these results was taken into consideration by use of a sensitivity analysis which showed no noticeable affect. In the follow up 6 weeks after the end of treatment, a further improvement of the symptoms was noted.

**Conclusion:** This study shows that an osteopathic treatment for women with persistent, unspecific backache post partum brings about a clinically relevant improvement of the pain symptoms and a reduction of the impediment on daily life. The positive effect from an osteopathic treatment gives women, who are suffering, new hope that, in the future,

they will be registered as a group and taken more seriously.

**Randomized osteopathic manipulation study  
(ROMANS): pragmatic trial for spinal pain in primary care.**

Williams NH, Wilkinson C, Russell I, Edwards RT, Hibbs R, Linck P and Muntz R.

**Background:** Spinal pain is common and frequently disabling. Management guidelines have encouraged referral from primary care for spinal manipulation. However, the evidence base for these recommendations is weak. More pragmatic trials and economic evaluations have been recommended.

**Objectives:** Our aim was to assess the effectiveness and health care costs of a practice-based osteopathy clinic for subacute spinal pain.

**Methods:** A pragmatic randomized controlled trial was carried out in a primary care osteopathy clinic accepting referrals from 14 neighbouring practices in North West Wales. A total of 201 patients with neck or back pain of 2–12 weeks duration were allocated at random between usual GP care and an additional three sessions of osteopathic spinal manipulation. The primary outcome measure was the Extended Aberdeen Spine Pain Scale (EASPS). Secondary measures included SF-12, EuroQol and Short-form McGill Pain Questionnaire. Health care costs were estimated from the records of referring GPs.

**Results:** Outcomes improved more in the osteopathy group than the usual care group. At 2 months, this improvement was significantly greater in EASPS [95% confidence interval (CI) 0.7–9.8] and SF-12 mental score (95% CI 2.7–10.7). At 6 months, this difference was no longer significant for EASPS (95% CI 1.5 to 10.4), but remained significant for SF-12 mental score (95% CI 1.0–9.9). Mean health care costs attributed to spinal pain were significantly greater by £65 in the osteopathy group (95% CI £32–£155). Though osteopathy also cost £22 more in meantotal health care cost, this was not significant (95% CI £159 to £142).

**Conclusion:** A primary care osteopathy clinic improved short-term physical and longer term psychological outcomes, at little extra cost. Rigorous multicentre studies are now needed to assess the generalizability of this approach.

Keywords: Back pain, economic evaluation, neck pain, randomized controlled trial, spinal manipulation.