# Osteopathic Treatment of Patients with Chronic Non-Specific Neck Pain: Development of a Study Protocol

by

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A Thesis submitted to the
Post-graduate School of
Osteopathic Clinical Research
In partial fulfillment of the requirements for the
Degree of Master of Science in Osteopathic Clinical Research

A.T. Still University
2010

# Approval Page

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# Abstract

**Osteopathic Treatment of Patients with Chronic Non-Specific Neck Pain: Development of a Study Protocol**. Schwerla Florian, 2010: Thesis, Post-graduate School of Osteopathic Clinical Research, A.T. Still University of Health Sciences./M.Sc./Osteopathic Clinical Research.

**Background:** Chronic non-specific neck pain (CNP) is a syndrome commonly encountered in the western world and is characterized with inconsistent etiology, pathology and symptoms. Among the many different contemporary therapeutic approaches available none seems compellingly superior to any other. As osteopaths, we see and treat many patients with CNP in our daily practice with encouraging perceived outcomes. Empiric evidence suggests that osteopathic interventions might be effective in alleviating CNP symptoms. However, the effectiveness of an osteopathic treatment approach to neck pain has so far been addressed in only a few small pilot trials. There have been no large clinical trials specifically assessing the effectiveness/efficacy of osteopathic treatment on patients with chronic non-specific neck pain.

**Objective:** The aim of this master thesis was to develop a study design and protocol of a randomized controlled multi-center trial on the osteopathic treatment of patients with CNP. Available information will be analyzed and further strategies will be developed to scrutinize the role of an osteopathic approach.

**Methods:** A comprehensive literature search of clinical trials, systematic reviews, meta-analyses, and guidelines in MEDLINE, EMBASE, the Cochrane Library, and other important databases published from 2000 through 2009 were screened for the latest relevant literature on CNP. In addition, trials were analyzed concerning methodological implications. A systematic review was conducted for trials on the osteopathic treatment of patients with CNP, and two small recently finished German pilot trials of a series of osteopathic treatments of CNP were analyzed.

**Results:** Based on the findings of the literature review and other sources the following study protocol has been developed. In a randomized controlled multi-center trial with two groups a total of 150 subjects, 75 in each group with chronic non-specific neck pain will be included. The subjects allocated to the intervention group will receive five custom-tailored osteopathic treatments over 8 weeks. Two

follow-ups, 3 and 6 months after the end of the treatments will be carried out. Subjects in the control group will remain untreated („waiting list“). Main outcome measure: neck related disability (Neck Disability Index, NDI); secondary parameters are pain intensity over the past 14 days measured by a visual analogue scale (VAS), health-related quality of life (SF-36), work disability, and psychosocial factors (DAPOS).

**Conclusion:** This master thesis presents the rationale and design of a randomized controlled trial to determine the effectiveness of osteopathic treatment for patients with CPN.

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# Chapter 1: Introduction

## *1.1. Background*

Neck pain is as ubiquitous a symptom as headaches, abdominal pain, or back pain. From a life-course perspective, most people will have their first experience with neck pain early in life. This statement is supported by many studies, which have demonstrated the occurrence of neck pain in childhood and adolescence (Guzman et al., 2008b; Hogg-Johnson et al., 2008). Most people can expect to experience some degree of neck pain in their lifetime. In many cases, this will amount to nothing more than mild discomfort, which does not require treatment and has no major impact on either work or other activities. However, some people will go on to develop prolonged or repetitive episodes of neck pain, which may become persistent and debilitating (Haldeman, Carroll & Cassidy, 2008). If no specific underlying pathology is found neck pain is designated as non-specific. Although non-specific neck pain is not a life-threatening disease, it can negatively affect patients' quality of life, cause pain and stiffness, and may result in substantial medical consumption, absenteeism and disability. (Vonk, Verhagen, Geilen, Vos & Koes, 2004) Over the past two decades, there has been an explosion of studies on neck pain. This is indicative of the growing recognition of the personal and societal burden associated with this problem. It also suggests that clinicians, researchers, and policy-makers may be finding it difficult to keep up with this vast literature (Carroll et al., 2008a). Between 2003 and 2009 10 Cochrane Reviews scrutinized a wide variety of interventions. In 2002, the International Task Force on Neck Pain and its Associated Disorders was established, funded by the Bone and Joint Decade 2000-2010, an organization of the WHO. The goal of the Bone and Joint Decade is "to improve the health-related quality of life for people with musculoskeletal disorders throughout the world" (Lidgren, 2009). It was becoming evident that neck pain and its associated disorders − including headaches and pain radiating into the upper back and arms − were much more common than anyone had previously believed. Neck-related pain has become a major cause of disability around the world, for example in North America about 5% of the general population is disabled because of neck pain. One of the goals of the Task

Force was to complete a systematic search and critical review of the scientific literature on neck pain and its associated disorders, including the epidemiology, diagnosis, prognosis, economic costs, and treatment of neck pain and its associated disorders (Lidgren, 2009). The results of this systematic review of the literature and best evidence synthesis were published in 2008 (Haldeman et al., 2008). Furthermore, other important systematic reviews concerning chronic neck pain have been published in recent years. In 2001, the Philadelphia Panel developed *Evidence-Clinical Practice Guidelines on Selected Rehabilitation Interventions for Neck Pain* (Philadelphia Panel, 2001). A systematic review on neck pain was published in 2007 in the British Medical Journal (BMJ) Book *Clinical Evidence* (Binder, 2007b). The systematic reviews of the BMJ publishing group summarize the current state of knowledge and uncertainty about the prevention and treatment of clinical conditions based on thorough searches and appraisal of the literature. It describes the best available evidence from systematic reviews and RCTs. In the same year, the Canadian Institute for the Relief of Pain and Disability published a comprehensive literature review for neck pain (Kerr & White, 2007); and in 2008 the Orthopedic Section of the American Physical Therapy Association published *Clinical Practice Guidelines on Neck Pain, linked to the International Classification of Functioning, Disability, and Health* (Childs et al., 2008)

Nevertheless, there is little scientifically acceptable evidence about the effectiveness of intervention strategies for non-traumatic chronic neck pain (Carroll et al., 2008c).

In the field of osteopathy, much research has been carried out in the last years to evaluate the efficacy/effectiveness of an osteopathic treatment approach to low back pain (Andersson et al., 1999; Licciardone et al., 2003). A recent meta-analysis of Licciardone, Brimhall and King (2005) for low back pain suggests osteopathic treatment is effective. Currently, the *Osteopathic Trial* for chronic low back pain (Licciardone, King, Hensel & Williams, 2008) has set out to scrutinize these findings.

As osteopaths, we see and treat many patients with chronic neck pain in our daily practice with encouraging perceived outcomes. However, the effectiveness of an osteopathic treatment approach to neck pain has so far been addressed in only a few pilot trials. Based on positive results of two small German RCTs on the subject (Schwerla et

al., 2008; Tempel, Steffen, Ruetz & Schwerla, 2008), a pivotal study into the potential of an osteopathic treatment approach for patients suffering from chronic non-specific neck pain seems to be warranted, if not overdue.

## *1.2. Objective*

I would like to propose the following task as the objective of my master thesis: *"The development of a study protocol on the osteopathic treatment of patients with chronic non-specific neck pain (CNP)."*

In this master thesis available information will be analyzed and further strategies will be developed to scrutinize the role of an osteopathic approach in the treatment of chronic non-specific neck pain.

# Chapter 2: Review of the Literature

## *2.1. Systematic Literature Review of the Latest Relevant Literature on Chronic Non-Specific Neck Pain*

### *2.1.1. Objective*

The following questions should be investigated: What is the current state of research in relation to definition, classification, epidemiology, diagnosis, and therapy of chronic non-specific neck pain? A special emphasis will be given to analyze trials on neck pain from other manual therapy disciplines (physiotherapy, physical therapy, chiropractic) in that these will have some common elements.

### *2.1.2. Methods*

A comprehensive literature search was performed in the following databases from 2000 to 2009:

- Cochrane Library (CDSR, DARE, CENTRAL, CMR and HTA),
- MEDLINE
- EMBASE
- CINAHL
- PsychINFO
- MANTIS
- PEDro
- Clinical Evidence
- Register of clinical trials

Searches were conducted for studies on neck pain, such as guidelines, studies on prevalence, incidence, etiology, diagnosis, management, and therapy. Study design criteria included the following study types listed in the electronic databases: meta-analyses, systematic reviews, RCTs , and cohort studies. Studies were not included involving subjects with acute neck pain, neck pain due to whiplash injury, or those with headaches, whether or not they were clearly cervicogenic in nature.

Search strategies:

**COCHRANE** Library, Issue 1, 2009, including Cochrane Reviews (CDSR), Other Reviews (DARE), Clinical Trials (CENTRAL), Methods Studies (CMR), and Technology Assessments (HTA), via http://www.cochrane.org/

Cochrane Database of Systematic Reviews (CDSR) identifies an intervention for a specific disease or other problem in healthcare, and determines whether or not this intervention works. To do this, authors locate, appraise and synthesize evidence from as many relevant scientific studies as possible. They summarize conclusions about effectiveness and provide a unique collation of the known evidence on a given topic, so that others can easily review the primary studies for any intervention. Systematic reviews differ from other types of review in that they adhere to a strict design in order to make them more comprehensive, thus minimizing the chance of bias and ensuring their reliability. DARE complements the CDSR by quality-assessing and summarizing reviews that have not yet been carried out by the Cochrane Collaboration. CENTRAL includes details of published articles taken from bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources. The HTA database brings together details of completed and ongoing health technology assessments (studies of the medical, social, ethical and economic implications of healthcare interventions) from around the world. The aim of the database is to improve the quality and cost-effectiveness of healthcare (*The Cochrane Library*, 2009).

1.) Search:
#1 MeSH descriptor neck pain explode all trees
Results in: Cochrane Reviews [12], Other Reviews [36], Clinical Trials [238], Technology Assessments [5]
2.) Search:
#9 (neck pain)
#10 (non-specific)
#11 (chronic)
#12 (#9 AND #10 AND #11)
Results in: Cochrane Reviews [23], Other Reviews [3], Clinical Trials [10]]
3.) Search:
#11 (neck disorder):ti
#12 (neck pain):ti
#13 (neck pain):kw
#14 (#11 OR #12 OR #13)
Results in: Cochrane Reviews [15], Other Reviews [39], Clinical Trials [547], Methods Studies [5], Technology Assessments [8]

**MEDLINE**: Date 03/2009, via http://www.ncbi.nlm.nih.gov/pubmed/

1.) Search: "non-specific neck pain"
Details: non-specific[All Fields] AND ("neck pain"[MeSH Terms] OR ("neck"[All Fields] AND "pain"[All Fields]) OR "neck pain"[All Fields]) → Results: 99/14 Reviews
2.) Search: "nonspecific neck pain"
Details: nonspecific[All Fields] AND ("neck pain"[MeSH Terms] OR ("neck"[All Fields] AND "pain"[All Fields]) OR "neck pain"[All Fields]) → Results: 120 /20 Reviews
3.)

| Search | Most Recent Queries | Result |
|---|---|---|
| #8 | Search neck pain[TI] AND chronic<br>Limits: published in the last 10 years, Randomized Controlled Trial | 48 |
| #7 | Search neck pain[TI] AND chronic<br>Limits: published in the last 10 years, Practice Guideline | 1 |
| #6 | Search neck pain[TI] AND chronic<br>Limits: published in the last 10 years, Review | 31 |
| #5 | Search neck pain[TI] AND chronic<br>Limits: published in the last 10 years, Meta-Analysis | 8 |
| #4 | Search neck pain[TI] AND chronic<br>Limits: published in the last 10 years | 237 |
| #3 | Search neck pain AND chronic<br>Limits: published in the last 10 years | 1185 |
| #2 | Search neck pain AND chronic | 1722 |
| #1 | Search neck pain | 11605 |

**EMBASE** (03/2009), via http://www.embase.com/

Search: *"neck pain"/ → 1595 records
(neck pain and chronic).m_titl. → 160 records

**PEDro** (03/2009), via http://www.pedro.org.au/

Search: "neck pain" in title AND chronic → 82 records (1 guideline, 16 systematic reviews and 65 clinical trials)

**CINAHL** (03/2009), via http://www.ebscohost.com/cinahl/

Search: TI "neck pain" and chronic
Limiters - Publication Year from: 2000-2009; English Language; Research Article; Exclude Pre-CINAHL; Exclude MEDLINE records, Search modes - Find all my search terms → 37 records

**PsychINFO** (03/2009), via http://www.apa.org/psycinfo/

Search: neck pain.ti. AND chronic.af. AND non-specific.af. →17 record
neck pain.ti. and chronic.af. → 67 records

**MANTIS** (03/2009), via http://www.chiroaccess.com/Start.aspx

Search: Title & Abstract, Search Phrase: "chronic neck pain",
Restrict Search to Years: 2000-2009 → 136 records

**BMJ Clinical Evidence** (03/2009), via http://clinicalevidence.bmj.com/ceweb/index.jsp

**Register of clinical trials,** via http://www.clinicaltrials.gov/

Full text articles, where available, were found online from EBSCO, OVID, Science Direct (via ATSU, https://my.atsu.edu/).

### *2.1.3. Results*

#### *Definition*

MEDLINE defines neck pain as "discomfort or more intense forms of pain that are localized to the cervical region. This term generally refers to pain in the posterior or lateral regions of the neck." Other MeSH-Term entry terms are: cervicalgia or cervical pain.

Some published definitions of commonly used nomenclature are (Kerr & White, 2007):

- *Non-specific neck pain* is defined as pain in the neck area, with or without radiation to the extremities (Philadelphia Panel, 2001); neck pain due to the strain of muscles and joints rather than to some serious problem such as a broken bone; or neck pain where no specific cause can be identified (Clinical Knowledge Summaries, 2007; Hoving et al., 2001). Whiplash may be included in this definition.
- *Uncomplicated neck pain* is neck pain that may or may not radiate to the arms, base of the skull, upper back, face, and scalp. The pain is poorly localized. It has multi-factorial causes and the natural history is poorly understood (Clinical Knowledge Summaries, 2007). Whiplash may be included in this definition.
- *Mechanical neck disorder* is described as neck pain with or without referral to a proximal extremity and includes conditions with muscle, joint, ligament, disc or degenerative involvement (Gross et al., 2004). Whiplash is included in this definition.
- *Cervical syndrome* is inferred if there is limited neck movement and radiation

pain provoked by test movements (Buchbinder, Goel, Bombardier & Hogg-Johnson, 1996).

- *Cervical spondylosis* is a degenerative process (osteoarthritis) of the cervical spine. It can result in the narrowing of the spinal canal and neural foramina and is most common at C4-7 levels (Clinical Knowledge Summaries, 2007). The pain can be acute or chronic and may radiate to the skull, shoulder, upper chest, and upper back, and neurological signs may be present.
- *Disc herniation* is an abnormal protrusion of a portion of the disc material. The symptoms include chronic radiating pain. There are often associated osteophytic changes.
- *Tension neck syndrome* is defined as two tender spots or palpable hardening plus muscle tightness in neck movements (Buchbinder et al., 1996).
- *Myofacial pain syndrome* is pain of a muscular origin and the involved muscles include trapezius, multifidi, splenius cervicis, levator scapulae, supraspinatus, and infraspinatus (Kung et al., 2001). Trapezius myalgia would be classified here.
- *Whiplash* described by Spitzer is an acceleration-deceleration mechanism of energy transfer to the neck, which may result from rear-end or side-impact, predominantly in motor vehicle collisions (Spitzer et al., 1995).
- *Cervical radiculopathy* is a disorder of the spinal nerve root and can cause neck pain that radiates to an upper limb (Clinical Knowledge Summaries, 2007). There are no universally accepted diagnostic criteria (Wainner et al., 2003). Neurological deficits may be found at different levels (nerve root C5 until T1) (Clinical Knowledge Summaries, 2007).

### *Classifications*

#### 1.) Depending on the duration

Most of the medical literature divides neck pain into categories determined by the duration of the symptoms because the category of neck pain influences the choice of treatment (Kerr & White, 2007).

- Acute neck pain is from its onset through to 30 days of symptoms (<4 weeks)
- Sub-acute neck pain is symptoms that last from 30 to 90 days

- Chronic neck pain is pain lasting longer than 90 days. (>12 weeks) (Kroeling, Gross, Houghton & Cervical Overview Group, 2005)
- There is not, however, a broad consensus on defining these neck pain categories. In much of the medical literature neck pain is divided into only two categories: acute pain may be defined as neck pain that lasts fewer than or equal to 6 weeks; and chronic neck pain may be defined as lasting longer than 6 weeks (Kerr & White, 2007).

The Neck Pain Task Force (Guzman et al., 2008b) proposes the following categories for the duration of neck pain: 1) transitory neck pain which lasted fewer than 7 days; 2) short-duration neck pain that lasted 7 days or more, but fewer than 3 months; 3) long-duration neck pain that lasted 3 months or more.

The European guidelines for the management of chronic non-specific low back pain (Airaksinen et al., 2006) defines chronic low back pain as analogous to low back pain persisting for at least 12 weeks. This means that we deal with cases that have lasted for very long periods of time, and cases of recurrent pain in which the current episode has lasted for approximately 12 weeks.

### 2.) Depending on the etiology or symptoms

There is no consistent clinical classification system for neck or cervical pain in the literature (Hoving et al., 2001). Neck pain often occurs in combination with limited movement and poorly defined neurological symptoms affecting the upper limbs. The pain can be severe and intractable, and it can occur with radiculopathy or myelopathy. Predominantly radicular symptoms arising in the cervical spine should be classified under the section on neck pain with radiculopathy (Binder, 2007b).

Many authors approach the study of neck pain in a way which suggests a view that all neck pain has a local pathologic cause, and that this cause can be identified and treated. Other authors seem to consider neck pain as a primarily non-organic problem with psychological and social roots (Guzman et al., 2008b). There is also a tendency to separate neck pain into categories based on their linkage to particular events or precipitating factors such as whiplash-associated disorders (WAD) (Spitzer et al., 1995), occupational neck pain, sports-related neck pain, and neck pain of unknown origin (often called non-specific neck pain) (Borghouts, Koes & Bouter, 1998). These varied

approaches often imply different etiological models for neck pain (Guzman et al., 2008b).

The Neck Pain Task Force specifies neck pain as pain located in the anatomic region of the neck as outlined in Figure 1, with or without radiation to the head, trunk, and upper limbs.

The causes of simple neck pain are often unclear and seem to be multi-factorial, and treatments are similar − no classification has been shown to reliably identify subgroups of people who respond in clinically important different ways to particular interventions. “Nevertheless, it may be important to distinguish subgroups, particularly whiplash-associated disorders, from other simple neck pain conditions so that treatment can be directed appropriately at all the associated symptoms and consequences” (Childs, Fritz, Piva & Whitman, 2004).

The BMJ Review *Clinical Evidence on Neck Pain* differentiates between non-specific neck pain und whiplash (Binder, 2007b):

> “In this review, we have differentiated non-specific (uncomplicated) neck pain from whiplash, although many studies, particularly in people with chronic pain (duration longer than 3 months), do not specify which types of pain are included. Most studies of acute pain (duration less than 3 months) are confined to whiplash. Non-specific neck pain is defined as pain with a postural or mechanical basis, often called cervical spondylosis. It does not include pain associated with fibromyalgia. Non-specific neck pain may include some people with a traumatic basis for their symptoms, but does not include people for whom pain is specifically stated to have followed sudden acceleration–deceleration injuries to the neck (whiplash).”

For low back pain there is a similar classification in literature: the European guidelines for low back pain (Airaksinen et al., 2006) proposes a simple and practical classification, which has gained international acceptance. Low back pain is divided into three categories: specific spinal pathology, nerve root pain/radicular pain, and non-specific low back pain. Recommendations are given in relation to non-specific chronic low back pain, that is low back pain that is not attributable to a recognizable, known specific pathology, for example, infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or

cauda equina syndrome.

In recent years, many new proposals for classification systems have been created. The Neck Pain Task Force (Guzman et al., 2008b) proposes to expand and adapt the WAD classification (the Quebec Task Force on WAD proposed a well-known classification system which categorized neck pain which occurs after a traffic collision into grades 0 to 4 (Spitzer et al., 1995)) by integrating it with the pain classification system proposed by Von Korff, Ormel, Keefe and Dworkin (1992) and recommends the following clinical classification system for neck pain that prompts the individual to seek or require healthcare (Guzman et al., 2008a):

- Grade I: There are no symptoms or signs to seriously suggest major structural pathology (such as vertebral fracture, dislocation, injury to the spinal cord or nerves, infection, neoplasm, or systemic disease including the inflammatory arthropathies) and no or little interference with daily activities. This is frequently the case.
- Grade II: No signs of major pathology, but major interference with daily activities. This occurs less frequently (<10% of people report having experienced this severity of pain during the previous year). Clinical intervention may be sought to decrease symptoms.
- Grade III: Neck pain with neurological signs or symptoms (radiculopathy). This is uncommon but may require specific tests and treatments.
- Grade IV: Neck pain with signs of major pathology (e.g., serious instability or spinal infection). Rare but might require urgent tests and treatments.

In the Netherlands a multi-disciplinary consensus was recently reached (Huisstede, Miedema, Verhagen, Koes & Verhaar, 2007). A Delphi survey for classification of "musculoskeletal **c**omplaints of **a**rm, **n**eck and/or **s**houlder not caused by acute trauma or by any systemic disease," (CANS) was developed, which helps professionals to classify patients unambiguously. The experts classified 23 disorders as *specific* CANS, because they were judged as diagnosable disorders. All other complaints were called *non-specific* CANS. For the neck region they defined cervical disc hernia as specific, radiating neck complaints and tension neck syndrome as non-specific.

To classify and define common musculoskeletal conditions the Orthopedic Section of the American Physical Therapy Association (APTA) created evidence-based practice guidelines (and recommendations, based on the scientific literature published prior to 2007) for orthopedic physical therapy management of patients with musculoskeletal impairments of the cervical region (Childs et al., 2008). The ICF terminology (WHO's *International Classification of Functioning, Disability, and Health*) related to impairments of body function and body structure, activity limitations, and participation restrictions were used (World Health Organization, 2001).

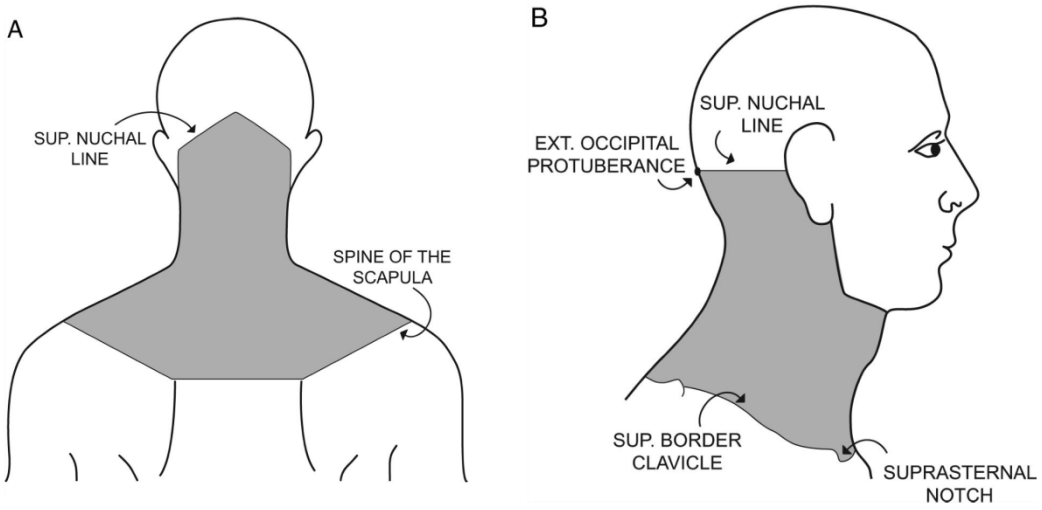



*Figure 1.* The anatomic region of the neck from the back (A) and the side (B) as defined by the Bone and Joint Task Force on Neck Pain (Guzman et al., 2008b)

## *Epidemiology*

### 1.) Prevalence

Before 1998, no studies had specifically documented the prevalence of neck pain and its related disability in North America. Côté, Cassidy and Carroll (1998) conducted the *Saskatchewan Health and Back Pain Survey,* which was mailed to 2184 randomly selected Saskatchewan adults aged 20-69 years. The Chronic Pain Questionnaire was used to classify the severity of chronic neck pain. This cross-sectional study showed that neck pain was highly prevalent, because the age-standardized lifetime prevalence of neck pain was found in 66.7% of the cases. That means that neck pain affects about two-thirds

of people at some stage.

In a comprehensive systematic and critical review Fejer, Kyvik and Hartvigsen (2006) determine the prevalence of neck pain in the world population. In this review, 56 original papers were included in total. Fejer et al. (2006) find a mean point prevalence of 7.6% (range 5.9-38.7%), mean one-year prevalence of 37.2% (range 16.7-75.1%), and mean lifetime prevalence of 48.5% (range 14.2-71.0%). Previous attempts at reviewing the literature on neck pain prevalence also showed wide prevalence ranges (Côté et al., 1998). Similar numbers are reported by Haldeman, Carroll, Cassidy, Schubert and Nygren (2009):

> "Depending on the case definitions used, the 12-month prevalence of neck pain ranged from 12.1% to 71.5% in the general population, and from 27.1% to 47.8% in workers. However, neck pain with associated disability was less common: 12-month prevalence estimates ranged from 1.7% to 11.5% in the general population. Each year, between 11% and 14.1% of workers reported being limited in their activities because of neck pain."

The Bone and Joint Task Force on neck pain write that "neck pain is common in the adult general population, with typical 12-month prevalence estimates from 30% to 50%" (Hogg-Johnson et al., 2008).

Although considerable heterogeneity in prevalence estimates was found, the following trends are evident:

- Prevalence is highest in middle age. The average neck pain prevalence estimates increase with longer prevalence periods (Fejer et al., 2006).
- In nearly all of the studies, women reported more neck pain than men (Fejer et al., 2006).
- Acute neck pain resolves within days or weeks but becomes chronic in about 10% of people. Ten percent of males and 17% of females have reported neck pain that lasted longer than 6 months (Binder, 2007b; Bovim, Schrader & Sand, 1994).
- In the 2003, US National Health Interview Survey, 14.7% of adults age 18 and older reported they had experienced neck pain during the past 3 months that lasted one day or more (Lethbridge-Cejku, Schiller & Bernadel, 2004).
- Neck pain has a large impact on healthcare expenditure, attributed to visits to

health care providers, sick leave, disability, and the related loss of productivity (Borghouts et al., 1999; Hoving et al., 2001).

- About 15% of hospital-based physiotherapy in the UK, and 30% of chiropractic referrals in Canada are for neck pain (Waalen, White & Waalen, 1994). In the Netherlands, neck pain accounts for up to 2% of general practitioner consultations (Binder, 2007b). A US study from the National Ambulatory Medical Care Survey reported an average of 10.2 million visits to healthcare facilities for neck pain (Riddle & Schappert, 2007).
- Neck pain is the second largest cause of time off work, after low back pain (Philadelphia Panel, 2001). A significant proportion of direct healthcare costs associated with neck disorders are attributable to visits to healthcare providers, to sick leave, and to the related loss of productive capacity (Gross et al., 2004).
- Acute neck pain is usually the result of injury or accident, most often road vehicle accidents associated with whiplash (Philadelphia Panel, 2001).
- Whiplash is the most common cause of neck pain associated with chronic musculoligamentous conditions. It is estimated that 6.2% of all Americans (approximately 15.5 million) currently suffer from late whiplash syndrome. Annual medical costs associated with whiplash injuries are estimated to range from $3.6 billion in the UK to $10 billion in the US (Poorbaugh, Brismée, Phelps & Sizer, 2008). Whiplash injuries follow sudden acceleration-deceleration of the neck, such as in road traffic or sporting accidents. Up to 40% of people continue to report symptoms 15 years after the accident (Binder, 2007b).

## 2.) Incidence

Although neck pain is a common source of disability, little is known about its incidence. In a further cohort study Côté, Cassidy, Carroll and Kristman (2004) randomly selected 1100 Saskatchewan adults to determine the annual incidence of neck pain. The age and gender standardized annual incidence of neck pain was 14.6%. Each year, 0.6% of the population developed disabling neck pain. The annual rate of resolution of neck pain was 36.6% and another 32.7% reported improvement. Among subjects with prevalent neck pain at the baseline, 37.3% reported persistent problems. Women are more likely than men to develop neck pain, more likely to suffer from persistent neck

problems, and less likely to experience resolution. Contrary to prior belief, most individuals with neck pain do not experience complete resolution of their symptoms and disability (Côté et al., 2004). Picavet and Schouten (2003) find that the incidence of chronic neck pain increases with age.

A systematic review of Côté et al. (2008) demonstrate that neck pain is a significant health problem in workers. Each year it can be expected that at least 5% of the working population will develop frequent or persistent neck disorders and that depending on their occupations, up to 10% will probably experience at least one episode of activity limitations because of neck pain.

There is a lack of evidence that workplace interventions were effective in reducing the incidence of neck pain in workers. Eliminating insurance payments for pain and suffering, and improving benefits disability costs were both associated with a lower incidence of whiplash claims and faster recovery from symptoms (Haldeman et al., 2009).

### *Etiology/Risk factors*

Etiological factors for chronic non-specific neck pain include poor posture, anxiety, depression, neck strain, or occupational or sporting activities, but they are often multi-factorial and poorly understood (Binder, 2007a). A review of Palmer and Smedley (2007) shows that there is some evidence that neck pain with palpation tenderness is causally related to workplace exposures.

Several studies have reported lower neck muscle strength in patients with chronic neck pain compared to healthy controls. In one study, Ylinen et al. (2004) evaluated the association between the severity of neck pain and disability with neck strength and range of movement in women suffering from chronic neck pain. For the study, 179 female office workers with chronic neck pain were selected. However, no statistically significant correlation was found between perceived neck pain and the disability indices and the maximal isometric neck strength and ROM measures.

Haldeman et al. (2009) summarize the results of the Task Force on Neck Pain as follows:

> "Analysis of risk factors for neck pain suggest that this disorder has a multi-factorial etiology. Non-modifiable risk factors for neck pain included age, gender,

and genetics. Modifiable risk/protective factors for neck pain include smoking, exposure to environmental tobacco, and physical activity participation. In the workplace high quantitative job demands, low social support at work, sedentary work position, repetitive work, and precision work increased the risk of neck pain.“

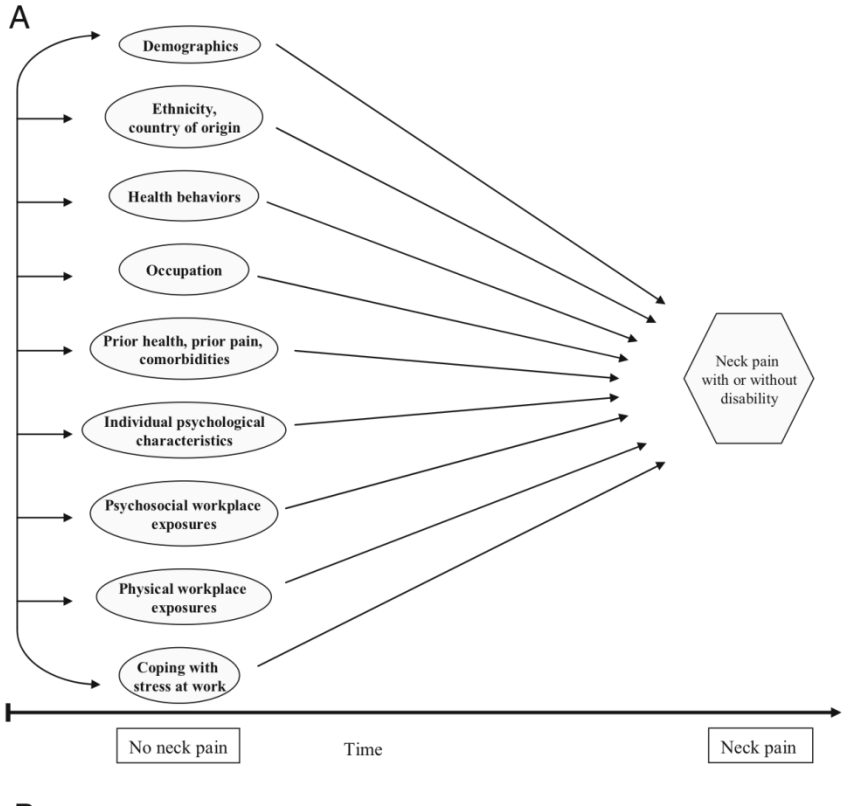
There is no evidence to support the assumption that degenerative disc changes are a risk factor for neck pain without radiculopathy. Poor psychological health is a risk factor for neck pain and is often associated with it (Croft et al., 2001; Hogg-Johnson et al., 2008). However, there is also an association between depression and chronic neck pain and LBP (Philadelphia Panel, 2001).

For primary prevention purposes, school healthcare professionals should pay attention to preteens and early adolescents practicing vigorous exercise (predictor of traumatic pain), reporting headaches (predictor of non-traumatic pain), and reporting day-time tiredness (predictor of both types of pain) (El-Metwally, Salminen, Auvinen, Macfarlane & Mikkelsson, 2007).

Risk factors associated with neck pain in workers include age, previous musculoskeletal pain, high quantitative job demands, low social support at work, job insecurity, low physical capacity, poor computer workstation design, and work posture, sedentary work position, repetitive work and precision work. Côté et al. (2008) write:

“We found preliminary evidence that gender, occupation, headaches, emotional problems, smoking, poor job satisfaction, awkward work postures, poor physical work environment, and workers’ ethnicity may be associated with neck pain. There is evidence that interventions aimed at modifying workstations and worker posture are not effective in reducing the incidence of neck pain in workers.”

Neck pain has a multi-factorial etiology and its development is dependent on the presence of more than one risk factor. Today the factors that predispose a worker to developing neck pain can be identified with a reasonable level of certainty. However, little about the process involved in the development of neck pain and disability is known. The studies reviewed by the Neck Pain Task Force have all assumed (through their design and analysis) that risk factors only have direct effects on neck pain and disability (Figure 2) (Côté et al., 2008).




Notes: Ovals represent risk factor *domains*. The hexagon represents the main outcome. Solid arrows represent an association between a risk factor domain and an outcome. The curved arrows illustrate that risk factor domains are correlated

*Figure 2.* Traditional approach to conceptualize associations between risk factors and the incidence of neck pain (Côté et al., 2008)

### *Course and Prognosis*

Carroll et al. (2008b) find that most of the prognostic factors identified in the literature have only a modest association with the outcome of neck pain. They suggest caution in drawing firm conclusions at this time.

As a general rule, many environmental and personal factors combine to cause neck pain and influence its course (Ariëns, van Mechelen, Bongers, Bouter & van der Wal, 2001; Guzman et al., 2008b). The prognosis for acute neck pain is very good but becomes more unpredictable once it becomes chronic (Binder, 2007a). Most people with neck pain do not experience a complete resolution of symptoms. Between 50% and 85% of those who experience neck pain at some initial point will report neck pain again 1 to 5 years later. The prognosis for neck pain also appears to be multi-factorial. Younger age

was associated with a better prognosis; whereas poor health and prior neck pain episodes were associated with a poorer prognosis. Psychological factors are important in prognosis for neck pain in the general population. Poorer prognosis was also associated with poor psychological health, worrying, and becoming angry or frustrated in response to neck pain. Greater optimism, coping that involves self-assurance, and having less need to socialize were all associated with better prognosis (Carroll et al., 2008b).

Workers who engaged in general exercise and sporting activities were more likely to experience improvement in neck pain. Post-injury psychological distress were prognostic of poorer recovery in WAD (Carroll et al., 2008b; Haldeman et al., 2009).

In a cohort of individuals of working age seeking primary care for non-specific back or neck pain, it can be expected that about half of the population (52%) will report pain and disability at the 5-year follow-up. A significant proportion will report recurrence or continual pain and healthcare consumption. Pain and disability were associated with recurrence or continual pain and healthcare consumption (Enthoven, Skargren & Oberg, 2004). In a study by Woodhouse and Vasseljen (2008), the main finding is that patients with chronic neck pain show altered motor control in the cervical spine. Compared to asymptomatic controls both whiplash and chronic neck pain patients show reduced conjunct motion, particularly during primary cervical rotation. They find no indications for a difference between traumatic and non-traumatic neck pain patients.

### *Diagnosis*

For the diagnosis of chronic non-specific neck pain, all available methods of manual, machine-aided, and psychological diagnostic approaches should be used in order to find the best suitable treatment (Haldeman, 1996; Hardin & Halla, 1995). In about 70% of patients, however, no definite diagnosis can be made (Bogduk, 1995).

The most important conditions which need to be differentiated from non-specific neck pain are (Barry & Jenner, 1995; Binder, 2007a)

- Soft tissue lesions – acute neck strain, acute torticollis
- Fibromyalgia and psychogenic causes
- Mechanical lesions – disc prolapse, diffuse idiopathic skeletal hyperostosis
- Inflammatory – rheumatoid, ankylosing spondylitis, polymyalgia rheumatica
- Metabolic – Paget’s disease, osteoporosis, gout, pseudo-gout

- Infective – osteomyelitis, TB
- Malignancy – primary tumors, secondary deposits, myeloma
- Adjacent pathology – shoulder or acromioclavicular disease

Often degenerative changes are blamed for the complaints, yet there is no scientific evidence for a clear causal relation, as these changes have a similar prevalence in patients who do not suffer from such complaints (Bogduk, 1995). The same conclusion is drawn by the Task Force on Neck Pain: "The finding of degenerative changes on imaging has not been shown to be associated with neck pain" (Haldeman et al., 2009).

Most biomechanical neck disorders will improve without requiring diagnostic X-rays or laboratory tests. Such studies are reserved for patients with histories or physical findings that suggest cord or nerve root compression or systemic illness. These disorders are uncommon causes of neck pain but require thorough evaluation and immediate treatment (Borenstein, 1998). When a patient exhibits neck pain, a medical history and physical examination should be performed, in which the main goal is to rule out any serious problems or red flags. Red flags indicate that there is a need to refer the patient to a physician for further investigation (Kerr & White, 2007).

Red flag symptoms and signs indicating the need for more detailed investigation are (Binder, 2007a; Clinical Knowledge Summaries, 2007):

- Myelopathy (compression of the spinal cord)
- Malignancy, infection, inflammation (fever, loss of weight, history of malignancy)
- Severe trauma/skeletal injury (history of trauma, previous neck surgery, osteoporosis, increasing and unremitting pain)
- Vascular insufficiency (dizziness and blackouts on movement)
- Refer if pain becomes intractable or if complications arise

For investigation of patients with suspected non-specific neck pain, there are many recommendations:

- Plain radiographs of the cervical spine may show a loss of normal cervical lordosis suggesting muscle spasm, but most other features of degenerative disease are common in asymptomatic people and correlate poorly with clinical symptoms

(Gore, Sepic & Gardner, 1986).

- MRI scan is the investigation of choice in patients suspected of having more serious pathology, but the findings need to be interpreted with care, as significant MRI abnormalities are common in asymptomatic people too (Boden et al., 1990).
- Nordin et al. (2008) also conclude that there is "no evidence that common degenerative changes on cervical MRI are strongly correlated with neck pain symptoms" and that "common degenerative changes in the cervical spine identified by MRI are at best fair to moderately reproducible."
- Rubinstein and van Tulder (2008) present an overview of the best available evidence on diagnostic procedures for neck and low back pain. They conclude that relatively little is known about the accuracy of such procedures. Although most spinal conditions are benign and self-limiting, the real challenge to the clinician is to distinguish serious spinal pathology or nerve-root pain from non-specific neck and low back pain. In general, there is much more evidence on diagnostic procedures for the low back than there is for the neck. The diagnostic accuracy of neurological signs and tests is unclear. Orthopedic tests of the neck, such as Spurling's or the upper-limb tension test, are useful to rule in or rule out a radiculopathy, respectively. With patients 50 years of age or older, plain spinal radiography together with standard laboratory tests are highly accurate in identifying underlying systemic disease.
- Haldeman et al. (2009) summarize that the assessment for fracture in the emergency room and the diagnosis of neck pain with radiculopathy are of value, but there is little evidence that diagnostic procedures for neck pain without severe trauma or radicular symptoms have validity and utility. Computerized tomography scans have better validity and utility in cervical trauma for high-risk or multi-injured patients. The clinical physical examination is more predictive at excluding a structural lesion or neurologic compression than at diagnosing any specific etiologic condition in patients with neck pain. All other assessment tools such as electrophysiology, imaging, injections, discography, functional tests, and blood tests lack validity and utility. Reliable and valid self-assessment questionnaires given to neck pain patients can provide useful information for

management and prognosis. Findings of degenerative changes on imaging has not been shown to be associated with neck pain.

- Poorbaugh et al. (2008) write:

> "If the history is to be relevant, it must examine details associated with five clinical questions, or clinical "W's" that include "Who?" "What?" "Where?" "When?" and "Why?" The question of "Who?" refers to the patient's gender, age, occupation, and coping style. The question "What?" identifies the primary or chief complaints of the patient that includes pain, sensory changes, and motor deficits. The question "Where?" addresses the location of the symptoms, whereas "When?" examines the initiation and changes in symptoms since initial onset. The answers to these questions help identify if there are any patterns of symptom aggravation or alleviation. Lastly and most important in the history of a whiplash patient, the question "Why?" addresses the etiology of symptom onset and aggravation."

Yellow flags are psychosocial risk factors that may potentially increase the risk of developing long-term disability and work loss. Yellow flags should be identified early in order to determine if these factors need to be addressed to improve the patient outcomes through cognitive and behavioral management strategies. The importance of psychological factors in the transition from acute to chronic pain is apparent. In fact, psychological factors appear to be more potent than biomechanical or biomedical factors. Psychological factors might be useful in predicting those at risk of developing persistent pain and disability. The presence of yellow flags does not mean that the neck pain is solely psychological. It is real pain, and there is a need for symptom control alongside psychosocial interventions (Kerr & White, 2007).

Cervical radiculopathy is compression or injury to a nerve root in the cervical spine. The most common causes of cervical radiculopathy are cervical disc herniation of and entrapment in the root canal. Cervical disc herniation occurs when the nucleus pulposus bulges or breaks through the annulus of the intervertebral disc. Posterior herniation causes symptoms by compressing the cord or a nerve root, or by stretching the posterior longitudinal ligament or posterior annulus. Cervical disc herniation occurs most frequently at the levels of C5 to C7. The reflexes are usually diminished at the

appropriate level (Binder, 2007a; Clinical Knowledge Summaries, 2007).

### *Therapy*

In the last 10 years, a series of systematic literature reviews have been published on various interventions for neck pain:

- Cochrane Library − 10 reviews from the years 2003-2009 investigate the following interventions on neck pain: acupuncture, electrotherapy, exercises, massage, manipulation and mobilization, work conditioning, mechanical traction, injection therapies, multidisciplinary biopsychosocial rehabilitation, and patient education. It was only for acupuncture that the reviews found moderate evidence for a relief of pain. The Cochrane Reviews deal broadly with neck pain and neck disorders. There is no special differentiation done for example between non-specific and WAD (see Table 1).
- Cochrane Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) − Among others, these databases contain further reviews which scrutinize interventions such as physiotherapy, radiofrequency procedures, manual therapy, botulinum toxin, laser therapy, and cevical pillows. Once more, no special differentiation between the various forms of neck pain was considered (see Table 2).
- Binder (2007b) summarizes the evidence found by a Clinical Evidence synoptic review for non-invasive treatments for simple neck pain:

  > "The evidence about the effects of individual interventions for neck pain is often contradictory because of poor quality RCTs, the tendency for interventions to be given in combination, and for RCTs to be conducted in diverse groups. This lack of consistency in study design makes it difficult to isolate which intervention may be of use in which type of neck pain."

  This review differentiated between non-specific (uncomplicated) neck pain from whiplash, although many studies do not specify which types of pain are included (for results see Table 3).
- The Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders conducted a systematic review for the treatment of neck pain and non-invasive interventions (Hurwitz et al., 2008):

> "For non-specific neck pain the evidence suggests that manual and supervised exercise interventions, low-level laser therapy, and perhaps acupuncture are more effective than no treatment, sham, or alternative interventions; however, none of the active treatments was clearly superior to any other in either the short- or long-term."

Table 4 shows the non-invasive interventions for non-specific neck disorders, by type of population and, based on the synthesis of the literature, and the likelihood of each intervention being helpful in the short-term. For all interventions, treatment courses were generally short (12 weeks or less), effects (if any) were small, and clear evidence of effectiveness in the long-term (six months or longer) is lacking for all noninvasive interventions. There is no evidence of dose-response or duration-response with any non-invasive treatment. One of the conclusions of this review is that there is no evidence that a particular course of care with any intervention improves the prognosis for non-specific neck disorders.

- The Literature Review of the Canadian Institute for the Relief of Pain and Disability on Neck Pain (Kerr & White, 2007) lists systematic reviews for non-specific neck pain or mechanical neck pain concerning with manual therapy. As far as these reviews are not yet listed in the tables, they will be shown in Table 5.
- RCTs - The systematic literature search revealed many RCTs for the intervention of CNP. Most of them are part of the systematic reviews shown in Table 1 to 5. See Table 6 for some RCTs from the last 2 years which have not been listed in systematic reviews yet.

Table 1: *Systematic reviews from the Cochrane Library*

| Autors | Title / Results |
|---|---|
| Karjalainen et al., 2003 | Multi-disciplinary bio-psychosocial rehabilitation for neck and shoulder pain among working age adults.<br>Summary: There is not enough evidence to show whether or not multi-disciplinary bio-psychosocial rehabilitation programs are helpful for people with neck and shoulder pain. |
| Schonstein, Kenny, Keating & Koes, 2003 | Work conditioning, work hardening and functional restoration for workers with back and neck pain<br>Authors' conclusions: There is evidence that physical conditioning (functional restoration/work conditioning/hardening) programs that include a cognitive-behavioural approach can reduce the number of sick days lost for workers with chronic back pain. There is no evidence that specific exercises are effective in reducing sick days lost for workers with either acute or chronic back pain. |
| Gross et al., 2004 | Manipulation and mobilisation for mechanical neck disorders<br>Conclusions: Multi-modal care, including mobilization (movement imposed onto joints and muscles) or manipulation (adjustments) plus exercise, is beneficial for pain relief, functional improvement and global perceived effect for sub-acute/chronic mechanical neck disorder with or without headaches. The evidence did not favor manipulation or mobilization done alone or in combination with various other physical medicine agents. It was not possible to determine which technique or dosage was more beneficial, or if certain subgroups benefited more from one form of care than another. |
| Kroeling et al., 2005 | Electrotherapy for neck disorders<br>Authors' conclusions: No definitive statements on electrotherapy for MND could be made. The current evidence on galvanic current (direct or pulsed), iontophoresis, TENS, EMS, PEMF and permanent magnets is either lacking, limited, or conflicting. Possible new trials on these interventions should have larger patient samples and include more precise standardization and description of all treatment characteristics. |
| Kay et al., 2005 | Exercises for mechanical neck disorders<br>Results: There is unclear evidence of benefit for a stretching and strengthening program in chronic mechanical neck disorder. There is strong evidence of benefit favoring a multimodal care approach of exercise combined with mobilizations or manipulations for sub-acute and chronic MND with or with headache in the short and long term. |
| Trinh et al., 2006 | Acupuncture for neck disorders<br>Authors' conclusions: There is moderate evidence that acupuncture relieves pain better than some sham treatments, measured at the end of the treatment. There is moderate evidence that those who received acupuncture reported less pain at the short term follow-up than those on a waiting list. There is also moderate evidence that acupuncture is more effective than inactive treatments for relieving pain post-treatment and this is maintained at the short-term follow-up (Moderate evidence denoted findings in a single, high quality RCT or consistent findings in multiple low-quality trials) |
| Haraldsson et al., 2006 | Massage for neck disorders<br>Authors' conclusions: No recommendations for practice can be made at this time because the effectiveness of massage for neck pain remains uncertain. Pilot studies are required to characterize massage treatment (frequency, duration, number of sessions, and massage technique) and establish the optimal treatment to be used in subsequent larger trials that examine the effect of massage as either a stand-alone treatment or part of a multimodal |

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|---|---|
| | intervention |
| Peloso et al., 2007 | Medicinal and injection therapies for mechanical neck disorders<br>Results: In participants with chronic neck disorders with or without radicular findings or headaches, there was moderate evidence from 5 high-quality trials that botulinum toxin A intramuscular injections had similar effects as saline in improving pain, disability, or global perceived effect. |
| Graham et al., 2008 | Mechanical traction for neck pain with or without radiculopathy<br>Authors' conclusions: The current literature does not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived effect |
| Haines, Gross, Burnie, Goldsmith & Perry, 2009 | Patient education for neck pain with or without radiculopathy<br>Authors conclusions: This review has not shown effectiveness for educational interventions in various disorder types and follow-up periods, including advice to activate, advice on stress coping skills, and neck school. |

Table 2: *Systematic reviews DARE and HTA*

| Authors | Title/Results |
|---|---|
| Carlsson, Norlander, Rundcranz & others, 1999 | Evidence-based physiotherapy in patients with neck pain<br>Authors' conclusion: The literature review shows that few of the therapies used by physiotherapists to relieve neck pain have effects that are scientifically documented. Most therapies have not been assessed by scientifically acceptable methods. |
| Kjellman, Skargren & Oberg, 1999 | A critical analysis of randomized clinical trials on neck pain and treatment efficacy: a review of the literature<br>(27 RCTs, with a total of 2,075 participants)<br>Authors' conclusion: Few randomized clinical trials on neck problems are of high methodological quality and comprise a sufficiently long follow-up time. In the studies that did show high quality, three different interventions led to a slight tendency towards positive results but the number of publications considered was inadequate to allow general conclusions to be drawn. |
| Geurts, van Wijk, Stolker & Groen, 2001 | Efficacy of radio frequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials<br>Authors' conclusion: There was limited evidence that RF heating of the dorsal root ganglion is more effective than placebo in chronic cervicobrachialgia. |
| Philadelphia Panel, 2001 | Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain<br>(For chronic neck pain, there were three RCTs (n=223), one controlled clinical trial of therapeutic exercises (n=73), and one RCT (n=26) of therapeutic ultrasound)<br>Authors' conclusion: There is scientific evidence to support and recommend the use of proprioceptive and therapeutic exercises for chronic neck pain, but there is a lack of evidence regarding the inclusion or exclusion of thermotherapy, therapeutic massage, EMG biofeedback, mechanical traction, therapeutic ultrasound, TENS, electrical stimulation, and combined rehabilitation interventions in the daily practice of physical rehabilitation of sufferers of acute and chronic neck pain. |
| Gross et al., 2002 | Manual therapy for mechanical neck disorders: a systematic review<br>(20 RCTs (n=1,387) were included)<br>Authors' conclusion: There was insufficient evidence to draw definitive conclusions. The evidence suggested that manual therapies plus exercise are the most effective treatments for improving pain and satisfaction in patients with |

| | |
|---|---|
| | mechanical neck disorder, with or without neck pain. Manipulation alone, mobilization alone and both treatments combined appeared to be less effective |
| Oduneye, 2004 | Spinal manipulation for chronic neck pain<br>Authors' conclusion: No randomized controlled trials could be found comparing spinal manipulation with placebo or no treatment for chronic neck pain. It was, therefore, not possible to draw conclusions about the effects of spinal manipulation relative to the natural progression of this condition. |
| Sycha, Kranz, Auff & Schnider, 2004 | Botulinum toxin in the treatment of rare head and neck pain syndromes: a systematic review of the literature<br>(18 RCTs (n=951) were included in the review)<br>Authors' conclusion: There is persuasive evidence for the role of BoNT in the treatment of pain associated with cervical dystonia. However, there is a risk of adverse effects, particularly at higher doses. |
| Chow & Barnsley, 2005 | Systematic review of the literature of low-level laser therapy (LLLT) in the management of neck pain<br>Authors' conclusion: Limited evidence suggests that LLT at infrared wavelengths appears to be effective for the treatment of neck pain |
| Rickards, 2006 | The effectiveness of non-invasive treatments for active myofascial trigger point pain: a systematic review of the literature<br>(23 studies (n=1,321) were included in the review)<br>Authors' conclusion: There is significant evidence for the short-term effectiveness of laser therapy on pain intensity and the immediate benefits of TENS. There are however insufficient data to determine the long-term effectiveness of TENS. The evidence for the effectiveness of frequency modulated electrical muscle stimulation, electrical muscle stimulation, high voltage galvanic stimulation and interferential current is limited. Ultrasound is no more effective than placebo. The evidence for physical and manual therapies is moderate, owing to the high level of heterogeneity in this group. |
| Shields, Capper, Polak & Taylor, 2006 | Are cervical pillows effective in reducing neck pain?<br>(5 studies (n=134) were included in the review)<br>Authors' conclusion: There was insufficient evidence to conclude whether cervical pillows reduce chronic neck pain. |
| Vernon, Humphreys & Hagino, 2007 | Chronic mechanical neck pain in adults treated by manual therapy: a systematic review of change scores in randomized clinical trials.<br>(16 trials (n=2,115 were included in the review)<br>Authors' conclusion: There is moderate to high quality evidence showing clinically important improvements after spinal manipulation and mobilization for patients with chronic neck pain not due to whiplash and without arm pain and headaches, but insufficient evidence to support massage therapy. |

Table 3: *Results of BMJ Clinical Evidence: non-specific neck pain (Binder, 2007b)*

| Evidence | Intervention | Remarks |
|---|---|---|
| Likely to be beneficial | - Acupuncture<br>- Exercise and postural treatment (pilates, yoga, Alexander technique)<br>- Manipulation (with or without exercise or advice)<br>- Mobilization | - Acupuncture may be more effective than some types of sham or inactive treatment at improving pain relief and quality of life at the end of treatment or in the short term.<br>- Manipulation and mobilization may reduce chronic pain more than usual care or less active exercise. |
| Unknown effectiveness | - Bio-feedback<br>- Different combinations of multimodal treatment for non-specific neck pain versus each other<br>- Drug treatments (analgesics, antidepressants, epidural corticosteroids, epidural local anesthetics, muscle relaxants, NSAIDs) for non-specific neck pain<br>- Heat or cold<br>- PEMF treatment for non-specific neck pain<br>- Patient education<br>- Soft collars and special pillows<br>- Spray and stretch<br>- TENS<br>- Traction | - Analgesics, NSAIDs, antidepressants, and muscle relaxants are widely used to treat chronic neck pain, but it is not known whether they are effective. |
| Definitions<br>Manipulation: a manual treatment involving the use of short or long-lever high-velocity thrusts directed at one or more of the cervical spine joints and does not involve anesthesia or instrumentation. Manual treatment is usually performed by chiropractors or osteopaths.<br>Mobilization**:** any manual treatment to improve joint function which does not involve high-velocity movement, anesthesia, or instrumentation. Usually performed by physiotherapists. | | |

Table 4: *Non-invasive interventions for non-specific Neck Disorders and the likelihood of being helpful in the short term: from the Bone and Joint Decade 2000 – 2010 Task Force on Neck Pain and Its Associated Disorders (Hurwitz et al., 2008)*

| Population | Likely Helpful (Worth Considering) | Possibly Helpful (Might Consider) | Likely Not Helpful (Not Worth Considering | Not Enough Evidence to Make a Determination |
|---|---|---|---|---|
| Non-specific neck pain (Neck pain not associated with WAD) | - Manipulation<br>- Mobilization<br>- Supervised exercises<br>- Manual therapy plus exercises (manipulation, mobilization, massage)<br>- Acupuncture<br>- Low-level laser therapy<br>- Analgesics | - Percutaneous neuromodular therapy<br>- Brief intervention using cognitive behavioral principles | - Advice alone<br>- Collars<br>- Passive modalities (heat therapy, ultrasound, TENS, electrical muscle stimulation)<br>- Exercise instruction<br>- Botulinum toxin A | - Magnetic stimulation<br>- Massage<br>- Traction<br>- NSAIDS<br>- Other drugs |

Table 5: *Canadian Institute for the Relief of Pain and Disability: a selection of systematic reviews for non-specific neck pain or mechanical neck pain and manual therapy (Kerr & White, 2007)*

| Author | Intervention | Clinical implication |
|---|---|---|
| Ernst, 2001 | Safety of spinal manipulation | No reliable data exist about the incidence of serious adverse events. These data indicate that mild and transient adverse events seem to be frequent. |
| Ernst, 2003 | Chiropractic spinal manipulation | None of the 4 trials convincingly demonstrated the superiority of CSM over control interventions. |
| Sarig-Bahat, 2003 | Exercise therapy | The evidence identified could not support the effectiveness of group exercise, neck schools or single sessions of extension-retraction exercises. |
| Ernst, 2004 | Spinal manipulation | Spinal manipulation generated no advantage over general practitioner care, analgesics, physical therapy, exercise or back school. |
| Weiner & Ernst, 2004 | Complementary and alternative approaches to the treatment of persistent musculoskeletal pain. | The benefits of spinal manipulation for persistent low back and neck pain have not been convincingly shown to outweigh its risks (21 RCTs and 2 reviews). |
| Bronfort, Haas, Evans & Bouter, 2004 | Spinal manipulation and mobilization | There is moderate evidence that mobilization is superior to physical therapy and family physician care in both the short and long term. There is limited evidence that SMT is inferior to physical therapy in both the short and long term. |
| Solly, 2004 | Cervical Postero-anterior mobilization | Whilst the current findings are promising, there is a need for more research and higher quality publication. |
| Clare, Adams & Maher, 2004 | Efficacy of McKenzie therapy for spinal pain | There are also insufficient data available on neck pain patients. |
| Sarigiovannis & Hollins, 2005 | Manual therapy | 12 RCTs met the inclusion criteria. The effectiveness of spinal manual therapy on non-specific neck pain remains inconclusive. |
| Ernst & Canter, 2006 | Spinal manipulation | The conclusions of these reviews were largely negative, except for back pain where spinal manipulation was considered superior to sham manipulation but not better than conventional treatments. |
| Gemmell & Miller, 2006 | Comparative effectiveness of manipulation, mobilization and the activator instrument | 5 such studies were identified. The methodological quality was mostly poor. Findings from the studies were mixed and no one therapy was shown to be more effective than the others. |

Table 6: *Single RCTs from the last 2 years, not yet listed in systematic reviews*

| Author | Intervention | Clinical implication |
|---|---|---|
| Sherman, Cherkin, Hawkes, Miglioretti & Deyo, 2009 | Randomized trial of therapeutic massage for chronic neck pain | - 64 patients<br>- "This study suggests that massage is safe and may have clinical benefits for treating chronic neck pain at least in the short term."<br>- effectiveness trial |
| González-Iglesias, Fernández-de-las-Peñas, Cleland & Gutiérrez-Vega, 2009 | Thoracic spine manipulation for the management of patients with neck pain: a randomized clinical trial. | - 45 patients<br>- "The results of our study suggest that thoracic spine thrust manipulation results in superior clinical benefits that persist beyond the 1-month follow-up period for patients with *acute* neck pain."<br>- control: electro-thermal therapy |
| Vonk et al., 2009 | Effectiveness of a behaviour graded activity program versus conventional exercise for chronic neck pain patients | - 139 patients<br>- "No significant differences between treatments were found in their effectiveness of managing patients with chronic neck pain. In both groups some patients reported recovery from complaints and daily function but the proportion of recovered patients did not exceed 50% during the 12-month follow-up period."<br>- efficacy trial |
| Lindell, Johansson & Strender, 2008 | Sub-acute and chronic, non-specific back and neck pain: cognitive-behavioral rehabilitation versus primary care. A randomized controlled trial | - 125 patients<br>The results were equivalent over 18 months. However, there were indications that cognitive-behavioral rehabilitation in the longer run might be superior to primary care, it might be superior in terms of healthcare visits only.<br>- effectiveness trial |
| Häkkinen, Kautiainen, Hannonen & Ylinen, 2008 | Strength training and stretching versus stretching only in the treatment of patients with chronic neck pain: a randomized one-year follow-up study. | - 101 patients<br>- No statistically significant differences in neck pain and disability were observed between the two home-based training regimes.<br>- effectiveness trial |
| Borman, Keskin, Ekici & Bodur, 2008 | The efficacy of intermittent cervical traction in patients with chronic neck pain. | - 42 patients<br>- "In conclusion, no specific effect of traction over standard physiotherapeutic interventions was observed in adults with chronic neck pain." |
| Brockow, Heissner, Franke & Resch, 2008 | Evaluation of the efficacy of subcutaneous carbon dioxide insufflations for treating *acute* non-specific neck pain in general practice: a sham controlled randomized trial. | - 126 patients<br>- The study indicates that subcutaneous carbon dioxide insufflations are not superior to sham ultrasound for treating patients with acute non-specific neck pain.<br>- efficacy trial |
| Schellingerhout et al., 2008 | Which subgroups of patients with non-specific neck pain are more likely to benefit from spinal manipulation therapy, | - 329 patients<br>- "In conclusion we identified three characteristics that facilitate a deliberate treatment choice, to optimize benefit of |

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| | physiotherapy, or usual care? | treatment in patients with non-specific neck pain: age, pain intensity, and (no) accompanying low back pain." |
| Walker et al., 2008 | The effectiveness of manual physical therapy and exercise for mechanical neck pain: a randomized clinical trial. | - 94 patients<br>- An impairment-based MTE program resulted in clinically and statistically significant short and long-term improvements in pain, disability, and patient-perceived recovery. |

### *Management*

Borghouts et al. (1999) describe the management in patients with chronic non-specific neck pain in general practice. Included were 517 patients with chronic non-specific neck pain in general practices in the Netherlands. The study shows that once non-specific neck pain has become chronic, only 44% of the patients seek help from their GP on an annual basis. In spite of the fact that the patients' conditions are non-specific and chronic, GPs still find indications for further diagnostics in two-thirds of the patients. About one-third did not receive a therapeutic modality and one-third was not referred.

Vos, Verhagen, Passchier and Koes (2007) conducted a similar study for the management of acute neck pain in general practice in the Netherlands.

> "At baseline GPs prescribed medication for 42% of patients, mostly non-steroidal anti-inflammatory drugs (56%) or muscle relaxation medication (20%); 51% were referred to a physiotherapist. 74% of referred patients reported recovery at the end of the follow-up year, whereas 79% of non-referred patients reported recovery. Frequently given advice by the GP was to 'wait and see' (23%), 'improve posture' and 'stay active' (22%) or to 'take a rest' (18%). Self-care by patients included different sources of heat application (79%) and exercises (57%). Complementary medicine was used in 12% of cases and 39% of patients visited their GP again during follow-up. Consultation of a medical specialist and ordering of X-rays rarely occurred. To conclude: Management by GPs included a strategy to 'wait and see' for an expected favorable natural course supported by medication, or referral to a physiotherapist."

Feleus, Bierma-Zeinstra, Miedema, Verhaar and Koes (2008) come to a similar conclusion:

"In non-traumatic arm, neck and shoulder complaints, analgesics and referral for physiotherapy were the treatment options most frequently used, followed by corticosteroid injections and referral for medical specialist care. Patients with a non-specific diagnosis were more frequently referred for physiotherapy and less frequently to a medical specialist compared to patients with a specific diagnosis. Corticosteroid injections were mainly applied in specific diagnoses."

The Clinical Knowledge Summaries of the National Library of Health (Clinical Knowledge Summaries, 2007) recommended the following goals for the management of neck pain:

- To recognize possible serious specific causes of pain in the neck − red flags
- To recognize psycho-social barriers to recovery − yellow flags
- To recognize disability caused by simple neck pain
- To relieve pain
- To improve ability to function and alleviate disability
- To prevent recurrence and the development of chronicity

### *2.1.4. Discussion*

#### *Methods*

For the development of the search strategies the main aim was to identify the most important reviews of previous years to obtain a full clinical picture. The aim was not to find all available trials, which is usual for a normal systematic review for an intervention. It seemed to be justified that the literature search was made very specific. Therefore, predominant search terms like *chronic neck pain* in the title or *neck pain* as a MeSH-Term were used. A similar specific search strategy suggests the Cochrane back group for neck pain as follows:

24. neck muscles.sh.
25. exp Neck/
26. exp neck pain/

27. whiplash injuries.sh.

28. neck.ti,ab.

29. or/24-28

Carroll et al. (2008a) writes in "Methods for the best evidence synthesis on neck pain and its associated disorders" that MEDLINE contained about 90-95% of all relevant studies on that topic. This was also found to be true in this literature search.

## *Results*

### 1.) Definition / Classification

There are many published definitions of the commonly used nomenclature. The very term chronic *non-specific* neck pain implies that specific causes must have been excluded (by medical doctors and according to defined standards, e.g. guidelines), and that the pain has shown no tendency to resolve spontaneously as is the case in most instances. Classification of non-specific neck pain in the literature is not uniform. Classifications are arbitrarily based on for example localization, duration (acute, chronic), pathophysiology or predominant symptoms.

### 2.) Therapy

Different therapeutic interventions for CNP are suggested in the literature, yet neither their efficacy or effectiveness nor their modes of action have been convincingly documented to date.

Among the reviews found, there was a large number of Cochrane Reviews. The Cochrane Library is the single most reliable source for evidence on the effects of healthcare. Cochrane Reviews are conducted to the highest standard of methodological quality. They have been found to be of comparable or of better quality than reviews published in print journals and are updated more frequently (Jadad et al., 1998). The incorporation of these results into one's decision-making process can lead to improved patient outcomes (Hoving et al., 2001). A BMJ article by the GRADE Working Group entitled *Grading quality of evidence and strength of recommendations* states that the creation of an evidence-based recommendation requires an approach that takes into account study design and quality, consistency and directness judging the quality of evidence for each important outcome (Atkins et al., 2004). For qualitative analysis of trial

results some Cochrane Reviews use the following *levels of evidence* (Sackett, Straus, Richardson, Rosenberg & Haynes, 2000; van Tulder, Furlan, Bombardier, Bouter & Editorial Board of the Cochrane Collaboration Back Review Group, 2003):

- *Strong evidence* − denotes consistent findings in multiple, high-quality, randomized controlled trials
- *Moderate evidence* − denotes findings in a single, high-quality, randomized controlled trial or consistent findings in multiple, low-quality trials
- *Limited evidence* − indicates a single, low-quality, randomized trial
- *Unclear evidence* − denotes inconsistent or contradictory results in multiple randomized trials
- *No evidence* − means no studies have been identified

The Cochrane Back Group describes similar evidence levels:

- *High quality evidence* − there are consistent findings among 75% of RCTs with low risk of bias that are generalizable to the population in question. There are sufficient data, with narrow confidence intervals. There are no known or suspected publication biases.
- *Moderate-quality evidence* − one of the domains is not met
- *Low-quality evidence* − two of the domains are not met
- *Very low-quality evidence* − three of the domains are not met

The neck pain literature review of the Canadian Institute for the Relief of Pain and Disability (Kerr & White, 2007) defines:

> "*Strong research evidence* is typically based on high quality randomized controlled trials (RCTs) and the results are free of significant doubts about their general applicability for a given similar condition among a similar patient population applying the same inclusion and exclusion criteria."

The Bone and Joint Decade 2000 –2010 Task Force on Neck Pain classify "likely helpful" (worth considering), "possibly helpful" (might consider), "likely not helpful" (not worth considering, and "not enough evidence to make determination." The BMJ Clinical Evidence Review identify in likely to be beneficial" and "unknown effectiveness."

The question of clinical relevance is another important criterion of assessment of the literature. The Cochrane Back Group recommends a number of criteria with which one can determine whether the trial is clinically relevant:

- Are the patients described in detail, so that you can decide whether they are comparable to those you see in your practice?
- Are the interventions and treatment settings described well enough, so that you can provide the same for your patients?
- Were all clinically relevant outcomes measured and reported?
- Is the size of the effect clinically important?
- Are the likely treatment benefits worth the potential harm?

After evaluation of the literature, interventions with strong research evidence or high quality evidence could not be found in any review. Moderate positive evidence (or likely helpful, likely to be beneficial) existed under certain circumstances for manipulation and mobilization, as well as for acupuncture.

Only the review of Vernon et al. (2007) assigns the grade moderate to high-quality evidence for the treatment of neck pain with manual therapy. Until this time, the Cochrane Review by Gross et al. (2004) and the work of Bronfort et al. (2004) had formed the standard for evaluating the evidence for the treatment of neck pain by manipulation or mobilization. The review from Vernon et al. (2007) differs from these works in several ways. This review includes not only studies of manipulation and mobilization but also of massage and other manual therapies. The review includes several studies that Gross et al. (2004) and Bronfort et al. (2004) exclude because they were not studies comparing manipulation or mobilization to another form of therapy. The primary difference between these reviews and the review of Vernon et al. (2007) lies in the analysis of change scores within groups, so as to identify levels of improvement as opposed to determining whether differences between groups occurred as a measure of the effectiveness of the manual therapy treatment.

The reviews of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain were one of the most important sources. They conducted a comprehensive systematic

search and critical review of the literature published between 1980 and 2006 to assemble the best evidence on neck pain. They found 1203 relevant studies, and 552 (46%) were accepted for their scientific merit. These studies comprise of the best evidence synthesis on the epidemiology, assessment and classification, interventions, course, and prognosis of neck pain (Carroll et al., 2008a). The methodological quality of research may have improved substantially over the past decade since the Quebec Task Force report on Whiplash Associated Disorders (WAD) was published, for example for intervention studies from 26% to 47% (Carroll et al., 2008c). However, as Carroll et al. (2008c) report, there are important gaps in the current literature, for example:

- Little is known about the actual course of neck pain or the determinants of that course
- Clear priority to investigations of modifiable risk and prognosis factors need to be given
- What are the factors that prevent neck pain-related activity limitations and disability
- We urgently need to validate red flags for patients presenting to clinicians for non-emergency neck pain
- We have little scientifically acceptable evidence about the effectiveness of intervention strategies for non-traumatic neck pain

One key point of this review is that important questions remain about the effectiveness of commonly used interventions for neck pain. The review revealed common reasons for finding that the scientific validity of RCTs had been compromised: these are inadequate sample size, failure to consider the clinical importance of findings, and inadequate reporting of baseline characteristics.

In addition, the Bone and Joint Decade 2000-2010 Task Force on Neck Pain developed evidence-based guidance and clinical practice implications about how to best assess and treat patients with neck pain (Guzman et al., 2008a). As a result, the authors conclude that a shift in how neck pain and associated disorders are regarded are necessary because some findings run counter to widely held beliefs, for example:

- Less than one-quarter of the general population who report a new episode of neck pain will seek conventional medical care for that pain. It would seem that many

people who experience neck pain consider it a fact of life rather than a disease or injury that needs to be diagnosed and fixed (Hogg-Johnson et al., 2008).

- Neck pain and associated disability are multi-factorial, and they are seldom caused by a single event or factor (Côté et al., 2008).
- Common degenerative changes in the cervical spine seen in radiographs or scans are most often unrelated to neck pain (Nordin et al., 2008).
- A number of alternative and complementary medicine interventions have more evidence of efficacy than conventional medical care (Hurwitz et al., 2008).
- Often less is more when dealing with neck pain treatments, and multiple visits and treatments may make neck pain and disability worse rather than better (Hurwitz et al., 2008).

Given the lack of a gold standard assessment for neck pain, a prognostic criterion seems reasonable and most relevant to the person with neck pain. The patient may not care what his or her diagnosis is; what is important is the outcome. For example, regardless of the diagnosis, patients want answers to questions such as: “Am I going to get better? How long will it take to get better? Will I be able to return to work and my usual activities?” (Hurwitz et al., 2008).

**Summary:**

- The definition of neck pain without specific causes is difficult. Therefore, it is usually referred to as non-specific neck pain.
- There is no consistent classification system for neck pain.
- The etiology of uncomplicated neck pain is unclear.
- Prognostic factors have only a modest association with outcome.
- In about 70% of the cases, no definite diagnosis can be made.
- Out of the variety of therapeutic approaches available no single one seems to be compellingly superior.
- There is little scientifically acceptable evidence about the effectiveness of intervention strategies.
- No standard therapy for chronic non-specific neck pain is available.

## 2.2. Analysis of Interventional Trials on Chronic Non-Specific Neck Pain Concerning Methodological Implications

### 2.2.1. Objectives

The following questions should be answered:

- Which study design was used in most cases?
- What are the main outcome measurements and assessment instruments used in trials for CNP?

### 2.2.2. Methods

The methods of literature search are already described in Chapter 2.1.2. The evaluation was carried out on the clinical trials found in the literature search according to the objectives described above.

### 2.2.3. Results

#### Study design

The 32 trials of the Cochrane Review of Gross et al. (2004) “Manipulation and mobilization for mechanical neck disorders” were analyzed with regards to their study designs.

Five trials assessed the effect of 6 to 20 sessions of manipulation. The comparisons were wait list control, soft tissue treatments, high-technology exercise, manipulation with low-technology exercise, tenoxicam with ranitidine, low voltage electrical acupuncture, and physiotherapy. In 3 trials manipulation was compared to mobilization. Three further trials compared one manipulation technique to another. Four trials compared mobilization against cold pack, transcutaneous electrical nerve stimulation, and acupuncture. Six trials assessed manipulation and mobilization, compared to a placebo group, no treatment group, physiotherapy care, general practitioner care, and exercise. Six trials compared manipulation or mobilization in combination with various physical medicine agents against no treatment controls; placebo tablets; exercise; combined exercise/traction/massage; various combinations of manipulation; intermittent collar use; ultrasound and ultraviolet light; massage/munaripack; heat or electric muscle stimulation; a combination of massage,

manual traction, electrical stimulation, analgesics, and education.

The situation in other reviews is similarly complex. The *Chiropractic clinical practice guideline: evidence-based treatment of adult neck pain not due to whiplash* of the Canadian Chiropractic Association (2005) write:

> "Only 7 of the treatment studies included what their authors considered to be placebo groups. Of these 7 studies, we consider only 3 studies to have used effective placebos. This merely reflects how difficult it is to design valid placebos in a chiropractic practice laden with physical contact modalities that are, by design, tailored to each patient's unique needs. In addition, research is susceptible to including placebos that are an incremental part of the studied treatment (e.g., palpation compared with palpation plus acupuncture) or an independent treatment modality (e.g., "manual contact", with no segmental movement compared with mobilization)."

Their research recommendation for a study design stated: "Where ethical, we strongly recommend the inclusion of a no-treatment group in comparative studies of chiropractic treatments, to ensure these are useful to the front-line chiropractor."

### *Assessment instruments*

Sleszynski & Glonek (2005) write about osteopathic outcomes-based research in the JAOA:

> "Outcomes data can be divided into three groups: input (subject stratification by diagnosis), intervention, and outcomes. Measuring clinical outcomes has been facilitated by the addition of symptom data (chief complaint), as well as functional assessments. Analysis of clinical outcomes and the incorporation of those results into the clinical setting leads to the practice of what is called *evidence-based medicine."*

#### 1.) Outcome measures

There are several outcome measures specifically for neck pain:

- The BMJ Clinical Evidence Review on neck pain (Binder, 2007b) describes for outcome measurements: pain; range of movement; function; return to work; level

of disability; and adverse effects of treatment.

- The Literature Review Neck Pain of the Canadian Institute for Relief of Pain and Disability (Kerr & White, 2007) advises:

  "If you are involved in effectiveness research, the trials should include outcomes to measure the six core domains. These domains are pain, physical functioning, emotional functioning, patient global ratings of satisfaction, negative health states and adverse events, and patient disposition. These questionnaires should be done again at a future date (3 months or a year)."

- In a Cochrane Review, Karjalainen et al. (2003) write:

  "We looked for the following types of outcome in the selected studies: Pain intensity (e.g., visual analogue scale, ordinal scale), global status (e.g., overall improvement), disorder specific functional status (e.g., neck disability index), generic functional status or quality of life (e.g., SF36, 15-D, Sickness Impact Profile, Health Assessment Questionnaire), ability to work (e.g., sickness absence, return to work, number of days off work), health care consumption and costs (e.g., physician's consultations, psychologist's or social worker's consultations, physiotherapy, intake of analgesics), satisfaction with treatment."

- The Task Force on Neck Pain state that "there are many recommendations that multiple validated outcome measures should be assessed at regular intervals. At a minimum, these should include measures to determine: pain intensity; functional ability; medication usage; work status; and subjects' global satisfaction" (Carragee et al., 2008).

- Nordin et al. (2008) describe in the review *Assessment of neck pain and its associated disorders* (*Results of the Bone and Joint Decade 2000 –2010 Task Force on Neck Pain*) 13 self-administered instruments used for the clinical evaluation of patients with neck pain. Most of the questionnaires were designed specifically to evaluate patients with neck pain, several questionnaires were designed to evaluate disorders of the spine in general, and yet others were generic. Specific focus of these questionnaires were: pain and self-assessment, function/disability and self-assessment, psychosocial items and self-assessment,

and finally health care utilization and self-assessment (see Table 7 and 8). It would also be useful to obtain return to work data on the first treatment, immediately post treatment and at 3 or 12 months.

- Chiu, Lam & Hedley (2005a) investigate the correlations among pain, physical impairments, disability, and patient satisfaction in patients with chronic neck pain. Moderate correlation is noted between disability and patient satisfaction, and between disability and pain. A fair relation is found between pain and patient satisfaction, but only examples of weak relations are found between physical impairments and pain. They conclude: "No strong correlations were found among disability, patient satisfaction, pain, and physical impairments. The findings support the suggestion that clinicians should address as many relevant aspects of a presenting clinical entity as possible in the management of chronic neck pain."
- The International Association for the Study of Pain describe pain as "an unpleasant sensory and emotional experience"− a subjective experience (IASP Task Force for Taxonomy, 2004). As such, pain can usually best be ascertained by what the patients report about their pain, although this way of assessing pain can have its limitations (Guzman et al., 2008b).

Some instruments will be described in detail below:

### 2.) Specific instruments (see Table 7)

- *Chronic Pain Questionnaire*: Côté et al. (1998) write:

  "To account for the different dimensions of pain, the Chronic Pain Questionnaire was used. The Chronic Pain Questionnaire is a valid and reliable instrument that grades pain on a seven-item self-report Guttman scale. The Chronic Pain Questionnaire has been demonstrated to have good psychometric properties in the general population as well as with patients with low back pain, headache, and temporomandibular joint disorders. Overall, increasing grades on the Chronic Pain Questionnaire are associated with employment status, pain-related disability, increasing levels of depression, decreasing levels of self-rated health, increasing frequency of opioid analgesic use, and higher number of pain-related physician visits.

Finally, the Chronic Pain Questionnaire has good convergent validity when compared with the SF-36 general health questionnaire."

- *Neck Disability Index*: This questionnaire is discussed extensively in the literature. Pietrobon, Coeytaux, Carey, Richardson and DeVellis (2002) report that "the Neck Disability Index (NDI) is probably the most well known and it assesses neck pain and disability." It is a validated 10-item questionnaire; seven items are related to activities of daily living, two items are related to pain and one to concentration. The patient chooses from 6 different levels of functional ability. The index is then scored as a percent of maximal pain and disability. "The NDI is a neck-specific questionnaire, which overlaps with other measures, showed moderate to good agreement with the SF-36" (Nordin et al., 2008), and "The Neck Disability Index (NDI) is the most widely used and most strongly validated instrument for assessing self-rated disability in patients with neck pain. It has been used effectively in both clinical and research settings in the treatment of this very common problem. It has strong psychometric characteristics and has proven to be highly responsive in clinical trials. As of late 2007, it has been used in approximately 300 publications; it has been translated into 22 languages, and it is endorsed for use by a number of clinical guidelines" (Vernon, 2008). A translation of the NDI into German is available.
- The study by Gay, Madson and Cieslak (2007) compares the sensitivity to change of the NDI and the Neck Bournemouth Questionnaire (NBQ) in patients with chronic uncomplicated neck pain. Outcome measures include standardized response means between a pain VAS and each questionnaire. Both questionnaires are more sensitive to change than the pain VAS. There is moderate correlation between the change scores of all three outcome tools. In their conclusion they write:

  „The NDI and the NBQ performed comparably in this group of patients with chronic uncomplicated neck pain. Both are sensitive to change and would be efficient outcome tools in studies of chronic neck pain. Both had acceptable internal consistency and are appropriate for use as single-outcome scales."
- *Patient-Specific Functional Scale*: Another recommended tool is the Patient-

Specific Functional Scale for measuring disability (Westaway, Stratford & Binkley, 1998). However this questionnaire has limited use when comparing results between patients, as is required in randomized controlled trials (Nordin et al., 2008).

### 3.) Generic instruments (see Table 8)

- *Visual Analogue Scale:* The VAS is the most cited pain measure, largely because it is simple to use, has good psychometric properties and is often cited as the gold standard against which other questionnaires are judged (Wainner et al., 2003). The VAS is a generic pain instrument and is best at detecting change in patients who improve (Bijur, Silver & Gallagher, 2001; Price, McGrath, Rafii & Buckingham, 1983). It has been used to show a weak association between pain and disability and a negative correlation between neck strength output and pain (Ylinen et al., 2004). VAS for pain is a 100 mm horizontal or vertical line. For more precise results, Wainner et al. (2003) suggest using three VAS scales: one for the worst pain in the preceding 24 hours, one for the least pain in the preceding 24 hours, and one for current pain.
- *Numeric Rating Scale:* The Numeric Rating Scale (NRS) is clinically simpler to complete than the VAS; albeit the VAS may have better psychometric properties in the research setting. The numeric rating scale uses the numbers 1 to 10 instead of a 100 mm line (Breivik, Björnsson & Skovlund, 2000; Lara-Muñoz, De Leon, Feinstein, Puente & Wells, 2004).
- *SF-36:* Some researchers and clinicians like to include quality of life measures such as the SF-36 Questionnaire to measure overall health status (Ware & Sherbourne, 1992). The EQ-5D may be more easily interpreted and simpler to complete and is useful for research purposes. The SF-36 may not be responsive to change in neck pain clinical trials as a whole unit, but it will inform the therapist of the overall perceived health including social functioning, physical functioning, mental health and role limitations. This information is in line with the WHO's goals of reducing disability and increasing function.
- Waddell, Newton, Henderson, Somerville and Main (1993) developed the *Fear-*

*Avoidance Belief Questionnaire* (FABQ) in order to measure such beliefs in patients with low back pain. It is a 16-item self-report questionnaire, in which each item is graded on a 7-point Likert Scale (strongly disagree to strongly agree). The clinical message in the investigation of Lee, Chiu and Lam (2006) was:

> "The Fear-Avoidance Beliefs Questionnaire is a valid and reliable tool for patients with neck pain. It has been shown to demonstrate very good content validity, a high degree of test retest reliability and internal consistency, good construct validity and medium responsiveness."

A translation (and validation) in German is available (Pfingsten, Kröner-Herwig, Leibing & Kronshage, 2000).

- *Avoidance-Endurance Questionnaire:* Hasenbring, Hallner and Rusu (2008) state that fear-avoidance responses (FAR) and endurance responses (ER) play a prominent role in the maintenance of low back pain (LBP): "Until now, there is a lack of reliable and valid instruments covering FAR and ER." They developed and validated the Avoidance-Endurance Questionnaire (AEQ): "The AEQ has shown as a reliable and valid measure to assess pattern of fear-avoidance endurance-related responses to pain. Both aspects seem to play a role in the maintenance of LBP."
- *Depression, Anxiety, and Positive Outlook Scale (DAPOS*). The DAPOS was developed by Pincus, Williams, Vogel and Field (2004):

  > "The aim of this study was to develop a reliable and brief tool to assess mood in pain patients. Non-somatic items concerning depression, anxiety and positive outlook were extracted using exploratory factor analysis from commonly used instruments (the Beck Depression Inventory and the Hospital Anxiety and Depression Scale) completed by over 900 chronic pain patients. The DAPOS performed well, indicating that it is a reliable measure of the three mood states with good initial evidence of validity in these samples."

Table 7: *Specific self-assessment questionnaires designed for patients with neck pain (Nordin et al., 2008; Vernon, 2008)*

| **Questionnaire/Acronym/Reference (Alphabetical by title)** | **Constructs Measured** |
|---|---|
| Bournemouth Questionnaire (BQ) – modified for patients with CNP (Bolton & Humphreys, 2002) | Pain/Activities of daily life/Psychosocial status |
| Cervical Spine Outcome Questionnaire (CSOQ) (BenDebba, Heller, Ducker & Eisinger, 2002) | Pain/Function/Disability/Psychosocial status/ Health care utilization |
| Chronic Pain Questionnaire (Côté et al., 1998; Von Korff et al., 1992) | Pain/Disability |
| Copenhagen Neck Functional Disability Scale (CNFDS) (Jordan, Manniche, Mosdal & Hindsberger, 1998) | Function/Disability |
| Core Outcomes for Neck Pain (White, Lewith & Prescott, 2004) | Pain/Disability |
| Functional Rating Index (Feise & Michael Menke, 2001) | Function/Disability |
| Global Assessment of Neck Pain (GANP) (Fejer, Jordan & Hartvigsen, 2005) | Function/Disability |
| Neck Disability Index (NDI) (Bremerich, Grob, Dvorak & Mannion, 2008; Hains, Waalen & Mior, 1998; Vernon, 2008) | Pain/Function/Disability |
| Neck Pain and Disability Scale (NPDS) (Wheeler, Goolkasian, Baird & Darden, 1999; Wlodyka-Demaille et al., 2004) or (NPAD) (Goolkasian, Wheeler & Gretz, 2002), German version available | Function/Disability |
| NHANES-ADL (neck) (Cook et al., 2006) | Function/Disability |
| Nordic Questionnaire (Kuorinka et al., 1987) | Musculoskeletal symptoms |
| Northwick Park Neck Pain Questionnaire (NPQ) (Hoving, O'Leary, Niere, Green & Buchbinder, 2003; Leak et al., 1994) | Function/Disability |
| Patient-specific functional scale self-reports with neck dysfunction (Westaway et al., 1998) | Pain |
| The Copenhagen Neck Functional Disability Scale, Neck Disability Index (NDI), the Patient-Specific Functional Scale, and Bournemouth Neck are available at: *http://www.chiro.org/LINKS/outcome.shtml#QA*<br><br>The Northwick Park Neck Pain Questionnaire are available at: *http://www.cebp.nl/?NODE=77&SUBNODE=1137* | |

Table 8: *Instruments not designed specifically for neck pain and generic instruments*

| **Questionnaire/Acronym/Reference (Alphabetical by title)** | **Constructs Measured** |
|---|---|
| Aberdeen Spine Pain Scale (extended) (APS) (Williams, Wilkinson & Russell, 2001) | Pain |
| Avoidance-Endurance Questionnaire (AEQ) (Hasenbring et al., 2008) | Fear/Endurance |
| Beck Depression Inventory (BDI, BDI-II) (Duyur Cakit, Genç, Altuntaş & Erdem, 2009; Esenyel, Caglar & Aldemir, 2000) | Severity of depression |
| Current Perceived Health 42 Profile (CPH42) (Chiu, Lam & Hedley, 2005b) | Pain/Function/Disability/Psychosocial status |
| Depression, Anxiety, and Positive Outlook Scale (DAPOS) (Pincus et al., 2004) | Depression/anxiety |
| EQ-5D http://www.euroqol.org | Measure of health outcome |
| Fear-Avoidance Belief Questionnaire (FABQ) (Waddell et al., 1993) | Fear |
| Hospital Anxiety and Depression Scale (HADS) (Blozik et al., 2009) | Anxiety/Depression |
| McGill Pain Questionnaire (Dworkin et al., 2009; Melzack, 1975) | Pain |
| MOS 36-item Short-Form Health Survey (SF-36) (Morfeld, Bullinger, Nantke & Brähler, 2005; Ware & Sherbourne, 1992), German version available | Quality of life |
| Perceived Impact of Problem Profile (PIPP) (Pallant, Misajon, Bennett & Manderson, 2006) | Disability and Health (ICF) |
| Problem Elicitation Technique (PET) (Hoving et al., 2003) | Pain/Function/Disability/Psychosocial status |
| Sickness Impact Profile (SIP) (Olson, O'Connor, Birmingham, Broman & Herrera, 2000) | Function/Disability |
| Taylor Manifest Anxiety Scale (TMAS) | Anxiety |
| Visual Analogue Scale (VAS) (Price et al., 1983; Wlodyka-Demaille et al., 2004) | Pain/Function/Disability |

### *2.2.4 Discussion*

As already discussed in detail in Chapter 2.1.4 for the results of clinical trials, there are on one hand many studies, but on the other hand, the methodological quality is limited, and they do not reveal that a particular therapy is effective. The trials described in the various reviews used are extremely heterogeneous in study designs. The

overwhelming majority of studies compared different therapies with each other: however in most cases, no evidence of effectiveness exists for the treatment of the control group.

In the literature, there is a large consensus on which outcome parameters for neck pain should be measured. Parameters which should always be collected are:

- Intensity of pain
- Disorder specific functional status/disability
- Quality of life

The following parameters such as sickness absence/work status, medication usage, emotional functioning/psychosocial status are recommended.

It seems to be especially important to identify the psychosocial status. Esenyel et al. (2000) examined patients with myofascial pain using different interventions. Depression and anxiety associated with chronic pain were assessed using the Beck Depression Inventory (BDI) and the Taylor Manifest Anxiety Scale (TMAS). The BDI scores indicated depression in 22.9% of the patients. High anxiety scores on the TMAS were present in 89.3% of the patients. They conclude that "patients with myofascial pain syndrome had higher scores for anxiety than for depression."

For all outcome parameters described above, many of specific and generic instruments with proven validity are available.

**Summary:**

- No clearly preferred study design can be identified from the literature. The choice of a control group is heterogeneous; few studies are placebo controlled studies or were carried out as waiting list design studies.
- The most commonly used questionnaire is the NDI.
- Pain intensity can be measured with the VAS as well as with the NRS.
- Quality of life should also be measured. The MOS 36-item Short Form Health Survey (SF-36) seems to be the best suited instrument because it includes bodily as well as mental aspects.

## *2.3. A Systematic Literature Review of Trials on Osteopathic Treatment of Patients with Chronic Non-Specific Neck Pain*

### *2.3.1. Objective*

- Are there clinical studies on CNP in which the efficacy/effectiveness of osteopathic treatment is investigated? The main focus of this systematic review is on the methodology used rather than quantifying the effects of osteopathic treatment.
- Analyses of the identified studies for information which is important for the development of a new study protocol.

### *2.3.2. Methods*

Inclusion criteria: Only trials were included in which it was obvious that osteopathic treatment (or OMT) as intervention was carried out according to the principles and the philosophy of osteopathic medicine (Ward, 2003). The term *spinal manipulation* on its own was not a sufficient criteria. There had to be trials exclusively for CNP. Studies that investigated the whiplash syndrome (WAD) were not included.

1.) Systematic search for published studies in the medical databases: the Cochrane Library, MEDLINE, EMBASE, CHINAL, PsychINFO, MANTIS, PEDro and Clinical Evidence. A more sensitive search strategy was developed for MEDLINE. The other databases were analyzed with regard to osteopathic treatment as described in Chapter 2.1.2.

| Search | Most Recent Queries | Result |
|---|---|---|
| #21 | Search #20 AND #14<br>Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review | 121 |
| #20 | Search #18 OR #19<br>Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review | 4050 |
| #19 | Search neck disorder* OR cervical pain OR Cervicalgia<br>Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review | 4050 |
| #18 | Search “Neck Pain"[MeSH]<br>Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review | 707 |
| #14 | Search #10 OR #11 OR #12<br>Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review | 1715 |
| #13 | Search #10 OR #11 OR #12 | 13045 |
| #12 | Search Osteopath* | 7240 |
| #11 | Search Osteopathic Manipulative Treatment* OR Treatment*, Osteopathic Manipulative OR OMT | 466 |
| #10 | Search “Manipulation, Osteopathic”[MeSH] OR “Osteopathic Medicine”[MeSH] OR “Manipulation, Orthopedic”[MeSH]) OR “Manipulation, Chiropractic”[MeSH] OR “Chiropractic”[MeSH] | 8070 |

2.) Systematic search for published and unpublished studies in osteopathic databases: OSTMED DR, Osteopathic Research as well in osteopathic journals (e.g. IJOM, OMPC), conference reports (e.g. ICAOR, OCCTIC, AOA) and websites of various schools of osteopathy:

Osteopathic Research, via http://www.osteopathic-research.com/:

In this database studies and theses from European countries are listed (e.g. Austria, Germany, Italy, French, the Netherlands and the UK)

Search: All fields: “neck pain” → 62 records
All fields “neck pain and chronic” → 19 records
All fields “neck pain AND osteopath*” → 6 records

OSTMED-DR, via http://www.ostmed-dr.com:

Database changed 2008 from OSTMED to OSTMED.DR

Advanced Search: Keyword “neck pain” → 92 records
Title “neck pain” → 8 records

Osteopathic Journals:

- International Journal of Osteopathic Medicine (IJOM): Journal is listed in

EMBASE (see search in EMBASE)

- Osteopathic Medicine and Primary Care (OMPC): Journal is listed in BMC (PubMed) (see search in MEDLINE via PubMed)

Osteopathic Institutions:

- Osteopathic Research Center (ORC), personal communication with J. Licciardone (http://www.hsc.unt.edu/orc/)

Conference Reports

- American Osteopathic Association (AOA): Abstracts of the Annual AOA Research Conference 1999 to 2008, published in JAOA
- Osteopathic Collaborative Clinical Trials Initiatives Conference (OCCTIC): Conference reports no longer available on the Internet
- International Conference on Advances in Osteopathic Medicine 1999-2008 (ICAOR1-7) via http://www.bcom.ac.uk/research/icaor

Schools of Osteopathy:

- British Schools of Osteopathy (BSO): *The Osteopathic Research and Treatment Bulletin* is now published in IJOM under: *Research and treatment bulletin*
- Canadian College of Osteopathy (CEO): Theses 1986-2008 (http://www.osteopathiecollege.com/)

### *2.3.3. Results*

Only 5 trials were found in the literature on the osteopathic treatment of patients with CNP. Two trials did not fulfill the inclusion criteria (see Table 9).

### *2.3.4. Discussion*

Even though CNP is a relevant problem today, which is shown by the amount of trials and reviews on this topic, there has been hardly any osteopathic research carried out. Table 10 presents the details of the identified trials.

Table 9: *Osteopathic trials for chronic non-specific neck pain*

| Author | Title | Study design | Published in |
|---|---|---|---|
| Fryer, Alvizatos & Lamaro, 2005 | The effect of osteopathic treatment on people with chronic and sub-chronic neck pain | Pilot study (no control group) | IJOM 2005 |
| Schwerla et al., 2008 | Osteopathic treatment of patients with chronic non-specific neck pain | RCT | Forsch Komplement Med 2008 |
| Tempel et al., 2008 | Osteopathy as an effective treatment alternative to physical therapy for patients suffering from chronic non-specific neck pain. | RCT | Conference report 2008 |

Excluded trials:

| Author | Title | Study design | Published in | Reason for exclusion |
|---|---|---|---|---|
| McReynolds & Sheridan, 2005 | Intramuscular ketorolac versus osteopathic manipulative treatment in the management of acute neck pain in the emergency department | RCT | JAOA 2005 | Acute neck pain |
| Williams et al., 2003 | Randomized osteopathic manipulation study (ROMANS): pragmatic trial for spinal pain in primary care. | RCT | Fam Pract 2003 | Acute or sub-acute neck pain |

Table 10: *Comparison of the relevant osteopathic trials for chronic non-specific neck pain*

| | Schwerla et al., 2008 | Tempel et al., 2008 | Fryer et al., 2005 |
|---|---|---|---|
| Study design | RCT<br>(external, block wise)<br>Efficacy trial | RCT<br>(external, block wise)<br>Effectiveness trial | Pilot study |
| Control group | Sham ultrasound | Physiotherapy | No control group |
| Patients assessed for eligibility | 135 | 211 | Not stated |
| Number of subjects | 41 (23/18) | 60 (31/29) | 17 |
| Number of therapists | 3 | 2 | 4 |
| Primary outcome | Pain intensity | Pain (intensity, duration, frequency) | - Pain (quality and intensity), disability |
| Secondary outcome | - Neck specific disability<br>- Quality of life | - Neck specific disability<br>- Quality of life | |
| Assessment instruments | - NRS<br>- Nordic Questionnaire<br>- Northwick Pain Questionnaire<br>- SF-36 | - VAS (intensity)<br>- Likert Scale<br>- Nordic Questionnaire<br>- SF-36 | - McGill Pain Questionnaire<br>- VAS<br>- NDI |
| Number of osteopathic/control treatments | 5/9 | 5 /18 | 6 |
| Osteopathic diagnosis | Standardized examination form | Individual (black box) | Not stated |
| Osteopathic treatment | Only structures in dysfunction | Only structures in dysfunction | Semi-standardized |
| Treatment period | Osteopathic treatment: all 12 to 20 days<br>Ultrasound: every 4 to 10 days | Osteopathic treatment: every 2 weeks<br>Physiotherapy:<br>1 to 2 times a week | Osteopathic treatment: twice a week for 2 weeks, once a week for a further 2 weeks |
| Follow-up | 3 months later | 3 months later | - |

## *2.4. A Comprehensive Analysis of Two Recently Finished German Trials of a Series of Osteopathic Treatments of Chronic Non-Specific Neck Pain*

### *2.4.1. Objective*

- Analysis of the trials
- Identification of further information potentially relevant for the design of future studies via personal communication with the authors

Whereas analysis of indentified studies is usually restricted to information provided in the publication, personal contact to those who carried out the studies was established (in the study Schwerla et al. (2008), this had already occurred before writing up the paper) to make sure to consider any potentially useful pieces of information to optimize the protocol. This may include, for instance, any personal experience gained while conducting the studies.

### *2.4.2. Results*

The main results of both trials are presented in Table 11.

Table 11: *Main results of the two German trials*

| | | |
|---|---|---|
| Tempel et al., 2008 | | |
| Average pain intensity, VAS-score (0 to 10) | Inter-group difference (beginning-end) | -.76 (95% CI=-.2 to -1.3), p<.013 |
| | Within group changes (beginning-end) | Osteopathic group: improvement 54%<br>2.26 (95% CI=1.8 to 2.7), p<.0005<br>Control group: improvement 34%<br>1.53 (95% CI= 1.2 to 1.9), p<.0005 |
| | Follow-up (3 months later) | Osteopathic group: .1% worsening<br>Control group: 22% worsening |
| SF-36, physical summary score | Inter-group difference (beginning-end) | -5.3 (95% CI=-8.1 to -2.5), p<.0005 |
| | | |
| Schwerla et al., 2008 | | |
| Average pain intensity, NRS-score (0 to 10) | Inter-group difference (beginning-end) | -1.73 (95% CI=-3.1 to-.3), p<.009 |
| | Within group changes (beginning-end) | Osteopathic group<br>2.47 (95% CI=1.4 to 3.6), p<.0005<br>Control group:<br>.75 (95% CI=-.1 to 1.6), p<.090 |
| | Follow-up (3 months later) | Osteopathic group: 13% improvement<br>Control group: 6% improvement |
| Northwick Pain Questionnaire (0 to 100) | Inter-group difference (end of treatment) | -9 (95% CI=17.3 to -.2), p<.045 |
| SF-36, bodily pain subscale | Inter-group difference (end of treatment) | 14.6 (95% CI=2.6 to 26.6), p<.019 |

### *2.4.3. Recommendations from the Authors*

After personal correspondence with the authors, problems with the study design or suggestions for improvement were considered. Anne Bischoff, who was mainly involved with the completion of the study Schwerla et al. (2008) is referred to as Trial A; and René Tempel from the study Tempel et al. (2008) will be referred to as Trial B in the following:

#### *Subject recruitment*

There were no problems with subject recruitment (compared to other clinical studies). Tempel states:

> "To recruit our patients, we talked to local physicians, physiotherapists and colleagues in person or told them in writing about the study and osteopathy. Originally, we had planned to put notices into physician's practices, pharmacies

and practices for physiotherapy. This though, seemed to be too impersonal and therefore we decided to talk to everyone directly and bring him or her the handouts for physicians and patients personally. As we were well known as therapists in our work regions, we did not have any problems with this approach. 211 interested patients who had heard about the study from one of the sources named above, argues for this approach, too."

### *Eligible criteria*

In Trial A, an osteopathic criterion for inclusion was defined, which means that at least four of seven examined regions of the cervical spine had to present an osteopathic dysfunction. This should ensure that patients who showed no osteopathic dysfunction were not included into the study, as might be the case with hypermobile patients or psychogenic superposed patients. As reported in Chapter 2.4.4., this led to significant problems in interpretation. This inclusion criteria was left out in Trial B, which, according to the authors, did not cause serious problems. The number of such patients was very small.

Furthermore, patients in Trial A with WAD >grade 3 and the "Late Whiplash Syndrome" were excluded; patients in Trial B who showed problems more than six months after a whiplash (which is the definition of „Late Whiplash Syndrome") were excluded.

### *Sham treatment*

In Trial A ultrasound as a sham treatment did not only offer advantages but also severe disadvantages. Ultrasound can only be a reliable form of therapy if the patient receives treatment at least once a week. Therefore, both groups had to be treated twice as often as osteopathy would have required. This meant an unnecessary and extensive cost of time for therapist and patient. Furthermore, it was only possible to treat 41 patients within the study time frame. Different sham treatments could have treated twice as many patients in the same time period. Moreover, because of the large difference in treatment times (about 270 minutes in the control group and 500 minutes in the treatment group), a difference in empathy cannot be ruled out.

### *Questions on pain*

The following questions on pain appeared:

- The intensity of pain just before treatment
- The average intensity of pain since the last treatment
- The worst intensity of pain since the last treatment

Other questions, for example “average intensity of pain during the last three months” and “the worst pain within the last three months” should be excluded because they did not show much differentiation between the two groups. This can be explained by the fact that the question is not very significant and overburdens the patients because:

- The length of time is judged too long for clear conclusions. A good example is the question “How was the weather on average during the last three months?” – it is difficult to give a clinical answer to that question.
- The pain does not affect daily life as much, so it cannot be easily judged in retrospect.

### *Evaluation of pain*

Rating chronic pain was very difficult for some of the patients. They indicated that their pain blends into their daily lives so much that they do not even realize it, even when it is constantly there. Instead of asking for information about average pain it makes more sense to enquire about constant pain.

In addition, there were difficulties ranking pain when the pain at the cervical spine faded but appeared or increased somewhere else. Patients had problems judging their cervical spine pain independently from other pain. Here it makes sense to add another pain scale to accommodate the acute pain separate from the cervical spine.

### *Assessment of stress*

Psychological strain plays a role when chronic pain develops. It was shown that the pain increased in stressful situations. To be able to draw explicit conclusions, patients should be able to indicate their individual perceptions of stress at that moment. This allows the correlation of stress and pain to be recorded as well. To differentiate between physical and emotional stress is also sensible.

### *Questions for case history*

Some of the patients' information on their life situation in relation to their neck pain could not be evaluated. Information about profession does not allow conclusions about posture and physical pressure to be drawn. Besides, this does not include housewives and mothers and their daily pressure. Information should be gathered about the daily pressure and work time in a differentiated way, for example:

| | | | |
|---|---|---|---|
| Daily pressure | Posture at work | Sitting | ☐ |
| | | Standing | ☐ |
| | | Changing | ☐ |
| | Physical pressure | Heavy | ☐ |
| | | Moderate | ☐ |
| | | Light | ☐ |
| | | None | ☐ |
| Estimation of weekly work times | At work | | ..... |
| | In private life | | ..... |

### *On demand medication*

Questions about medication have to be carefully defined. The following hints were contained in the medication diaries of the trials:

- Only the time frame since the last treatment was important
- Only medication for the neck pain was relevant

Neither studies allowed for medication because only few patients (i.e. 7 out 41) took medication regularly to treat their neck pain. Possible reasons might be that:

- Patients within the study were more cautious about medication than patients who were not part of the study
- The average pain (between 4.6 and 4.8. on the scale) seemed to be at a bearable level.

A study with more subjects should be in the position to evaluate statistically the use of medication. The patients' diaries combined with the results of anamnesis showed that not many patients took painkillers regularly against the discomfort caused by the neck pain. If so, they usually took painkillers in the case of additional normal discomfort or if they had to be fit for special appointments.

### *Standard form for osteopathic examination*

To focus with examination and treatment only on the cervical spine is not satisfactory because this approach does not cope with the osteopathic principles very well. In addition, chronic non-specific neck pain cannot be clearly diagnosed in 70% of the patients. With so many non-point diagnoses, broad research for the reasons and treatment of the whole body offers many advantages. The black box method was used in study B (every therapist uses his or her own treatments and experience). This supports the osteopathic philosophy but depends on the qualities of the therapist.

In contrast, study A defined a plan of action before the start of the study. Every therapist who entered the study executed the same plan of action. This questionnaire proved very good in practice:

- It keeps a record of tests and treatment of the whole body in a transparent and comprehensible way.
- It enables a quick and easy review of all the osteopathic dysfunctions of the body.
- Diagnostic tests can be practiced and synchronized by the therapists before the start of the study.
- Dysfunctions can be statistically interpreted in detail.

The collection of osteopathic dysfunctions as secondary parameters was important in both studies. This helps to show functional coherency within the body and match with one of the keynotes of osteopathy - *the body is a functional entity*. With osteopathic diagnostic findings dysfunctions in regions away from the cervical spine could be discovered, such as e.g. the lumbar region or the gastrointestinal tract.

### *Correlation between the patient's history and osteopathic findings*

During anamnesis, the abdomen was frequently seen to be affected with *diseases* or *operations*. Whether that was a statistical coincidence or if there is a connection, could only be examined further in a study with more patients.

### *Treatment period*

Patients in neither study exhibited an explicit improvement from the fourth treatment and 14 days after the last treatment. It could be worth increasing the interval

between treatments after the third session. Then, the success of every treatment might be observed better. The examination also showed that the patients had less continuous pain during the time of the treatment which did not diminish. Therefore, an additional follow-up makes sense. Six months after the end of the therapy the patients should be questioned again.

### *2.4.4. Experience from a Manuscript Review Process*

The study by Schwerla et al. (2008) was first submitted for publication in *Spine* but was restricted there; that followed a submission in *Forschende Komplementärmedizin* (FKM) and an acceptance. In addition, a comment was printed in *Focus on Alternative and Complementary Therapies* (FACT). The reviewer's comments mainly covered questions about the design of the study, sham treatment, ethical aspects, osteopathic medicine, and philosophy. Extracts of the reviewing process are listed below so that this experience can be utilized for future publications:

Comments of the reviewer from the journal *Spine*:

- *1.) Presumably five osteopathic "dysfunction" subgroups are identified for which there are apparently subgroup-specific osteopathic treatments. Unfortunately, your study sample is too small to stratify to analyze the outcomes of your five subgroups. Nevertheless, what was the relative prevalence of these five dysfunctions? Were most or all of your patients in one or two of them with no one in the other 3 or 4? Were there 1 or 2 dysfunctions whose outcomes were especially good while outcomes in the other subgroups were not good? Perhaps the conventional osteopathic treatments for one or two of your dysfunctions are excellent but are ineffective for the others.*
  Answer: we are afraid, we may not understand, what's meant here. If it were possible to identify subgroups, we would no longer be talking about „non-specific neck pain".
- *2.) "The main aim was to investigate whether an individually adapted osteopathic treatment is superior to sham treatment in chronic non-specific neck pain." Here again, you refer to "individually adapted" treatment but you provide insufficient information or citations regarding how that treatment is individually determined.*
  Answer: we have rephrased the relevant sentence in the subsection „osteopathic treatment".

- *3.) Your assessment techniques seem cloaked in secrecy. What evidence supports the "teaching guidelines of COE" regarding reliability and validation, or are they merely the consensus of osteopathic experts? If the latter, acknowledge and state clearly.*
  Answer: point taken! In fact, most guidelines do not exceed evidence level four. This is now explicitly mentioned in the text.
- *4.) "The intervention group received 45 minutes of osteopathic treatment at the first treatment session, and then alternating at every other treatment session." Please comment on the strong role of placebo effect given the great disparities in patient/clinician contact and hands-on care between your two interventions.*
  Answer: now explicitly addressed in the discussion section. Total osteopathic treatment time was about 270 min in the control group and about 500 min in the treatment group.
- *5.) "At each of the nine subsequent therapeutic sessions, patients were examined." Why? Did the outcome of these re-examinations influence care or classification? Did any patients' classifications, and therefore treatments, change as a result of these re-examinations?*
  Answer: we have tried to better describe the fact that osteopaths ALWAYS thoroughly examine their patients – and then treat the actual dysfunctions.
- *6.) "The evaluation of the osteopathic examination form should also show in what areas of the body dysfunctions were more frequently encountered." So your dysfunctions were not confined to the cervical spine. What role, if any, did non-cervical dysfunctions play in your treatment selection for chronic neck pain? Before you stated your inclusion criteria included: "they had to show osteopathic dysfunctions in at least four of the seven areas of the cervical spine investigated". Now you talk about dysfunctions elsewhere. This is confusing.*
  Answer: we hope to have clarified this aspect in the text now. Whether or not dysfunctions in the area of pain are required for inclusion into a study, an osteopath will never restrict to treat only those dysfunctions, but will always treat all dysfunctions detected regardless of their location.
- *7.) "Successfully completed six years of in-service vocational training comprising 1350 hours of teaching." The length of training is irrelevant if there is no interexaminer reliability as a result. Given the longevity of osteopathic care and the enthusiasm of its practitioners, we should expect a number of studies demonstrating high interexaminer reliability. Please either cite these studies or acknowledge their absence as a significant research void in osteopathic assessment methods.*

Answer: nevertheless, “1350 hours of training” is an important aspect of the dimension “structural quality” (refer to Donabedian). The dimension of “process quality” is implicitly covered by the fact that all osteopaths have to pass very rigorous clinical exams at the end of their training. There are indeed only very few studies on the reliability of osteopathic testing. In this study, we tried to scrutinize the efficacy of osteopathic treatments of CNP reported by therapists and patients. If efficacy could not be observed, even excellent interexaminer reliability would be meaningless.

- *8.) "The therapist rather treats all dysfunctions that he considers relevant and that are being identified during thorough examination." This implies that there are relevant and irrelevant dysfunctions. How is "relevance" determined? So are we to presume that irrelevant dysfunctions have no clinical validity. So what is the definition of dysfunction again?*

  Answer: every clinician intuitively groups his/her observations and findings into “relevant” and “not relevant” concerning considerations to treat. It would probably be beyond the scope of this paper to go further into detail here. Briefly, osteopaths apply a 3-point scale (0 = no dysfunction, 1 = partly/weak dysfunction, 2 = fully established dysfunction). “Relevant” refers to scale 2 dysfunctions.

- *9.) Not until the last paragraph of your paper do you inform us that some or much of the treatment was directed elsewhere in the body. This must be stated in your Methods section where most readers would have made the incorrect assumption that the osteopathic treatment was directed at the cervical spine - only. This gets back to your system's determination of which bodily dysfunctions are relevant to the chronic neck pain complaint and how have you determined such relevance.*

- *10.) The intervention studied is presented as a black box. It cannot be replicated, except by hiring the same therapists. No treatment algorithms seem to be laid down. Although the “osteopathic techniques employed conformed with the teaching guidelines of the European College of Osteopathy by necessity, it is not clear whether this is also a sufficient specification of the treatments employed.*

  Answer: the actual performance of a therapist is always dependent on technical skills and the actual circumstances. It is, therefore, strictly speaking, never possible to exactly replicate a “personally delivered” treatment. We tried to “standardize” technical skills (see “osteopathic treatment”) and to monitor performance (documentation of what was done) as good as possible, thus in keeping with the procedure of many other comparable studies.

- *11.) The power of the study is insufficient to determine a potential differential therapist effect. Since the authors employed three therapists in order to address generalizeability, this needs to be discussed.*

  Answer: it is not sensible to determine a single therapist's effect anyway (golden rule for studies involving therapists: you need more than one therapist if you want to study the effect of the therapy rather than the therapist). In fact, studying only one therapist (with the appropriate number of patients included) would preclude any generalizability of results. We are aware that variation between therapists (centre effects) cannot be assessed with the numbers treated by each of them – but that was not part of the question under study, and may now be addressed in another study. One could even argue that it might be unethical to include the necessary number of patients in a first trial.

Comments of the reviewer from FKM:

- *1.) Study design: "The authors state that they have performed a sham-controlled trial because patients of both groups (verum and sham) received an ultrasound treatment without any ultrasound discharge. This is not a sham therapy in terms of methodology. It is a basal therapy in both groups and in the verum group osteopathic treatment was added."*

  Answer: we are very grateful for this comment, since we obviously weren't precise enough in our description of this aspect and the rationale behind it. We have now clarified the issue in the discussion section and amended the text accordingly where appropriate.

- *2.) "Although the authors tried to make the difference among interventions very small, the patients of the verum group knew that they received more therapy. As far as I understood it correctly, the patients were not blinded for treatment and the outcome measures are subjective ratings which are suspectable for the placebo effect. In so far a specific effect is not proven by the chosen study design. Because of the long lasting effect in the osteopathic group it could be assumed. An appropriate sham intervention would have been an unspecific touching of a non-professional person for the same time as the verum treatment. This would have been as expensive as the additional sham ultrasound performance."*

  Answer: there are often more than one proper way of defining a control intervention. Our choice may be associated with some disadvantages, the suggested alternative, although a smart approach clearly would come with others. "Touch" in any form cannot be assumed to be an "inert" form of intervention. In addition, it may be difficult to train people naive to osteopathy to apply touch for three quarters of an hour in a credible way. We are,

however, very thankful for the reviewer's suggestion and will consider his point for future projects.

- *3.) Ethics: "The authors should report in detail what they have told the participants about the mode of treatment of each study group. It sounds to me as if the authors did not disclose that the ultrasound was inactive. This would be an ethical conflict."*
  Answer: this is indeed an inherent problem of all efficacy trials, in particular when a non-pharmacological intervention is under investigation. We therefore tried to handle this aspect in the way we found described in the majority of respective papers, i.e. therapists told the patients that there is no evidence of efficacy for any of the therapies applied in the study.

Comments of the reviewer from FACT:

- *1.) "While I am intrigued by the results, I am also confused as to the methods. As I read the paper, it is not clear to me exactly what was done to each participant. I understand that each person was osteopathically diagnosed at each visit; all received sham ultrasound and some received osteopathic treatment. But the diagnostic protocol is not defined. The methods note that participants had to show osteopathic dysfunction in at least 4 of the 7 areas of the cervical spine investigated, but this is also undefined. Does this refer to motion abnormality of some sort, or some other physical finding?"*
  Answer: we did indeed not explicitly describe details of the diagnostic protocol which was defined according to "Foundations of Osteopathic Medicine", where osteopathic examination methods and procedures have been categorized in four categories: General impressions, regional motion testing, superficial and deep tissue evaluation, local characteristics of motion. For diagnosis of somatic dysfunction four criteria are used: **T**issue texture abnormalities, **A**symmetry of bony landmarks, **R**estriction of motion and **T**enderness or soreness to examiner pressure (TART) (Ward, 2003).
- *2.) "Given so many different forms of osteopathic treatment, I would also like to have seen some reporting of what kinds of interventions were used, and in what frequency. Given the small sample size, it would not have been fruitful to look at individual treatment responses to each form of intervention, but a larger trial will be able to do just that. What we know now is simply that an osteopathic regimen of care is more effective than sham ultrasound, but not which element of care is responsible for that fact. This is not to criticize the authors, who were cautious in their interpretation of their results, but simply to note the obvious. Further work will need to look at classifying the neck pain, as well as better focusing in on the various interventions."*

Answer: DJ Lawrence’s conclusion that “what we know now is simply that an osteopathic regimen of care is more effective than sham ultrasound” perfectly matches the objective of this study. The authors intended to scrutinize patients’ perspective in the first place. In a best practice model the “classic” osteopathic approach was investigated, an individualized therapeutic approach guided by dysfunctions diagnosed at respective treatment sessions.

We do not quite agree with the statement that there are “many different forms of osteopathic treatment”, but there is certainly a good deal of different techniques to choose from. As the paper states, “the treating therapists chose techniques which correspond to techniques written in the "Foundations of Osteopathic Medicine", details of which could not be presented due to lack of space. Since we were not convinced that from the documentation of the techniques used in a mere 41 patients a reliable pattern may be derived, we decided not to present this information in the paper. This should, however, be an essential bit of information in future, larger trials of this type. Finally, “simply to note the obvious”, other, future sensible approaches may indeed include studies focusing on different questions, e.g. those raised in the comment.

**Summary:**

- The main points of criticism were related to osteopathic diagnosis and treatment. It is very clear that the reviewers are not familiar with osteopathic principles and philosophy and therefore do not fully understand the course of action. On the other hand it is nearly impossible to analyze osteopathic principles within the limited frame of an article. It will be necessary to refer to osteopathic literature more often for publication.
- Some of the acknowledged methodological aspects will be responded to in Chapter 4.

# Chapter 3: Study Protocol

This chapter contains the final version of the study protocol and takes into account all relevant findings from the literature review described in detail in Chapter 2. All relevant aspects of the study protocol are discussed in Chapter 4.

## *3.1. Introduction*

Neck pain is as ubiquitous a symptom as headaches, abdominal pain, or back pain. From a life-course perspective, most people will have their first experience with neck pain early in life. This statement is supported by many studies which have demonstrated the occurrence of neck pain in childhood and adolescence (Guzman et al., 2008b; Hogg-Johnson et al., 2008). Most people can expect to experience some degree of neck pain in their lifetime. In many cases, this will amount to nothing more than mild discomfort which does not require treatment and which has no major impact on work or other activities. However, some people will go on to develop prolonged or repetitive episodes of neck pain which may become persistent and debilitating (Haldeman, Carroll & Cassidy, 2008).

If no specific underlying pathology is found, neck pain is designated as non-specific. Although non-specific neck pain (CNP) is not a life- threatening disease, it can negatively affect a patient's quality of life, cause pain and stiffness, and may result in substantial medical consumption, absenteeism, and disability (Vonk, Verhagen, Geilen, Vos & Koes, 2004).

Over the past two decades, there has been an explosion of studies on neck pain. This reflects the growing recognition of the personal and societal burden associated with this problem (Carroll et al., 2008a). Between 2003 and 2009, 10 Cochrane Reviews scrutinized a wide variety of interventions. In 2002 the International Task Force on Neck Pain and Its Associated Disorders was established, funded by the Bone and Joint Decade 2000-2010, an organization of the WHO. It was becoming evident that neck pain and its associated disorders were much more common than anyone had previously believed. Neck-related pain has become a major cause of disability around the world, for example in North America, about 5% of the general population is disabled because of neck pain (Lidgren, 2009).

Nevertheless there is little scientifically acceptable evidence about the effectiveness of intervention strategies for non-traumatic chronic neck pain (Carroll et al., 2008c).

Osteopaths in the US and Europe see and treat many patients suffering from chronic non-specific neck pain in their daily practice and the perceived outcomes are encouraging. In Europe, osteopathic dysfunctions will be diagnosed individually for each patient on the day of treatment and will be treated in accordance with these individual diagnoses in the visceral, parietal, and cranio-sacral systems (custom-tailored therapy). Based on the positive results of two, small, German pilot studies on CNP (Schwerla et al., 2008; Tempel, Steffen, Ruetz & Schwerla, 2008) there is empirical evidence that this approach is successful.

The following study protocol is to analyze the question as to whether this type of osteopathic approach actually leads to better results than the natural course of the disease.

## *3.2. Objective*

### *3.2.1. Primary Objective*

The primary objective is to test the null hypothesis that a series of test-dependent osteopathic treatments are not superior to watchful waiting in alleviating CNP symptoms.

### *3.2.2. Secondary Objective*

In addition, the protocol intends to study relevant aspects associated with the clinical problem and approaches the following questions:

- Can medication be reduced?
- Is it possible to reduce work disability days?
- Which were the main osteopathic dysfunctions that were found?
- Is there a difference between treating osteopathic practitioners (e.g. outcome, diagnosis and treatment)?
- Is there a correlation between a patient's history and osteopathic findings?
- Is there a correlation between psychosocial factors and symptoms of chronic non-specific neck pain?

## *3.3. Definition*

MEDLINE defines neck pain as: “Discomfort or more intense forms of pain that are localized to the cervical region. This term generally refers to pain in the posterior or lateral regions of the neck.” Other MeSH-Term entry terms are: cervicalgia or cervical pain.

There is no consistent clinical classification system for neck pain or cervical pain in the literature (Hoving et al., 2001). *Non-specific neck pain* is defined as pain in the neck area, with or without radiation to the extremities (Philadelphia Panel, 2001) or neck pain due to the strain of muscles and joints rather than to some serious problem such as a broken bone or neck pain where no specific cause can be identified (Clinical Knowledge Summaries, 2007; Hoving et al., 2001). Whiplash may also be included in this definition.

Other published definitions of commonly used nomenclature are (Kerr & White, 2007): *uncomplicated neck pain* (Clinical Knowledge Summaries, 2007), *mechanical neck disorder* (Gross et al., 2004), *cervical syndrome* (Buchbinder, Goel, Bombardier & Hogg-Johnson, 1996), *cervical spondylosis* (Clinical Knowledge Summaries, 2007), *tension neck syndrome* (Buchbinder et al., 1996), *myofacial pain syndrome* (Kung et al., 2001).

Most of the medical literature divides neck pain into categories determined by the duration of the symptoms, because the category of neck pain influences the choice of treatment (Kerr & White, 2007) such that:

- Acute neck pain is from its onset through to 30 days of symptoms (<4 weeks)
- Sub-acute neck pain is symptoms which last from 30 days to 90 days
- Chronic neck pain is pain which lasts more than 90 days. (>12 weeks) (Kroeling, Gross, Houghton & Cervical Overview Group, 2005)

## *3.4. Study Design*

To scrutinize the null hypothesis in a valid manner, the study design shall include the following features:

- Clinical
- Prospective
- Randomized
- Controlled (2-armed)
- Open
- Follow-up after 3 and 6 months

The study is designed as a 2-armed, randomized, controlled, multi-center trial, which compares osteopathic treatment with a waiting list group (untreated). It follows the standards of the Declaration of Helsinki (*World Medical Association declaration of Helsinki. Recommendations guiding physicians in biomedical research involving human subjects*, 1997) and the ICH-GCP Guideline for Good Clinical Practice (Guideline for Good Clinical Practice, 2002).

Subjects will be randomly assigned to one of the two groups (for details on randomization see Chapter 3.9.).

- Osteopathic intervention group (referred to as *osteopathic group*), and
- Untreated group (referred to as *waiting-list* group)

## *3.5. Research Staff*

Project coordinator or Contract Research Organization (CRO): A project coordinator for the study will provide centralized overall project leadership. During the study, the coordinator will have overall responsibility for every aspect of the research project, including recruitment, subject safety, adherence to the study protocol, and quality of data control.

All relevant aspects are defined in advanced in writing and are documented (Standing Operation Procedures: SOPs).

Onsite monitoring: A study nurse will be in charge of the onsite monitoring in intervals not fewer than 3 months.

Statistician: Within 1 month after the end of the treatment the statistician receives the Case Record Forms (CRF) of the patients which completed the intervention. Within a further period of 4 weeks, data are be entered into a computer program and tested for completeness and plausibility. Should the data be either incomplete or flawed the project coordinator is to inform the study center.

Participating therapists: A trial-specific training session is to be organized before the beginning of the practical work to enable consistent protocol implementation, including the provision of treatment.

## *3.6. Setting*

Osteopaths will carry out the study in their private practices. As the proposal is a multicenter study, it is possible to cover the population in both rural and urban areas. Participating therapists are required to have successfully completed the highest possible level of osteopathic education in their country (in Germany at present approximately 1,300 hours), and to have practiced as a full-time Osteopath for least 5 years without interruption.

Number of centers: 10 osteopathic sites are to collaborate.

## *3.7. Subject Recruitment*

Participants will be identified from the general population. Recruitment will be carried out through word of mouth, advertisements in local newspapers, and flyers displayed in surgeries, clinics, and pharmacies. Subjects with constant or intermittent neck pain for at least 3 months are sought. Terms other than “chronic non-specific neck pain” to be used in recruiting subjects include “cervical pain,” and “cervicalgia” (for the flyer see Appendix B).

Interested candidates will be initially screened with a telephone interview to make a preliminary decision whether they may meet the inclusion criteria (for the telephone checklist see Appendix B).

Consent will be obtained from all subjects, and participants may withdraw at any time without penalty (for the consent form see Appendix B). The sample in this proposed research project includes both male and female subjects of all racial and ethnic categories.

## 3.8. Eligibility Criteria

### 3.8.1. Inclusion Criteria

To be eligible for consideration as a trial subject, a participant must meet all of the following criteria:

- Patients are included if they are between 20 and 65 years of age.
- The episode of neck pain must be of a duration of more than 3 months.
- The neck pain has to be the patient's main complaint at the initial examination. The patients must have a primary complaint of non-specific neck pain that is located at least partly in the area anywhere within the region bounded superiorly by the superior nuchal line, inferiorly by an imaginary line through the tip of the first thoracic spinous process and laterally by sagittal planes tangential to the lateral borders of the neck.
- Non-specific neck pain is diagnosed according to common clinical standards. Patients can only be included if they present the results of a current clinical investigation from a physician without evidence of any of the following aspects:
  - Neurological examination if there are signs of neurological disturbed functions.
  - Blood tests if there are hints of pathologic vessel or blood irregularities as well as infections.
  - X-rays of the cervical spine (two levels) (or CT and MRI) showing evidence of traumatic, infectious, or tumorous changes.
- Actual pain intensity, average pain intensity, and the worst pain intensity during the last 14 days must exceed 40% on the Visual Analogue Scale (VAS) (Bijur et al., 2001).
- Sufficient language skills to understand and complete trial questionnaires.
- Give written informed consent for clinical screening and, if selected, for trial participation; agree to forego any type of osteopathic manipulation

### 3.8.2. Exclusion Criteria

*General* exclusion criteria are:

- Obesity: BMI ≥ 30 kg/m$^2$ (WHO, 2000)

- Adjacent pathologies, such as shoulder or acromioclavicular disease, condition involves predominantly arm symptoms, headache not of a cervical origin but associated with the neck.
- Psychiatric illness.
- Current pregnancy or plan to become pregnant during the course of the trial.
- Late whiplash syndrome (for a definition see chapter 4.2); whiplash associated disorders (WAD) only in cases in which the accident happened during the previous 6 months. If the WAD had happened 6 months before that, the patients will be excluded if they answer the following question with yes: “Do you think your complaints are the consequence of this accident?”
- Undergoing treatments like physical therapy, manual therapy, chiropractic spinal manipulation, and acupuncture during the past 3months.
- Recent or actual therapy with corticosteroid medication and ongoing treatment with anticoagulants.
- A pending insurance claim, involvement in current litigation or a pending pension application associated with neck pain.
- Sick leave associated with neck pain at time of enrollment.

*Study-specific* exclusion criteria: diagnoses medically assessed by a physician before admittance of the patients based on symptoms, mandatory physical examination, and X-ray (appearance of red flags), such as:

- Severe trauma/skeletal injury/fractures: neck symptoms are related to a motor vehicle accident or significant trauma, especially with irreversible injuries of the cervical spine (e.g. cerebrocranial trauma, instability or rupture of the cervical ligaments).
- New trauma in the previous 3 months or neck surgery in the previous 12 months.
- Severe osteoarthritis of the cervical spine (the diagnoses will be made by the physician at the clinical screening by X-ray).
- Cervical radiculopathy (e.g. cervical disc herniation with neurological deficiencies) or myelopathy (e.g. compression of the spinal cord) .
- Vascular insufficiency (dizziness and blackouts on movement).

- Chronic inflammatory disorders (e.g. rheumatic diseases, ankylosing spondylitis, polymyalgia rheumatica) or infectious diseases (e.g. osteomyelitis, TB).
- Signs of serious pathology such as malignancy (primary neoplasm, metastases), unremitting and increasing pain.
- Fibromyalgia.
- Neck pain related to neurological disease (e.g. spasmotic torticollis).

*Manipulation-specific* exclusion criteria or contraindications to cervical manipulation, such as:

- Calcium metabolism disorders (e.g. osteoporosis).
- Circulatory disorders of the A. vertebralis.
- Modifications of the cervical spine caused by damage during surgery or radiation.
- Diabetes mellitus.

#### *3.8.3. Execution Criteria*

If the patient has taken medication for muscle relaxation 48 hours before osteopathic treatment, no structural manipulation is contraindicated.

## *3.9. Randomization*

Based on a computer-generated randomization list with variable block length of 4-8 for each therapist (Altman & Bland, 1999) an adequate allocation concealment will be performed externally by an external trustworthy research organization (e.g. CRO) or via the internet throughout the trial to ensure that comparable numbers of subjects are assigned to each treatment group.

## *3.10. Outcome Parameter*

#### *3.10.1. Main Outcome Parameter*

- Neck-related disability

### *3.10.2. Secondary Outcome Parameters*

- Pain intensity
- Quality of life
- On demand medication
- Work disability
- Psychosocial factors
- Osteopathic dysfunctions

### *3.10.3. Assessments*

The main outcome parameter will be measured by the Neck Disability Index (NDI, Vernon, 2008). The NDI questionnaire has to be answered by all patients at baseline, before each treatment session, and 3 and 6 months after the end of the intervention (Follow-ups). Subjects choose the statement that best describes their situation in each of 10 sections. Each section deals with an aspect of disability such as from pain (including headaches), and the ability to perform tasks like personal care, lifting, reading, driving, and recreation. Each item is scored out of 5 for a maximum total score of 50. Care should be taken in reporting the score as either out of 50 or as a percentage out of 100. Using this system, a score of 10-28% (5-14 points) is considered to constitute mild disability, 30-48% (15-24 points) moderate, 50-68% (25-34 points) severe, and 72% or more (> 34 points) is complete (NDI see Appendix C).

Secondary outcome parameters will be measured by:

- Visual Analogue Scale (VAS): The VAS has to be answered before randomization (see inclusion criteria), before each treatment session, at the end of intervention, and at the follow-up. This measure is commonly used to assess changes in pain over time during the study. It consists of a horizontal line (e.g. 100 mm) labeled as “no pain” at the left end and “worst possible pain” at the right (for the VAS see Appendix C). The patients will be asked about their current pain, as well as their worst pain and average pain during the last 14 days.
- Medical Outcomes Study Short Form – 36 Health Survey (SF-36). Retrospective modified time period from 4 to 2 weeks (for the SF-36 see Appendix C).

- Work disability: Subjects who work will be asked to complete the following survey item: “During the past 2 weeks, how many days did neck pain keep you from going to work?”
- Medication diary: Participants will be asked to keep diaries of medication taken during the study period (for the medication diary see Appendix C).
- Depression, anxiety, and positive outlook scale (for the DAPOS see Appendix C).

## *3.11. Baseline Data Collection*

Baseline data will be collected at the initial appointment including the sociodemographic and clinical characteristics of participants. This includes age, gender, height and weight, and the NDI, which serves as the primary outcome measure. Other baseline measure includes three VAS for neck pain, generic health status (SF-36), and the DAPOS questionnaire, as these are secondary outcome measures. Repeated measures of the primary and secondary outcome variables are performed during the trial as indicated in Table 12.

## *3.12. Intervention*

### *3.12.1. Intervention Group*

Five osteopathic treatments will be administered over a 10-week period (see Table 12).

#### *Osteopathic diagnosis*

Actual osteopathic dysfunctions will be diagnosed and documented at every session to monitor changes over the course of treatments. For documentation purposes, all therapists will use a standardized examination form. This form is also important to report any modifications which occur in the treatment, not only in the cervical spine but also in the whole body. As an examination form the “Outpatient Osteopathic SOAP Note Form,” developed by the American Academy of Osteopathy, will be used, extended with details for coverage of osteopathic dysfunctions (for the examination form see Appendix D).

The diagnostic protocol will be used according to *Foundations of Osteopathic Medicine*, which categorizes osteopathic examination methods and procedures into four

categories: general impressions, regional motion testing, superficial and deep tissue evaluation, and local characteristics of motion. For diagnosis of somatic dysfunction four criteria are used: tissue texture abnormalities, asymmetry of bony landmarks, restriction of motion and tenderness or soreness to examiner pressure (TART) (Ward, 2003).

At every osteopathic treatment session, only those structures for which actual osteopathic findings (dysfunctions) are present will be treated. According to the principles of osteopathy the location of dysfunction will not be restricted to the area of the cervical spine alone, dysfunctions can arise and be diagnosed in the whole body, on a parietal, visceral or cranial level. To evaluate the presence and severity of osteopathic dysfunctions an evaluation system from 0 to 2 will be used: "0" for no dysfunction, "1" for mild to moderate dysfunction, and "2" for severe dysfunction.

#### *Osteopathic treatment*

Dysfunctions will be treated with cranial, visceral, or parietal techniques according to individual findings. Pragmatically, the trial protocol will be limited to the osteopathic techniques listed in the *Glossary of Osteopathic Terminology* (Ward, 2003): articulatory treatments (ART), balanced ligamentous tension (BLT), cranial treatments/osteopathy in the cranial field/cranial osteopathy (CR), counterstrain treatments (CS), direct treatments (DIR), facilitated positional release treatments (FPR), high-velocity low-amplitude (thrust) treatments (HVLA), indirect treatments (IND); integrated neuromusculoskeletal release (INR), ligamentous articular strain (LAS), muscle energy treatments (ME), myofascial release treatments (MFR), soft tissue treatments (ST), and visceral manipulative treatments (VIS). These 14 techniques include the vast majority of techniques used in patients with CNP.

Subjects will be allowed to take their usual medication. If necessary, medication for pain can be taken, but this has to be documented in the medication diary.

### *3.12.2. Control Group*

The control group will be untreated (waiting) during the 2-month period. Subjects allocated to the control group are required to fill out all questionnaires at the first session (see Table 12). The practitioner then tells them that the first osteopathic treatment is only

possible 2 months later. For the results of the study, only the osteopathic treatment period and the waiting period will be statistically compared. Consecutively, the patients of the control group receive also five osteopathic treatments at the same intervals. These treatments of the control group are only additional confirming results because it is not part of the randomized study any more.

## *3.13. Sample Size Calculation*

Sample sizes for this study were calculated using the response rates and variances in the principal outcome measures from previous trials. According to the common standard in clinical trials, type I error was set at .05, and type II error at .2 (i.e. a power of 80%). The parameter "neck related disability" as measured by means of the NDI was used to determine the sample size. The trial was designed to be able to detect an (clinically meaningful) overall difference in changes between the two groups of 10 points with assumed SDs of 20 points (thus an effect size of .5). The sample size calculation estimated that 64 subjects would be required in each group to detect such a difference. In order to account for potential additional variation due to the multi-center nature of the trial, it seems reasonable to aim at including 75 subjects in each group. For the second outcome measurements a total sample of 150 provides statistical power greater than 95% in detecting clinical relevant outcomes (e.g. a 2-point reduction in the pain intensity scale and a 10-point difference between groups on the SF-36).

Analysis: A priori: Compute required sample size
(Program: G*Power 3, retrieved June 2009 from
www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3)

| Input: | | | Output | | |
|---|---|---|---|---|---|
| Tail(s) | = | Two | Noncentrality | | |
| Effect size d | = | 0,5 | parameter δ | = | 2,828427 |
| α err prob | = | 0,05 | Critical t | = | 1,978971 |
| Power (1-β err prob) | = | 0,80 | Df | = | 126 |
| Allocation ratio N2/N1 | = | 1 | Sample size group 1 | = | 64 |
| | | | Sample size group 2 | = | 64 |
| | | | Total sample size | = | 128 |
| | | | Actual power | = | 0,801460 |

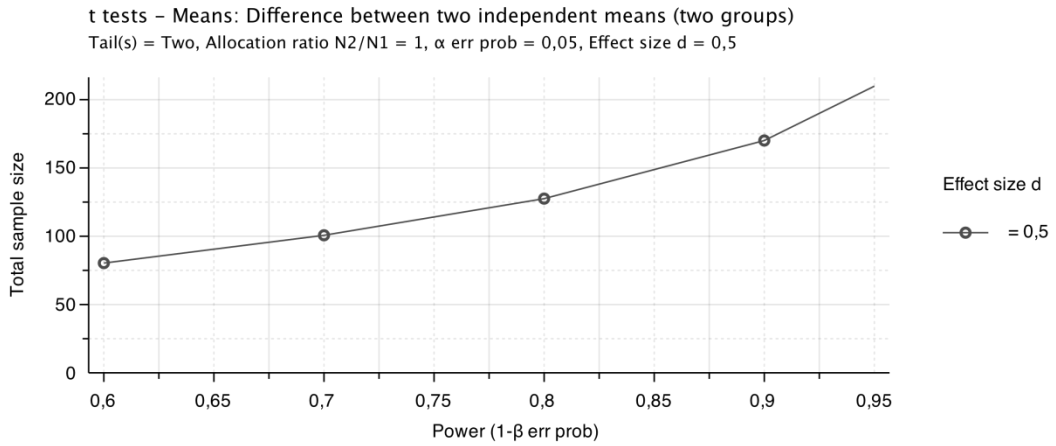


*Figure 3*. Sample size calculation

## *3.14. Statistical Analysis*

Primary analysis will be an intention to treat analysis. For patients with missing values for T6 (see Table 12), the last valid measurement will be carried forward (last observation carried forward). If the drop out rate exceeds 10% in the intervention group, a per protocol analysis will be carried out as well.

To check if randomization was successful, baseline variables between groups will be compared using $Chi^2$ tests for binary variables, independent t-tests for comparing means of continuous variables, and the Mann-Whitney U test for comparing distributions of ordinal variables. In the confirmatory analysis, changes relating to different aspects of the primary outcome measure neck related disability (quantified on the NDI) in the course of the treatment (e.g. between baseline and follow-up values), will be compared between groups by t-tests (unpaired, 2-sided). For all comparisons, $p < .05$ will be considered statistically significant (two-tailed); and 95% confidence intervals (CI) will be calculated for all point estimates.

Because the treatments in the waiting list group after 8weeks cannot be compared directly with the intervention group, all subsequent data from this group will only be analyzed descriptively. Moreover, an analysis of covariance with additional covariates will be performed to account for potential baseline differences.

## *3.15. Ethical Aspects*

The study protocol will be approved by the Institutional Review Board (IRB) according to the rules and regulations of the country in which the study will be conducted. Any adverse effect occurring during the course of treatment, regardless of the direct association of the treatment, will have to be reported to the project coordinator.

The study will be registered as a Phase III trial at www.ClinicalTrials.gov.

## *3.16. Quality Assurance/Patient Safety*

For reasons of quality assurance, the feasibility of the clinical trial protocol as well as the documentation forms will be tested prior to the begin of the study by two practitioners on 10 pilot cases.

For patients' safety, a study insurance will be taken out. At the start the patients will receive information about the course of study and about osteopathy from their local practitioner. The initial clinical screening makes certain that all exclusion criteria have been considered. The informed consent governs the right of the patient to exit the study at anytime (see Appendix B). Participants will also be asked at the end of treatment period about any side effects of treatment. Potentially serious events will be immediately referred to the patient's medical practitioner or the closest hospital emergency department.

## *3.17. Patients' Pathway through the Study, Time Table*

With flyers displayed in surgeries, clinics and pharmacies, subjects with constant or intermittent neck pain for at least 3 months are invited to take part in the study (see Appendix B). In this leaflet, a telephone number for further information will be given.

A questionnaire including the main inclusion and exclusion criteria will be used during telephone screening to exclude non-potential subjects (see Appendix B). Additional important basic conditions will be clarified (e.g. the acceptance for X-ray, no time of absence during the osteopathic treatments, and that the neck pain is the patient's main problem). This structured telephone interview serves to confirm independently trial eligibility, and provides an opportunity to clarify or update medical history information if needed, or to perform any other necessary clinical examinations or tests to confirm trial eligibility. Written information about the study, about osteopathy, and informed consent

will be sent to those participants who pass the telephone and clinical screening.

Following this, subjects are to visit their osteopathic practitioner for a (approximately) 2-hour session to: (1) confirm of all the inclusion/exclusion criteria, and (2) sign the informed consent. If eligible, (3) randomization allocates the subjects to one of the two groups. (4) All subjects have to fill out the questionnaires, the VAS, medication diary, and the work disability survey. For the subjects of the osteopathic group, (5) history will be taken, and (6) osteopathic diagnoses, and (7) the first treatment will be performed.

Additional treatments and data collection will occur during 1-hour sessions, 2, 4, 6, and 8 weeks after randomization. At each consultation, the patients will be required to fill out the NDI questionnaire and the VAS. Medication diary, work disability survey, and perceived stress scale have to been filled out during the whole course of the study. The questionnaire SF-36 and DAPOS will only be collected at the beginning and end of the study, and at the follow-ups. A follow-up will be carried out 3 and 6 months after the end of treatment.

Information about adverse events and side effects will be collected by the treating practitioner after each treatment session.

The flow of subjects from recruitment through randomization is presented in Figure 4. An overview of the clinical trial protocol and timetable is presented in Table 12.

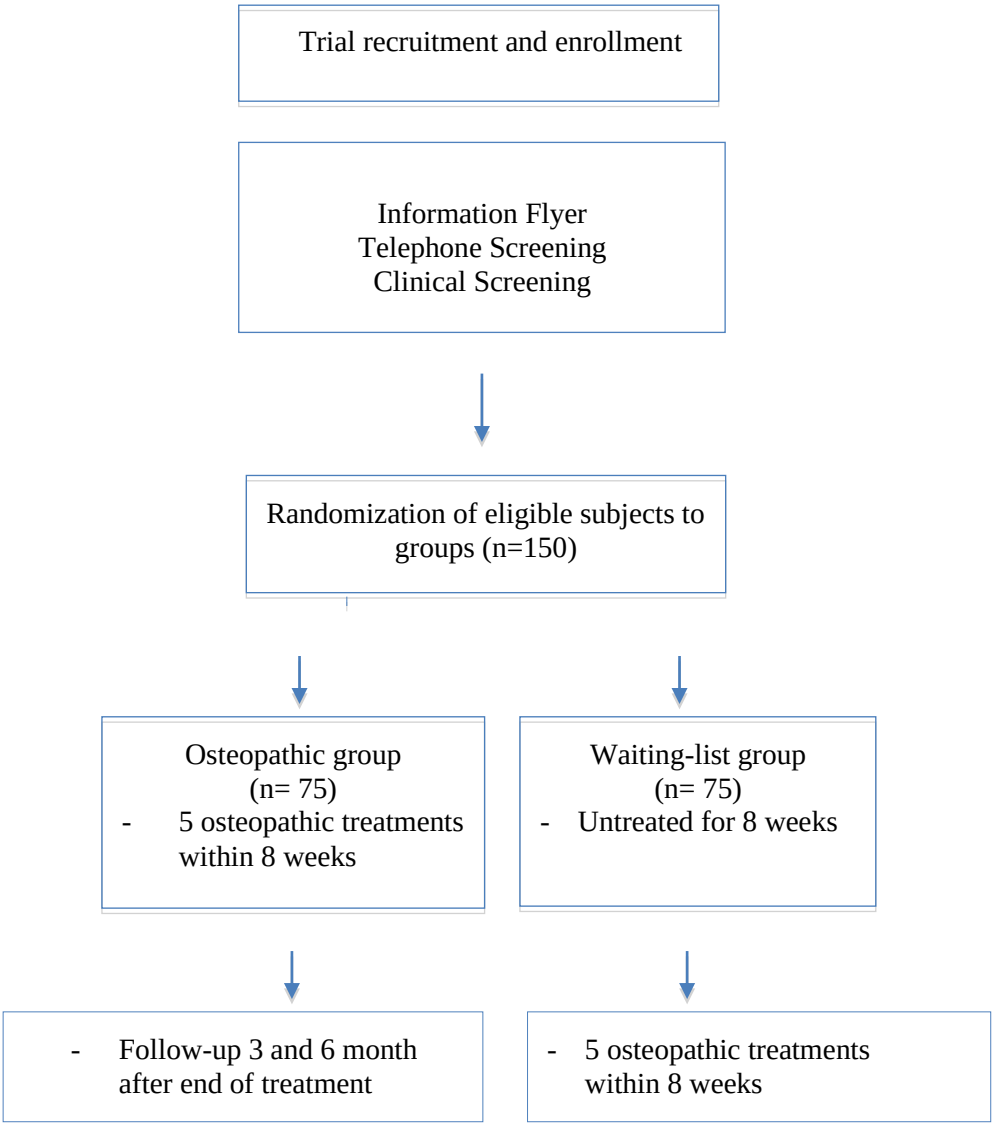


*Figure 4.* Flow of subjects from recruiting through randomization and treatment

Table 12: *Timetable*

| Task | Pre-Randomization | Post-Randomization | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Weeks | | 0 | 2 | 4 | 6 | 8 | 10 | Month after T6 | 3 | 6 |
| Time points | T0 | T1 | T2 | T3 | T4 | T5 | T6 | | T11 | T12 |
| Recruitment | x | | | | | | | | | |
| Telephone screening | x | | | | | | | | | |
| Clinical screening | ♦ | | | | | | | | | |
| Information about study | x | | | | | | | | | |
| Information osteopathy | x | | | | | | | | | |
| Inclusion criteria | | x | | | | | | | | |
| Informed consent | | ♣ | | | | | | | | |
| Randomization | | x | | | | | | | | |
| **Intervention group** | | | | | | | | | | |
| Data collection | | | | | | | | | | |
| Sociodemographic data | | ♣ | | | | | | | | |
| Neck disability index | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ | | ♣ | ♣ |
| Visual analogue scale | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ | | ♣ | ♣ |
| SF-36 | | ♣ | | | | | ♣ | | ♣ | ♣ |
| Work disability measure | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ | | | |
| Perceived stress scale | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ | | | |
| Medication diary | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ | | | |
| DAPOS | | ♣ | | | | | ♣ | | ♣ | ♣ |
| OOSNF-History | | x | | | | | | | | |
| OOSNF-Examination | | x | x | x | x | x | | | | |
| Allocated treatment | | x | x | x | x | x | | | | |

| Weeks | | waiting | | | | 0 | 2 | 4 | 6 | 8 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Time points | T0 | T1 | | | | T5 | T6 | T7 | T8 | T9 | T10 |
| **Control group** | | | | | | | | | | | |
| Data collection | | | | | | | | | | | |
| Sociodemographic data | | ♣ | | | | | | | | | |
| Neck disability index | | ♣ | | | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ |
| Visual analogue scale | | ♣ | | | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ |
| SF-36 | | ♣ | | | | ♣ | | | | | ♣ |
| Work disability measure | | ♣ | | | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ |
| Perceived stress scale | | ♣ | | | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ |
| Medication diary | | ♣ | | | | ♣ | ♣ | ♣ | ♣ | ♣ | ♣ |
| DAPOS | | ♣ | | | | ♣ | | | | | ♣ |
| OOSNF-History | | | | | | x | | | | | |
| OOSNF-Examination | | | | | | x | x | x | x | x | |
| Allocated treatment | | | | | | x | x | x | x | x | |

Explanations: **x** = therapist, ♣ = subject, ♦ = physician, OOSNF = Outpatient Osteopathic SOAP Note Form, SF-36 = Medical Outcomes Study Short Form – 36 Health Survey, DAPOS = Depression, anxiety, and positive outlook scale, T10 = first follow-up, 3 months after end of treatment, T11 = second follow-up, 6 months after end of treatment.

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# Chapter 4: Discussion

## *4.1 General Considerations*

As osteopathic clinicians, we work on the level of primary care. This means that the outcome is most important and all disruptive factors are allowed. From the patients view, the most important goals are satisfaction and success (Clancy & Eisenberg, 1998).

Today, more and more patients visit osteopaths, so it is important that evidence has a solid basis. For osteopaths, it is primarily the question of the effect which is of clinical importance. However, the osteopathic literature only has a few trials on the effectiveness of osteopathic treatment. To prove an effect of an intervention today the randomized controlled trial (RCT) is the gold standard. There will be very different questions which have to be answered. The appropriate choice of the study design always depends on the objective being investigated. In the following, the different aspects will be discussed, and the reasons will be given for the design of the present study protocol.

### *4.1.1. Randomized Controlled Trial*

In clinical research randomized, placebo controlled studies are nowadays seen as the gold standard. This is certainly correct for pharmaceutical research; however in complementary and alternative medicine, this kind of study design is hard to arrange and has become increasingly controversial in recent years (Kaptchuk, 2001; Resch, 1998). Koshi and Short (2007) describe it as well in their review *Placebo theory and its implication for research and clinical practice*:

> "The gold standard in clinical trial design is the double-blind placebo-controlled trial with two arms: an active group and a placebo group. In order to conclude that a treatment is effective, the outcome must be better than placebo."

They then continue and ask the question: "Is this design appropriate to enable us to conclude that a therapy is effective?"

The randomized controlled trial is not identical with the double-blind or placebo controlled trial, as is often wrongly assumed, since these are merely specific variations of the randomized trial with limited applicability. On the EbM hierarchy pyramid, RCT is at

the top position, but it is not defined that this kind of a study needs to be double-blinded or placebo controlled. Whether a double-blinding or a placebo (or sham) group is necessary, depends on the kind of question. By strict definition, RCT is only the randomized assignment to different treatment groups.

Fletcher and Fletcher (2005) describe in their book *Clinical Epidemiology*:

> "The terms single-blind (patients) and double-blind are sometimes used, but their meanings are ambiguous. It is better simplify to describe what was done. Blinding is often made possible for studies of drug effects by using a placebo. However, for many important clinical questions, such as the effects of surgery, radiotherapy, diet or the organization of medical care, blinding of patients and their physicians is difficult if not impossible."

The problems of blinding which they described can be transferred very well to complementary medicine and osteopathy.

With the deployment of assessments like the NDI, VAS, or SF-36 the internal validity of a study equals an evaluator-blind study because the evaluator cannot influence the main outcome parameter. In the broadest sense, we could call it a simple blinded study.

### *4.1.2. Efficacy/Effectiveness*

As Resch (2008) describes in a discussion paper about clinical trials, there are different layers of problems:

> "Potential *point of views* may be those of the basic researcher (scientific knowledge: can it work), the clinician (usefulness: does it work), the purchaser (cost-effectiveness: outcome for money), the patient (function, wellbeing: value for money). If, for instance, patients have to pay out of their own pocket, what they pay for is what they get, and the most important issue for them (as well as for the responsible provider) is value."

In this context, it is important in the study design to deal with two concepts that play an important role here: *efficacy* and *effectiveness*. Both are terms that are often incorrectly used interchangeably in the literature. *Explanatory trials* generally measure efficacy - the benefit a treatment produces under ideal conditions (Roland & Torgerson,

1998). Point of view is focused here on the specific effect − can it work? − under experimental (ideal) circumstances ("taking the pill"). This is called efficacy (Fletcher & Fletcher, 2005; Haynes, 1999). *Pragmatic trials* measure effectiveness − the benefit the treatment produces in routine clinical practice (Roland & Torgerson, 1998). The focus here is on the overall effect − does it work? − under ordinary circumstances ("offering the pill"). This is called effectiveness (Fletcher & Fletcher, 2005; Haynes, 1999).

The emphasis in an efficacy trial is on internal validity, which allows for a causal link to be established between the intervention and the primary outcome. It is therefore typically conducted under ideal, highly controlled circumstances in clinical research settings (Nash, McCrory, Nicholson & Andrasik, 2005). An efficacy trial tends to focus on a narrow population, using very stringent inclusion and exclusion criteria to define a quite homogeneous population (Kraemer, 2003). With an efficacy approach, an experimental study is conducted to estimate the maximum treatment benefit possible on a primary outcome measure. Efficacy trials require homogeneous samples, optimal equipment and maximum skills, in other words an academic environment. Efficacy studies follow the classic rules of RCTs (Nash et al., 2005). The results of these studies cannot be assumed to automatically translate into clinical practice effectiveness (Streiner, 2002).

However, an "every day life" environment requires an effectiveness trial, to access real world variation in the condition and some realistic heterogeneity in therapeutic skills. The central question in an effectiveness study is treatment response and feasibility in a population that is representative of the intended target audience. While maintaining internal validity, effectiveness studies are designed to maximize external validity (Nash et al., 2005). These types of studies provide a realistic view of the treatment response on variables other than the primary outcome measure in settings where interventions occur more naturally (Kraemer, 2003). In creating a heterogeneous, representative sample of the targeted population, eligibility criteria are broadly set (Glasgow, Lichtenstein & Marcus, 2003; Kraemer, 2003). Interventions in effectiveness studies may not be as precisely specified as those in efficacy studies. Effectiveness studies may compare different management strategies or complex interventions which comprise several different treatments.

The decision where to "pitch" a RCT between the extreme poles of efficacy and effectiveness trial depends on the state of knowledge about that treatment. Kraemer (2003) state in his article *Rules of evidence in assessing the efficacy and effectiveness of treatments*:

> "At one time, it was argued that an efficacy trial is a scientifically clear and rigorous study, whereas an effectiveness trial is scientifically "dirty." This has led to the peculiar situation that efficacy trials yielded valid but limited results that did not generalize well, whereas effectiveness trials yielded results likely to not be valid."

Both problems − effectiveness or efficacy − can be responded to with a randomized controlled study design. The question "can it work" will need a randomized, placebo controlled, double-blind study design.

When the definition of NIH about "research" and "clinical research" is examined, there is no differentiation between efficacy and effectiveness trials: NIH defined research as: "Research means a systematic investigation to develop or contribute to generalizable knowledge", and defines human clinical research as:

> "(1) Patient-oriented research. Research conducted with human subjects for which an investigator directly interacts with human subjects. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research" (Hirschfeld, 2008).

If we consider the definition of "Evidence based Medicine" as well, the question of what is right − an efficacy or effectiveness trial − does not arise. David Sackett defines EbM as follows:

> "The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Sackett, Rosenberg, Gray, Haynes & Richardson, 1996).

There are clear signs that research nowadays considers perspectives of effectiveness studies as well, for example the Health Technology Assessment (HTA) Programme, which is part of the National Institute for Health Research (NIHR) in the UK. The HTA program produces independent research information about the effectiveness, costs, and broader impact of healthcare treatments. They play an important role through a new joint health research strategy. It is planned to speed up the translation of advances in basic science into applied research, converting excellent basic discoveries into innovations that directly benefit patients and help prevention. It answers the questions by investigating four main factors: whether the technology works, for whom, at what cost, and how it compares with the alternatives (National Institute for Health Research, 2009).

### *4.1.3. Clinical-Ethical Aspects for the Development of a Study Design*

The Declaration of Helsinki (revised Oct 2000) states:

> "The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists."

To define the kind of control group, the main question of whether there is a evidence-based standard therapy available needs to be addressed. It is, in principle, only ethically acceptable to introduce a placebo arm into a clinical trial if there is no (or weak) evidence that the current "standard intervention" is efficacious. The control treatment must be the best standard therapy currently available for the condition being treated. Since a standard therapy is not available in CNP (see Chapter 2.1.3, therapy), the only options for the control group's treatment are "untreated" or "placebo" (sham) (see Figure 5).

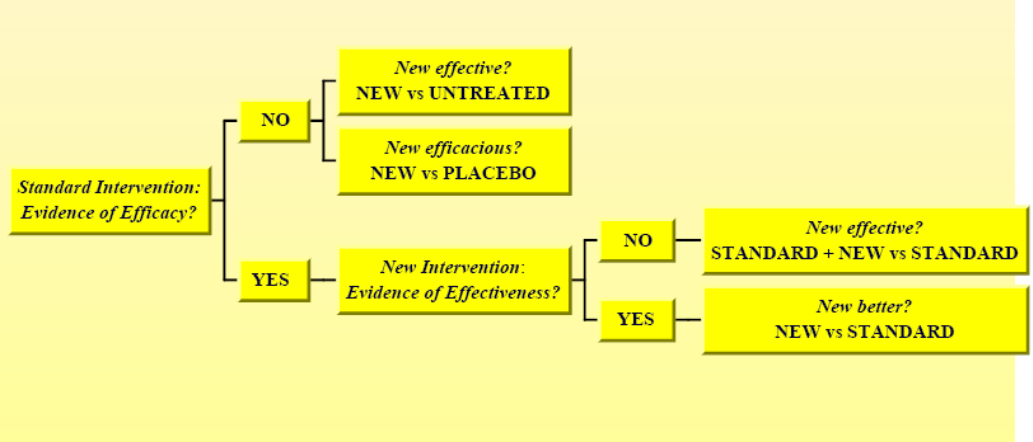


*Figure 5.* Choice of control group in randomized controlled trials (K.L. Resch, personal communication, Oct. 2007)

The thinking, as often described in studies of manual therapy as: "an appropriate sham intervention would have been an unspecific touching of a non-professional person for the same time as the verum treatment" cannot be agreed with. It cannot be expected that a patient does not identify 45 to 60 minutes of unspecific touch of a layman as sham treatment. If this unspecific touch is conducted by an osteopath, the following sentence applies: "Touch" in any form cannot be assumed to be an "inert" form of intervention.

It is often argued that this study design is unethical with the non-treated control group (waiting list). However, the ethical problem only occurs if patients are withheld something. They receive therapy in this case albeit two months later. There is no withholding of therapy from the patient. Patient agreement is through informed consent. The precondition for practicing this waiting list design is that the patient shows a constant course of disease − the symptoms should not change significantly during the waiting time. Another precondition is that the patient does not start another therapy during this period.

### *4.1.4. Methodic Aspects for the Development of a Study Protocol*

Another question needs to be addressed for the choice of the control group: "Is there reliable evidence on the underlying mechanism ("mode of action") of the index treatment to allow for reliable exclusion of specific components of the placebo/sham intervention?" Many placebo controlled and 3-armed trials have produced results that suggest that what was meant to be a placebo (here an "inert" intervention) might have had some specific effect as well. In general, if the mode of action of the index treatment is not

known, it may be hard or even impossible to exclude reliably that the placebo/sham intervention has to some extent the same mode of action.

One example of such a constellation is acupuncture versus particular forms of sham acupuncture. In a trial, Cherkin et al. (2009) randomized a total of 638 adults with chronic mechanical low back pain to individualized acupuncture, standardized acupuncture, simulated acupuncture, or usual care. At 8 weeks, mean dysfunction scores for the individualized, standardized, and simulated acupuncture groups improved by 4.4, 4.5, and 4.4 points, respectively, compared with 2.1 points for those receiving usual care. Although acupuncture was found to be effective for chronic low back pain, tailoring needle sites to each patient and penetration of the skin appear to be unimportant in eliciting therapeutic benefits. These findings raise questions about acupuncture's purported mechanisms of action. It remains unclear whether acupuncture or our simulated method of acupuncture provide physiologically important stimulation or represent placebo or non-specific effects.

Other studies showed similar effects when employing sham acupuncture (Linde et al., 2006) or sham osteopathy (Licciardone et al., 2003). The study of Licciardone show this fact very clearly that the treatment effects do not differ significantly between sham and real osteopathic intervention. The use of placebo or sham controlled trial designs will not therefore detect the whole characteristic effect and may generate false negative results. Consequently, other approaches, such as randomized pragmatic designs (effectiveness trials) and randomized cluster designs, are more appropriate and rigorous (Paterson & Dieppe, 2005).

A common feature for all personally delivered therapies, such as any kind of manual therapy, psychology or occupational therapy is the interaction between patient and therapist. Osteopathic manipulative treatment is an ongoing interaction between the unique structure and function of the patient and the skills of the physician, including the belief systems of both individuals (Patterson, 2007). It is virtually impossible for an experienced osteopath to carry out an intervention without knowing whether the intervention is intended as an active or placebo treatment. In carrying out an osteopathic clinical study design, it is not feasible to blind the osteopath while the treatment is being given.

### *4.1.5. Osteopathic Perspective*

One question we must ask ourselves is how we understand osteopathic clinical research − considering osteopathic principles and philosophy or considering osteopathic features in an allopathic context?

In Europe, osteopathy is an independent discipline within complementary medicine. In the US, Osteopathic Manual Medicine (OMM) is recognized by the National Institutes of Health (NIH) as a mainstream medical discipline, Osteopathic Manual Treatment (OMT) in isolation is classified by the NIH's National Center of Complementary and Alternative Medicine (NCCAM) as one of several promising "complementary" procedures among a variety of other heterogeneous manipulative and body-based practices (Kuchera, 2007).

There are two principal models of osteopathic practice in the world today, described by the international osteopathic profession as *osteopathic physicians* whose scope of practice includes pharmaceutical medicine and surgery; and *osteopaths* whose scope of practice typically does not include pharmaceutical medicine and surgery. The *Glossary of Osteopathic Terminology* (Ward, 2003) define *Osteopathic Manipulative Treatment (OMT)* as: "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 includes all manual therapeutic techniques utilized by osteopathic practitioners." The term OMT is mainly used in the US; in European countries, the terms osteopathy or osteopathic treatment are more common.

What is the situation of osteopathy like, and what does osteopathic clinical research mean? Osteopathic research means to quest holistically and show the holistic effect, following osteopathic principles and philosophy. On the one hand the *National OMM Research Synergy White Paper* (2003) describes in its conclusion about osteopathic research:

> "Given today's emphasis on evidence-based medicine, it is critical that the osteopathic profession study and evaluate the efficacy of the osteopathic approach to patient care in a timely and scientifically rigorous manner, and that it investigate mechanisms of action where possible."

Furthermore, it emphasizes studies about efficacy, without considering its feasibility.

On the other hand, Irvin Korr (one of the most important osteopathic researchers) emphasized in 1991 the importance of the question "does it work?" and thus the effectiveness of osteopathic research in his article *Osteopathic research: The needed paradigm shift* in the Journal of the *American Osteopathic Association*:

> "It is essential, therefore, that assessments of effectiveness of OMT be of OMT *as it is practiced,* as an integral part of the total interaction between physician and patient, and not as an isolated, contrived, and standardized procedure which, though nicely amenable to statistical analysis, is totally unrelated to clinical reality. "As it is practiced" means that experimental designs must be such as to accept as given (1) that OMT, unlike medications, and their dosages, cannot be made standard and uniform; (2) that the placebo response is an integral, inseparable part of the patient's total response to Osteopathic medical care."

Patterson (2007) fully differentiates between "explanatory" and "pragmatic" trials in his article *Research in OMT: What is the question and do we understand it*? He focuses on the philosophy of osteopathic medicine (according to the article of Korr, 1991) and the patient as "the heart of the healing process". He emphasizes that "additional variables can have a dramatic effect on health outcomes". He pointes out that a randomized placebo controlled trial in osteopathy can only investigate specific techniques:

> "Although the RCT certainly can be useful in situations where a specific osteopathic technique is under investigation, it does not help researchers analyze all the questions the osteopathic medical profession wants to ask ….In other words, a system cannot be analyzed by breaking it into its individual components and a priori assuming that some of those components are of no value or akin to epiphenomena."

Furthermore, Patterson comments that the right choice of the study design is dependent on "the kind of research question," that "the process of asking the right questions of OMT will lead to better-understood comparison groups," and that "if the

research question involves the effect of OMT itself, it is simply not possible to factor out placebos…"

In a recent journal editorial, Lucas and Moran (2006) raise critical questions regarding the relevancy of contemporary osteopathy research in the evolving healthcare environment. Their ultimate challenge to the osteopathic profession is to provide support to the clinical effectiveness of osteopathy. Licciardone (2007) states in the *International Journal of Osteopathic Medicine* that the osteopathic profession has been challenged over the past decade to provide clinically relevant research.

**Summary:**

- It is intended to conduct a randomized controlled trial, the commonly accepted golden standard for studies into causation of intervention and effect.
- For the chosen objective of the trial, the effectiveness of the osteopathic treatment should be assessed. This question can only be answered with a pragmatic trial.
- Blinding of patients and practitioners is very difficult and almost impossible; however it is unnecessary for the present study question. We can talk here of an evaluator-blind trial because of the chosen assessment instruments.
- The choice of an untreated control group seems appropriate and ethical.
- The chosen design of the control group (no sham group), as well as diagnosis and treatment are conform to the principles of osteopathy.

## *4.2. Eligible Criteria*

The inclusion criteria should guarantee an authentic case of CNP. The pain must be of sufficient intensity to permit a clinically worthwhile effect to be demonstrated. In this study, the neck pain should have an intensity greater than or equal to 4 out of 10 on the VAS. The age of the patient was restricted to 20-65 years because at a younger or older age the body's response to a treatment is different. Moreover, there is greater risk of complications in elderly people.

Many trials for CNP include WAD. But in this protocol a differentiation is made: Patients with Late Whiplash Syndrome and WAD during the last 6 months are excluded.

LWS has been described as a disorder that is characterized by a constellation of clinical profiles including neck pain and stiffness, persistent headache, dizziness, upper limb paresthesia, and psychological emotional sequelae which persist more than 6 months after a whiplash injury (Poorbaugh et al., 2008). The patient can participate in the study if the WAD occurred more than 6 months ago and the complaints are not the consequence of this accident. Most patients can not remember accidents in the past.

Differential diagnosis results from anamnesis and clinical screening. In Europe, most osteopaths are not physicians, so here it is necessary that a physician performs the clinical screenings. If patients suffer from psychiatric illness they are excluded because in this case neck pain can be an associated symptom without medical cause. Following a physical therapy or high-velocity thrust, there is normally an adaptation process because the patient is in a modified reaction situation. This process should be finished fist. Also, medication can cause changes in the patient. For example, corticosteroids regularly taken lead to osteoporosis. Anticoagulants alter the viscosity of the blood and can cause circulatory problems. Even patients with diabetes mellitus are excluded due to the changed metabolic situation of the organism.

The motivation for improvement of neck pain could be diminished through a pending insurance claim, a pending pension application, or a current sick certificate. Osteoarthritis (Definition in MEDLINE: “A degenerative joint disease involving the spine. It is characterized by progressive deterioration of the spinal articular cartilage, usually with hardening of the subchondral bone and outgrowth of bone spurs (osteophyte)”) is a contraindication for structural manipulation (high-velocity thrusts) and therefore is excluded.

If the patient has taken medication for muscle relaxation the strain of muscles will be lowered and structural manipulation is contraindicated. Therefore, for their own safety patients are required to fill out the questionnaire for medication before every treatment.

### *4.3. Assessments*

In Chapter 2.2.3., the different outcome parameters and assessment instruments for studies on CNP were described and discussed in detail in Chapter 2.2.4. Based on the recommendations of the pilot studies, a scale for perceived stress measures was added.

The instrument used most often is the Perceived Stress Scale (PSS) (Cohen, Kamarck & Mermelstein, 1983). The PSS is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to reveal how unpredictable, uncontrollable, and overloaded respondents find their lives. There are three versions of the scale: the 4-item, 10-item, and the 14-item version. The 10-item version is recommended since it has maximum reliability, although the 4-item version can be used for telephone interviews and situations where the number of items is critical. This scale assessed the amount of stress in one's life rather than in response to a specific stressor and has been used widely in studies of both mental and physical health.

## *4.4. Intervention*

### *4.4.1. Osteopathic Diagnosis and Treatment*

In two German trials (Schwerla et al., 2008; Tempel et al., 2008), the most pronounced and common dysfunctions were not only in the cervical spine but also in the visceral system as well as in the ventral thoracic fascia and the abdomen. As a consequence, this leads to the necessity of individual diagnosis of the whole person, because the studies mentioned clearly indicate that CNP is related with visceral problems (problems in the visceral structure). There are osteopathic diagnostic findings that indicate that a dysfunction in the cervical spine is associated with a structure problem in visceral areas. Interestingly, constraint of motion and symptoms of the cervical spine are often not caused by blocked cervical vertebras but through musculoskeletal or visceral structures. This means we cannot tell from the beginning which structure has a dysfunction – we have to guide ourselves within the osteopathic diagnosis.

Osteopathy or osteopathic treatment (as it is called in Europe) tries to follow the osteopathic principles as given from A.T. Still. In *The Foundations for Osteopathic Medicine* (Ward, 2003), these principles are modified 1997 from the editors as follows:

1) The body is a unit; the person is a unit of body, mind, and spirit.
2) The body is capable of self-regulation, self-healing, and health maintenance.
3) Structure and Function are reciprocally interrelated.
4) Rational therapy is based upon an understanding of the basic principles of body unity, self-regulation, and inter-relationship of structure and function.

Because osteopathy recognizes that all parts of the body work together to create healing, the mind and spirit is considered part of this holistic system. Therefore, osteopathy considers that disorder in body structure can cause or exacerbate mental problems like depression. In turn, it is thought that mental disorder can cause or exacerbate physical disease. It means that each part affects each other part and that the "whole" is greater than merely the sum of these parts (Korr, 1991).

Osteopathic thought and practice seek to integrate the musculoskeletal system into the total community of organs and systems and to give it its rightful place in the total organismic scheme (Korr, 1991). In the case of a dysfunction, the deranged structure affects the body's self-healing mechanisms. An osteopath believes in the natural power of our body to overcome disease. And if the organism can not find its balance again, the osteopath can help to bring the healing process forward. An osteopath increases the body's ability of adaptation or compensation. A.T. Still's famous axiom "Find it, fix it and leave it alone" is of high significance in osteopathy. At first, you need the ability of palpation to "find it" – which is equivalent to clinical diagnosis. Next, you need a concept to treat what you found ("how to fix it"). And at last the principle of minimal intervention ("leave it alone") – confidence in the body's self healing mechanisms.

In this context osteopathic treatment can be defined as "custom-tailored" or "individualized". If we look at the research question *("To evaluate whether a series of osteopathic treatments might be effective in alleviating CNP symptoms")* from a point of view of the different osteopathic principles, we can analyze:

- Custom-tailored (osteopathic treatment) means tailoring a therapy to each individual patient. Each person has to be treated as a unique individual not as a disease entity. The treatment has to be tailored specifically for each patient's particular needs. The patient has to be seen in his wholeness, including body, mind, and spirit.
- Non-specific means that the patient does not have a specifically defined disease (e.g. heart attack) and its etiology can not be exactly defined. The reason of the disease can be various and may be based on body, mind or spirit.

- Clinically effective means that the effectiveness of the osteopathic treatment is analyzed. All aspects that occur when a patient visits an osteopath will be considered (e.g. positive placebo effects).

Previous pilot studies recommend a longer interval time between the osteopathic treatments. Nevertheless, the interval of 2 weeks was maintained. Longer intervals would destroy the relation between treatment time (now 8 weeks) and waiting time (now 8 weeks). The length of the study corresponds to the usual length of treatment in an osteopathic surgery.

In this protocol special emphasis was taken in controlling treatment sustainability. Studies are frequently criticized that no follow-ups were carried out. Therefore, in this protocol 2 follow-ups are planned after the treatments end. To make it easier for the patients, only the NDI and the VAS will be retrieved. Other trials showed that it is difficult to receive feedback if the questionnaires are sent by post; however, asking patients by phone is not possible for this assessment .

### *4.4.2. Outpatient Osteopathic SOAP Note Form*

One of the persistent challenges facing the osteopathic medical profession has been the lack of a reliable, easy-to-use, validated system for recording, collecting, and evaluating clinical findings in a format that is suitable for long-term data collection. As a result of the recent emphasis on outcomes-based research in the field of medicine, the creation and use of a standardized tool for the osteopathic profession has been pursued with increasing urgency.

In 1989, the Louisa Burns Osteopathic Research Committee (LBORC), the research branch of the American Academy of Osteopathy (AAO), began looking into a solution to these and other problems - as well as looking forward to larger possibilities for osteopathic medical research once these initial challenges were addressed. The original SOAP (Subjective, Objective, Assessment, Plan) Notes Form (SNF), which was designed, published, and distributed in 1998, covers the range of examination and treatment activities performed by osteopathic physicians during a patient encounter, enabling physicians to record data on a standard osteopathic musculoskeletal examination, enumerate any musculoskeletal dysfunctions found, document any OM

techniques used, and report patient response to treatment. The 1998 SNF was a first step in providing standardized documentation for osteopathic outpatient practice in the US. A more recent 4-page form is known as the Outpatient Osteopathic Single Organ System Musculoskeletal Exam Form Series (SOS-FS).

The SNF and the SOS-FS are valid and reliable tools that could readily fill this gap with widespread adoption within the osteopathic medical profession. In fact, preliminary studies have successfully used the 1998 SNF to collect and report the incidence of disease entities within a family practice setting. Retrospective analysis indicated that the use of the SNF could be extended to outcomes research into the efficacy of osteopathic intervention and medical science research.

In a survey *Outpatient Osteopathic SOAP Note Form: Preliminary Results in Osteopathic Outcomes-Based Research* (Sleszynski & Glonek, 2005), the authors used participant-completed and previously validated Outpatient Osteopathic SOAP Note Forms (SNFs) to obtain answers to 17 outcome-based questions that the profession must address to meet the new challenges and demands of outcomes-based research. They concluded that many questions specific to a selected physician's practice could be examined, for example:

- Which OM techniques does a particular osteopathic physician use most frequently?
- What is the average number of body regions per patient visit that a particular osteopathic physician treats with OMT?
- What is the patient response rate to OMT that a particular osteopathic physician has by body region?
- What is the particular osteopathic physician's patient-improvement rate after he or she provides OMT?

Advantages:

- Standardized program and procedure
- International classification (ICD)
- Evaluated data can be used as basis for an osteopathic database
- International comparison of osteopathic trials is possible

Disadvantages for European osteopaths:

- Osteopaths are not aware of this system
- An adaptation to the European situation may be necessary
- Not all of osteopathic dysfunction and treatment modalities are represented
- Before this form can be used, a feasibility trial may be necessary

In this study protocol the intention is to gather first experiences in Europe with this SOAP Note Form. However, to describe all osteopathic dysfunctions in the cervical spine an additional specific examination form was developed. Further dysfunctions in other parts of the body will be gathered in a black box manner. Every region in the body will be investigated with global tests and then, if necessary, special structures will be tested. So it is warranted that the patient will be seen as a whole according to the principles of osteopathy.

### *4.4.3. Adverse Events*

Rubinstein et al. (2007) conducted a prospective, multi-center, observational cohort study, in which 79 chiropractors participated and 529 subjects were recruited. Most patients had chronic, recurrent complaints of neck pain and disability. Adverse events following any of the first three treatments were reported as 56%; and 13% of the study population reported these events to be severe in intensity. Adverse events may be common but are rarely severe in intensity.

In a recent review Gouveia, Castanho and Ferreira (2009) evaluate the tolerability and safety of chiropractic procedures. The literature reports multiple neurological complications of spinal manipulation, some of which are clinically relevant and even life threatening. They performed an electronic search in PubMed and the Cochrane Library for the years 1966 to 2007. All articles that reported adverse reactions associated with chiropractic were included irrespective of type of design. The search identified 46 articles which included data concerning adverse events. Most of the adverse events reported were benign and transitory; however, there are reports of complications that were life threatening, such as arterial dissection, myelopathy, vertebral disc extrusion, and epidural hematoma. The frequency of adverse events varied between 33% and 60.9%, and the frequency of serious adverse events varied between 5 strokes/100,000 manipulations to

1.46 serious adverse events/10,000,000 manipulations and 2.68 deaths/10,000,000 manipulations.

Studies on adverse effects of osteopathic structural manipulations do not exist. Manipulations (e.g. high-velocity thrusts) for the cervical spine are used in osteopathy much less than in chiropractic. Because respecting the physiological barrier, the rate of complications in osteopathy is much lower than mentioned above. As the joint has to be blocked with different parameters, less power is necessary for manipulation.

## *4.5 Statistics*

### *4.5.1. Sample Size Calculation*

In a recent review in the BMJ, *Reporting of sample size calculation in randomized controlled trials*, Charles, Giraudeau, Dechartres, Baron and Ravaud (2009) assess the quality of reporting of sample size calculation, ascertain accuracy of calculations, and determine the relevance of assumptions made when calculating sample size in randomized controlled trials. They write:

> „The importance of sample size determination in randomized controlled trials has been widely asserted, and according to the CONSORT statement these calculations must be reported and justified in published articles. The aim of an a priori sample size calculation is mainly to determinate the number of participants needed to detect a clinically relevant treatment effect. Some have asserted that oversized trials, which expose too many people to the new therapy, or underpowered trials, which may fail to achieve significant results, should be avoided“.

The usual conventional approach is to calculate sample size with four parameters: Type I error, power, assumptions in the control group (response rate and standard deviation), and expected treatment effect. Type I error and power are usually fixed at conventional levels (5% for type I error, 80% or 90% for power). Assumptions related to the control group are often pre-specified on the basis of previously observed data or published results, and the expected treatment effect is expected to be hypothesized as a clinically meaningful effect. The uncertainty related to the rate of events or the standard

deviation in the control group and to treatment effect could lead to lower than intended power (Charles et al., 2009).

### *4.5.2. Clinical Relevance*

In some publications, characteristics are given for a clinical relevant improvement of an outcome parameter (Kerr & White, 2007):

- The Cochrane Review on neck pain and exercise defined a minimal clinically important difference between treatments for the purpose of that review as 10 points on a 100-point pain intensity scale.
- A minimal clinically important difference of 5 neck disability index units or 10% was considered relevant for the neck disability index (NDI scale 0-30).
- The Philadelphia Panel decided that evidence of clinically important benefit is defined as 15% greater relative to a control based on panel expertise and empiric results.
- The Canadian *Chiropractic clinical practice guideline: evidence- based treatment of adult neck pain not due to whiplash* used the guide that a treatment effect size less than .5 was clinically unimportant; that an effect size from .5 to .79 was moderately important; and .8 or more, important.

## *4.6. Conclusion*

This master thesis sets out to analyze available information from previous trials, to further develop respective research and treatment strategies, and to strengthen the evidence on the subject by means of rigorous scientific research. It also attempts to meet the demand expressed in the *National OMM Research Synergy White Paper* prepared by the Osteopathic Research Task Force (*National OMM Research Synergy White Paper*, 2003):

> "… The results of evidence-based research on osteopathic manipulative medicine will be a key component of many areas of the profession including in education, clinical care, health policy and reimbursement. This issue must be of the highest priority for the osteopathic profession…"

Furthermore, the thesis carefully takes into consideration the plea of Joel D. Howell, as expressed in a letter to the *New England Journal of Medicine* titled *The Paradox of Osteopathy* (Howell, 1999):

> "The long-term survival of osteopathic medicine will depend on its ability to define itself as distinct from and yet still equivalent to allopathic medicine. That argument may best be articulated not in theoretical terms, but by demonstrating treatment outcomes."

The conceptual foundation of the study is to determine the impact of a holistic osteopathic approach embracing to the four osteopathic principles. Gevitz (2006) underlines the importance of osteopathic principles and states:

> "..They are those fundamental tenets of osteopathic medicine that guide how a physician approaches patients in health and disease. They offer a framework on how to evaluate the myriad intrinsic and extrinsic factors that bear upon wellness and sickness. They also provide meaning to what osteopathic physicians (DOs) do to keep patients healthy or restore them to health. For DOs, these principles are especially important with respect to the formation and maintenance of a professional identity that is distinct from that of allopathic physicians (MDs)."

There are different types of research designs, which contribute to our understanding about treatment efficacy and treatment effectiveness. As Kerr and White (2007) write in their review about neck pain:

> "The confidence the practitioner has in integrating the evidence will depend on a variety of factors and how they relate to the circumstances of the particular patient, their context, experiences and expectations as well as the strength and quality of the research."

The proposed multi-center clinical trial will utilize two groups: an osteopathic group, and an untreated group to measure the effectiveness of osteopathic treatments in the daily practice. Therapeutic touch and placebo effect can not been excluded, and they are not relevant for the present study design. The proposed multi-center trial will have a sufficient cohort size to minimize the risk of false negative results.

The clinical implications of this study will be the reflections on the potential consequences of the finding for the patient (e.g. individual benefit, value for money) and the daily practice of the osteopath (e.g. improvement of service or outcome, treatment strategies). Since neck pain is a common problem and available therapeutic options are of limited potential, the outcome of this research may have a substantial impact for patients and osteopaths alike.

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# Appendix A

Condensed Study Protocol

## *Condensed Study Protocol*

**Purpose**

To test the null hypothesis that a series of test dependent osteopathic treatments are not superior to watchful waiting in alleviating chronic non-specific neck pain symptoms.

| Condition | Intervention |
|---|---|
| Chronic non-specific neck pain | Procedure: Osteopathic treatment |

Official title: Osteopathic Treatment of Patients with Chronic Non-Specific Neck Pain. A Randomized Controlled Trial of Effectiveness
Study type: Interventional
Study design: Clinical, prospective, randomized, controlled (2-armed), open, multicenter, follow-up after 3 and 6 months

Secondary objectives:

- Reduction of medication
- Reduction of work disability days
- Areas of osteopathic dysfunctions
- Differences between the treating therapists
- Correlations between history and osteopathic findings
- Correlation of psychological factors with neck symptoms

**Further study details**

Estimated Enrollment: 150
Estimated centers: 10 Osteopathic Practices

| Arms | Assigned interventions |
|---|---|
| 1: No intervention | Procedure: Waiting list<br>- Untreated for 8 weeks<br>- Adjacent 5 osteopathic session |
| 2: Experimental Osteopathy | Procedure: Osteopathy<br>- 5 therapeutic sessions during the first 8 weeks (all 2 weeks)<br>- Follow-up 3 and 6 month after end of treatments |

Primary Outcome Measures:

- Neck related disability (measured by the Neck Disability Scale NDI) [Time frame: Baseline, 2, 4, 6, 8, 10, 22, and 34 weeks]

Secondary Outcome Measures:

- Pain intensity (Visual Analogue Scale VAS)
  [Time frame: Baseline, 2, 4, 6, 8, 10, 22, and 34 weeks]
- Quality of life (SF-36 Health Survey)
- Psychosocial factors (DAPOS)
  [Time frame: Baseline, 10, 22, 34 weeks]
- Medication (Medication diary)
- Work disability (Questionnaire)
  [Time frame: Baseline, 2, 4, 6, 8, 10 weeks]
- Osteopathic dysfunctions (Examination form)
  [Time frame: Baseline, 2, 4 ,6 ,8 weeks]

**Eligibility**

Ages eligible for study: 20 years to 65 years
Genders eligible for study: Both
Accepts healthy volunteers: No

Inclusion criteria:

- The episode of neck pain must be of more than 3 months duration.
- Neck pain had to be the patient's main complaint.
- Non-specific neck pain diagnosed according to common clinical standards.
- Actual pain intensity must exceed 40% on the VAS.
- Sufficient language skills to understand and complete trial questionnaires.
- Given written informed consent for clinical screening.

Exclusion Criteria:

- Obesity: BMI ≥ 30 kg/$m^2$
- Late whiplash syndrome; Whiplash associated disorders (WAD) in the previous 6 months
- Undergoing treatments like physical therapy, manual therapy, chiropractic spinal manipulation, acupuncture within the previous 3 months.
- Regular intake of corticosteroid medication and ongoing treatment with anticoagulants
- A pending insurance claim, involvement in current litigation or a pending pension application, existent sick certificate
- Pregnancy
- Adjacent pathology (e.g. acromioclavicular disease)
- Neck pain related to neurological disease, psychiatric illness
- Severe trauma/skeletal injury/fractures, new trauma in the previous 3 months or neck surgery in the previous 12 months
- Osteoarthritis of the cervical spine, cervical radiculopathy or myelopathy, vascular insufficiency, fibromyalgia
- Inflammatory disorders, infectious diseases, malignancy

- Calcium metabolism disorders
- Circulatory disorders of the A. vertebralis
- Diabetes mellitus

**Locations**: …….
**Contacts:** Project coordinator: ……..

# Appendix B:

Information Forms

***Information Flyer***

# Do you have neck pain??

We are currently looking for patients suffering from chronic neck pain to participate in a large scale study. Despite it being a common complaint and although there are a variety of therapy symptoms, there is still very much to be learnt about the treatment of the disease.

You are invited to participate in this research study. The purpose of the study is to investigate the effectiveness of osteopathic treatment. Osteopathy is an established recognized system of healthcare which relies on manual contact for diagnosis and treatment.

There is no charge for participating in the study.

Individuals interested in taking part in the study are invited to seek further information by calling the free telephone number ……..

*Telephone Questionnaire*

**Nr.: ……** **Study Center: …….. Date: ……**

| | | | |
|---|---|---|---|
| | Gender | Male | Female |
| | Marital status | Married | Single |
| | Occupation | Employed | Self-employed |
| **1)** | How old are you? (date or years) | | < 20 → exclude<br>> 65 → exclude |
| **2)** | Have you ever had neck problems, e.g. pain or disabilities | YES | NO → exclude |
| **3**) | For how long have you had neck pain? | Less than 3 month → exclude | More than 3 month |
| **4)** | Is neck pain your main health problem? | YES | NO → exclude |
| **5**) | Are you pregnant? | YES → exclude | NO |
| **6)** | For the study a clinical screening by a physician is necessary as well as an X-ray not more than 1 year old. Do you agree with this? | YES | NO → exclude |
| **7**) | Are you going to be absent for a period of time in the near future? | YES → exclude | NO |
| **8)** | Do you have a sickness certificate from your doctor? | YES → exclude | NO |
| **9**) | Is there a current pending pension application because of your neck pain? | YES → exclude | NO |
| **10)** | Is there a pending insurance claim? | YES → exclude | NO |
| **11**) | Have you ever suffered from whiplash injury in the past? | YES | NO |
| | **a)** If YES, did the symptoms last more than 6 months after the whiplash (late whiplash syndrome)? | YES → exclude | NO |
| | **b)** If YES, did the whiplash occur within the last 6 months | YES → exclude | NO |
| | **c)** If YES, do you believe that the whiplash is responsible for your | YES → exclude | NO |

neck pain today?

| | | |
|---|---|---|
| **12**) | Have you ever had a severe trauma or fracture with irreversible injury of the cervical spine? Have you had a neck surgery in the previous 12 months? | YES → exclude NO |
| **13)** | Besides neck pain, do you have other diagnosed diseases?<br>If YES, please list them: | YES NO<br>Cervical disc herniation, compression of spinal cord, vascular insufficiency, rheumatic disease, fibromyalgia, neoplasm, neurological diseases → exclude |
| **14)** | Do you suffer from osteoporosis or diabetes mellitus? | YES → exclude NO |
| **15)** | Do you take medication regularly or receive injections?<br>If YES, please list them: | YES NO<br>Corticosteriod medication, anticoagulants → exclude |
| **16)** | Are you currently receiving any other therapy for your neck pain at the moment (like physical therapy**,** chiropractic, acupuncture)?<br>If Yes, do you agree to stop these therapies temporarily during the time of the study? | YES NO<br>YES NO → exclude |
| **17)** | Have you undergone a chiropractic manipulation in the last 3 months? | YES → exclude NO |
| **18)** | What is your average pain on a scale from 1 to 10?<br>What is your worst pain on a scale from 1 to 10? | < 4 → exclude |

Patient suitable: ☐ Patient not suitable: ☐

Name: .....
Street:.....
Zip code/city:.....
Telephone:.....

## *Study Information for Patients*

Dear Patient

We would like to thank you for your interest in the study of chronic non-specific neck pain. Non-specific neck pain is a general term for complaints of the cervical vertebrae (neck). Despite it being a common complaint and although there are a variety of therapy options, there is still much to be learnt about the treatment of the disease. The study is to investigate whether osteopathic treatment is effective and can positively affect the symptoms.

If you are interested in participating in the study, we ask if you could first be examined by your physician and bring along with you two X-rays of your cervical vertebrae (neck) which are no older than 3 months. If you have already had X-rays taken within the previous year and you have suffered no serious incident (e.g. an accident, or exceptional pain etc.) since then, these images will suffice.

To clearly measure any effects of the therapy used, we kindly ask you to do the following throughout the study:

- If possible, avoid taking any muscle relaxants 2 days before each treatment session
- Refrain from receiving any other kind of therapy
- Not to undergo any chiropractic manipulations

There will be two groups in this study. One group will begin with treatments immediately; and due to organization, the other group will begin 8 weeks later. However, an initial examination will take place immediately for both groups. You will be randomly placed in one of these groups.

You will incur no risk during the osteopathic treatment. However, there is the possibility that after treatment, there will be a worsening of symptoms, muscle soreness, or fatigue. The study lasts 10 weeks and consists of five osteopathic treatments free of charge. You can decide to stop the treatment at any stage, but all we ask is that you inform your therapist and say why.

We plan to conduct a follow-up questionnaire 3 and 6 months after treatment to evaluate the longer term effects. For a scientific evaluation of the study, it is necessary to gather this clinical data. Your anonymity is guaranteed at all times.

Your willingness to participate may well contribute to alleviating the future suffering of others with chronic neck pain. We would like to thank you for your support and wish you all the best for the coming study.

Your study team

Enclosed you will find additional information about osteopathy and a leaflet about neck pain

## *Information about Osteopathy*

**What is Osteopathy?**

Osteopathy is an established recognized system of healthcare which relies on manual contact for diagnosis and treatment. It respects the relationship of body, mind and spirit in health and disease; it lays emphasis on the structural and functional integrity of the body and the body's intrinsic tendency for self-healing. Osteopathic treatment is viewed as a facilitative influence to encourage this self regulatory process.
Pain and disability experienced by patients are viewed as resulting from a reciprocal relationship between the musculoskeletal and visceral components of a disease or strain.

For what kinds of problems can osteopathic treatment help?
While often identified with the treatment of back pain, osteopathic treatment is useful in a wide variety of health complaints. The application of osteopathic principles in clinical practice varies with the training, interest and license of the individual practitioner. A partial list of complaints in which osteopathic treatment would commonly be applied would include:

* Back pain
* Headache
* Neck pain
* Shoulder pain
* Non anginal chest pain
* Athletic or overuse strain injuries

Depending on individual practitioner expertise, osteopathic manipulative treatment may make a significant contribution to the health care management in the following diagnoses:

* Muscle or ligament strains, ankle, elbow, knee
* Traumatic injuries without laceration or fracture
* Pregnancy and childbirth, gestation, labor and post-partum
* Muscle tension headache independent or associated with migraine
* Sinusitis, allergic rhinitis, Otitis media
* Infant colic, plagiocephaly
* Osteoarthritis
* Pneumonia, bronchitis, congestive heart failure
* Hypertension
* Gastric reflux, non acute cholecystitis
* Anxiety and depression
* Vertigo

**How Does an Osteopath Work?**

Osteopathic diagnosis requires observation and palpation (touch) of the body. This may involve the immediate area of the complaint or distant parts of the body. This may involve your being placed in various positions on a treatment table. The degree of disrobing for diagnosis and treatment is variable among cultures and training. If unclear about the type of contact or involvement, ask for clarification at the time you call for an appointment.

Osteopathic literature is diverse and covers 125 years of practice history. Most osteopaths should have a grounding in common osteopathic principles and techniques, however, there is variation in breadth and depth of different topics and techniques. Additionally, some are trained as full physicians, some are trained as physiotherapists. Avenues to certification or registration by governments and other regulatory bodies varies among nations.

The World Osteopathic Health Organisation, retrieved May, 2009, from http://www.woho.org/

**Patient leaflets from the BMJ Group**

# Neck pain

**Neck pain usually starts suddenly. But it often starts to feel better after a few days and is usually gone after a week or so. If it doesn't go away or it gets worse, you may need treatment.**

We've looked at the best and most up-to-date research to produce this information. You can use it to talk to your doctor and decide which treatments are right for you.

## What happens?

There are different types of neck pain. Each has different causes.

- Simple (or uncomplicated) neck pain is the most common type of neck pain. You might never know the exact reason for your neck pain, but it might be because of bad posture or stress. Or you may have strained your neck muscles or ligaments (the strands of tissue that hold bones together) or slept awkwardly. If you're older, neck pain may be caused by wear and tear of the bones in your neck and the shock-absorbing discs between them.
- Sometimes the root of a nerve is squashed or injured as it comes out between the bones in the neck. It can happen when a bone or discs in your neck press on a nerve.
- Whiplash is common after car crashes and sports injuries. To learn more, see our information on whiplash.

## What are the symptoms?

Most neck pain starts suddenly, and usually improves after a couple of days. Your neck will be sore and painful, especially when you try to move it. The pain may spread to your head and shoulders.

You should tell your doctor if your arm or hand feels numb, weak or tingling, as this may mean you have a problem with a nerve in your neck. You might also have a slipped disc pressing on a nerve. Or a muscle spasm might be pinching a nerve. You should also see your doctor if your neck pain doesn't start to feel better after a few days, or if it gets worse.

Your doctor can rule out serious causes of neck pain by examining your neck. You might also have an X-ray of your neck, a CT scan or an MRI scan. Sometimes doctors do blood tests to look for inflammation or more serious causes.

## What treatments work?

There are lots of different treatments for simple (uncomplicated) neck pain.

**Treatments without medicines**

- Your neck will probably be less painful after **manipulation** or **mobilisation** by a chiropractor, osteopath or physiotherapist. If you are treated by a trained therapist, manipulation is unlikely to do any harm.
- **Exercises** to strengthen your neck muscles and improve your flexibility may help long-term neck pain. A physiotherapist may be able to show you what exercises work best.
- **Combining manipulation and exercise** may be especially helpful if you have had neck pain for a long time.
- Some research suggests that **acupuncture** could help with neck pain. But not all the studies are good quality, so it's hard to be sure.
- Many other treatments have been tried for neck pain, but there's not enough good research to say whether they help. These treatments include hot and cold packs, treatment with a machine that sends small electrical signals into your nerves (called transcutaneous electrical nerve stimulation, or TENS for short), soft collars and special pillows.

**Medicines**

There isn't any specific research that shows drugs help neck pain, but your doctor may recommend one or more of the following.

- **Painkillers**. You can buy milder painkillers in a pharmacy, such as paracetamol. But you'll need a prescription from your doctor to get stronger ones. Some strong painkillers can cause withdrawal symptoms when you stop taking them.
- **Nonsteroidal anti-inflammatory drugs (NSAIDs)**. NSAIDs, such as ibuprofen, are painkillers that also reduce inflammation. You can buy ibuprofen from a pharmacy. For other NSAIDs, such as diclofenac or naproxen, you need a prescription from your doctor. NSAIDs can cause stomach pains and diarrhoea.
- **Antidepressants**. Your doctor might prescribe an antidepressant if you have had neck pain for a long time, especially if the pain keeps you awake at night. Antidepressants can cause side effects such as a dry mouth, constipation, nausea and dizziness.
- **Muscle relaxants**. Muscle relaxants are sometimes used for people in severe pain from muscle spasms, but they are only used for a short amount of time. They include benzodiazepines, such as diazepam (brand name Valium). Muscle relaxants can make you feel sick, dizzy or drowsy. It's also possible to become dependent on these drugs if you take them for too long. This means you get side effects when you stop taking them.

Treatments for neck pain caused by an injured nerve (cervical radiculopathy) have not been as well studied as those for simple neck pain. Doctors sometimes recommend injections or surgery.

- Having **an injection of steroids** into the spinal cord in your neck may reduce your pain. But more research is needed. There is a small risk that you could get an infection or a swelling full of pus (an abscess) after this treatment.
- There's no evidence that **surgery** can help people with neck pain caused by nerve problems. An injection of steroids might work just as well. More research is needed into this treatment.

## What will happen to me?

Neck pain usually goes away after a few days or weeks. But it can come back or last longer. One study found that roughly 1 in 10 people have long-term neck pain.

## *Study Information for Physicians*

**Osteopathic treatment of patients with chronic non-specific neck pain. A randomized controlled trial.**

Dear Physician,

Within the scope of a research project ..... we are to conduct a study on osteopathic treatment of patients with chronic non-specific neck pain (CNP). We would very much appreciate it if you could complete the diagnostic described below about your patient.

Osteopathy is a unified therapy form which treats the manual dysfunctions of the joints, soft-tissue, and organs to restore their functional imbalance. (For further information, please see the information leaflet enclosed)

The subject of our clinical study is chronic non-specific neck pain. This is of interest to us because:

- it occurs frequently
- it leads to significant impairment on the quality of life
- high social and medical costs are incurred

To ensure the study follows the necessary scientific procedure, we require patients who fulfill particular criteria: CNP should be the patient's main complaint, and the pain should have been continuously present for the previous 3 months. You can find all other criteria and information contained in the leaflet enclosed, should you wish to support our study. Only those patients who fulfill all the necessary criteria will be included in the study. Participation in the study incurs the patient no costs what so ever!

Should you have any questions, please do not hesitate to contact the address above.

Yours faithfully

Address of the study center: ……..

### *Documentation of the Physician*

This documentation is a form which is to be completed by the participating physician before treatment begins. It contains information for the physician, so that no other influences in the form of physical therapy, structural manipulation or medication for muscle relaxation can arise during the study. It is to help the physician examine the exclusion criteria more easily and simultaneously permit documentation; and hence, ensure a medical safe-guard. The document is to be completed by the physician, signed and then stamped. It is then kept with the patient's records and only then can the patient be accepted into the study program.

Dear Physician,

Thank you very much for your involvement within the scope of our study on chronic non-specific neck pain!

For your information:
During the study the patient should not

- get physical therapy
- get a structural manipulation
- take medication for muscle relaxation 48 hours before osteopathic treatment

Is this acceptable in your opinion? Yes ☐ No ☐

If you have answered the question with YES, please complete the following page.

If you have any further questions, please do not hesitate to contact:

Name :.....
Address:.....
Telephone :.....

We thank you for your cooperation.

Yours faithfully

**Clinical screening form** Patient: .....

We ask you for the following clinical findings:

1.) X-ray examination of the cervical spine (two levels). X-rays should be not older than 12 months with the exception of an event which required an X-ray.

- ☐ X-ray allows osteopathic treatment
- ☐ X-ray allows **no** osteopathic treatment

2.) Neurological examination

- ☐ not necessary
- ☐ necessary, result:.....

3.) Ultrasound examination

- ☐ not necessary
- ☐ necessary, result:.....

We ask you to confirm that the following diseases are **not** present:

- ☐ Infectious diseases (bacterial or viral)
- ☐ Diabetes mellitus
- ☐ Osteoporosis
- ☐ Neoplasm's
- ☐ Neurological diseases
- ☐ Osteoarthritis
- ☐ Inflammatory disorders (e.g. rheumatic diseases)
- ☐ Irreversible injuries of the cervical spine
- ☐ Cervical herniation with neurological deficiences, myelopathy
- ☐ Calcium metabolism disorders
- ☐ Circulatory disorders of the A. vertebralis
- ☐ Psychiatric illness
- ☐ Corticosteroid medication, treatment with anticoagulants

Are any of this diseases the reason for the chronic non-specific neck pain?

Yes ☐ No ☐

**stamp / signature of physician**

## *Informed Consent*

| | |
|---|---|
| Title: | Osteopathic treatment of patient with chronic non-specific neck pain |
| Project coordinator: | …… |
| Sponsor: | …… |

### I. Purpose:

You are invited to participate in a research study. The purpose of the study is to investigate the effectiveness of osteopathic treatment. You are invited to participate because you are suffering of chronic non-specific neck pain. A total of 150 participants will be recruited for this study. The trial will be carried out in different osteopathic private practices. Participation will require 5 osteopathic treatments of 1-hour duration of your time over 8 weeks.

### II. Procedures:

If you decide to participate, you will be required to fill out some questionnaires, answer questions about your pain, your medication, and work disability at the beginning and end of the study, as well as before every treatment session. In addition 3 and 6 months after the end of treatment some of the questionnaires have to be filled out once more. There will be two groups in the study. One group will begin with the treatments immediately; the other group will begin two months later. You will be randomly assigned to one of these groups. You will be allowed to take your usual medication. If necessary, medication for pain can be taken, but this has to be documented. The five treatments over 8 weeks will be given by the same osteopath in his or her private practice. There will be no charge for the treatments.

### III. Risks:

In this study, you will not have any more risks than you would have in normal day life. However, there is the possibility that after treatment there will be a worsening of symptoms, muscle soreness or fatigue. If you experience a worsening after two days, please contact your practitioner.

### IV. Benefits:

Participation in this study may benefit you personally. We hope that your neck pain will improve and your symptoms will be alleviated. Overall, we hope to gain information about osteopathic treatment of chronic non-specific neck pain, because no satisfying therapy is known today.

## V. Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled.

## VI. Confidentiality:

We will deal with all records with the utmost confidentiality. An identification number will be used rather than your name on study records. Only your personal practitioner will have access to the information you provide. It will be stored in a locked cabinet. Your name and other facts that might reveal your identity will not appear when we present this study or publish its results. The findings will be summarized and reported in a group form. You will not be identified personally.

## VII. Contact Persons:

Please feel free to contact the project coordinator, phone …. or email……. if you have questions about this study, or if you have questions or concerns about your rights as a participant in this research study.

## VIII. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep.
If you are willing to volunteer for this research, please sign below.

_____

Participant Date

_____ _____

Project Coordinator or Contract research Organization Date

# Appendix C:

Assessment Instruments

## *The Neck Disability Index (NDI)*

**ID-Nr.: ……  Study Center: …….. Date: ……**

Please read instructions:
This questionnaire has been designed to give your osteopath information as to how your neck pain has affected your ability to manage everyday life. Please answer every section and mark in each section only the ONE box that applies to you. We realize that you may consider that two of the statements in any one section relate to you, but please just mark the box that most closely describes your problem.

### SECTION 1 - PAIN INTENSITY

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

### SECTION 2 - PERSONAL CARE (Washing, Dressing, etc.)

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

### SECTION 3 - LIFTING

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

SECTION 4 - READING

- ☐ I can read as much as I want to with no pain in my neck.
- ☐ I can read as much as I want to with slight pain in my neck.
- ☐ I can read as much as I want to with moderate pain in my neck.
- ☐ I can't read as much as I want because of moderate pain in my neck.
- ☐ I can hardly read at all because of severe pain my neck.
- ☐ I cannot read at all.

SECTION 5 - HEADACHES

- ☐ I have no headaches at all.
- ☐ I have slight headaches which come infrequently.
- ☐ I have moderate headaches which come infrequently.
- ☐ I have moderate headaches which come frequently.
- ☐ I have severe headaches which come frequently.
- ☐ I have headaches almost all the time.

SECTION 6 - CONCENTRATION

- ☐ I can concentrate fully when I want to with no difficulty.
- ☐ I can concentrate fully when I want to with slight difficulty.
- ☐ I have a fair degree of difficulty in concentration when I want to.
- ☐ I have a lot of difficulty in concentrating when I want to.
- ☐ I have a great deal of difficulty in concentrating when I want to.
- ☐ I cannot concentrate at all.

SECTION 7 – WORK

- ☐ I can do as much work as I want to.
- ☐ I can only do my usual work, but no more.
- ☐ I can do most of my usual work, but no more.
- ☐ I cannot do my usual work.
- ☐ I can hardly do any work at all.
- ☐ I can't do any work at all.

SECTION 8 – DRIVING

- ☐ I can drive my car without any neck pain.
- ☐ I can drive my car as long as I want with slight neck pain.
- ☐ I can drive my car as long as I want with moderate neck pain.
- ☐ I can't drive my car as long as I want because of moderate pain in my neck.
- ☐ I can hardly drive at all because of severe pain in my neck.
- ☐ I can't drive my car at all.

SECTION 9 - SLEEPING

- ☐ I have no trouble sleeping.
- ☐ My sleep is slightly disturbed (less than 1 hour sleepless).
- ☐ My sleep is mildly disturbed ( 1-2 hours sleepless).
- ☐ My sleep is moderately disturbed ( 2-3 hours sleepless).
- ☐ My sleep is greatly disturbed ( 3-5 hours sleepless).
- ☐ My sleep is completely disturbed ( 5-7 hours sleepless).

SECTION 10 - RECREATION

- ☐ I am able to engage in all my recreation activities with no neck pain at all.
- ☐ I am able to engage in all my recreation activities, with some pain in my neck.
- ☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.
- ☐ I am able to engage in a few of my usual recreation activities because of pain in my neck.
- ☐ I can hardly do any recreation activities because of pain in my neck.
- ☐ I can't do any recreation activities at all.

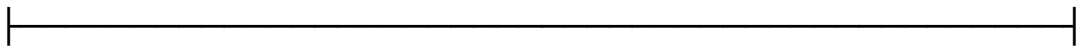
Instructions:
Each item is scored out of 5 for a maximum total score of 50. Care should be taken in reporting the score as either out of 50 or as a percentage out of 100. Using this system, a score of 10-28% (i.e., 5-14 points) is considered to constitute mild disability; 30-48% is moderate; 50-68% is severe; 72% or more is complete.

*Visual Analogue Scale (VAS)*

**ID-Nr.: ……** **Study Center: …….. Date: ……**

**1. Actual pain intensity**

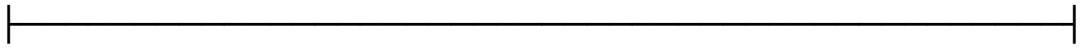
How severe is your neck pain today? Place a vertical mark on the line below to indicate how bad you feel your neck pain today.



No Pain (0%) — Pain as bad as it could possibly be (100%)

**2. Worst pain intensity**

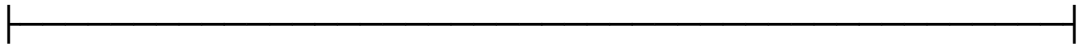
In the last 14 days: How severe was your worst neck pain. Place a vertical mark on the line below to indicate how bad your worst neck pain was.



No Pain (0%) — Pain as bad as it could possibly be (100%)

**3. Average pain intensity (continuous pain)**

In the last 14 days: How severe was your average neck pain. Place a vertical mark on the line below to indicate how bad your average neck pain was.

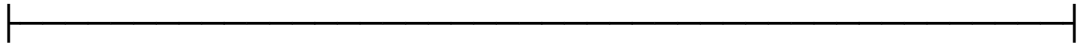


No Pain (0%) — Pain as bad as it could possibly be (100%)

**4.) Pain not in the neck region**

If there was pain besides your neck pain within the last two weeks, please answer the following questions:

- In what region of the body did the pain occur? ……..
- How intense was the pain?



No Pain (0%) — Pain as bad as it could possibly be (100%)

**ID-Nr.: ……** **Study Center: …….. Date: ……**

### *Work Disability*

Please answer the following survey item (only if you are an employee):
"During the past 2 weeks, how many days has neck pain kept you from going to work?"

…….. days

### *Perceived Stress Measure*

Perceived Stress Scale- 4 Item

Instructions: The questions in this scale ask you about your feelings and thoughts during the last 2 weeks. In each case, please indicate with a mark how often you felt or thought a certain way.

| | Never | Almost ever | Some-times | Fairly often | Very often |
|---|---|---|---|---|---|
| 1. In the last 2 weeks, how often have you felt that you were unable to control the important things in your life? | 0 | 1 | 2 | 3 | 4 |
| 2. In the last 2 weeks, how often have you felt confident about your ability to handle your personal problems? | 0 | 1 | 2 | 3 | 4 |
| 3. In the last 2 weeks, how often have you felt that things were going your way? | 0 | 1 | 2 | 3 | 4 |
| 4. In the last 2 weeks, how often have you felt difficulties were piling up so high that you could not overcome them? | 0 | 1 | 2 | 3 | 4 |

*SF-36*

**SF-36 Health Survey**

**ID-Nr.: ……  Study Center: ..……  Date: ……**

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by making the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

| | (Circle one) |
|---|---|
| Excellent…… | 1 |
| Very good…….……. | 2 |
| Good…….. ……..…. | 3 |
| Fair…… | 4 |
| Poor……... | 5 |

2 COMPARED TO TWO WEEKS AGO, how would you rate your health in general NOW?

| | (Circle one) |
|---|---|
| Much better now than two weeks ago……. | 1 |
| Somewhat better now than two weeks ago……. | 2 |
| About the same as two weeks ago…….. | 3 |
| Somewhat worse now than two weeks ago…… | 4 |
| Much worse now than two weeks ago…… | 5 |

3 The following questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

(Circle one number on each line)

| ACTIVITIES | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|
| a. *Vigorous activities*, such as running, lifting heavy objects, participating in strenuous sports | 1 | 2 | 3 |
| b. *Moderate activities*, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 |
| c. Lifting or carrying groceries | 1 | 2 | 3 |
| d. Climbing *several* flights of stairs | 1 | 2 | 3 |
| e. Climbing *one* flight of stairs | 1 | 2 | 3 |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 |
| g. Walking *more than one mile* | 1 | 2 | 3 |
| h. Walking *several blocks* | 1 | 2 | 3 |
| i. Walking *one block* | 1 | 2 | 3 |
| j. Bathing or dressing yourself | 1 | 2 | 3 |

4 During the PAST TWO WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

(Circle one number on each line)

| | Yes | No |
|---|---|---|
| a. Cut down on the *amount of time* you spent on work or other activities | 1 | 2 |
| b. *Accomplished less* than you would like | 1 | 2 |
| c. Were limited in the *kind* of work or other activities | 1 | 2 |
| d. Had *difficulty* performing the work or other activities (for example, it took extra effort) | 1 | 2 |

5 During the PAST TWO WEEKS , have you had any of the following problems with your work or other regular daily activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

(Circle one number on each line)

| | Yes | No |
|---|---|---|
| a. Cut down on the *amount of time* you spent on work or other activities | 1 | 2 |
| b. *Accomplished less* than you would like | 1 | 2 |
| c. Didn't do work or other activities *as carefully* as usual | 1 | 2 |

6 During the PAST TWO WEEKS , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle one)

Not at all…….. 1
Slightly…… 2
Moderately……... 3
Quite a bit……. 4
Extremely……. 5

7 How much BODILY pain have you had during the PAST TWO WEEKS ?

(Circle one)

None……. 1
Very mild……. 2
Mild…….. 3
Moderate…….. 4
Severe…….. 5
Very severe…….. 6

8 During the PAST TWO WEEKS , how much did PAIN interfere with your normal work (including both work outside the home and housework)?

(Circle one)

Not at all……... 1
A little bit……. 2
Moderately……3
Quite a bit…… 4
Extremely……. 5

9 These questions are about how you feel and how things have been with you DURING THE PAST TWO WEEKS . For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST TWO WEEKS :

(Circle one number on each line)

| | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| a. Did you feel full of life | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Have you been a nervous person? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Have you felt so down in the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Have you felt calm and peaceful? | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have a lot of energy? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Have you felt downhearted and depressed? | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Have you been a happy person? | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? | 1 | 2 | 3 | 4 | 5 | 6 |

10 During the PAST TWO WEEKS , how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting friends, relatives, etc.)?

(Circle one)

All of the time……. 1
Most of the time…….. 2
Some of the time…….. 3
A little of the time…….4
None of the time…….. 5

11 How TRUE or FALSE is EACH of the following statements for you?

(Circle one number on each line)

| | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|
| a. I seem to get sick a little easier than other people | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent | 1 | 2 | 3 | 4 | 5 |

THANK YOU FOR COMPLETING THESE QUESTIONS !

***DAPOS***

The Depression, Anxiety and Positive Outlook Scale (DAPOS)

**ID-Nr.: ……  Study Center: …….. Date: ……**

We would like to know how you have been feeling in the last two weeks. Please circle a number for each statement indicating how often you feel that way, where 1 = almost never, and 5= almost all the time.

| | Almost never | | | | Almost all the time |
|---|---|---|---|---|---|
| 1. I feel like a failure | 1 | 2 | 3 | 4 | 5 |
| 2. I get a frightened feeling, as if something awful is about to happen | 1 | 2 | 3 | 4 | 5 |
| 3. I feel guilty | 1 | 2 | 3 | 4 | 5 |
| 4. I can laugh and see the funny side of things | 1 | 2 | 3 | 4 | 5 |
| 5. I am disappointed in myself | 1 | 2 | 3 | 4 | 5 |
| 6. I get a frightened feeling, like butterflies in the stomach | 1 | 2 | 3 | 4 | 5 |
| 7. I feel cheerful | 1 | 2 | 3 | 4 | 5 |
| 8. I blame myself constantly | 1 | 2 | 3 | 4 | 5 |
| 9. I get a sudden feeling of panic | 1 | 2 | 3 | 4 | 5 |
| 10. I look forward with enjoyment to things | 1 | 2 | 3 | 4 | 5 |
| 11. I think about harming myself | 1 | 2 | 3 | 4 | 5 |

For Scoring:
Items 1, 3, 5, 8 and 11= depression
Items 2, 6 and 9= Anxiety
Items 4, 7 and 10= positive outlook.

*Medication Diary*

**ID-Nr.: ……** **Study Center: …….. Date: ……**

**Part 1: Long-term medication**

| Do you regularly take medication for your neck complaints? | |
|---|---|
| Medication and dosage? | |
| How often? (e.g. 1-0-1) | |
| Change in medication:<br>Date?<br>Drug and dosage? | |

| Do you regularly take medication because of other diseases? | |
|---|---|
| Which disease? | |
| Medication and dosage? | |
| How often? (e.g. 1-0-1) | |
| Change in medication:<br>Date?<br>Drug and dosage? | |

Please fill out this part before the first osteopathic treatment (T0). During the course of treatments only if there is a change in medication.

**ID-Nr.: ……** **Study Center: …….. Date: ……**

**Part 2: Muscle relaxants**

Have you taken muscle relaxants within the last 48 hours? (e.g. Musaril, Myoson, Trancopal dolo)

Yes □ No □

**Part 3: On demand medication**

Please write down, if you have taken any medication within the last 14 days

| Date | Medication type & amount taken |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |

Please fill out this part before every osteopathic treatment.

# Appendix D:

Protocol of Intervention

## *Outpatient Osteopathic SOAP Note Form*

# Outpatient Health Summary

*wak SOAP version 5: 091102b*

| | | | | | |
|---|---|---|---|---|---|
| **Patient's Name** | | **Date** | **Update:** | | |
| **Date of Birth** | **Sex** | **Phone Numbers:** | **Home** | | |
| **Marital Status:** M S D W | | | **Work** | | |
| **Significant Others:** | | **DNR Status: Resuscitate?** | **Yes** | **No** | **Qualifications:** |
| **Religion:** | | **Next of Kin:** | | | |

| | | | | |
|---|---|---|---|---|
| **Social History:** | **Employment** | **Occupation** | **Education** | |
| | **Tobacco** | **ETOH** | **Drugs** | **Sex Hx** |
| | | | | |
| **Family History:** | **M** | **Siblings** | **Others:** | |
| | **F** | | | |

**Past Medical History**

| CPT# | Start Date | Problem / Diagnosis | Medications | Start | Stop |
|---|---|---|---|---|---|
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**Allergies, Adverse Drug Reactions:**

**Health Maintenance**

| Parameter | Dates | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **DPT/DT/TD** | | | | | | | | |
| **OPV** | | | | | | | | |
| **MMR** | | | | | | | | |
| **HIB** | | | | | | | | |
| **Influenza** | | | | | | | | |
| **Hepatitis** | | | | | | | | |
| **PPD/Tine** | | | | | | | | |
| **Pneumovax** | | | | | | | | |
| **H & P** | | | | | | | | |
| **Eye exam** | | | | | | | | |
| **Dental exam** | | | | | | | | |
| **PAP smear** | | | | | | | | |
| **Mammogram** | | | | | | | | |
| **Urinalysis** | | | | | | | | |
| **Hemoccult** | | | | | | | | |
| **Cholesterol** | | | | | | | | |
| **Sigmoidoscopy** | | | | | | | | |
| **Others** | | | | | | | | |

**Past Surgical History**

| Date | Type |
|---|---|
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| | |

**Consultants**

Funded by a grant from the Bureau of Research. 
Designed to coordinate with the Established Outpatient Osteopathic SOAP Note Form. Recommended by American Association of Colleges of Osteopathic Medicine.

# Outpatient Osteopathic SOAP Note History Form

*wak SOAP version 5: 091102b*

| | |
|---|---|
| Office of: | |
| For office use only: | |

**Patient's Name** _____ **Date**_____ **Age**_____

**HISTORY**

**S** (See Outpatient Health Summary Form for details of history)

**Patient's Pain Analog Scale:** Not done

NO PAIN — WORST POSSIBLE PAIN

## CC

## History of Present Illness

**Level: HPI**

| Elements | | OR Status of ≥ 3 chronic or inactive conditions | | | |
|---|---|---|---|---|---|
| | Location | | | II | 1-3 elements reviewed |
| | Quality | | | III | |
| | Severity | | | IV | ≥ 4 elements OR status of ≥ 3 chronic conditions |
| | Duration | | | V | |
| | Timing | | | | |
| | Context | | | | |
| | Modifying factors | | | | |
| | Assoc. Signs and Sx | | | | |

**Review of Systems** (Only ask / record those systems pertinent for this encounter.) Not done

**Level: ROS**

| | | | |
|---|---|---|---|
| | Constitutional (Wt loss, etc.) | II | None |
| | Eyes | III | 1 system pertinent to the problem |
| | Ears, nose, mouth, throat | | |
| | Cardiovascular | IV | 2-9 systems |
| | Respiratory | V | ≥ 10 systems |
| | Gastrointestinal | | |
| | Genitourinary | | |
| | Musculoskeletal | | |
| | Integumentary (skin, breast) | | |
| | Neurological | | |
| | Psychiatric | | |
| | Endocrine | | |
| | Hematologic/lymphatic | | |
| | Allergic/immunologic | | |

**Past Medical, Family, Social History** Not done

**Level: PFSH**

| | | | |
|---|---|---|---|
| | Past history / trauma | II | None |
| | | III | |
| | Allergies: | IV | 1 history area |
| | Medications: | V | ≥ 2 history areas |
| | | | |
| | | | |
| | Family history | | |
| | Social history | | |

**Overall History = Average of HPI, ROS or PFSH:** **II** (1-3 HPI) **III** (1-3 HPI, 1 ROS) **IV** (4+ HPI, 2-9 ROS, 1 PFSH) **V** (4+ HPI, 10+ ROS, 2+ PFSH)

Signature of transcriber: _____ Signature of examiner: _____

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# Outpatient Osteopathic SOAP Note Exam Form

*wak SOAP version 5: 091102b*

| Office of: | |
|---|---|
| For office use only: | |

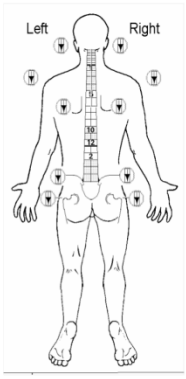
**O** Not done

**Patient's Name** _____ Date _____ Sex: Male Female

* Vital Signs (3 of 7) Wt. _____ Ht. _____ Temp. _____

Reg. Pt. position for recording BP:

Resp. ____ Pulse ____ Irreg. Standing_____ Sitting_____ Lying_____




**Level of GMS**

| | | |
|---|---|---|
| | **II** | 1-5 elements |
| | **III** | 6+ elements |
| | **IV** | 2+ from each or 6 areas OR 12+ elements in 2+ areas |
| | **V** | Perform all elements ≥ 9 areas |

**Key to the Severity Scale**
**0** = No SD or background (BG) levels
**1** = More than BG levels, minor TART
**2** = Obvious TART (esp. R and T), +/- symptoms
**3** = Key lesions, symptomatic, R and T stand out

| | Methods Used For Examination | | | | | Region Evaluated | Severity | | | | Somatic Dysfunction and Other Systems |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | All | T | A | R | T | | 0 | 1 | 2 | 3 | MS / SNS / PNS / LYM. / CV / RESP. / GI / FAS. / etc. |
| *1 | | | | | | Head and Face | | | | | |
| | | | | | | Neck | | | | | |
| | | | | | | Thoracic T1-4 | | | | | |
| | | | | | | T5-9 | | | | | |
| | | | | | | T10-12 | | | | | |
| *2 | | | | | | Ribs | | | | | |
| | | | | | | Lumbar | | | | | |
| | | | | | | Sacrum / Pelvis | | | | | |
| | | | | | | Pelvis / Innom. | | | | | |
| | | | | | | Abd ./ Other | | | | | |
| *3 | | | | | | Upper R | | | | | |
| *4 | | | | | | Extremity L | | | | | |
| *5 | | | | | | Lower R | | | | | |
| *6 | | | | | | Extremity L | | | | | |

Signature of transcriber: _____ Signature of examiner: _____

Funded by a grant from the Bureau of Research. 
Designed to coordinate with Outpatient Osteopathic SOAP Note Form. Recommended by American Association of Colleges of Osteopathic Medicine.

## Outpatient Osteopathic Assessment and Plan Form

*wak SOAP version 5: 091102b*

| Office of: | |
|---|---|
| For office use only: | |

**A** **Patient's Name** _____ **Date** _____

| Dx No. | ICD Code | Written Diagnosis | Dx No. | ICD Code | Written Diagnosis |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | 739.0 | Somatic Dysfunction of Head and Face | | 739.4 | Somatic Dysfunction of Sacrum |
| | 739.1 | Somatic Dysfunction of Neck | | 739.5 | Somatic Dysfunction of Pelvis |
| | 739.2 | Somatic Dysfunction of Thoracic | | 739.9 | Somatic Dysfunction of Abd / Other |
| | 739.8 | Somatic Dysfunction of Ribs | | 739.7 | Somatic Dysfunction of Upper Extremity |
| | 739.3 | Somatic Dysfunction of Lumbar | | 739.6 | Somatic Dysfunction of Lower Extremity |

Physician's evaluation of patient prior to treatment: First visit Resolved Improved Unchanged Worse

**P**

| All not done **Region** | OMT Y | OMT N | Treatment Method | Response R | I | U | W |
|---|---|---|---|---|---|---|---|
| Head and Face | | | | | | | |
| Neck | | | | | | | |
| Thoracic T1-4 | | | | | | | |
| T5-9 | | | | | | | |
| T10-12 | | | | | | | |
| Ribs | | | | | | | |
| Lumbar | | | | | | | |
| Sacrum | | | | | | | |
| Pelvis | | | | | | | |
| Abdomen/Other | | | | | | | |
| Upper Extremity | | | | | | | |
| Lower Extremity | | | | | | | |

ART BLT CR CS DIR FPR HVLA IND INR LAS ME MFR ST VIS OTH

Meds: _____ PT: _____

Exercise: _____ Other: _____

Nutrition: _____ Remarks: For

**Complexity / Assessment / Plan (Scoring)** *Default to level 2—same criteria

| Problems | | Risk (presenting problem(s), diagnostic procedure(s), Management options) | | Data | Maximum Points |
|---|---|---|---|---|---|
| Self-limiting | 1 (2 max.) | | | Lab | 1 |
| Estimated problem improved / stable | 1 | Minimal = Min. | | Radiology | 1 |
| Estimated—worsening. | 2 | Low | | Medicine | 1 |
| New—no workup | 3 (1 max.) | Moderate = Mod. | | Discuss with performing physician | 1 |
| New—additional workup | 4 | High | | Obtain records or Hx from others | 1 |
| | | | | Review records, discuss with physician | 2 |
| | | | | Visualization of tracing, specimen | 2 |

| Problems Level I | Level II | Level III | Level IV | Level V | Risk Level I | Level II | Level III | Level IV | Level V | Data Level I | Level II | Level III | Level IV | Level V |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| * | ≤1 pt. | 2 pt. | 3 pt. | ≥4 pt. | * | Min. | Low | Mod. | High | * | ≤1 pt. | 2 pt. | 3 pt. | ≥4 pt. |

Requires only 2 above 3 (problems, risk and data). Level of complexity = average of included areas.

**Traditional Method—Coding by Components**

| | I | II | III | IV | V |
|---|---|---|---|---|---|
| History | | | | | |
| Examination | | | | | |
| Complexity / Assessment Plan | * | | | | |
| **Final level of service** | | | | | |

All these areas required. Average of three levels of service.

**Optional Method—Coding by Time**

When majority of the encounter is counseling / coordinating, the level is determined by total time

| | I | II | III | IV | V |
|---|---|---|---|---|---|
| New patients (minutes) | 10 | 20 | 30 | 45 | 60 |
| Established patients (minutes) | * | 10 | 15 | 25 | 40 |
| **Final level of service** | | | | | |

Dictate total time and counseling / coordinating time plus a brief description of topics discussed

**Minutes spent with the patient:** 10 15 25 40 60 >60

**Follow-up:** 1 2 3 4 5 6 7 8 9 10 11 12 **Units:** D W M Y PRN

**OMT performed as Above:** 0 areas 1-2 areas 3-4 areas 5-6 areas 7-8 areas 9-10 areas

**Other Procedures Performed:** CPT Codes: _____ Written Dx: _____

| **E/M Code:** | **New** | | | | | **EST** | | | | | | **Consults** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Write 992 plus . . .*** | | *02* | *03* | *04* | *05* | . . . | *11* | *12* | *13* | *14* | *15* | . . . | *41* | *42* | *43* | *44* | *45* |

Signature of transcriber: _____ Signature of Examiner _____

explanations see: Outpatient Osteopathic SOAP Note Form Series and Usage Guide, American Academy of Osteopathy (http://www.academyofosteopathy.org/SOAP)

Instead of the Patient name here will be written the Identification Number

**ID-Nr.: ……** **Study Center: …….. Date: ……**

Additional questions about the daily pressure and work time

| | | | |
|---|---|---|---|
| Daily pressure | Posture at work | Sitting | ☐ |
| | | Standing | ☐ |
| | | Changing | ☐ |
| | Physical pressure | Heavy | ☐ |
| | | Moderate | ☐ |
| | | Light | ☐ |
| | | None | ☐ |
| Estimation of weekly work times | At work | | ..... |
| | In private life | | ..... |

*Special Osteopathic Examination Form*

**ID-Nr.: ……** **Study Center: …….. Date: ……**

| Regions of the cervical spine | Right | | | Left | | |
|---|---|---|---|---|---|---|
| Sutura occipitomastoidea | | | | | | |
| - Compression | 0 | 1 | 2 | 0 | 1 | 2 |
| - Gliding Occipital bone anterior | 0 | 1 | 2 | 0 | 1 | 2 |
| - Gliding Occipital bone posterior | 0 | 1 | 2 | 0 | 1 | 2 |
| Ventral fascia of the neck | 0 | 1 | 2 | 0 | 1 | 2 |
| M. sternocleidomastoidea | 0 | 1 | 2 | 0 | 1 | 2 |
| Mm. scaleni | 0 | 1 | 2 | 0 | 1 | 2 |
| C0/C1 | | | | | | |
| - Compression | 0 | 1 | 2 | 0 | 1 | 2 |
| - Translation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Gliding anterior | 0 | 1 | 2 | 0 | 1 | 2 |
| - Gliding posterior | 0 | 1 | 2 | 0 | 1 | 2 |
| C1/C2 | | | | | | |
| - Compression | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| C2/C3 | | | | | | |
| - Later flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| C3/C4 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| C4/C5 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| C5/C6 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| C6/C7 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |

| Regions of the cervical spine | Right | | | Left | | |
|---|---|---|---|---|---|---|
| C7/Th1 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| Th1/Th2 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| Th2/Th3 | | | | | | |
| - Lateroflexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Rotation | 0 | 1 | 2 | 0 | 1 | 2 |
| - Flexion | 0 | 1 | 2 | 0 | 1 | 2 |
| - Extension | 0 | 1 | 2 | 0 | 1 | 2 |
| 1. Rip | | | | | | |
| - High | 0 | 1 | 2 | 0 | 1 | 2 |
| - Down | 0 | 1 | 2 | 0 | 1 | 2 |
| 2. Rip | | | | | | |
| - High | 0 | 1 | 2 | 0 | 1 | 2 |
| - Down | 0 | 1 | 2 | 0 | 1 | 2 |

| Body region | | | |
|---|---|---|---|
| Upper extremities | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Lower Extremities | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Thoracic spine | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Lumbar spine | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Pelvis | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Visceral Organs | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Cranial dysfunctions | | | |
| - Global tests | + | - | |
| - Specific test | Dysfunction | | |
| Structure | 0 | 1 | 2 |
| …….. | 0 | 1 | 2 |
| Central tendon / sacro-cranial system / Dura | + | - | |
| Fluid level | + | - | |

*Documentation of Treatments*

**ID-Nr.: ……  Study Center: …….. Date: ……**

| Osteopathic dysfunction | Used technique |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |