Development of a Study Protocol on the Osteopathic Treatment of Late Whiplash Syndrome

by

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Approval Page

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Acknowledgement Page

For my wife, Karen

In memoriam, Erbprinz G-M. von Sachsen-Altenburg, Hzg. z.S.

Omnis cognitio intelligibilium ortum habet ex cognitione sensibilium secundum aliquem modum; substantia animae et natura sunt de numero cognoscibilium intelligibilium; ergo cognitio earum ortum habebit ex cognitione sensibilium.

(Albertus Magnus, *De homine* 1200-1280)

Glossary

ATSU	Andrew Tailor Still University
BDI	Beck Depression Inventory
CRF	Case Record Form
CONSORT	Consolidated Standards of Reporting Trials
CRO	Contract Research Organization
EBM	Evidence-based medicine
HRQL	Health Related Quality of Life
MeSH	Medical Subject Headings
MSc	Master of Science
LWS	Late Whiplash Syndrome
MVC	Motor Vehicle Collision
NAS	Numeric Analogue Scale
NDI	Neck Disability Index
OMT	Osteopathic Manipulative Treatment
OMM	Osteopathic Manipulative Medicine
RCT	Randomized Clinical Trial
ROM	Range of Motion
SF-12	Short Form 12 Questionnaire
SF-36	Short Form 36 Questionnaire
SOAP	Outpatient Osteopathic Note Form (Subjective, Objective, Assessment, Plan)
SOEF	Standardized Osteopathic Examination Form
TART	Tissue texture abnormality, Asymmetry of position, Restriction of motion, Tenderness
QTF	Québec Task Force
VAS	Visual Analogue Scale
WAD	Whiplash Associated Disorder
WDQ	Whiplash Disability Questionnaire

Abstract

Osteopathic Treatment of Patients on Late Whiplash Syndrome: Development of a study protocol. Kaiser Albrecht K., 2010: Thesis, Post-graduate School of Osteopathic Clinical Research, A.T. Still University of Health Sciences/M.Sc. /Osteopathic Clinical Research.

Background: Whiplash is a common injury associated with motor vehicle accidents and causes chronic pain, disability, activity limitations, and often psychological distress. The clinical sequelae and manifestation resulting from this trauma six months after the accident is defined as late whiplash syndrome (LWS), and describes symptoms like somatic dysfunction, pain, disability, as well as psychological and psychosocial factors. The estimated incidence rate for LWS varies between 18 to 45%. For whiplash complex only evidence about conservative treatments effects delivered by manual therapies other than osteopathic treatment exists. Empirical evidence has shown that osteopathic treatment has positive effects on late whiplash syndrome.

Objective: Development of a study protocol that allows the assessment of osteopathic treatment of LWS in a randomized controlled multi-center setting. Based on the results, the present status and future prospects of osteopathic treatment of LWS will be outlined.

Methods: Literature analysis is based on a comprehensive search of published materials on the whiplash syndrome complex, including clinical trials, systematic reviews, meta-analyses, and guidelines published between 1999 and 2009 in Medline, Embase, the Cochrane Library, and other important databases. The material was analyzed screening for the latest relevant literature of the whiplash complex and in terms of intervention and assessment methods. Assessment instruments, outcome variables, and application of treatment modalities were analyzed for the study protocol; out of these findings the protocol was developed.

Results: The literature review and statistical planning revealed that the following study design will be suitable: a randomized controlled multi-center trial will include a

total of 140 subjects with LWS, 70 in each group. Study group subjects will receive four individually tailored osteopathic treatments over 8 weeks, and follow-up examinations, three and six months after the end of treatment. Control group subjects will remain untreated during the study group treatment phase but receive the same treatment thereafter ("waiting list"). Main outcome measure will be whiplash related disability as assessed with the Whiplash Disability Questionnaire (WDQ); secondary outcome measure are pain intensity over the past 14 days, measured by a visual analogue scale (VAS), health-related quality of life (SF-12), and psychosocial factors measured with Beck Depression Inventory (BDI).

Conclusion: This master thesis outlines the rationale and suitable design of a randomized controlled trial to determine osteopathic treatment effectiveness in patients with LWS.

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Chapter 1: Introduction

1.1 Background

In Germany ca. 18 to 25% of all patients with whiplash injuries suffer from the effects even up to one year after the incident (Schnabel et al., 2002). The patients exhibit a variety of symptoms, which cannot be easily attributed to any one cause. The examination and treatment of these patients is–in contrast to patients with acute whiplash injury–not standardized and is discussed in the literature rather conflictingly (Spitzer et al., 1995).

Patients who visit an osteopathic practitioner are often suffering from the aftereffects of an injury, especially after road traffic accidents. It is remarkable that conventional treatment methods generally result in no discerning improvement with these patients. The experience of the author of this study, together with other osteopathic colleagues, has shown that traumatized patients with an unclear pattern of pain respond positively to osteopathic therapy. The sharpened powers of perception osteopaths have, combined with the knowledge of anatomy, enables them to detect and treat dysfunctional structures. This was validated in a pilot study in 2003 (Kaiser, Gietz, & Kastner, 2003).

Clinical research of osteopathy requires validated studies, whose findings need to be robust enough to stand up to independent studies of other disciplines of the CAM. At the end of the Master of Science in Osteopathic Clinical Research degree program at the Post-graduate School of Clinical Research Science at the A.T. Still University, it is the author's wish to develop a study protocol on the treatment of late whiplash syndrome (LWS) to enhance the quality of education and understanding.

1.2 Objective

The development of a study protocol for a clinical trial on the efficacy and effectiveness of osteopathic treatment for patients with LWS.

Chapter 2: Systematic Literature Review

2.1 Systematic Literature Review on Late Whiplash Syndrome (LWS)

2.1.1 Objective.

The aim of the systematic literature research is to identify and collect studies from the last 10 years which give some clinical indication of the latest research on LWS. Furthermore the purpose is also to gain an overview of the questions of classification, epidemiology, etiology, diagnosis, prevalence, incidence, management, and therapy.

2.1.2 Methods.

2.1.2.1 Databases and search terms.

The scientific literature databases were searched for references to whiplash syndrome complexes for the period 1999-2009. The primary source was the database MEDLINE (PubMed) at the National Library of Medicine in Bethesda, Maryland. The search strategy was developed by the author and was refined with the help of various experts and librarians. The search strategy utilized Medical Subject Headings (MeSH) keywords as well as text in the title and abstract of the paper to locate as many of the publications as possible (see Appendix 6, Table A). The following databases were searched:

- MEDLINE
  [http://www.ncbi.nlm.nih.gov/pubmed/]
- Cochrane Library, (DARE, CENTRAL)
  [http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME]

- Register of clinical trials (ClinicalTrials.gov UAL)
  [http://clinicaltrials.gov/]

- EMBASE
  [http://www.embase.com/]

- PEDro
  [http://www.pedro.fhs.usyd.edu.au/redirect.html]

- MANTIS
  [http://www.healthindex.com/MANTISDatabaseOverview.html]

- PsychINFO
  [http://www.apa.org/psycinfo/]

- Clinical Evidence
  [http://clinicalevidence.bmj.com/ceweb/index.jsp]

- Cinahl
  [http://www.ebscohost.com/cinahl/]

The following keywords were used in the search: “whiplash injuries” (MeSH), “neck injuries” (MeSH), “spinal injuries” (MeSH) , “sprains and strains” each used in combination with “cervical,” “neck,” “whiplash syndrome,” “whiplash associated disorders,” “WAD,” “late whiplash syndrome,” “accidents, traffic” (MeSH), “motor vehicle accident” (according to the recommendations of the Cochrane Back Review Group (http://www.cochrane.iwh.on.ca/) for the search strategy “Part C: Specific search for neck problems” in MEDLINE and HealthStar (Ovid)).

The search strategy was expanded in an additional search to include literary search which aimed to match “whiplash injury” and “post traumatic stress disorders” (“anxiety,” “depression,” “trauma”).

Furthermore highly relevant articles were located with the help of the function “related articles” on the Pubmed research site of publications with a similar indexing.

Other studies were also considered important. These included systematic reviews, RCTs, and cohort studies concerned with whiplash syndrome which reported non-invasive clinical intervention in either German or English.

2.1.2.2 Query results.

Medline: Date 05/2009, Restriction: Data period 1999-2009

Table 1: *MEDLINE Query Results*

Search	Most Recent Queries	Results
#5	RCT AND whiplash injury	98
#4	Practice guideline AND whiplash injury	13
#3	Review AND whiplash injury	289
#2	Whiplash injury AND published in the last 10 years	1,085
#1	Whiplash	2,695

Cochrane Library, Edition 2, 2009, Restriction: Data period 1999-2009

Table 2: *Cochrane Library Query Results*

Search	Most Recent Queries	Results
	Cochrane Reviews (CDSR – Cochrane Database of Systematic Reviews)	6
	NHS-CRD-Dare Reviews (National Institutes of Health – Center for Reviews and Dissemination – Database of Abstracts of Reviews of Effects)	22
	Cochrane Library Central	151
	Technology Assessments (National Institutes of Health – Center for Reviews and Dissemination – Health Technology Assessment Database)	7

Embase, Restriction: Data period 1999-2009

Table 3: *EMBASE Query Results*

Search	Most Recent Queries	Results
#5	RCT AND whiplash injury	13
#4	Chronic AND whiplash injury	6
#3	Practice guideline AND whiplash injury	6
#2	Review AND whiplash injury	12
#1	Whiplash injury	1919

MANTIS, Restriction: Data period 1999-2009, 12 hits which were also listed in the MEDLINE database.

2.1.2.3 Inclusion Criteria.

Studies which were published from 1999 onwards were included. Earlier studies were considered if they reported on the conservative treatment with whiplash syndrome in systematic reviews or following scientific guidelines which are relevant for the development of the protocol of this study. Clinical trials written in German or English, systematic reviews, scientific guidelines published in peer-reviewed journals were taken into consideration. In addition unpublished manuscripts, studies and reports, together with extracts from books which were relevant for the protocol development of the study were included.

2.1.2.4 Exclusion Criteria.

Studies which reported on the clinical syndromes or contained data which did not refer to a clinical trial or the development of a study protocol were excluded. Symptoms like “pain,” “disability,” or “well-being” which did not arise from a “traffic accident” or “motor vehicle accident” were not considered. Non-conservative interventions (medication therapy, invasive procedures) or experimental trials (cadaver trials, crash test simulations or laboratory experiments) were also not considered.

All relevant studies and protocols were entered in “Endnote” with their abstract and wherever possible as a PDF file to allow for further evaluation during the protocol development.

2.1.3 Results.

Initially 75 of the extracted studies met the inclusion criteria and fulfilled the goal to determine the further development of the study protocol.

2.1.3.1 Terminology.

Whiplash injury of the cervical vertebrae is signified by a physical acceleration and deceleration trauma (Gay & Abbott, 1953). Spitzer et al. (1995) defines whiplash injury as:

> an acceleration-deceleration mechanism of energy transfer to the neck. It may result from rear-end or side-impact motor vehicle collisions, but can also occur during diving or other mishaps. The impact may result in bony or soft-tissue injuries (whiplash-injury), which in turn may lead to a variety of clinical manifestations called Whiplash-Associated Disorders.

This trauma turns the head, neck, and upper thoracic spine into a ballistic pendulum at the moment the movement (acceleration and deceleration) occurs. This is a consequence of the body regions being exposed to the differing strengths of velocity. This is, for example, the case when the torso is accelerated forward and the cranium due to its inertia, initially remains in its original position. Once the acceleration phase has come to an end, a counter motion occurs (rebound) due to the visco-elastic nature of the soft-tissue. As a consequence the neck vertebrae are at least either hyper-extended or hyper-flexed. The rebound motion can in certain circumstances be further exacerbated by acceleration or deceleration in the opposite direction to the original motion. An example of this mechanism is the injury suffered by a passenger in a stationary motor vehicle who has hit a car in front following a rear-end collision.

Certainly mechanical dislocation trauma can cause whiplash injury; however observations by Castro et al. (2001) are clearly indicative of a psychological effect regarding the symptoms of certain patients. In one trial a placebo rear-end collision was carried out on 51 volunteers. The patients were informed that a biomechanical collision would take place; whereas in reality the collision lay clearly under the threshold velocity. The trial resulted in 20% of the test subjects experiencing whiplash syndromes.

A special case of whiplash injury is the *Whiplash Shaken Infant Syndrome* producing injuries to the cervical vertebrae resulting from violent shaking of infants (Bonnier, Nassogne, & Evrard, 1995). Although research in to this tragic occurrence is of grave importance, it will not be discussed in this study.

2.1.3.2 Classification.

According to clinical criteria, soft-tissue injury is divided into three grades of injury, which is the clinical standard for all guidelines related to whiplash (Spitzer et al., 1995):

- Grade I: Microscopic lesions in the tissue but there is no occurrence of structural change. The pain is initially slight or not even present. Local tenderness may develop later as well as a trace edema.

- Grade II: Distinct strain on the soft-tissue structure but no tearing. Symptoms begin immediately after the injury. Obvious–yet not visible–swelling and restitutio ad integrum.

- Grade III: Disruption of the continuity of the soft-tissue structure. Symptoms begin immediately after the injury. Obvious swelling and discolorment. Recovery generally takes three to six months, but it is not always complete.

2.1.3.3 Epidemiology.

Due to the wide variability regarding the definition and diagnosis criteria of whiplash injury, exact data on the frequency of occurrence are hard to obtain. Undoubtedly there have been more cases in the last few decades; and it can be assumed that between 60 and 80% of those involved in motor vehicle accidents suffer injuries which are whiplash injuries. The incidents of these types of injuries are estimated to be 1-3.2/1,000 per year for European countries; and in Germany 80,000 to 250,000 such injuries occur each year (Jansen et al., 2008).

Around 60% of the affected patients are unable to work for a longer period of time because of the whiplash injury (Buitenhuis, de Jong, Jaspers, & Groothoff, 2009).

In Germany 18 to 25% of patients suffering from whiplash injury still have problems up to one year after the original incident (Schnabel et al., 2002). From an international perspective the proportion of patients who continue to suffer a loss of quality of life because of the complaint is estimated to be at around 10% (Barnsley, Lord, Wallis, & Bogduk, 1994). According to this estimation there are 8,000-25,000 new patients each year in Germany who require treatment for LWS. These figures compare well with actual US data, which shows between 14 and 42% of whiplash patients develop chronic

complaints (longer than six months); about 10% of them has constant, severe pain. Internationally the chronic complaints lie between 20 and 40% (Scholten-Peeters et al., 2003).

2.1.3.4 Symptoms and signs.

The most conspicuous symptoms–and by far the most common–are pain and stiffness in the neck region; the pain can also spread to the back of the head (less common in the temples and forehead) and the shoulders. With less severe cases these symptoms can be first felt with movement; with more severe cases the pain can also be felt at rest. The stiffness can appear some time after the pain. The frequency of the complaints is shown by a meta-analysis of the literature review. A meta-analysis of data of recent literature review pooled five clinical studies on the subject with 441 patients: Norris and Watt (1983) (n=61); Maimaris, Barnes, and Allen (1988) (n=102); Hildingsson and Toolanen (1990) (n=93); Radanov, Di Stefano, Schnidrig, and Ballinari (1991) (n=78); Drottning, Staff, Levin, and Malt (1995) (n=107). See Table 4.

Table 4: *Frequency of Whiplash-related Symptoms*

Symptom	**Total number**	**Prevalence (%)**	**Studies**
Neck pain	334	94	1–4
Neck stiffness	195	96	1, 3
Interscapular pain	107	35	5
Headache	334	44	1–4
Numbness/paraesthesia	232	22	1, 3, 4
Vertigo	232	15	1, 3, 4
Eye symptoms	232	12	1, 3, 4
Hearing symptoms	232	13	1, 3, 4
Sleeping problems	78	35	3
Memory problems	78	15	3
Signs of stress	107	30	5

Source: Adapted from Jansen et al. (2008).

2.1.3.5 Diagnosis.

In contrast to most other injuries, the structure of the trauma following a whiplash injury is largely unclear. Strictly speaking there is no bone damage, so that principally the damage in the synovial capsula, zygapophysial joints, ligaments, tendons, skeletal muscle, articular cartilage, spinal nerves and blood vessels are considered (Claussen, 1999). According to Wenngren, Pettersson, Lowenhielm, and Hildingsson (2002) some patients develop microscopic lesions in the brain stem region, which the authors believe may be connected with a poor prognosis.

X-rays are not diagnostically groundbreaking and merely serve as a way to verify any bone injuries. In addition other imaging procedures are often not very helpful: ultrasound can help with the identification of bleeding and damage to blood vessels;

however soft-tissue swelling, if present, is not in proportion to the severity of the injury. Furthermore the hemodynamic change described by Seric, Blazic-Cop, and Demarin (2000) is not corroborated in the literature. Although MRT examinations can be used to detect lesions in the Ligg. alaria (Krakenes et al., 2002), there is no clear relationship between them and the severity of the symptoms. It has yet to be investigated to what extent patients, with or without LWS, differ with regards to this change in the hemodynamism and laxation of the upper vertebral ligaments. Whiplash injury is first and foremost a clinical diagnosis (Volle & Montazem, 1997).

2.1.3.6 Burden of disease.

Given the apparent mild injury, the consequences are comparably serious. According to data from the Québec Task Force, the following work disability days occur (Spitzer et al., 1995):

- 50% of patients return to the normal daily routine within a month
- 26% are not capable of working between two to five months
- 12.5% (15.3% of the multiply injured) cannot work for over six months
- 1.9% are not able to work for more than a year.

2.1.3.7 Therapy.

Treatment of whiplash injury is interdisciplinary and multimodal. There is no clear data on pathogenesis; and hence there is no corresponding therapy guideline, that is the choice of treatment ensues empirically (Castro, Kügelgen, Ludolph, & Schröter, 1998). With respect to the three different grades of soft-tissue damage introduced earlier, the following recommended therapeutical interventions should be noted (Schnabel et al., 2002):

- Grade I: Normal activity preserved; reassurance and information; active movement and exercise of the cervical vertebrae; short-term mobilization or manipulation and traction; possibly analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) for a very short period of time. Examples for the single modalities which are frequently used in Grade I with vague efficacy are (Jansen et al., 2008):
    - soft cervical collar
    - warmth/cold
    - massage
    - acupuncture
    - diathermy
    - ultra-sound
    - laser
    - spray and stretch
    - electromagnetic therapy

The protracted application of passive treatment, medication, medical certificates for time off work, operations and immobilization in Grade I are contraindicated (Schnabel et al., 2002).

- Grades II and III: Activity restricted for some weeks; reassurance and information; soft collar for a maximum of 72 hours; active movement and exercise of the cervical vertebrae; short-term mobilization or manipulation and traction; on demand analgesics or NSAIDs for a few weeks. Surgical intervention in a few special cases, for example with progressive neurological symptoms. Examples for the single modalities which are frequently used in Grades II and III with vague efficacy are (Jansen et al., 2008):

- passive treatment
- long-term prescription of sedatives, tranquilizers, muscle relaxants and analgesics
- manual therapy over a longer time period
- infiltration and joint and soft-tissue injections

The application of passive treatment for more than three weeks as well as the long-term prescription of opiates and sedatives in Grades II and III are contraindicated (Schnabel et al., 2002).

A heuristic model below reveals the possible consequences of whiplash injury (

Figure 1):

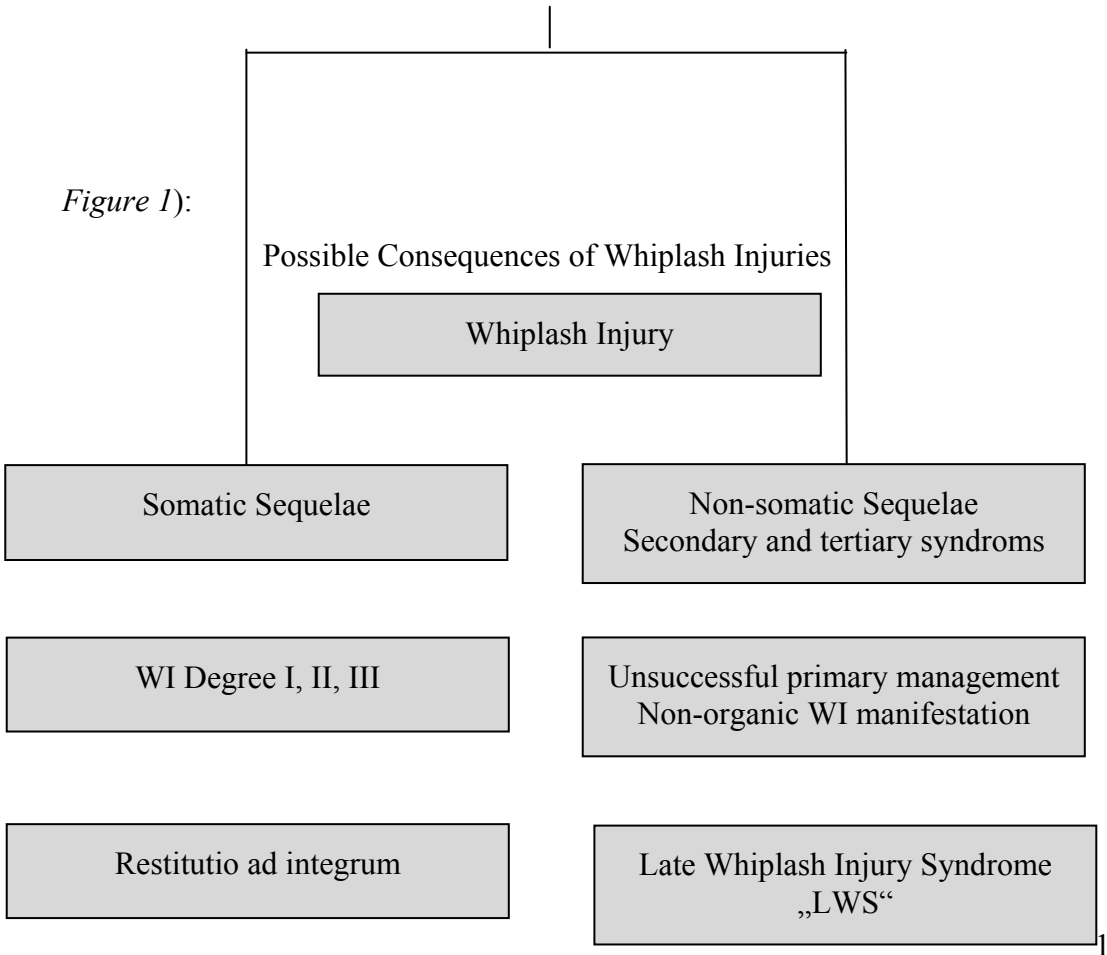

Figure 1: Heuristic model of whiplash injury prognosis (Kaiser et al., 2003).

It is difficult to provide a prognosis at the time of injury as to how the complaints will develop. The severity of the collision–typically indicated by the speed of the impact or the extent of the vehicle damage–is an inadequate predictor. It is preferable to establish a relationship with the severity of the initial symptoms, especially if there are neurological problems. Furthermore female patients and those who are older make prognosis more difficult; and also the influence of psychological factors, which can be difficult to quantify, are discussed in the literature.

The interaction between doctor and patient at the initial treatment stage appears to be significant. The Québec Task Force names the following iatrogenic factors which can impair the prognosis (Spitzer et al., 1995):

- Patient confusion through diagnostic uncertainty or incorrect diagnosis
- Over and under diagnosis
- A lack of or ineffective reassurance of the patient with regards to the long-term prognosis
- Contradictory treatment recommendations
- Protracted application of treatment methods, even if they are ineffective
- Over-prescription of medicine in regards to dosage and course length
- Reluctance to introduce a multi-disciplined diagnosis and treatment strategy

2.1.3.8 Prognosis.

Some patients of whiplash injuries develop chronic pain syndromes which can be both subjectively and socioeconomically debilitating. LWS is defined as a combination of various symptoms more than six months following the whiplash injury. Typical symptoms of LWS include (Balla, 1980):

- Pain in the head and neck
- Stiffness in the neck region
- Depression and anxiety

According to a psychophysiological study by Moog, Quintner, Hall, and Zusman (2002) the pain of at least some of the patients is related to the central nervous system and hence not the result of local morphological pain residue. This is also supported by the result of a study by Scott and Sanderson (2002), which excludes muscle damage as the cause of LWS.

Lesions and central nervous system dysfunctions are just as difficult to substantiate, even with the more meticulous imaging diagnostics (Radanov et al., 1999). A functional MRT study by Freitag, Greenlee, Wachter, Ettlin, and Radue (2001) shows however that patients with LWS have a functional disruption in the central nervous system, which is responsible for coordinating movement.

Whilst LWS symptoms are themselves interrelated, they are weakly correlated with objective physical or radiological symptoms after the motor vehicle accident. It is therefore generally difficult to provide a prognosis at the time of the actual accident concerning the risk of LWS occurring. Hijioka, Narusawa, and Nakamura (2001) find in a study of 400 patients the following risk factors:

- rear-end collision with much damage to the vehicle (MVC)
- patients over 30
- hospital stay following the accident

The factor of age is due to the fact that children and adolescents develop whiplash injuries after a rear-end collision less frequently and are also less likely than adults to suffer from the later syndromes which develop (Boyd, Massey, Duane, & Yates, 2002). Furthermore Suissa, Harder, and Veilleux (2001) identify that being a woman is also a factor which raised the risk of experiencing symptoms of pain following an accident.

According to Bonuccelli et al. (1999) a prevalence of vertebral spondylosis may unfavorably influence the prognosis as well.

When regarding psychosocial cofactors, one observation that can be made is that members of medical professions are more likely to develop acute symptoms after a rear-end collision than other occupational groups; however they are less likely to develop LWS (Virani, Ferrari, & Russell, 2001).

Bosma and Kessels (2002) show that patients with LWS clearly have a more pronounced tendency for somatization and a more active and stronger symptom-oriented coping style compared to other patient groups.

It is clear that not only psychological but also physical factors play a role in the pathogenesis of LWS, that is along with the symptoms themselves, it is also the manner in which the patient copes with the complaint. This led Balla (1982) to the hypothesis that the development of LWS predominantly depends on social variables. Soderlund and Lindberg (2001) independently reach the same conclusion that the examination and treatment of patients with LWS requires an integrated physiotherapeutic and cognitive-behavioral approach.

Therefore the treatment is by definition interdisciplinary; however an appropriate approach to treatment by no means equates to a guarantee of success (Sterner et al., 2001; Ferrari, 2002).

If the pathogenesis of LWS is taken into consideration, then it becomes obvious that treatment basically has to begin directly after the accident, so that the patients' "flawed" coping can be corrected (Provinciali, Baroni, Illuminati, & Ceravolo, 1996; Ferrari, 2002). Schnabel et al. (2002) for example achieve good results with early mobilization following whiplash injury. This observation also highlights that in principle treatment becomes more difficult the later it is deployed after the accident.

2.1.4 Résumé.

The systematic literature review was appropriate to identify studies which provide a detailed overview to the clinical relevance for the further steps to develop the study protocol.

2.2 Systematic Literature Review on the Osteopathic View on LWS

2.2.1 Objective.

The aim of the systematic literature review is not only to identify and extract osteopathic intervention studies from the past 10 years but also to summarize the results. The studies are clearly concerned with the treatment modality "osteopathic treatment" and "OMT" in whiplash syndrome. They should allow for a better clinical understanding and serve as a methodological statement for the formation of a new study protocol.

2.2.2 Methods.

Following from 2.1.2.1 the aforementioned search strategy was to search for studies up to 2009 using the MeSH "osteopathic manipulative treatment," "osteopathy," "osteopathic medicine," "osteopathic physicians" and "manipulation, orthopedic," as well as title words "manipulation(s)," and "manual therapy." In combination with keywords used in the first review on LWS: "whiplash injuries" (MeSH), "neck injuries" (MeSH), "spinal injuries" (MeSH) and "sprains and strains" each used in combination with "cervical." "neck," "whiplash syndrome," "whiplash associated disorders," "WAD," "late whiplash syndrome," "accidents, traffic" (MeSH), and "motor vehicle collision" (See Appendix 6, Table B). The following databases were searched:

- MEDLINE
  [http://www.ncbi.nlm.nih.gov/pubmed/]

- Cochrane Library, (DARE, CENTRAL)
  [http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME]

- Register of clinical trials (ClinicalTrials.gov UAL)
  [http://clinicaltrials.gov/]

- EMBASE
  [http://www.embase.com/]

- PEDro
  [http://www.pedro.fhs.usyd.edu.au/redirect.html]

- Clinical Evidence
  [http://clinicalevidence.bmj.com/ceweb/index.jsp]

- Cinahl
  [http://www.ebscohost.com/cinahl/]

Highwire.standford was specifically searched for Grey Literature (personal communication from the osteopathic indexer, Bob Sanders, of ATSU). Furthermore a manual search was carried out in any available standard osteopathic textbooks in English and German. The literature was supplemented with the MeSH "somatic dysfunction."

2.2.3 Query results.

The search in MEDLINE considering any aspect associated with osteopathy and related terms "OMT," "whiplash injuries," and all aspects of osteopathy revealed four sources, all of which were single case studies (Heilig, 1963; Magoun, 1964; Lalli, 1972; Harakal, 1975). An extended search with the keywords "manipulation, orthopedic" and "chiropractic" was carried out, which resulted in 28 hits where osteopathic treatment was not performed. The were no query results in peer reviewed journals of osteopathic clinical trials.

The hand searching hits of standard osteopathic textbooks were: Kuchera and Kuchera (1994); Kuchera and Kuchera (1996); Magoun (1998); Paoletti (2001); Ward, Hruby, Jerome, and Jones (2002); DiGiovanna, Schiowitz, and Dowing (2005); Johnston, Friedman, and Eland (2005); Parsons and Marcer (2005); Hinkelthein and Zalpour (2006); Nelson and Glonek (2007); and Richter and Hebgen (2007).

2.3 Review of Trials with Methodological Implications for the Planned Study

2.3.1 Objective.

In this review clinical trials of the treatment of WAD or LWS were evaluated concerning methodological aspects potentially relevant for the protocol development, for example: cohort characteristics; inclusion and exclusion criteria; modality of intervention; duration and frequency of interventions; onset on therapy after MVC; outcome measurements; and sample size.

2.3.2 Methods.

2.3.2.1 In-/exclusion criteria.

The following selection criteria were employed for evaluating the literature:

- Controlled clinical trials and cohort studies which studied the effect of conservative treatment procedure of whiplash syndrome or whiplash associated disorders in Grades WAD I und II.
- Only studies with control groups made up of conservative treatments modalities (vs. no treatment, vs. placebo) were included in the selection. Included in the conservative treatment modalities were osteopath or osteopathic treatment (OMT); chiropractic (SMT); manipulation and mobilization; orthopedic (SMM, MT); physiotherapy; and rehabilitation.

- At least one clinically relevant outcome variable had to have been examined as a feature of the study[1]: perceived pain; neck related disability; global functioning; or well-being (depression, anxiety, fear avoidance). Furthermore the measured instruments had to be identifiable.

Studies which investigated the parameters "period of disability," "missing time at work," "cost effect," "adverse effect," or "harm" were not included and nor were single case studies or studies which deployed an intervention that was not conservative.

2.3.2.2 Operationalization.

All studies identified in systematic review as shown below were screened for methodological aspects. The study selection was conducted according to the described inclusion and exclusion criteria. Each study was classified in a journal text and assigned to the following variables: "author"; "year of publication"; "title of the study"; "type of study design"; "outcome"; "operationalization"; "time since whiplash injury"; "type of intervention"; and "number of participants." The assessment of the methodological quality of the study–based on an quantitative inspection and extraction of the study variables–was not the subject matter of this examination (Appendix E: Characteristics of Included Studies).

2.3.3 Results.

In total 49 randomized clinical intervention studies on the effect of different therapy were reviewed. Furthermore six cohort studies on observations of whiplash patients over time, two methodical studies on the validation of questionnaires, and two study protocols on conduction clinical trials involving whiplash injury were reviewed and

[1] There was no difference for the outcome variables whether the parameters measured were primary or secondary.

a variety of potentially relevant information (see variables listed above) were extracted and entered into a database.

2.3.3.1 Construct dimensions and outcome measurement.

Independent of whether primary or secondary outcome parameters were actually investigated, they were classified into seven groups to evaluate the identified outcome variables: disability, emotional well-being, global functioning, pain intensity, pain quality, range of motion (ROM), and self perceived recovery (Berzon, Hays, & Schumaker, 1993).

2.3.3.2 Methods of measurement.

Table 5 displays the distribution of the outcome variables, and most studies captured several variables. The most common was pain intensity (32.8%), followed by disability (21.5%) and ROM (17.2%). The assessment of emotional well-being (11.8%) occurred just as frequently as global functioning. Self-perceived recovery and pain quality were only seldomly examined.

Table 5: *Frequency of Outcome Variables*

	Frequency	**%**
Pain intensity	61	32.8
Disability	40	21.5
ROM	32	17.2
Global functioning	22	11.8
Emotional well-being	22	11.8
Self perceived recovery	5	2.7
Pain quality	4	2.2
Total	186	100.0

Allocating the outcome variables to the utilized assessment instruments resulted in the following classification shown in Table 6:

- Self perceived recovery was generally measured with the Likert Scales (80%). This involves a scale with which respondents specify their level of agreement to a statement. The possible answers are predetermined and are either numbers or words which are increasing in intensity along a horizontal axis.

- ROM was almost entirely measured with various technical equipment (87.5%); of these the goniometer was used the most frequently. It is a geometric instrument which is attached to the head and held in place with pins and measures the ROM, which is the mobility of the head in relation to the shoulder girdle. This is possible for all six directions of head movement (Mealy, Brennan, & Fenelon 1986).

- Global functioning was mostly measured with the SF-36 (77.3%) as well as the short form, the SF-12 (9.1%). The validated SF-36 is a standardized questionnaire to capture the health-related quality of life. It comprises eight subscales which can be further divided into two groups: psychological and physical. The values entered in the questionnaire form a quantitative representation of the subjective health from the

view of the respondent. Reliability and validity of the procedure is considered to be good–also when evaluating patients with back pain. Furthermore it can be used for telephone screening (McHorney, Ware, & Raczek, 1993; McHorney, Ware, Lu, & Sherbourne, 1994; Zwingmann, Metzger, & Jäckel, 1998).

- In 77% of the cases the subjective perceived pain intensity was obtained using a numerical (NRS) or visual analogue scale (VAS). Both forms of the scale allow patients to categorize the pain between the range of "0" (no pain) and "10" (maximum pain). Both scales also have an excellent construct validity and display a high correlation with each other (Neugebauer, Ure, Driever, & Troidl, 1994); and hence the choice of assessment instrument depends on practical considerations (Jensen, Karoly, & Braver, 1986). The Likert Scales are clearly used much less frequently (13.1%).

- Pain quality was mostly measured with the McGill Pain Questionnaire (75%), which is based on a questionnaire filled in by the patient, covering three verbal descriptors: sensory, affective, and evaluative. Accordingly the pain intensity and also how the pain develops over time is measured using the Pain Rating Index (PRI).

As concerning the ranking of the assessment instruments with disability-related functional impairment, the Neck Disability Index (NDI) was used in 45% of the cases and the WDQ in 10%. In principal both are based on the very well-established Oswestry Index; however the WDQ focuses more on whiplash related complaints.

The WDQ is a modified 13-item version of the NDI. The scale is comprised of 13 items with a rating of 0 to 10, where a higher number indicates a stronger impairment. The WDQ is shown to be validated with regards to content, construct, and internal consistency (Pinfold et al., 2004) and a validated German translation exists (Vernon, 2008). Furthermore it can be used for telephone screening.

How emotional well-being was measured varied greatly. The most frequently used instrument was the Likert Scales (13.6%). Another questionnaire used (9.1%) was the Beck Depression Inventory (BDI), which is a self-evaluative test developed by Beck,

Ward, Mendelson, Mock, and Erbaugh (1961) to measure the extent of depressive symptoms. The BDI is validated, reliable, consistent, and sensitive, and therefore a highly practical instrument (Sullivan, Adams, Rhodenizer, & Stanish, 2006). It contains 21 groups of statements (A-U), within each there are four possible replies (0-3), which describe the intensity of the item. The respondent chooses the response which has been the most fitting in the last seven days.

Table 6: *Distribution of the Most Frequently Employed Assessment Instruments by Outcome Variable*

Outcome variable	**Measurement tool**	**Frequency**	**Percentage**
Pain intensity	VAS/NRS	47	77
Disability	NDI	18	45
Global functioning	SF-36	17	77.3
Range of motion	Technical devices* Likert Scales WDQ	12 8 4	87.5 13.1 10
Self perceived recovery	Likert Scales	4	80
Emotional well-being	Likert Scales	3	13.6
Pain quality	McGill Questionnaire BDI SF-12	3 2 2	75 9.1 9.1

Note: * Goniometer, 3 D, Inclinometer

2.3.3.3 Modalities of intervention.

To evaluate the different intervention modalities each of the interventions extracted from the studies were classified as either an active or a passive modality. This partitioning results from a recommendation to evaluate the different types of intervention modalities specifically for the effects of the therapies in systematic reviews (van Tulder, Malmivaara, Esmail & Koes, 2000; Verhagen, Scholten-Peeters, van Wijngaarden, de Bie, & Bierma-Zeinstra, 2007). Hence all interventions which were performed on patients without their active participation were denoted as a passive modality. Among these were manipulation; passive guided mobilization and manual therapy; and massage and electrotherapy (Brosseau et al., 2002; Dehner et al., 2009). In contrast interventions which the patients themselves carried out were classified as an active modality (Vernon & Humphreys, 2007; Dehner et al., 2009). Studies in which combinations of simultaneous active and passive modalities of treatment were applied in one study arm were counted as

an active modality. “Usual care,” “wait and see,” and “no treatment” were not classified, as they did not deal with any kind of therapeutic intervention.

Table 7 shows that in the literature examined active interventions at 54.2% are more common than passive (45.8%).

Table 7: *Number of Intervention Modalities Within Groups*

	Frequency	Percentage
Active	32	54.2
Passive	27	45.8
Total	59	100.0

Osteopathic treatment is seen as a passive intervention modality as described in the osteopathic studies from Kaiser et al. (2003), Schwerla et al. (2008), and Tempel, Steffen, Ruetz, and Schwerla (2008).

For the selection of suitable assessment instruments for an osteopathic intervention study, the observation therefore seems sensible to look for the distribution of outcome variables, utilized assessment instruments, and modalities of intervention. When modality of intervention is compared to outcome variable, which can be seen in Table 8, disability (20.5%) and ROM (19.3%) are found more frequently with active intervention modalities than passive (16.7% in both variables). On the other hand global functioning (12.5 vs. 16.7%) and self-perceived recovery (1.1 vs. 4.2%) are found more often with passive intervention modalities. For the other outcome variables there is little difference between the two forms of intervention modality (see Table 8).

Table 8: Distribution of Outcome Variables by Intervention Modality Within Groups

		Modality of intervention		Total
		Active	Passive	
Outcome Variable	Disability	18 (20.5%)	12 (16.7%)	30 (18.8%)
	Emotional well-being	9 (10.2%)	7 (9.7%)	16 (10.0%)
	Global functioning	11 (12.5%)	12 (16.7%)	23 (14.4%)
	Pain intensity	30 (34.1%)	24 (33.3%)	54 (33.8%)
	Pain quality	2 (2.3%)	2 (2.8%)	4 (2.5%)
	ROM	17 (19.3%)	12 (16.7%)	29 (18.1%)
	Self-perceived recovery	1 (1.1%)	3 (4.2%)	4 (2.5%)
Total		88 (100.0%)	72 (100.0%)	160 (100.0%)

The outcome variables with regards to the degree of chronicity for acute (and chronic) are presented in Table 9. It should be noted that descriptive pain intensity, with 36.0% (30.0); ROM, with 22.0% (11.7); and self-perceived recovery, with 3.0% (1.7) are used primarily in cases of acute whiplash injury. In contrast disability (17.0 vs. 21.7%), global functioning (11.0 vs. 20.0%), emotional well-being (9.0 vs. 11.7%), and pain quality (2.0 vs. 3.3%) appear more often in cases of chronic whiplash injuries.

Table 9: *Distribution of Outcome Variables by Degree of Chronicity Within Groups*

		Degree of chronicity		Total
		Acute	Chronic	
Outcome Variable	Disability	17 (17.0%)	123 (21.7%)	30 (18.8%)
	Emotional well-being	9 (9.0%)	7 (11.7%)	16 (10.0%)
	Global functioning	11 (11.0%)	12 (20.0%)	23 (14.4%)
	Pain intensity	36 (36.0%)	18 (30.0%)	54 (33.8%)
	Pain quality	2 (2.0%)	2 (3.3%)	4 (2.5%)
	ROM	22 (22.0%)	7 (11.7%)	29 (18.1%)
	Self-perceived recovery	3 (3.0%)	1 (1.7%)	4 (2.5%)
Total		100 (100.0%)	60 (100.0 %)	160 (100.0%)

Table 10 shows a significant correlation between the modality of intervention and the degree of chronicity of the dysfunctions: 65.8% of active intervention modalities occur with acute symptoms; compared to 66.7% of passive intervention modalities in the case of chronic symptoms ($Chi^2=5.74$; $p=0.017$).

Table 10: *Treatment Modality and Chronicity*

		Degree of chronicity		Total
		Acute	Chronic	
Modality of intervention	Active	25 (65.8%)	7 (33.3%)	32 (54.2%)
	Passive	13 (34.2%)	14 (66.7%)	27 (45.8%)
Total		38 (100.0%)	21 (100.0%)	59 (100.0%)

2.3.3.4 Consideration of placebo effects.

In principal the choice of a suitable placebo/sham treatment for studies on the efficacy of osteopathic manipulative treatment is not without its problems: ideally the placebo should raise the same expectations of success in the patients as the verum; simultaneously however there must not be any specific effects on the complaint itself (Fulda, Slicho, & Stoll, 2007). There have been hitherto relatively few studies which compare an osteopathic verum treatment to a placebo which mimics osteopathic treatment (Table 11).

Table 11: *Placebo Controlled Trials in Osteopathic Medicine*

Author(s)	**Placebo modality**	**Number of cases**	**Result**
Hoehler, Tobis, and Buerger (1981)	Soft-tissue massage	56 verum 39 placebo	No significant difference, substantial improvement in both groups
Gibson et al., (1985)	Short-wave diathermy	39 verum 33 placebo	No significant difference, substantial improvement in both groups
Licciardone et al., (2003)	Range of motion activities, light touch, and simulated OMT*	39 verum 33 placebo	No significant difference, substantial improvement in both groups

*Simulated OMT "consisted of manually applied forces of diminished magnitude aimed purposely to avoid treatable areas of somatic dysfunction and to provide minimal likelihood of therapeutic effect" (Licciardone et al., 2003)

In contrast to the findings by Licciardone (2007), the effectiveness of osteopathic treatment compared to placebo treatment has yet to be conclusively proven. This may well be because the placebo modalities carried out in Table 11 may also have specific effects (perceived placebo) and are therefore only suitable to a limited extent as a placebo for an osteopathic study design (Ernst & Resch, 1995). This is shown particularly clearly by the citied study from Licciardone et al. (2003), in which a study arm with untreated patients

was included alongside the sham treatment. The untreated patients showed no signs of improvement; whilst the results of the sham and verum treatments did not differ.

We will have to wait and see to what extent the sub-therapeutic ultra-sound treatment differs from other placebo modalities in measuring effectiveness against verum intervention. Therefore the only current acceptable possibility to test the effectiveness of osteopathic treatment is comparing untreated patients in a waiting list design.

2.3.4 Discussion.

The intervention studies examined indicate that in those concerned with whiplash injuries, active intervention is used more frequently than passive as a treatment modality. Furthermore active interventions are more commonly used in acute cases; passive interventions are more common in chronic ones. Outcome variables such as pain intensity, disability, and range of motion are the most commonly studied outcomes, followed by emotional well-being and global functioning. The instruments utilized here are visual analogue and numerical rating scales.

Neck disability impairment is predominantly measured with the NDI, which captures the range of motion with the aid of technical equipment, such as a goniometer. Global functioning is measured either with the SF-36 or the shorter version, the SF-12; less common is the Likert Scales. Emotional well-being, self-perceived recovery and pain quality–isolated with a suitable assigned outcome instrument–play a minor role. This appears at first glance strange as some published studies investigate the form of the emotional strain (emotional well-being), which however are measured with the Likert Scales instead of the proper valid instruments, for example the BDI, the Depression Anxiety Stress Scale (DASS), or the Hospital Anxiety and Depression Scale (HADS). Compared to these instruments, which give some good idea of the prevalence and distribution of the symptoms, the Likert Scales in contrast are bipolar, scaled assessment instruments and can lead to deviations from the mean. Moreover there is hardly any

information with regards to validation and reliability because the Likert Scales are often designed ad-hoc.

The WDQ has been specifically developed from the NDI for whiplash injury (Pinfold et al., 2004). It has been described in only one study protocol and has yet to be used in a clinical study.

A structured review of each included study was compiled, which allowed a transparent quantification and assessment of the outcome variables used and the corresponding instruments. The focus was on instruments used in conservative intervention modalities on the treatment of whiplash syndrome.

2.3.4.1 Operationalization.

The systematic preparation of the studies and the quantitative statistical classification in the above-mentioned groups were shown to be appropriate. Thereby any correlation could be observed between the measure instrument and frequency of the studied outcome measures. Further correlation was investigated with the state of health "acute" or "chronic." This classification is justified because some authors speak in favor of using different treatment modalities when faced with measuring the effect of therapy from the application of treatment modalities in treating acute versus chronic whiplash injury. The effects of therapy generated by comparable modalities of treatment differ between acute and chronic patient groups (Verhagen et al., 2007; Vernon & Humphreys, 2007).

Furthermore the question is which outcome variables are most suitable to measure the osteopathic treatment response and how the treatment modality effects arise (mode of action).

2.3.4.2 Outcome variables.

The systematic preparation of the outcome variables were shown to be both helpful and necessary when considering the study question. It enabled a representative view of the distribution of the commonly used outcomes to be determined. The classification in seven groups proved to be necessary for the observation and evaluation of each of the outcome variables. Each of these variables can be assigned to an assessment instrument without it losing its validity. Well-being was composed of pain, depression and other psychological impairment partly generated from global functioning from the SF-36 as described by the study author.

Post Traumatic Stress Disorder (PTSD) is examined in detail in only two studies (Kaiser et al., 2003; Holm et al., 2008). The connection between chronic pain and the psychological symptoms associated with whiplash injury is the subject of much discussion and the focus of much research; however the studies reviewed have not provided a clearer picture (Sullivan et al., 2006; Vernon, 2008). The explanation for this is that the participants in the studies are categorized as "non-psychiatric medical patients." Furthermore the psychosocial factors which accompanied the PTSD were essentially not the study question in most of the trials. In addition these intervention studies were neither conducted nor supervised by qualified psychologists or psychiatrists.

2.3.4.3 Outcome measurements.

The systematic preparation of the assessment instruments is a result of the classification of the determined outcome variables. All the assessment instruments used are–with the exception of the Likert Scales–validated, reliable and responsive assessments, and they are also available in German. They are able to describe specific illness-related symptoms and how they develop during the period of study and follow up.

2.3.4.4 Modalities of intervention.

Only studies with conservative modalities of intervention were included: studies with mono-modal interventions (chiropractic, osteopathy, manual therapy, traction, therapeutic ultrasound, and TENS) and multi-modal interventions (active physiotherapy per-protocol, therapeutic exercises in combination with apparatus-aided training or combined with forms of electrotherapy (TENS and TUS), home exercises and various forms of instruction (pamphlets and videos). It remains to be determined whether an increasing number of multi-modal intervention forms which have appeared in trials in recent years are simultaneously being applied in practice in study arms (Cote, Cassidy, Carroll, Frank, & Bombardier, 2001; Miettinen, Leino, Airaksinen, & Lindgren, 2004; Rebbeck, Refshauge, Maher, & Stewart, 2007; Stewart, Maher, Refshauge, Bogduk, & Nicolas, 2007).

2.3.4.5 Assignment of outcome variables to assessment instruments.

Suitable outcome variables and the corresponding assessment instruments for conservative intervention treatment of patients with chronic whiplash syndrome were selected after analysis of the literature revealed the following recommendations. Under the assumption that the osteopathic treatment takes the form of a passive modality of intervention, the following outcome variables should be measured with the respective instruments: pain intensity with the VAS/NRS; neck specific disability with the NDI; and global functioning with the SF-36 or SF-12. The question is whether the WDQ as a specific-disability designed questionnaire can replace the NDI when examining whiplash injury patients (Pinfold et al., 2004; Vernon, 2008).

Studies were found on the evidence about the effectiveness of therapeutic modalities of manual therapy and chiropractic with whiplash syndrome (Seferiadis, Rosenfeld, & Gunnarsson, 2004; Verhagen, Scholten-Peeters, de Bie, & Bierma-Zeinstra, 2004); however only one unpublished pilot study on the effectiveness of osteopathic treatment on whiplash injury was able to be identified (Kaiser et al., 2003).

If one examines the outcome variables and assessment instruments in osteopathic studies previously conducted on chronic non-specific neck pain (Schwerla et al., 2008; Tempel et al., 2008) and chronic low back pain (Licciardone, Brimhall, & King, 2005), pain, illness-related disability and global functioning are all found to be parameters in these studies.

2.3.4.6 Résumé.

Due to a scarcity of osteopathic studies dealing with this topic, it is not possible to reliably determine the usefulness of different outcome variables and assessment instruments and their use in osteopathic environment (Vaughan & DiVenuto, 2004).

The distinction made between active and passive forms of intervention is a prerequisite for the selection approach of outcome variables and assessment instruments of this study protocol.

For a clinical intervention study on an osteopathic treatment approach for whiplash injury, the following outcome variables are proposed as end points and applied in this study protocol:

- Perceived pain intensity with VAS 1-100
- Whiplash-specific disability with the WDQ as an extension of the NDI
- Global functioning with SF-36 or SF-12
- Well-being with the BDI

2.4 Somatic Dysfunction, Trauma and Whiplash Injuries Under Osteopathic Considerations

The theoretical focus of this chapter underlies considerations of the osteopathic principles and somatic dysfunctions to which osteopathy is applied on patients. These principles are defined by the founder of osteopathy, Andrew Taylor Still, and they are based as philosophical aspects for good clinical practice to the osteopathic community (Lane, 1918; Ward, 2003):

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.

Somatic dysfunction as a disorder in body structure is described by Korr (1997):

> 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.

Whiplash injury is generally classified as trauma typically depending on how it occurred. Trauma could for instance refer to a lesion or wound. The term concerns not only physical injury resulting from an external force but also a psychological injury in the sense of shock (primary trauma) (Seidler, 2002). Whiplash-related convalescence is not only a question of local somatic dysfunction; it is more often the case with persistent

whiplash that there is no adequate functional correlation with the overall pain intensity reported by the patients. The osteopathic approach to "somatic dysfunction" offers the possibility of a conceptional treatment application in this field, even though no experimental evidence so far exists for this model applied in the treatment of whiplash syndrome.

Experiencing and witnessing traumatic situations is part and parcel of being a human being. How this trauma is dealt with varies from person to person; and it is independent of the physical and psychological state of the individual affected.

2.4.1 Physical trauma response.

The different types of body tissue are able to react to an external force with adaptation and compensation. Hence the successful adaptation depends not only on the strength and direction of the force but also the physiological state (muscle hypotonus or hypertonus, defects already present, e.g. in the form of degenerative changes) of the affected region (Barral & Croibier, 1999; Poorbaugh, Brismée, Phelps, & Sizer 2007). According to the hypothetical model of some osteopaths, the kinetic energy which the body cannot release through either adaptation or compensation is absorbed and locked in the connective tissue of the body region affected. This means that this energy, which is not released, is stored in the body in the form of an *energy cyst*, and so the dissipation of the energy is prevented (Upledger, 1990; Paoletti, 2001). This energy cyst can develop over time into a source of irritation for vegetative structures; hence it can cause many symptoms in various body regions–also in those far removed from the original source (van Buskirk, 1990; Strittmatter, 1998). The traumatized tissue leads to viscerosomatic irritation by restriction of the nutritive function in different body regions. The clinical consequence is the development of organ pathology and associated structures (Magoun, 1976).

2.4.2 "Body memory."

Becker describes the human body as an integrated, dynamic functioning unit, which is completely affected, that is in its entirety, by traumatic events (Becker, 1959, 1965). Smith is also of the opinion that the human body can be considered as an extensive energy body with different levels and energy fields (Chaitow, 2001). Indisputable is the fact that the human body stores traumatic events (stress); hence Becker coined the phrase *tissue memory* (Frymann, 1998). Becker assumes that together with the memory and decision function of the central nervous system (CNS) (Upledger, 1987), there is also a storage mechanism known as tissue memory, which is independent of the CNS (Korr, 1997).

Selye (1976) develops these ideas further and comes to the conclusion that tissue memory serves simultaneously as both storage and protection pattern for future somatic behavior. The traumatization is stored in the tissue and the nervous system, and it is retrievable at anytime.

2.4.3 Osteopathic treatment of trauma-related dysfunctions.

There is agreement in the osteopathic literature that with regards to the traumatic irritation, the region of pain should not be the only focus of examination and treatment, but rather the referred pain and irritation need to be taken into consideration (Paoletti, 2001; Ward, 2003; Liem, Sommerfeld, & Wührl, 2008).

Also an injury which occurred some time in the past and apparently seems to have healed without any problems can develop into somatic dysfunction over time. Often the sources are clinically inactive, but there is a direct causal link with the acute complaints of the patient (Strittmatter, 1998). Based on the view that trauma places a strain on the entire body, one can conclude that the sources of trauma or dysfunction are not necessarily identical to the topography of the region of pain or dysfunction: they are often localized outside the region of pain; however they are still connected to the primary source of traumatization (Harakal, 1975; Frymann, 1998; Barral & Croibier, 1999). The comparison

with tension-coupled patterns of motion of a tensegrity system can illustrate here the model of somatic dysfunction and the clinical correlation (Ward, 2003; Lee, 2005; Pflüger 2008).

Only if the dysfunction and their associated restrictions are identified, is it possible to heal the organism with osteopathic treatment. By activating the blocked self-healing powers of the patient through special osteopathic techniques, the traumatized energy can be integrated in the body and released. A structural reintegration takes place here, in which the original energy cyst is replaced by a new, more suitable one (Chaitow, 2001; Lee, 2005). The irritation of the associated CNS is reorganized, providing that the original function of the damaged region is restored (van Buskirk, 1990; Paoletti, 2001).

2.4.4 The "somatic dysfunction" as an explanatory model of trauma consequences.

According to Burns, Chandler, and Rice (1948) and Lee (2005) this symptom complex is an expression of structural and functional tissue and cell membrane change, which osteopathy first defined as *osteopathic* or *bony lesion* and later as *somatic dysfunction* (Ward, 2003). This also includes: impaired or altered function of related components of the somatic (body framework) system; skeletal, arthrodial, and myofascial structures; and related vascular, lymphatic and neural elements. This view excludes an organic pathology in the sense of tissue–and hence cell–damage. Functional impairment is assumed and is defined by the following changes (Nelson & Glonek, 2007):

Biomechanics

1. The position of the element as determined by palpation and referenced to its adjacent structure
2. The directions in which motion is freer
3. The directions in which motion is restricted

Tissue tension

- Tissue texture abnormality
- Asymmetry of position
- Restriction of motion
- Tenderness

These four diagnostic criteria are abbreviated as the acronym TART (Nelson & Glonek, 2007; Ward, 2003).

The functional tissue stress resulting from whiplash injury can be assigned to the *Quebec Severity Classification of Whiplash Associated Disorders* (Table 12, Spitzer et al., 1995) and to types of somatic dysfunction (Nelson & Glonek, 2007).

Table 12: *Case Definitions of WAD*

Term	Definition
WAD Grade 0	No neck complaints or signs
WAD Grade I	Complaint of pain, stiffness or tenderness, but no physical signs
WAD Grade II	Complaint of pain, stiffness or tenderness, and musculo-skeletal signs (decreased range of motion, point, tenderness, etc)
WAD Grade III	Complaint of pain, stiffness or tenderness and neurological signs (decreased or absent deep tendon reflexes, weakness and sensory deficits). Could also have musculo-skeletal signs.
WAD Grade IV	Fracture or dislocation
LWS	Presence of pain, restriction of motion or other symptoms at six months or more after the injury, sufficient to hinder return to normal activities such as driving, usual occupation, and leisure

The hypothesis is that somatic dysfunctions as described by Nelson and Glonek (2007) can be assigned to Grades I and II of whiplash symptoms according to Spitzer et al. (1995). Table 13 details the combination of both aspects with regards to the whiplash target population. This is an attempt to combine somatic dysfunction with the

classification of WAD by Spitzer et al. (1995). Accordingly the types of somatic dysfunction mirror the WAD classification. Thus each type of somatic dysfunction has a counterpart to Grades I and II of whiplash injury.

Table 13: *Synopsis of Somatic Dysfunction and Associated WAD Classification*

Type	**Impairment**	**Somatic dysfunction - Tissue stress -**	**Relation to WAD classification and course**	**Osteopathic aspects**
Acute somatic dysfunction	Short-term	Altered components of body framework	I-II acute	Local mechanic segmental dysfunction
Chronic somatic dysfunction	Long-term	Altered components of body framework	I-II chronic	Persisting segmental dysfunction -postural stress -increase of neural response
Primary somatic dysfunction	Primary to etiology: -Initial-	Total pattern of body dysfunction	I-II acute-chronic	General mechanic -(traumatic) increase of neural response
Secondary somatic dysfunction	Secondary to etiology -subsequent-	Altered components of body framework	I-II chronic	Persisting segmental dysfunction -impedance or facilitation of autonomic pathways

Grades I and II are mainly the whiplash population who are included in conservative clinical intervention trials without any contraindication for treatment (Verhagen et al., 2007).

Somatic dysfunction is a concept of patient testing and test-dependent osteopathic treatment. Thus diagnostic as well as intervention occurs according to these principles. With regard to whiplash injury, Fryer, Morse, and Johnson (2009) describe "functional disturbance to tissues of the musculoskeletal system and related vascular and neurological components amenable to osteopathic manipulation" as a core aspect and hence forms the basis for developing this study (Willard & Patterson, 1994).

According to the synopsis the following procedure is necessary to develop a standardized osteopathic examination form.

2.4.5 Development of a Standardized Osteopathic Examination Form (SOEF).

With regards to data collection and documentation together with statistical evaluation, a consistent, standardized examination form should be the basis of the protocol and take the following requirements into consideration:

- Suitable, consistent recording and evaluation of patient data
- Uniform research infrastructure among cooperating osteopathic research groups for a multi-center study
- The tool must be appropriate to describe the number, exact localization, and the changes at the time of measurement of the examined and treated body regions and their dysfunctions. Furthermore the treatment techniques used have to be clearly documented to the dysfunctions in the form
- The collected data have to be able to be evaluated statistically

Moreover the central requirements for an osteopathic study protocol which apply are (Gerber & Miller, 1960; Cisler, 1994):

- The ability to model the osteopathic principals under investigation
- The illness-specific classification of the structures which are described in the osteopathic literature as somatic dysfunctional regions

These requirements meet the criteria of the AAO developed *Outpatient Osteopathic SOAP Note Form Series* (SNF-2E), which is a standardized validated documentation tool for the use in clinical trials. In addition its use is also recommended in the collection of patient data in clinical studies (Sleszynski, Glonek, & Kuchera, 2004). It is available in an electronic format (eSOAP) and can be used in collecting and evaluating

large data samples. As this tool is explicitly approved for modified applications, it is suitable for the collection of data for a specific osteopathic protocol (Nelson & Glonek, 2007).

In addition to this form, the body regions, structures, and the tests used which were describe in the osteopathic literature as being connected with mechanical trauma or whiplash syndrome were extracted. Twenty-five different regions were able to be distinguished. The examined regions were classified topographically to the individual body regions and structures; and the tests described were listed as single items in the form. These single items were classified with regards to the TART scoring system. Thus the quality of functional impairment was able to be tested (Nelson & Glonek, 2007).

This protocol procedure and design of the examination form was discussed with other osteopaths and designed as a SOEF (the feasibility of the protocol has already been successfully verified in a pilot study (Kaiser, 2003)). The following is a result of this procedure:

Topography of the SOEF		
Region	Test	Numbers
Cervical spine, (*arteria vertebralis*)	Safety Tests	(n=6)
Cervical, thoracal lumbal spine	Mobility (TART)	(n=14)
Sacrum, coccyx	Mobility (TART)	(n=2)
Visceral stucture	Mobility (TART)	(n=2)
Cranium, mandibula	Mobility (TART)	(n=5)
Hyoideum, clavicula, sternum	Mobility (TART)	(n=7)

1. Cervical spine: global compression (Frisch, 2001)
2. Cervical spine: global traction (Frisch, 2001)
3. Arteria vertebralis: De Klejyn-haemodynamic testing (Licht, Christensen, Svendensen, & Høilund-Carlsen, 1999)
4. Segment C1-C2: hypermobility/lateral testing (Sammut & Searle-Barnes, 2000)
5. Segment C2-C1: hypermobility/anterior-posterior testing (Greenman, 1998, p. 113)
6. Compression of the SSB: testing (Magoun, 1976, p. 135)
7. Os temporale: testing (Magoun, 1976, p. 153)
8. Sutura occipitomastoidea: testing (Magoun, 1976, p. 155)
9. Dura mater spinalis: testing for restriction (Upledger & Vredevoogd, 1994, pp. 89-90)
10. Lig. cervicopleurale: testing for restriction (Barral, 1991, p. 128)
11. Clavicula: testing for compression/decompression (Barral, 1991, pp 112-113)
12. Mandibula: testing for compression (Upledger & Vredevoogd, 1994, pp. 208-209)
13. Os hyoideum: testing for restriction (Paoletti, 2001, pp. 230-231)
14. Ventral cervical fascia: testing for restriction (Barral, 1991, p. 125)
15. Sternum: testing for restriction/lift (Ward, 2003, pp. 724-725)
16. Sternum: testing for intraosseous tension (Ward, 2003, pp. 724-725)
17. Lig. sternopericardiaca: testing for restriction (Barral, 1991, p. 119)
18. Gastric cardia: testing for restriction (Barral, 2002, p. 104)

19. Kidney mobility: testing for restriction (Barral, 2002, p. 180)

20. Cervical spine: testing for segmental mobility/C-0 to C-7 translation test (Greenman, 1998, pp. 206-212; DiGiovanna et al., 2005, pp. 132-136)

21. Thoracic spine segment/Th1-Th2: mobility test (Greenman, 1998, p. 234)

22. Ribcage/costa 1-costa 3: mobility test (Greenman, 1998, pp. 268-270)

23. Lumbar spine/Th 12-L1: mobility test (Barral, 2002, pp. 47-48)

24. Os sacrum: testing for mobility/restriction (DiGiovanna et al., 2005, pp. 315-316)

25. Os coccygis: mobility test (Peeters & Lason, 1994, p. 255)

All regions were tested according to TART qualities (Tissue texture abnormality, asymmetry of position, restriction of motion [right – left], tenderness) (see osteopathic examination form).

The tests were conducted in accordance to *Section VII Osteopathic Considerations in Palpatory Diagnosis and Manipulative Treatment* (Ward et al., 2002).

This osteopathic protocol form serves as a study-specific matrix and will be taken for each patient in the study. The somatic dysfunctions found, which are documented in the matrix, can then be transferred as items into the SOAP form. In the next step any additional dysfunctions which were not recorded in the matrix were incorporated in the SOAP (see http://www.academyofosteopathy.org/SOAP). The documentation of the osteopathic dysfunction is based on:

- The SOEF matrix (Appendix D)
- The Outpatient Osteopathic SOS Musculoskeletal Exam Form (SOAP) (Appendix D)

The advantages of these schemas are:

- A proven, single, validated system is available (in English)

- Complex standardized documentation is possible (supported by the software AAO-SNF EV)
- A precise coding on the basis that the ICD is transparent and recommended in the application of clinical studies (Sleszynski et al., 2004)
- With musculoskeletal complaints (here LWS) the following can be comprehensively described: the documentation of the incidence; severity of the symptoms; the regions treated; the treatment methods used; as well as all baseline characteristics
- The data for this multi-center clinical study can be collected centrally with the help of software-supported data collection (NYCOM eClinical Works)
- Comparability between different outcomes related studies may be possible

Chapter 3: Study Protocol Development

Based on the literature analysis in Chapter 2: the following section contains the actual study protocol, the relevant aspects of which will then be discussed in Chapter 4:

3.1 Introduction

Whiplash is a common injury associated with motor vehicle accidents and causes chronic pain, disability, activity limitations, and often psychological distress. The term whiplash describes an injury resulting from an "acceleration-deceleration mechanism of energy transfer to the neck" (Spitzer et al., 1995). The effect of this mechanism is mostly damage to soft tissue, bone and other body structures (Barnsley et al., 1994). The clinical sequelae and manifestation resulting from this trauma within six months after the accident is defined as WAD and describes a wide array of symptoms such as somatic dysfunction, pain, disability as well as psychological and psychosocial factors (Spitzer et al., 1995; Kuchera, 2007). Consequently LWS describes the chronic complications lasting more than six months, sometimes persisting for years after the initial MVC.

In 1995 the Quebec Task Force on Whiplash-Associated Disorders represented a milestone in filling a large knowledge gap concerning this problem. It is still the most cited monograph relating to whiplash syndrome and its associated disorders. One of the most important outcomes is a grading system to classify WAD symptoms in a numerical range system: WAD Grades 1-4. The classification of the severity of WAD graded 1-2 on the scale is the complex of symptoms often exhibited by patients visiting osteopathic clinics.

The individually tailored diagnosis and treatment of patients with LWS according to their visceral, parietal, and cranio-sacral system findings in osteopathic practices is commonplace in the US and Europe, and most therapists view the results as encouraging.

Empirical evidence for treatment effectiveness is scarce to date, but a small German pilot study on LWS (Kaiser et al., 2003) indicated that osteopathic treatment may be successful.

The study design presented will be suitable to substantially broaden the base for decision making on the effectiveness of an osteopathic approach to LWS treatment.

3.2 Objectives

3.2.1 Primary objective.

The main objective of the study is to determine the effect of test-dependent osteopathic treatment on whiplash injury-related disability in comparison to "watchful waiting."

3.2.2 Secondary objectives.

Secondly, a variety of different parameters will be documented in order to gain further insight into the study and to rate the plausibility of the main result. Secondary objectives include the following questions:

- Is there a reduction of pain?
- Which were the main osteopathic dysfunctions found?
- Can medication be minimized?
- Is there a difference between osteopathic therapists in their findings (e.g. outcome, protocols and treatment)?
- Is there a difference between male and female participants in recovery?
- Is there an association between a patient's history and osteopathic findings?
- Is there an association between dysfunctions and applied osteopathic techniques?
- Is there an association between psychological factors and the target symptoms?

- If a positive effect of osteopathic treatment is found, does it last over time?

3.3 Definition of LWS

For the purpose of this study, LWS is defined as the presence of pain, persistent headaches, upper limb paresthesia, dizziness, psychological and emotional sequelae, or restriction of motion at six months or more after the injury, sufficient to hinder return to normal activities such as driving, usual occupation, and leisure (Spitzer et al., 1995, Poorbaugh et al., 2007).

3.4 Study Design

Type of study: Randomized controlled trial with two arms (test-dependent osteopathic treatment versus watchful waiting) with standardized follow up examinations. The study is conducted as a waiting list design. This means that the patients who are randomly assigned to the control group receive the same treatment after the study phase which the treatment group received. There is no charge for any of the patients to participate in the study.

Null hypothesis: Osteopathic treatment is not superior to watchful waiting in terms of whiplash-related disability reduction.

Ethical requirements: It must comply with the international ethical benchmark standards (*World Medical Association Declaration of Helsinki: Recommendations guiding physicians in biomedical research involving human subjects, 1997*).

The study protocol is subject to IRB review.

Quality requirements: The study is designed to fulfil the standard requirements of good clinical practice (*ICH-GCP Guideline for Good Clinical Practice, 2002*).

The flow of subjects from recruitment through randomization is presented in Figure 2.

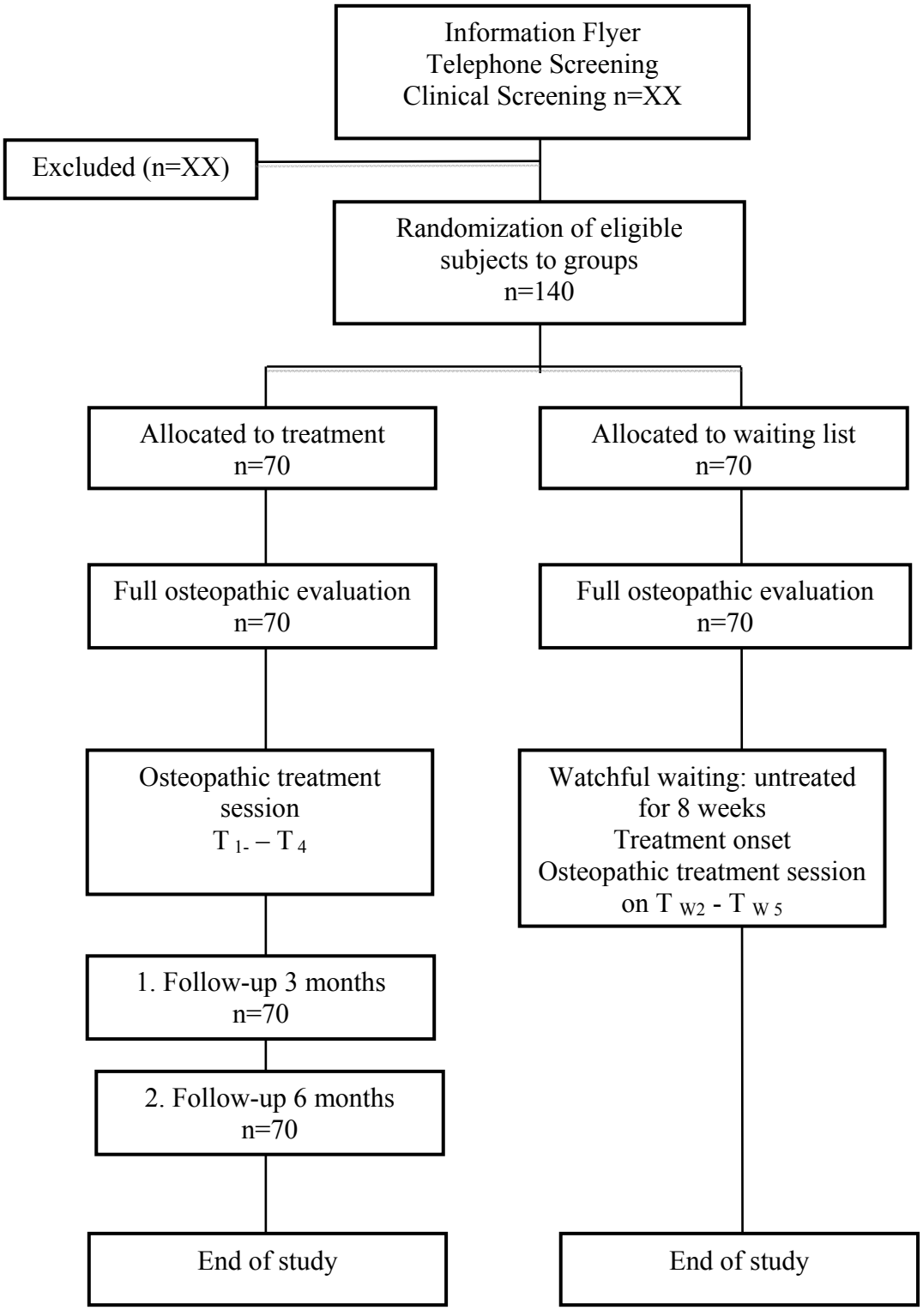

Figure 2: Flow of subjects from recruiting through randomization, treatment, and follow-up

3.5 Research Staff

Overall project leadership will be assumed by a project coordinator or Contract Research Organization (CRO). The coordinator will be responsible for the following issues that are defined and documented beforehand as Standing Operation Procedures (SOPs) as suggested by the GCP Step 5 Guideline (Section 3.2.2): subject recruitment, subject safety, study protocol adherence, process quality control, data entry monitoring, and assessment method adequacy. 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.

On-site monitoring: A study nurse will be in charge of the on-site monitoring in intervals no fewer than three months.

Statistician: An external statistical consultant who is otherwise not involved in the trial will receive the Case Record Forms (CRF) of patients within 1 month after treatment completion. (Evaluator-blinded) data is entered and controlled for plausibility and accuracy within 1 month after reception, and the data set is stored and backed up in two independent computer systems.

Therapists: At least 10 therapists from at least 8 osteopathic centers fulfilling defined professional criteria to ensure standardized and equivalent treatment proceedings and strict protocol adherence. Participating osteopathic therapists will meet at least once for one full day before the beginning of the trial to simulate the entire course of a patient through the study. Particular focus is the responsibility of the study coordinator.

3.6 Setting/Patient Recruitment

The entire study evaluation and treatment is to be conducted in respective research centers of the participating osteopaths. Each osteopath will be 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 continually as a full-time osteopath for least two years. A further prerequisite is the participation in an introduction training course for two days on how the study is to be conducted. This training session consists of training about the uniform use of the assessment instruments (questionnaires) evaluation, treatment, synchronization of techniques, and how somatic dysfunctions are to be documented and transferred to the computer databanks (introduction to the SOPF and SOAP software).

Number of subjects:	140 (70/70), see sample size calculation
Number of centers:	at least 8 osteopathic research centers should collaborate
Number of therapists:	at least 10 osteopaths should conduct the treatments

Participants will be actively recruited through advertisements in local newspapers, and flyers displayed in pharmacies and internet homepages. In these media forms, patients are specifically recruited who have already sought treatment in the field of traditional medicine because of chronic whiplash syndrome but who have not shown a satisfactory treatment outcome, albeit subjective or objective (primary care setting).

Interested candidates will be initially screened by telephone interview to make a preliminary decision whether they may meet the inclusion criteria (telephone checklist, see Appendix B). The study requires at least 10 osteopaths active in a mimimum of 8 research centers treating 140 patients.

Patients who have fulfilled the inclusion criteria are informed of the purpose of the study, and they will be asked whether they are willing or not to participate. Patients who are willing to participate will be informed, both verbally and in writing, about the purpose of the study and the methods. They will be required to provide written consent (see Appendix B) and are allowed to cancel their participation at any time before, during or

after the treatment period. Patients will be recruited without regard to their sex or ethnicity.

To make participation in the study more attractive to patients, a complimentary osteopathic verum treatment is offered at the end of the study for those patients in the waiting list group.

3.7 Eligibility criteria

The following eligibility criteria were determined:

3.7.1 Inclusion criteria.

- Whiplash injury with rear-end collisions from 6 months to 10 years ago: patients who had suffered whiplash injury with a rear-end collision at least 6 months ago–but no longer than 10 years ago–and who can trace their current complaints back to this accident are to be included in this study
- Aged between 18 and 65
- Willingness to participate in the study: the patient signs a written consent form, which confirms that the patient agrees to the participation conditions of the study and that the patient does so voluntarily
- Are the potential patients in a position to consent to treatment: to ensure the study progresses smoothly, especially with regard to the questionnaires, it is essential that the patient's German is of an adequate standard. Furthermore the patient has to be of age and sui juris
- The first evaluation involves reporting the level of pain: on the telephone or at the first meeting the patient is required to exhibit a pain intensity of a

minimum of 3 (=30%) on the visual analogue scale. The pain scale ranges from 0 (no pain) to 10 (maximum pain)

3.7.2 Exclusion criteria.

- Anomalies in the circumstances of the accident: only patients who suffer from whiplash injury following a MVC involving a rear-end collision are to be included. With regard to the accident the following points are relevant:
    - No head contact in the car during the accident
    - No subsequent collision with a vehicle in front
    - No loss of consciousness following the accident (Grade > 2)
    - A pending insurance claim, involvement in current litigation or a pending pension application
- Patients are required to present the results of a current clinical investigation from a physician and are excluded if they fail any of the following criteria:
    - General medical examination: there are no signs of infectious disease or contraindicators for an osteopathic treatment
    - X-rays, MRI or CT scans of the cervical vertebral spine
    - Neurological examination
    - Doppler-Sonography: if there is any suggestion of pathologic vessel or blood irregularities of the A. vertebralis, a Doppler-Sonography should be performed
- Pathological evidence from clinical or imaging examinations (X-rax/CT/MRT/Doppler) of cervical vertebrae, spinal cord, and nerve roots.

- Any other red flags (Greenhalgh & Selfe, 2006)
- Contra indications for manipulation (Kaiser et al., 2003)
- Osteopathic treatment: patients who have received osteopathic treatment within the previous six months are not to be included in the study because of the danger of distorting the study results
- Manipulation of the vertebral segments in the previous three months
- Regular intake of:
    - Corticosteroids
    - Anticoagulants
    - Psychopharmaca (Zenner, 1987): psychiatric disorders (major depression, hysteria, etc.) as well as the regular taking of psychopharmaca change the response of the patient
    - Muscle relaxants: muscle relaxants decrease the muscle tone; and hence there is a risk of injury with manipulation. For this reason the patients are required not to take any muscle relaxants within the previous 48 hours before each treatment
- Malignant disease (cancer) which is current or has occurred in the previous five years
- Angiopathy: with arteriosclerosis the manipulations are contraindicated because of the increased risk of damage blood vessels. It is especially necessary for circulatory disorders of the A. vertebralis (Zenner, 1987; Assendelft, Bouter, & Knipschild, 1996; Haldeman, 1996, Krakenes et al., 2002) to be excluded with the aid of Doppler-Sonography prior to treatment
- Diabetes mellitus

- Leisure activities which are especially associated with strain to the cranio-cervical system, such as boxing, bungee-jumping, and contact sports such as soccer or rugby

- Underlying or concomitant illnesses, which can influence the reaction of the body to the intervention treatment (e.g. pregnancy); osteopathic treatment within the previous three months

- Contraindications for manual therapy (e.g. osteoporosis, facet joint hypermobility of the vertebral and thoracic spine, or present or earlier radicular complaints)

3.8 Randomization

Block randomization will be performed externally throughout the trial to ensure that comparable numbers of subjects are assigned to each treatment group. The external organization hosts a computer-generated randomization list with variable block length of 4-8 for each therapist (Altman & Bland, 1999). Participants will be assigned to the respective groups once their date of birth and initials had been conveyed by telephone and their names were confirmed on the study list. The patients will be randomly assigned to two groups (see 3.12.4).

- Intervention group – test-dependent osteopathic treatment

- Control group – no treatment (waiting list)

Once the patients have given their informed consent, they will be randomly allocated according to a computer generated block randomization list to one of the groups described above. The block randomization is to be conducted separately for each research center.

3.9 Procedure

Suitable patients will be recruited in the run-up to the study with the aid of a telephone questionnaire and taking the inclusion and exclusion criteria into consideration (see Appendix B). The patients will then be assigned an ID number.

Potential patients selected through the telephone interview will be sent information and a consent form (see Appendix B). It informs about all relevant aspects of the study, explains the randomization process and the fact that patients may receive treatment only after a certain period of time. Once the consent form has been signed and returned, the patient will be allocated to one of the two study groups as described by the randomization protocol.

Each patient receives an initial examination (T_1) after randomization. This involves:

- The initial osteopathic questionnaire
- A standardized osteopathic protocol form
- VAS for assigning pain and pain in body regions
- The following questionnaires: WDQ, BDI, and SF-12
- A medication diary to record at home over T_1-T_4

The patients in the intervention group (T_1) are then to be treated; those in the waiting-list group will only be examined. An appointment will be made for the first osteopathic treatment after 8 weeks (T_{w2}).

The patients in the intervention group will receive an additional three treatments (T_2-T_4) at intervals of 14 days. The patients in the control group will be treated in the same way after the eight weeks of the waiting list period ($T_{W\,2}$- $T_{W\,4}$-).

Before each osteopathic intervention, an osteopathic examination will be conducted according to the osteopathic examination forms (SOAP, SOEF) and documented in a standardized way. This occurs for both groups once the questionnaires have been completed. After the final treatment of intervention group (T_5), follow-up appointments to evaluate treatment are planed at three months after the end of treatment (T_6). The second long-term follow-up (T_7) will occur six months after the end of treatment, both of them telephone interviews. Patients are requested to inform the project coordinator of any changes of address or telephone number.

3.10 Outcome Parameters

3.10.1 Main outcome parameter.

The primary parameter of interest is whiplash related disability, measured with the WDQ (Pinfold et al., 2004).

3.10.2 Secondary outcome parameters.

Secondary parameters of interest are:

- Pain intensity, measured with the VAS
- Quality of life, measured with the SF-12
- Psychological factors, measured with the BDI
- Osteopathic dysfunction, measured with osteopathic protocols
- On demand medication diary

3.10.3 Assessments.

The main outcome parameter will be measured by the WDQ (Pinfold et al., 2004). This questionnaire has to be answered by each patient at each investigation and treatment session as well after two weeks and the two long-term follow-ups after three and six months.

The subjects have to answer 13 questions in the questionnaires, which best describe their current situation. Each question deals with a specific aspect of their related disability. The items address pain levels, role performance, mobility, sleep disruption, tiredness, social

and leisure activity, emotional and concentration impairments. Each item is scored numeric from 0 to 10 for a maximum total score of 130 (for the WDQ see Appendix C).

For the assessment of secondary outcomes, the following methods will be employed:

- Pain will be measured with a 100 mm VAS ranging from "no pain" to "unbearable pain" (see Appendix C) before randomization, before each treatment session, at the end of intervention, and at all follow-up examinations. Subjects will be asked to assess current pain as well as the worst and the average pain between examinations. VAS pain measurement is an established and extensively validated method.

- VAS of four body regions:

  shoulder girdle

  low back region

  chest region

  abdominal region

- Medical Outcomes Study Short Form – 12 Health Survey (SF-12). Retrospective modified time period from four to two weeks (for the SF-12 see Appendix C).

- BDI (see Appendix C).

- Medication diary: subjects will be required to maintain an accurate protocol of all medications taken throughout the study period (Appendix C).

3.10.4 Baseline data collection.

Baseline data will be collected at the initial appointment (T_1) including the socio-demographic and clinical characteristics of participants. This includes time since injury, age, gender, height, weight, and the WDQ, which serves as the primary outcome measure.

Furthermore the baseline assessment includes pain and body region VAS, generic health status (SF-12), and the BDI questionnaire. Primary and secondary end points are reassessed during the course of the study according to Table 14.

3.11 Intervention

3.11.1 Intervention group.

The study group subjects will receive four osteopathic treatment sessions over the course of eight weeks, one treatment per week (T_1-T_4). This protocol applies to the control group after the end of the waiting period (T_{w1}-T_{w4}) (see Table 14).

3.11.1.1 Osteopathic diagnosis.

A unified procedure per protocol has to be developed for the data collection and documentation, as well as the statistical evaluation of the planned study due to whiplash syndrome–designed as a multi-center trial–which takes the following into consideration. Each of the 25 items of the developed osteopathic examination will be examined for each patient in each session (SOEF). The dysfunctions will be documented in this SOEF. In addition dysfunctions which are not described in this standardized osteopathic form will be in addition documented in the Outpatient Osteopathic SOAP Note Form (diagnostic protocol). This will be used according to *Foundations of Osteopathic Medicine* (described in 2.4.5). At every treatment session (T_1-T_4) the only structures which are to be treated have actual osteopathic dysfunctions. In line with osteopathic principles, the area of treatment will not only be restricted to the cervical spine with regard to the location of the dysfunctions; but the whole body will be examined on a parietal, visceral or cranial level. The evaluation forms (SOEF and SOAP) according to TART scoring system are to be used for computerized recording documentation.

3.11.1.2 Osteopathic treatment.

The treatment follows osteopathic principles according to the test-dependent dysfunctions which were evaluated for each treatment session. These dysfunctions are recorded in the protocol forms process. The applied osteopathic techniques used will be in accordance to the *Glossary of Osteopathic Terminology* (Ward, 2003). Each osteopath is free to decide the therapy techniques. There is no standardized treatment protocol. Black box defined. For documentation each osteopath records:

- treated regions
- treated structures
- applied techniques

(see Appendix D Protocol of Intervention). Treatment occurs at T_1, T_2, T_3, and T_4.

Table 14: *Course of Study; Intervention Group*

Course of the Study	**T_0**	**T_1**	**T_2**	**T_3**	**T_4**	**T_5**	**T_6 1st Follow up (3 months)**	**T_7 2nd Follow up (6 months)**
Data collection								
Telephone questionnaire	P							
Physician's letter	P							
Physician's documentation		P/ D						
Patient information		P						
Patient consent		P						
Initial questionnaire		P						
WDQ		P				P	P	P
SF-12		P				P	P	P
VAS pain		P	P	P	P	P	P	P
VAS pain-body region		P	P	P	P	P		
BDI		P				P	P	P
Medication diary		P..	P..	P..	P..	P		
Osteopathic examination		X1	X2	X3	X4	X5		
Osteopathic treatment		X1	X2	X3	X4			
Final questionnaire						P		

Notes: T = Appointment between practitioner and patient; T_1 to T_6 = ca. 12-week inclusive waiting time; X = osteopath; P = patient; D = doctor.

3.11.2 Control group.

Measurement in the control group takes place at point of time T_{w1}, T_{w2}, to T_{w6} in the same manner as in the study group. However this group will not be treated until about eight weeks later, starting at T_{w2}; and hence first after the observation time period "no treatment" the intervention group concludes. Treatment of control subjects is performed under equal technical and timing circumstances as in study subjects following the same protocol. The follow-ups for this group will also be a part of the evaluation (Table 15).

Table 15: *Course of Study; Control Group*

Course of study	**T** w_0	**T** w_1	**Waiting**	**T** w_2	**T** w_3	**T** w_4	**T** w_5	**T** w_6
Data collection								
Telephone questionnaire	P							
Physician's letter	P							
Physician's documentation		P/ D						
Patient information		P						
Patient consent		P						
Initial questionnaire		P						
WDQ		P		P				P
SF-12		P		P				P
VAS pain		P		P	P	P	P	P
VAS pain-body region		P		P	P	P	P	P
BDI		P		P				P
Medication diary		P..	P..	P..	P..	P..	P..	P
Osteopathic examination		X1		X2	X3	X4	X5	X6
Osteopathic treatment				X1	X2	X3	X4	
Final questionnaire								P

Notes: T = Appointment between practitioner and patient; T_1 to T_6 = ca. 16-week inclusive waiting time; X = osteopath; P = patient; D = doctor.

3.12 Statistical Methods

3.12.1 Statistical hypotheses.

According to the study objectives in Chapter 3.2 the following primary hypotheses regarding the main outcome parameter (WDQ score) can be derived:

1. The WDQ score after the treatment interval is lower in the treatment group (T_5) than in the control group (T_{w2}): $WDQ(T_5) < WDQ(T_{w2})$

2. The WDQ score in the treatment group is lower after the treatment interval than before: $WDQ(T_5) < WDQ(T_1)$

3. The treatment effect in the treatment group lasts over a time period of three and six months, resulting in the two combined hypotheses 3a and 3b:

    a. There is an overall effect of time: $WDQ(T_5,T_6,T_7) < WDQ(T_1)$

    b. The WDQ score after three and six months, respectively, is lower than before treatment: $WDQ(T_6) < WDQ(T_1)$ and $WDQ(T_7) < WDQ(T_1)$

The same hypotheses apply to the secondary outcome parameters pain reduction in cervical region (measured with VAS), and with reversed sign for quality of life (measured with SF-12). Other questions deriving from the secondary objectives formulated in Chapter 3.2 will be analyzed descriptively. Also the data collected after treatment of the control group can be used to repeat the tests of hypotheses 2 and 3, further strengthening or questioning the results obtained in the main analysis.

3.12.2 Statistical analysis.

To test hypotheses 1 (and the respective hypotheses for the secondary outcome parameters) the difference between the scores at T_1 and T_5 (T_{w1} and T_{w2} for the control

group, respectively) are calculated and then compared with student's t-test for unrelated samples (two-tailed). This procedure controls for any pre-existing differences between the treatment and control groups due to unsuccessful randomization.

To test hypotheses 2 and 3 analyses of variances for repeated measures (repeated measure ANOVA) with simple contrasts is conducted for the treatment group. Each measurement after treatment will be contrasted to the pretest measure, so that for each point in time a decision on treatment efficacy is possible (hypotheses 2 and 3b). The main effect of time is analyzed to test hypothesis 3a. The main assumption of sphericity will be tested with Mauchly's test. In case of violation a Greenhouse-Geisser correction will be performed. Drop outs will be excluded from this test (list-wise deletion).

The Type I error is fixed at .05 for all tests and all tests are performed two-way. Before testing, the data should be inspected for deviation from normality, either visually with Q-Q-diagrams or with Kolmogorov-Smirnov tests. In case of strong deviation from normality, alternative non-parametric tests may be considered but not necessarily be employed due to the robust nature of the student's t-test and ANOVA (Fields, 2005). Instead of the student's t-test, a Mann-Whitney U-Test can be performed and repeated measure ANOVA can be replaced with three Wilcoxon tests with Bonferroni correction.

3.12.3 Sample size calculation.

The necessary sample size to detect a clinically relevant difference in the primary outcome variable WDQ score for the inter-group comparison of hypothesis 1 is calculated with the program G*Power (Erdfelder, Faul, & Buchner, 1996) in Version 3.1.0 (retrieved Oct 2009 from http://www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3). Since the WDQ is a new instrument, it is not yet possible to define a clinically relevant score difference. Thus the effect size is fixed to Cohen's conventional level for a medium effect (d=.5).

Basis of calculation:

- Statistical test: difference between two independent means (two groups)
- Tails: 2
- Effect size: .5
- Type I error: .05
- Power: 0.8 (Type II error: .2)
- Allocation ratio of N2/N1: 1

This results in a necessary sample size of 126 patients (63 per group) to test hypothesis 1. It should be noted that the sample size of 64 patients is larger than necessary to detect an effect of d=.5 in the contrasted repeated measure ANOVA for testing hypotheses 2 and 3. To account for this the resulting effect sizes need to be taken into account when discussing the clinical relevance of the findings. Drop out rate is based on a 10% estimate assessed in an earlier study (Kaiser et al., 2003). Thus the sample size is calculated with 126/0.9 = 140.

3.12.4 Randomization.

Randomization is based on the sample size per group and the required number of blocks. An additional specification is that the size of each sample is the same, that is the block size varies between n=4 and n=8, yet containing an equal number of patients from each study arm.

3.13 Ethics

The study is in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki (amended Somerset West, Republic of South Africa).

The study protocol will be reviewed and certified by an Institutional Review Board (IRB) according to the respective legal and socioeconomical requirements of the country where the study center is located. The appropriate ethics committee will also have to grant approval.

Due to the recruitment method, standard treatments will not be withheld from the participating patients. The complete information regarding the aim and course of the study, the written consent of the participants and the identical treatment received by the control group after the study is conducted ensures that none of the patients involved will be placed at a disadvantage.

The trial will be registered online at www.ClinicalTrials.gov.

3.14 Funding and Conflicts of Interest

None of the osteopaths involved in the study will receive undue financial benefits in connection with the study participation. It is the responsibility of the study coordinator to make certain of no problematic conflicts of interest.

3.15 Quality Assurance/Patient Safety

Two osteopaths will conduct one small study prior to the start of the study. In this study the feasibility of the clinical study protocol together with documentation forms will be confirmed to establish quality assurance.

Patients' safety is utmost and each research center will have to have an appropriate insurance. Initial screening ensures that only eligible patients are allowed to participate. The patients will be fully informed about the course of the study, and should they so wish, they can terminate participation at anytime. Should there be side-effects or any negative consequences, the patients will be immediately referred to their physician or, if necessary, the nearest hospital.

Chapter 4: Discussion

The study protocol outlined here was developed to investigate the effectiveness of test-dependent osteopathic treatment of LWS. This syndrome is common, heavily burdens patients, and is responsible for substantial socioeconomic consequences in the form of lost hours of labor.

LWS is notoriously difficult to treat, not least due the complexity of the problem: further to the underlying structural problem resulting from the initial injury, psychological elements may play a role in the course of the illness as well as inappropriate coping (Verhagen et al., 2007). The systematic review of the literature on therapeutic options for the condition (see 2.1) revealed that a broad spectrum of different treatment modalities is being applied, typically a combination of several interventions, and that none of them so far has been identified as consistently successful (Verhagen et al., 2007).

Hence there is good reason for the quest for innovative treatment concepts. The current literature does not yet allow for valid conclusions on the effectiveness of osteopathic treatment of LWS, as an intensive literature search of all the relevant databases has shown (see 2.2). There is however positive anecdotal empirical evidence from osteopaths having treated the condition. At least one smaller clinical trial has reported promising results (Kaiser et al., 2003).

Therefore it seems worthwhile to conduct a study with high internal and external validity in order to produce more reliable evidence on the effectiveness of an osteopathic intervention. This master thesis sets out to compile a protocol for such a study.

4.1 The Protocol

4.1.1 Study design.

The golden standard for establishing causality between exposure and effect is undoubtedly the randomized controlled trial (RCT) (Fletcher & Fletcher, 2005). Given the fact that there is only empirical and preliminary evidence from osteopaths' daily practice, it seems logical to start from this very point that is scrutinizing those observations by means of an RCT in a pragmatic setting. At a later stage other aspects (efficacy, mode of action) may come into play. This approach ensures that the impact of the osteopathic intervention of the condition is valuable and clinically relevant. Since the underlying mechanisms of the osteopathic concept are not yet well understood, an RCT comparing the osteopathic intervention with a placebo (or sham) intervention would be associated with the inherent risk that the control arm has to some extent *specific* effects; thus leading to an underestimation of the true therapeutic potential of the osteopathic intervention. This problem has been discussed for instance for acupuncture: a treatment modality which in this respect has marked similarities with osteopathy (Fink, Rosted, Bernateck, Striesch-Scholz, & Karst, 2006).

The chosen design with the control group being treated after the waiting interval raises the question: why not follow up on the control group for six months to compare treatment and control group over the full length and thus have a strong argument on the long-term effects of osteopathic treatment. However from an ethical point of view it appears unacceptable to postpone the promised treatment for members of the control group over six months, especially since the treatment is for both groups an incentive to participate in the study. This clearly raises a conflict between methodological and ethical considerations. The chosen design poses a reasonable compromise: the comparison of control group and treatment group secures internal validity of possible immediate effects of treatment while the within-subject comparison over time gives insight into the stability of the effect.

4.1.2 Issue: Control/placebo group.

Further to the rationale for an effectiveness study as a first step discussed above, there are a variety of operational problems with introducing a sham arm into an RCT for osteopathic treatments (Fiechtner & Brodeur, 2002; Hancock, Mahler, Latimer, & McAuley, 2006). First it is because a credible placebo treatment should not be distinguishable to the patient from a verum treatment; hence it must be accompanied with manipulation (Koes, 2004). There are currently no generally accepted placebo/sham studies for osteopathic medicine which satisfy the requirements of the following parameters (Ward, 2003):

- Credibility
- Identical mean expectancy in patients
- Absence of specific evidence of effectiveness

In the few placebo controlled clinical trials in osteopathy, there exists a distinct improvement with the complaints, even after the placebo treatment (see Table 11); and although sub-therapeutic ultrasound therapy, which was recommended in a study (Fulda et al. 2007), has already been used in controlled osteopathic studies (Schwerla et al., 2008), it can not yet be regarded as established (Hrobjartsson & Gotzsche, 2001).

Therefore the protocol proposes a study with a waiting list design to compare the two groups: test-dependent osteopathic treatment versus no treatment (Jones, Jarvis, Levis, & Ebbut, 1996). This design was appropriate to show clear effects of osteopathic modalities in a therapeutic approach with different indicators (Licciardone et al., 2003).

4.1.3 Issue: Efficacy/Effectiveness.

The concept of the sham/placebo controlled trial is inherently related to the objective of the study: *efficacy* and *effectiveness*. Kienle (1974) had already emphasized

that only therapeutic relevant effects for the patient (effectiveness) apply when evaluating the therapy and not–or at best only as a secondary aim−changes in certain biological parameters. The validity of this assessment remains unchanged; and it is also reflected in a general paradigm shift in patient care, which is a still ongoing transition from a symptom-oriented to a patient-oriented concept of conservative treatment. This can also be seen as one of the milestones of the therapeutic osteopathic approach to patients (Patterson, 2007).

This concept has since found its way into German legislation (following the healthcare reforms of 2000) and carries the label "integrated care." In this contemporary sense it is always only the patient who can be treated; and hence the outcome of a medical intervention is no longer a technical parameter (efficacy) but the sustainable improvement of the patient's quality of life (effectiveness). According to Cassel (1982), the terms "suffering" and "quality of life," which are central to this concept, conspicuously fail to even appear in the medical literature of that time. However ending the suffering and healing the illness are in no way the same. Modern medicine has learnt (or is to learn) to integrate both as equivalent objectives into the treatment concept. Moreover it has to acknowledge that quality of life, like traditional "objective" measures of treatment success, has a permanent place in the evaluation of treatment effects resulting from a therapeutic approach.

The choice of end points in the planned study fully takes account of these considerations.

4.1.4 Issue: Eligibility criteria.

Due to the ambiguous diagnostic criteria and the considerable discrepancies with the definition of LWS, the selection of patients who qualify for participation in the study is not without its problems (Ferrari, Russel, Caroll, & Cassidy, 2005; Verhagen et. al., 2007).

To ensure the sample recruited for the study is as consistent as possible, high standards were set for the inclusion criteria; especially with regards to the defined population suffering from LWS. In contrast to some other studies in which the duration of the complaint was required to be of more than a year, this study includes patients with complaints lasting a minimum of six months, since chronicity can be safely assumed and defined as LWS (Balla, 1982; Jansen et al., 2008).

The inclusion and exclusion criteria were determined from the extensively reviewed literature on clinical trials on the treatment of LWS.

The sample selection was supposed to make sure that the subjects in both groups are comparable in terms of their prerequisites for treatment response and safety. This requires a careful selection of patients which are deliberately recruited in a clinic setting and fulfill the demand to gather a group with symptoms exposed to a MVC into one clinical syndrome with a grading system defined according to the QTF (Spitzer et al., 1995). Thus it is guaranteed to create a representative and heterogeneous sample of a target population to set eligibility criteria broadly to LWS grades I-II (Williamson, Williams, Gates, & Lamb, 2008). It should be noted for this study protocol that the selected group is not focused on a specific, whiplash-related single body structure (correlate) or region as is the focus of other studies (Ferrari et al., 2005; Elliott et al., 2006; Freeman, Centeno, & Katz, 2009). Osteopathic research in this field means the total organismic scheme as an integrated unit of musculoskeletal system, organs and central nervous system, in which somatic dysfunctions may be present in the target population under investigation in this protocol (Korr, 1997; Nelson & Glonek, 2007).

1. Treatment response and risk for complications resulting from manipulation are age-dependent; hence there is an age restriction in the selection process for patients (Poorbaugh et al., 2007).

2. Careful exclusion of patients at risk requires imaging of the cervical vertebrae (two levels) (X-ray, MRI, or CT) not older than 12 months without evidence of traumatic, infectious, or tumorous changes (Assendelft et al., 1996; Krakenes et al., 2002).

3. If a patient shows any sign or symptom of neurological disturbance, a careful clinical and, if required, technical examination is mandatory (Keller, Krause, & Röhl, 1998).

4. Patients must not have undergone manipulative treatment of the cervical joints within three months before the study because manipulation results in a continual process of adjustment lasting months and therefore a change of response to treatment reaction (Choiniere & Amsel, 1996, Poorbaugh et al., 2007).

5. Several drugs may interact with the process of treatment and evaluations and therefore have to be avoided:

   - Corticosteroids, if administered regularly, modify the reaction of the patient and result in osteoporosis (Bischoff, Nürnberger, & Voigt, 2002).

   - Anticoagulants cause a reduced blood viscosity and coagulability that may result in a greater risk of vascular insufficiency (dizziness and blackouts) or microvascular injury.

6. Patients with malignancies must be excluded because chemotherapy and radiotherapy result in a changed response of the patient (Baumgärtner, 1991).

7. Diabetes mellitus is another contraindication because it is frequently associated with, among others, advanced angiopathy (diabetic micro and macroangiopathy) that predisposes to vascular incidents during manipulation (Winkel, Vleeming, Fisher, Meijer, & Vroegen, 1985).

4.1.5 Issue: Assessment methods.

The choice of assessment instrument resulted from the attempt on one hand to obtain the most comprehensive description possible of the patient's specific condition; however without "overloading" the examination and treatment sessions with questions. The main symptoms of whiplash injury–pain and stiffness in the neck–were measured with the appropriate instruments based on the above literature review (see 2.3.4.5):

- Pain is measured with the VAS, an established gold standard
- Neck related disability is measured with the WDQ, which is a form of the established NDI and is especially developed for this assessment. The WDQ is yet to be utilized in a clinical study; however it is validated, and methodically speaking it does not have any disadvantages when compared to the NDI. Moreover it is better suited because of its focus on whiplash injury and regarding the discussion on "effectiveness" (see above)

Both assessment instruments for the condition and quality of life and well-being of patients selected (BDI and SF-12) comply to international standards. The SF-12 was preferred to the SF-36 due to fewer questions and the extensive, wide-ranging statements (Hopman et al., 2009).

Pain and global perceived effects and participation in daily activities are the focus in all studies which were reviewed (2.3.4.3). Furthermore well-being, such as psychological factors, has been shown to have consequences for mental state and quality of life as a bio-psychosocial model that influence patients' daily life after whiplash injury. Individual psychological factors may also influence pain and participation in daily activities and the way patients will respond to treatment (Poorbaugh et al., 2007; Williamson et al., 2008). Therefore it seems to be appropriate beside the physical outcome parameters to investigate aspects of psychological factors, focused on depression as an outcome parameter of interest (Buitenhuis et al., 2009). These outcome parameters, which were set in this study protocol, are also in accordance with requirements of the Cochrane Group for investigating effects of conservative treatments for this condition (Verhagen et

al., 2007; Cochrane Back Group, www.cochrane.iwh.on.ca/editorial.htm). Furthermore the outcomes also mirror the effects that can be influenced by an osteopathic therapeutic approach (Licciardone, 2008).

4.1.6 Issue: Diagnosis and intervention.

The diagnosis and interventions may closely follow osteopathic standards and principles, and they will be completely harmonized across all individual research centers. Furthermore they are supervised during the course of the study to ensure identical requirements and that each study center conducts the trial according to the study protocol. In this protocol a "custom-tailored" test-dependent osteopathic intervention is being proposed as the index treatment. The so-named "Black box" form, also defined as "treatment log" (Lamb et al., 2007), allows insight into the treatment process during the study (Scholten-Peeters et al., 2003). This approach has the disadvantage that potential positive effects can not directly be attributed to particular osteopathic techniques applied. However tendencies of correlation may be defined (Schwerla et al., 2008). This approach however closely mirrors the "original" and "holistic" principles of osteopathy as proposed by A.T. Still (Ward, 2003; Korr, 1997; Patterson, 2007).

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.

Following from above the diagnosis and treatment will be conducted as described in 2.4.5: standardized osteopathic documentations (SOEF and SOAP) of somatic dysfunctions and techniques chosen at every treatment sessions will allow for retrospective analysis of potential associations between successful treatment of different

somatic dysfunctions and clinical outcomes, and for identification of potential markers or predictors of clinical outcomes (Patterson, 2007). The osteopathic interventions should be seen as a monomodal concept in spite of various therapeutic techniques applied; nonetheless all of them followed the osteopathic principles, hypothesizing a (yet unknown) valid "mode of action" which underlies this therapeutic approach (Ward, 2003).

The diagnosis protocol follows the need for a reliable, validated system of recording, collecting and evaluating of clinical relevant findings in a patient individualized standardized osteopathic examination form. (SOAP, Sleszynski & Glonek, 2005). For this syndrome the individualized developed protocol form is an additional way of documenting the number of whiplash related dysfunctions (see 2.4.5, SOEF). Furthermore it can be seen as a synopsis of somatic dysfunction and their association to WAD classification. Thus it may be possible under osteopathic consideration to quantify patients' conditions and analyze clinical effects in relation to their whiplash associated somatic dysfunctions under study. Furthermore it may be possible to quantify response to meaningful outcomes over time (Licciardone, Nelson, Glonek, Sleszynski, & Cruser, 2005) It has to be tested how this individualized osteopathic protocol form (SOEF) can be linked as a matrix to the standardized tool (SOAP Note Form).

4.1.7 Issue: Control intervention.

For this protocol an untreated group was chosen as control group. This was sensible from a methodological standpoint as detailed above. It seems as well an acceptable choice from an ethical perspective, since immediate therapeutic action is not mandatory for the condition under study (LWS). However it is known that 12 months after injury only about 4% of patients are still in therapeutic care due to their whiplash injury (Poorbaugh et al., 2007).

4.1.8 Issue: Possible interrelations with post-traumatic reactions.

To ensure that the diagnostic effort is not overburdened, possible post-traumatic stress reactions are not to be captured. Some studies demonstrate evidence of psychological distress as a contributing factor for developing a LWS. However there is no conclusive evidence that an individual's psychological state is responsible for the development or outcome of LWS (Ferrari & Russel, 1999; Williamson et al., 2008) Although the role this plays on the pathological effects of outcomes to LWS may not be insignificant, it failed to show in earlier studies (Kaiser et al., 2003,) any significant interaction with the effect of osteopathic treatment of chronic whiplash injury. Thus it seems to be acceptable and appropriate to use a depression questionnaire to measure association between pain and disability to mental well-being (Olivegren, Jerkvall, Hagström, & Carlsson, 1999; Poorbaugh et al., 2007; Ferrari et al., 2005).

4.1.9 Issue: Statistics.

Because of the chosen design with four measurements of the primary outcome parameter for the treatment group and only two measurements for the control group it is not possible to test all hypotheses in a single step using a repeated measure ANOVA with treatment as between-subject factor; hence hypothesis 1 is tested separately with a t-test for independent groups while hypotheses 2 and 3 can be tested with a single ANOVA. The t-test on hypothesis 1 is performed on the differences of individual test scores between T_1 and T_5 to control for possible baseline differences in case randomization fails. This is justified because in the case of perfect randomization this procedure will have no effect at all. On the other hand it makes baseline comparisons with a statistical test unnecessary. Such a baseline comparison would be problematic from a theoretical point of view because in this case the H_0 would be the desired hypothesis with an unknown Type II error.

Although hypothesis 3 could also be tested with several student's t-tests for dependent measures controlling for Type I error accumulation, an analysis of an overall effect of time (hypothesis 2) would be impossible; hence ANOVA is preferable.

The chance to statistically detect an effect is directly dependant on sample size; thus it is necessary to optimize sample size a priori to avoid oversized or underpowered trials. The computation of the sample size requires the fixation of several parameters: statistical test, Type I error, Power (resp. Type II error), effect size and, for group comparisons, the group size allocation ratio. The fixation of Type I error on .05 and Type II error on .2 follows convention for relatively new fields of research as does the choice of two-tailed tests. Allocation ratio is fixed to 1 with equal size control and treatment group. The expected treatment effect, translated into an effect size, is hypothesized as a clinically meaningful effect and is usually pre-specified on the basis of observed data or published results in other studies. The editorial group for the Cochrane intervention review on whiplash syndrome (Verhagen et al., 2007) defines the minimal clinically important differences between treatment and non-treatment groups as a 15% improvement. For the WDQ this would be 20 point increase. Together with the standard deviation of 29.9 reported by Pinfold (2004) this would yield an expected effect size of d=.67 and a sample size of only 72 patients (36 per group). Since this instrument is still new, no actual effect estimates have been published so far, and it is still unclear how sensitive to change the instrument is, it appears more reasonable to use Cohen's conventional medium effect size of d=.5, resulting in a somewhat larger sample size of 128 patients (64 patients per group). On the other hand this sample is oversized for testing hypotheses 2 and 3. The interpretation of the findings with regards to the clinical relevance should take this into account by also considering the actual size of the effect. As a positive side effect, the sample size will still be large enough even with a significant drop out (10%) on the follow up.

The influence of other variables on treatment effect (e.g. sex, age) could be further analyzed with multivariate analyses. Since no hypotheses yet exist on such influences, they are not subject to statistical hypothesis testing in the proposed protocol. The same

holds for the analysis of medication. The data should be analyzed descriptively to further support interpretation of the findings on the main and secondary outcome parameters.

4.1.10 Resume.

The study protocol fulfills on the one hand the principles of clinical research in the field of osteopathy; and on the other hand it follows parts of the recommendations of the Editorial group: Cochrane Back Group on whiplash syndrome. The authors concluded the following implications for research (Verhagen et al., 2007; Cochrane Back Group, 2007):

> Large, high qualitative research trials are needed, focusing on appropriate allocation concealment, blinding, and adequate data presentation and analysis. The design and reporting of future trials should conform to the CONSORT-statement
>
> New research should measure outcomes relevant to the patients and responsive to the treatment under study. Follow-up should be of sufficient length to assess long-term effects
>
> New research reports should provide full data on outcomes measure, including the means and standard deviation or 95% confidence interval
>
> Future research should examine the effect of active treatments not only in pragmatic trials, comparing various interventions with each other, but also in more explanatory trials comparing the intervention with no treatment
>
> Further research should focus on chronic whiplash patients because there are a broad variety of treatments available, most treatments are costly, and data on effectiveness are not available

4.2 Implications of Findings

4.2.1 Aspects specific to the osteopathic medicine.

Should the study show a significant difference between the treated and waiting list patients as well as a clear improvement in the complaints with the latter following treatment, it would show the potential benefits of establishing osteopathic treatment modality for comparable syndromes The *National OMM Research Synergy White Paper* (2003) recommend:

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.

4.2.2 Blinding and control treatment in osteopathic trials.

The study laid out here does not tackle the problem of blinding nor offer a plausible yet ineffective control treatment for osteopathic intervention studies. Due to the absence of such studies, a comparison is conducted with untreated patients; and hence the question of blinding does not arise (Ernst & Resch, 1995; Koes, 2004). However this procedure describes nonspecific as well as specific osteopathic treatment effects. In contrast the specific effects of the placebo/sham treatment cannot be clearly distinguished with this type of control group (Fletcher & Fletcher, 2005).

To guarantee the most objective and unbiased evaluation, the randomization and the assessment is blinded and carried out by an independent statistician, who is otherwise not involved in the study.

4.2.3 Clinical-ethical questions for the development of a study design.

The study does not raise any ethical problems because the patients, without exception, have already been "treated" with traditional medicine but have shown no improvement, and established or generally recommended and available therapy has not been withheld. The control group (waiting list patients) has to get the best standard therapy which is currently available for the condition under study, according to the *Declaration of Helsiniki* (October 2000). This is the case here because an evidence-based standard treatment for LWS does not exist to date (Poorbaugh et al., 2007). Therefore the index treatment is a "therapeutic option" for this group of patients.

Objectively seen no harm can arise in the waiting list patients who do not receive treatment during the five-week period. Furthermore all patients are completely informed about the nature of the study; and hence no patient will feel put at a disadvantage.

4.3 Conclusion

The master thesis, as the result of a graduate program enrolled at the founding university of osteopathy, the A.T. Still University, Kirksville, MO and follows the rules by means of rigorous scientific research as it is required by the EBM for common applications in clinical practice.

- Finding relevant studies of a high quality
- Assessing their methodological characteristics
- Interpreting their results in light of the clinical question at hand

"…[I]n light of the clinical question at hand" is the therapeutic approach whether osteopathic treatment seems suitable to substantially broaden the base for decision making on the effectiveness of an osteopathic approach to LWS treatment. This approach is closely linked with two terms "somatic dysfunction" and "osteopathic manipulative treatment" (OMT) in the USA; defined as "osteopathic treatment" in Europe.

Both terms are parts of the osteopathic therapeutic concept in which the patient is recognized as an individual with self-healing power; and in the case of illness it is the aim to restore the self-healing mechanism. Thus the osteopath treats patients with somatic dysfunctions (manifestation of diseases) to reorganize the self-healing mechanism. This therapeutic approach takes place under the consideration of the principles of the founder of osteopathy, A.T. Still, in 1892. Because of a lack of evidence in this therapeutic application to whiplash syndrome, this master thesis may be seen as a contribution to the defined scientific evidence in osteopathic clinical research.

This protocol may be able to fill a gap for patients' well-being and as a scientific contribution to evidence-based osteopathy EBO (Licciardone, 2008).

The contribution in this set out protocol on LWS may mirror the need to integrate a holistic therapeutic concept into a rigorous study design. The character of the osteopathic concept (application of a holistic osteopathic approach) into a sound study is the core aspect in this thesis.

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Chapter 6: 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 late whiplash syndrome

Condition	Intervention
Late whiplash syndrome	Test-dependent osteopathic treatment

Official title: Osteopathic Treatment of Late Whiplash Syndrome.
A Randomized Controlled Trial of Effectiveness
Study type: Conservative Interventional
Study design: Clinical, prospective, randomized, controlled (2-armed), open multi-center, follow-up 3 and 6 months
Blinding Evaluator/outcome assessor-blinded to the study

Primary objective:
Reduction of whiplash related symptoms
Secondary objectives:
Reduction of pain intensity
Improvement in quality of life
Correlation of psychological factors with late whiplash symptoms
Frequencies of areas of osteopathic dysfunction
Reduction of medication
Association between psychological factors and the target symptoms
Lasting positive effects of osteopathic treatment

Further study details
Estimated enrollment: 140 (70/70)
Estimated centers: 8 osteopathic research centers

Arms	Assigned interventions
1: No intervention	Procedure: Waiting list - Untreated for 8 weeks - Adjacent 4 osteopathic sessions
2: Experimental Osteopathic treatment	Procedure: Osteopathy - 4 therapeutic sessions during the first 8 weeks (every 14 days) - Follow up: 3 and 6 months after the end of the treatments

Primary Outcome Measures:

- Whiplash related disability (measured by the WDQ)

[Time frame: Baseline, 1, 3, 5, 8, 22 and 34 weeks]

Secondary Outcome Measures:

- Pain intensity (VAS)

[Time frame: Baseline, 1, 3, 5, 8, 22 and 34 weeks]

- Quality of life (SF-12 Health Survey)

[Time frame: Baseline, 1, 3, 5,8, 22 and 34 weeks]

- Psychosocial factors (BDI)

[Time frame: Baseline, 1, 3, 5, 8, 22 and 34 weeks]

- Medication (Medication diary)

[Time frame: Baseline, 1, 3, 5, 8, 22 and 34 weeks]

- Osteopathic dysfunctions (Examination forms: SOEF, SOAP)

[Time frame: Baseline, 1, 3, 5, 8 weeks]

Eligibility

Ages eligible for study: 18 years to 65 years
Genders eligible for study: male and female

Inclusion criteria:

- Whiplash longer than 6 month after a motor vehicle collision
  Defined criteria at the motor vehicle collision
- Actual symptoms intensity must exceed 30% on the VAS
- Symptoms must be as a result of the motor vehicle collision
- Sufficient language skills to understand and complete trial questionnaires
- Given written informed consent for clinical screening

Exclusion Criteria:

- Undergoing treatments like physical therapy, manual therapy, chiropractic spinal manipulation, acupuncture within the past 3 months
- Undergoing osteopathic treatment within the past 6 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
- 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

- 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

Locations: (primary care setting) research centers in osteopathic practices

Contacts: Project coordinator:

Keywords for the Search Strategy

Table A: Search Strategy: Reference Keywords

Basic Strategy:		**Subheadings**
Terms combined with OR	AND	Terms combined with OR
Whiplash injury[MeSH]		Definition
Neck injury[MeSH]		Classification
Spinal injury[MeSH]		Epidemiology
Whiplash syndrome		Etiology
Accidents, traffic[MeSH]		Diagnosis
Late whiplash syndrome [MeSH]		Therapy
Whiplash associated disorders		Management
WAD[MeSH]		Prognosis
Post-traumatic stress disorders		Risk factors

Table B: *Search Strategy: Reference of Osteopathic Keywords*

Basic Strategy:		**Osteopathic keywords**
Terms combined with OR	AND	Terms combined with OR
Whiplash injury [MeSH]		Osteopathic treatment
Neck injury [MeSH]		Osteopathy
Spinal injury [MeSH]		Osteopathic medicine [MeSH]
Whiplash syndrome		Osteopathic physician
Accidents, traffic [MeSH]		Manipulation, orthopedic
Late whiplash syndrome [MeSH]		Osteopathic manipulation [MeSH]
Whiplash associated disorders		Mobilisation
WAD		Manual therapy
Post-traumatic stress disorders		

Chapter 7: Appendix B

Information Forms

Patient Information

Have you ever suffered from whiplash injury (motor vehicle accident)?

We are currently looking for patients suffering from whiplash injury for longer than 6 months 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.

Whiplash injury is defined as accident related symptoms of the spine (including headaches, dizziness, restriction of motion, and pain). Despite it occurring frequently and the variety of treatment possibilities, the results are often unsatisfactory.

The study is to investigate whether osteopathic treatment is effective and can positively affect the symptoms.

There is no charge for participating in the study.

If you are interested in participating in the study, we kindly ask you to answer the following questions:

1. Were you involved in a motor vehicle accident at least 6 months ago, but no longer than 10 years, which resulted in whiplash injury, and are you still suffering from the results of the injury?

   YES ☐ NO ☐

2. Is there a pending insurance claim because of your whiplash injury?

   YES ☐ NO ☐

3. Are you able to provide X-rays, NMR, or CT scans of the cervical spine (neck) which were taken following the accident?

   YES ☐ NO ☐

4. Are you between 18 und 65 years old?

   YES ☐ NO ☐

5. Is there a current pending pension application because of your whiplash injury?

   YES ☐ NO ☐

6. Have you received osteopathic treatment in the last 6 months?

YES ☐ NO ☐

The answers you give enable us to decide who can participate in the study. If you have any further questions about the study, please do not hesitate to contact the research center:

Address:

_____

_____

_____

Telephone Questionnaire

Telephone Questionnaire-Nr.:_____

Date:_____

male ☐ female ☐

1. How old are you? Should be: $18 \leq \leq 65$

2. Are you pregnant? YES ☐ = exclude NO ☐

3. 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 to this?
   YES ☐ NO ☐ = exclude

4. Are you going to be absent for a period of time in the near future?
   YES ☐ = exclude NO ☐

5. Have you ever suffered from whiplash injury resulting from a rear-end collision motor vehicle accident?
   YES ☐ NO ☐ = exclude

6. Was there any head contact with the interior of the car?
   YES ☐ = exclude NO ☐

7. Have you suffered from multiple whiplash injuries?
   YES ☐ = exclude NO ☐

8. When was the whiplash injury?
   more than 6 months ago ☐ within the last 6 months ☐ = exclude

9. How long have you been suffering from the symptoms?
   more than 6 months ago ☐ within the last 6 months ☐ = exclude

10. Describe your average pain resulting from the whiplash injury from a scale of 1 to 10.

    0___1___2___3___4___5___6___7___8___9___10

    no pain maximum pain

    < 3 ☐ = exclude > 3 ☐

11. Is there a current pending pension application because of your whiplash injury?

    YES ☐ = exclude NO ☐

12. Is there a pending insurance claim because of your whiplash injury?

    YES ☐ = exclude NO ☐

13. Have you ever had a serious injury or change to the cervical spine (neck) or?

    YES ☐ NO ☐

    If YES, what? .....

    (Exclusion criteria: operation, radiotherapy, or neurological diseases)

14. Besides neck pain, do you have other diagnosed serious diseases?

    YES ☐ NO ☐

    If YES, what? .....

    (Exclusion criteria: osteoporosis, rheumatism, cancer, arteriosclerosis of A. vertebralis, diabetes mellitus, metablolic disorders, neurological diseases, etc.)

15. Do you take medication regularly or do you receive injections?

    YES ☐ NO ☐

    If YES, what? .....

    (Exclusion criteria: corticosteriod medication, anticoagulants)

    Have you ever taken cortisone over a longer period of time?

16. Are you currently signed off work because of your whiplash injury?

    YES ☐ = exclude NO ☐

17. Are you currently undergoing any physical therapy (massage, physiotherapy)?

    YES ☐ NO ☐

18. If YES, do you agree to stop these therapies temporarily during the time of the study?
    YES ☐ NO ☐ = exclude

19. Have you undergone a manipulation on your spine in the last 3 months?
    YES ☐ = exclude NO ☐

20. Have you received osteopathic treatment in the last 6 months?
    YES ☐ = exclude NO ☐

If the patient is suitable for inclusion in the study:

Surname, Name:_____

Address:_____

Telephone: Private_____ Work: _____ Email:_____

Study Information for Patients

Dear Patient

We would like to thank you for your interest in the study of late whiplash syndrome.

Late whiplash syndrome is a general term for complaints of the cervical vertebral spine (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.

In Germany ca. 18 to 25% of all patients with whiplash injuries suffer from the effects even up to one year after the incident. The patients exhibit a variety of symptoms, which cannot be easily attributed to any one cause.

Patients who visit an osteopathic practice are often suffering from the after effects of an injury, especially after road traffic accidents. It is remarkable that conventional treatment methods generally result in no discerning improvement with these patients. The sharpened powers of perception osteopaths have combined with the knowledge of anatomy enables them to detect and treat dysfunctional structures.

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 spine (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

Procedure

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.

Which osteopathic technique used is decided by the osteopath. 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 8 weeks and consists of four 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 late whiplash injury. 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 places 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.

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 healthcare management in the following diagnoses:

- Muscle or ligament strains, ankle, elbow, knee
- Traumatic injuries without laceration or fracture
- Pregnancy and childbirth, labor and post-partum
- Muscle tension headache independent or associated with migraine
- Sinusitis, allergic rhinitis, paranasal sinusitis
- 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 when 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. In addition, some are trained as full physicians; some as physiotherapists. Avenues to certification or registration by governments and other regulatory bodies varies among nations.

Physician Letter

Scientific clinical study within the scope of osteopathy
Residual forms of whiplash injury/post-traumatic cervical syndrome following whiplash injury longer than 6 months (late whiplash syndrome)

Dear Physician

We are several registered osteopaths who are planning a study for the A.T. Stills University, Arizona. The study is to investigate the whether osteopathy can effectively treat the symptoms of late whiplash syndrome (LWS), so that patients can detect an improvement in their quality of life.

The study is to be conducted as a *waiting list design*, in which questionnaires (WDQ, SF-12, BID) and visual analogue scales (VAS) serve as outcome measurements.

To ensure the study follows the necessary scientific procedure, we require patients who fulfill particular criteria:

1. The patient was involved in a motor vehicle accident at least 6 months ago which resulted in whiplash injury. The accident was a rear-end collision with no head contact in the car, and the patient is still suffering from the results of the injury.
2. X-rays, NMR, or CT scans were taken following the accident, which can be used to show contraindications for osteopathic treatment.
3. The patient has never received osteopathic treatment.
4. The patient has no pending insurance claims.
5. The patient has no pending pension application.
6. The patient is between 18 and 65 years old.

The study takes around 8 weeks in total and consists of an initial interview and four osteopathic treatments free of charge. During the study, the patient should not receive any physical or chiropractic manipulations or massage, which may distort the study treatment outcomes. Of course, any medication currently prescribed can continue to be taken.

We would very much appreciate your support in finding participants for the study, and we look forward to hearing from you. We would like to take this opportunity to thank you in advance for your support and contribution.

Yours faithfully

Address of the study center:

Documentation of the Physician

Dear Physician

Thank you very much for your involvement within the scope of our study on late whiplash syndrome.

For your information: during the study the patient should not

- receive physical therapy
- receive 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
Neoplasms
Neurological diseases

Osteoarthritis
Inflammatory disorders (e.g. rheumatic diseases)
Irreversible injuries of the cervical spine
Cervical herniation with neurological deficiencies, myelopathy
Calcium metabolism disorders
Circulatory disorders of the A. vertebralis
Psychiatric illness
Corticosteroid medication, treatment with anticoagulants

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

Yes ☐ No ☐

stamp / signature of physician

Informed Consent

Title: Osteopathic treatment of patient with late whiplash syndrome

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 from late whiplash syndrome. A total of 128 participants will be recruited for this study. The trial will be carried out in different osteopathic private practices. Participation will require 4 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 additional questionnaires have to be filled out. There will be two groups in the study. One group will begin with the treatments immediately; the other group will begin 1 month 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 four 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 incur any more risks than you would 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 until after two days, please contact your practitioner.

IV. Benefits:

Participation in this study may benefit you personally. We hope that your whiplash-related symptoms will improve with the treatment. 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 the research is voluntary. If you decide at any time to stop the treatment, you can do so. You also carry no obligations to answer all the questions in the questionnaires, and you will incur no costs should you decide to leave the study.

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

Chapter 8: Appendix C

Assessment instruments

Initial Questionnaire

ID-Nr.:_____

Date_____ T(1)

1) Surname,
name:_____

2)
Address:_____

3) Telephone Private:_____
Work:_____

4) DOB:_____ male ☐ female ☐

5) Height:_____
Weight:_____

6) Marital status: Single ☐ Married ☐ Divorced ☐

7)
Occupation:_____
_

8) Name of current
physician:_____

9) Which medications are you currently taking?

_____
_____
_____
_____

10) How would you rate your current condition of health?

Excellent ☐ good ☐ average ☐ poor ☐

11) Please list all operations and accidents (and year they occurred):

_____

_____

_____

_____

12) Have you ever had problems or illnesses in the following organs or area of the body? Please circle.

heart	lungs	kidneys
skull	brain	spinal cord
eye	nose	ears
shoulder	neck	chest
stomach	intestines	liver

13) Which infectious diseases have you had (with year they occurred):

_____

_____

_____

_____

_____

_____

14) Please describe your current complaint and symptoms:

_____

_____

_____

_____

_____

_____

_____

15) Questions about non-specific symptoms:

Do you have a fever?	YES ☐	NO ☐
Are you sensitive to the cold?	YES ☐	NO ☐
Have you recently been losing a lot of weight?	YES ☐	NO ☐
Has your eyesight deteriorated in the last 6 months?	YES ☐	NO ☐
Have you received dental treatment in the last 6 months?	YES ☐	NO ☐

16) Which symptoms do you have?

Neck pain	YES ☐	NO ☐
Muscle stiffness in the neck and shoulder region	YES ☐	NO ☐
Inexplicable, worsening neck pain which improves at rest	YES ☐	NO ☐
Tension in the throat region with difficulties in swallowing	YES ☐	NO ☐
Painful restrictions of movement in the neck region	YES ☐	NO ☐
Pain in the chest and shoulder-arm region	YES ☐	NO ☐
Pain when moving arms or shoulders	YES ☐	NO ☐

Numbness in the arms	YES ☐	NO ☐
A feeling of swelling and/or coldness in the hands	YES ☐	NO ☐
Toothache for no reason	YES ☐	NO ☐
Nausea or the feeling of wanting to be sick	YES ☐	NO ☐
Impaired vision (e.g. seeing stars)	YES ☐	NO ☐
Impaired hearing (e.g. tinnitus)	YES ☐	NO ☐
Heart rhythm disturbances	YES ☐	NO ☐
Dizziness or problems balancing	YES ☐	NO ☐
Increased tiredness and sleeping disorders	YES ☐	NO ☐
Problems concentrating, irritability, forgetfulness, or anxiety	YES ☐	NO ☐

Questions about the motor vehicle accident

1) Date of the
accident:_____

2) How did it happen?

_____
_____
_____
_____
_____
_____
_____

3) Were you driving? ☐ Or a passenger? ☐

4) Were you wearing a seatbelt? YES ☐ NO ☐

5) Were you at fault? YES ☐ NO ☐

6) Were the police involved? YES ☐ NO ☐

7) Did your head hit any part of the car? YES ☐ NO ☐

8) Was the airbag activated? YES ☐ NO ☐

9) Which acute complaints have you had following the accident? Name the three most severe:

_____
_____
_____
_____

10) Which physicians have seen because of your whiplash injuries?

_____

_____

_____

_____

11) Which of the symptoms have the treatments so far not been able to improve?

_____

_____

_____

_____

12) Has there been any impairment in the quality of life of your life because of the accident?

Not at all ☐ a little ☐ quite a bit ☐ moderate ☐ extreme ☐

13) Have you received any psychotherapeutic support

(either before or after the accident)? YES ☐ NO ☐

Whiplash Disability Questionnaire

La Trobe University
School of Physiotherapy
Whiplash Disability Questionnaire

This questionnaire has been designed to provide information on the impact that your whiplash injury and symptoms have upon your lifestyle. Please circle a number in each section to indicate how you have been affected by the whiplash injury and symptoms. If one or more questions are not relevant to you, please leave that section blank.

Date: _____/_____/_____ Name: _____

1 How much **pain** do you have today?

0 1 2 3 4 5 6 7 8 9 10
No Pain — Worst pain imaginable

2 How much do your whiplash symptoms interfere with your **personal care** (washing, dressing etc)?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Unable to perform

3 How much do your whiplash symptoms interfere with your **work/home/study duties**?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Unable to perform

4 How much have your whiplash symptoms interfered with **driving or using public transport**?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Unable to travel in car/ use public transport

5 How much do your whiplash symptoms interfere with **sleep**?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Cannot sleep

6 How often do you experience **tiredness/fatigue** as a result of your whiplash injury/symptoms?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Always

7 How much do your whiplash symptoms interfere with **social activity**?

0 1 2 3 4 5 6 7 8 9 10
Not at all — Unable to socialise

Please turn the page

Whiplash Disability Questionnaire

8 How much do your whiplash symptoms interfere with **sporting activity**?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Unable to participate

9 How much do your whiplash symptoms interfere with **non-sporting leisure activity**?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Unable to participate

10 How often do you experience **sadness/depression** as a result of your whiplash injury/symptoms?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Always

11 How often do you experience **anger** as a result of your whiplash injury/symptoms?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Always

12 How often do you experience **anxiety** as a result of your whiplash injury/symptoms?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Always

13 How much difficulty do you have **concentrating** as a result of your whiplash injury/symptoms?

0	1	2	3	4	5	6	7	8	9	10
No difficulty										Unable to concentrate

Thank you for your cooperation

Minimum Detectable Change (90% confidence) 15 points.

Source: Pinfold et al (2004). Validity and internal consistency of a Whiplash-Specific disability measure. Spine 29(3): 263-268.

SF-12

The SF-12™ Health Survey

Instructions for Completing the Questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section ***Your Health in General*** below.

For each question you will be asked to fill in a bubble in each line:

1. How strongly do you agree or disagree with each of the following statements?

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
a) I enjoy listening to music.	○	●	○	○	○
b) I enjoy reading magazines.	●	○	○	○	○

Please begin answering the questions now.

Your Health in General

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

Excellent	Very good	Good	Fair	Poor
○	○	○	○	○

2. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
b. Climbing **several** flights of stairs	○	○	○

Please turn the page to continue.

3. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		YES	NO
a.	**Accomplished less** than you would like	○	○
b.	Were limited in the **kind** of work or other activities	○	○

4. During the **past 4 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)?

		YES	NO
a.	**Accomplished less** than you would like	○	○
b.	Didn't do work or other activities as **carefully** as usual	○	○

5. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
○	○	○	○	○

6. These questions are about how you feel and how things have been with you during the **past 4 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 4 weeks** . . .

		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.	Have you felt calm and peaceful?	○	○	○	○	○	○
b.	Did you have a lot of energy?	○	○	○	○	○	○
c.	Have you felt downhearted and blue?	○	○	○	○	○	○

7. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

***THANK YOU* FOR COMPLETING THIS QUESTIONNAIRE!**

Beck Depression Inventory

V 0477 | **Beck Depression Inventory** | CRTN: _____ CRF number: _____ | Page 14 | **Baseline** | patient inits: _____

BDI-II®

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

Subtotal Page 1

Continued on Back

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11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I don't consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.
1a I sleep somewhat more than usual.
1b I sleep somewhat less than usual.
2a I sleep a lot more than usual.
2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1–2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before.
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

3 4 5 6 7 8 9 10 11 12 A B C D E

_____ Subtotal Page 2
_____ Subtotal Page 1
_____ Total Score

NR15645

VAS Pain

ID-Nr.:_____

To be filled out at: T_{1-7} and T_{W1-8}

How much pain in the region of the neck do you experience *right now*?

(Check were appropriate)

No pain at all Unbearable pain

What was the *worst* pain in the region of the neck you experienced during the *past week*?

(Check were appropriate)

At rest 

In motion 

Under strain 

No pain at all Unbearable pain

What was the *average* pain in the region of the neck you experienced during the *past week*?

(Check were appropriate)

No pain at all Unbearable pain

VAS Body Regions

ID-Nr.:_____

To be filled out at: T_{1-7} and T_{W1-8}

Date	**Shoulder/upper back:** I rate my pain at the moment as
	|----------| no pain at all unbearable pain

Date	**Pelvis/lower back:** I rate my pain at the moment as
	|----------| no pain at all unbearable pain

Date	**Chest bone/rib-cage:** I rate my pain at the moment as
	|----------| no pain at all unbearable pain

Date	**Abdominal region:** I rate my pain at the moment as
	|----------| no pain at all unbearable pain

Medication Diary

Date: ……

Part 1: Long-term medication

Do you take medication regularly for your whiplash syndrome?	
Medication and dosage?	
How often? (e.g. 1-0-1)	
Change in medication: Date? Drug and dosage?	

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

Please fill out this part before the first osteopathic treatment (T_0). During the course of treatments only then if there is a change in medication. **Date: ……**

Part 2: Muscle relaxants

Have you taken muscle relaxants within the last 48 hours? (e.g. Musaril, Myoson, Trancopaldolo) YES ☐ NO ☐

Part 3: On demand medication

Please write down any medication you have taken within the last week.

Date	Medication type & amount taken

Please fill out this part before every osteopathic treatment.

Chapter 9: Appendix D

Protocol of Intervention

SOAP Note Form

Outpatient Health Summary

wak SOS version 5:091102

Patient's Name		**Date**	**Update:**
Date of Birth	**Sex**	**Phon**	**Home**
Marital Status: M S D W		**DNR**	**No** **Qualifications:**
Significant Others:		**Resu**	
Religion:		**Next of Kin:**	

Section I page 5

Social History:	**Employment**	**Occupation**		**Education**	
	Tobacco	**ETOH**			**Sex Hx**
Family History:	**M**	**Sibli**		**Others:**	
	F				

Section II page 5-6

Past Medical History

CPT#	Start Date	Problem / Diagnosis	Medications	Start	Stop

Section III page 6

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								

Section IV page 6

Past Surgical History

Date	Type

Section V page 6

Consultants

Section VI page 6

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1

Outpatient Osteopathic SOS History / Exam Form

wak SOS version 5:091102

Office of:

Patient's Name _____ **Date**_____

For office use only:

HISTORY

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

Patient's Pain Analog Scale: ☐ Not done

Section I page 7

NO PAIN — WORST POSSIBLE PAIN

CC

History of Present Illness — **Level: HPI**

Elements		
☐	Location	
☐	Quality	
☐	Severity	
☐	Duration	
☐	Timing	
☐	Context	
☐	Modifying factors	
☐	Assoc. Signs and Sx	

OR Status of ≥ 3 chronic or inactive conditions

_____

_____

_____

☐	II / III	1-3 elements reviewed
☐	IV / V	≥ 4 elements OR status of ≥ 3 chronic conditions

Review of Systems (Only ask / record those systems pertinent for this encounter.) ☐ Not done — **Level: ROS**

☐	Constitutional (Wt loss, etc.)
☐	Eyes
☐	Ears, nose, mouth, throat
☐	Cardiovascular
☐	Respiratory
☐	Gastrointestinal
☐	Genitourinary
☐	Musculoskeletal
☐	Integumentary (skin, breast)
☐	Neurological
☐	Psychiatric
☐	Endocrine
☐	Hematologic/lymphatic
☐	Allergic/immunologic

Section II page 7-8

☐	II	None
☐	III	1 system pertinent to the problem
☐	IV	2-9 systems
☐	V	≥ 10 systems

Past Medical, Family, Social History ☐ Not done — **Level: PFSH**

☐	Past history / trauma
☐	Family history
☐	Social history

☐	II / III	None
☐	IV	1 history area
☐	V	≥ 2 history areas

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)

O

Section III page 8

Signature of transcriber: _____ Signature of examiner: _____

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Outpatient Osteopathic SOS Musculoskeletal Exam Form

wak SOS version 5:091102

O ☐ Not done

Patient's Name _____ Date _____ Female ☐

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

Reg. ☐ Pt. position for recording BP:

Resp. ____ Pulse ____ Irreg. ☐ Standing _____ Sitting _____ Lying _____

Office of:

For office: use only

Section I page 8-9

* **Gait and Station:**

Body Type: Endo. ☐ Meso. ☐ Ecto. ☐

Posture: Excl. ☐ Fair ☐ Poor ☐

Gait: Symmetrical ☐ Asymmetrical ☐

Ant./Post. Spinal Curves: I N D

Cervical Lordosis ☐ ☐ ☐

Thoracic Kyphosis ☐ ☐ ☐

Lumbar Lordosis ☐ ☐ ☐

Section II page 9

I = increased; N = normal; D = decreased

Scoliosis (Lateral Spinal Curves):

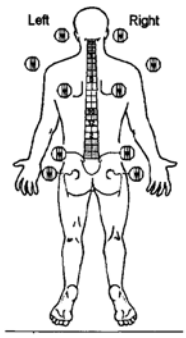
None ☐ Sitting ☐

Functional ☐ Standing ☐

Mild ☐ Prone/Supine ☐

Moderate ☐ Unable to Examine ☐

Severe ☐



Horizontal Planes

Notes

Section III page 9-10

* Gen. Appearance:	Y	N
Normal	☐	☐
***Cardiovascular**	☐	☐
Observation normal	☐	☐
Palpation normal	☐	☐
***Lymphatics**	☐	☐
No palpable nodes	☐	☐
Sensory intact	☐	☐
Mental status		
Oriented:		
In time	☐	☐
In person	☐	☐
In place	☐	☐
Good mood/ affect	☐	☐

Short leg? Equal ☐

Right: 1/8 ☐ ¼ ☐ ½ ☐

Left: 1/8 ☐ ¼ ☐ ½ ☐

Level of SOS

☐	II	1-5 elements
☐	III	6+ elements
☐	IV	12+ elements for musculoskeletal exam
☐	V	Perform all * Elements

* **Skin:**

	N	Ab		N	Ab		N	Ab
Head / neck	☐	☐	L. upper extremity	☐	☐	L. lower extremity	☐	☐
Trunk	☐	☐	R. upper extremity	☐	☐	R. lower extremity	☐	☐

Section IV page 10-11

* **Reflexes:**

		0	1	2	3	4
Biceps	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
Triceps	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
Brachio-Radialis	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
Patella	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
Achilles	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
Babinski	L	up ☐		down ☐		
	R	up ☐		down ☐		

Motor:

		1	2	3	4	5
C5	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
C6	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
C7	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
C8	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
T1	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
L4	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
L5	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐
S1	L	☐	☐	☐	☐	☐
	R	☐	☐	☐	☐	☐

Section V page 11

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	☐	☐	☐	☐	
*2	☐	☐	☐	☐	☐	Thoracic T1-4	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	T5-9	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	T10-12	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	Ribs	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	Lumbar	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	Sacrum / Pelvis	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	Pelvis / Innom.	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	Abd. / Other	☐	☐	☐	☐	
*3	☐	☐	☐	☐	☐	Upper Extremity R	☐	☐	☐	☐	
*4	☐	☐	☐	☐	☐	Upper Extremity L	☐	☐	☐	☐	
*5	☐	☐	☐	☐	☐	Lower Extremity R	☐	☐	☐	☐	
*6	☐	☐	☐	☐	☐	Lower Extremity L	☐	☐	☐	☐	

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Outpatient Osteopathic Assessment and Plan Form

wak SOS version 5:091102

A Patient's Name_____ I

Section I page 12

Office of:

For office use only:

Dx No.	ICD Code	Written Diagnosis	Dx No.	ICD Code	Written Diagnosis
	739.0	Somatic Dysfunction of Head and Face		.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

Section II page 12

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

P ☐ All not done

Region	OMT Y	OMT N	ART	BLT	CR	CS	DIR	FPR	HVLA	IND	INR	LAS	ME	MFR	ST	VIS	OTH	Response R	Response I	Response U	Response W
Head and Face	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Neck	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Thoracic T1-4	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
T5-9	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
T10-12	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ribs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lumbar	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sacrum	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pelvis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Abdomen/Other	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Upper Extremity	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lower Extremity	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Treatment Method

Section III page 12-13

Meds: PT:

Exercise:

Nutrition:

Section IV page 13

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

Problems		Risk: (Presenting problem(s), diagnostic procedure(s), and management options)		Data	Maximum Points
Self-limiting	1 (2 max.)	Minimal = Min.		Lab	1
Established problem improved / stable	1			Radiology	1
Established – 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

Level I	Level II	Level III	Level IV	Level V	Level I	Level II	Level III	Level IV	Level V	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 3 of the above 3 (problems, risk and data). Level of complexity

Section V page 14

Traditional Method—Coding by Components

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

All three 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
Outpatient consults (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 ☐

Section VI page 14-15

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: _____

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Standardized Osteopathic Examination Form

Date:_____ T( ) **IdNr.:_____**

1)Safety Tests: Cervical Spine

Compression	**positive☐**	**negative ☐**			
Decompression	**positive☐**	**negative ☐**			
De Klejyn Test	**positive☐**	**negative ☐**			
Hypermobility Tests					
C1-C2 (lateral testing)	**positive☐**	**negative ☐**			
C2-C1 (ant.-post. testing)	**positive☐**	**negative ☐**			
2) Structures (cranium/thorax)	**Restriction**	**right**	**left**	**medial**	
Compression SSB	**positive☐**	**negative ☐**			
Os temporale in exorot.	**positive☐**	**negative ☐**	**☐**	**☐**	
Sutura occ.-mast.	**positive☐**	**negative ☐**	**☐**	**☐**	
Dura mater spinalis	**positive☐**	**negative ☐**			
Lig. cervicopleurale	**positive☐**	**negative ☐**	**☐**	**☐**	
Clavicula dysfunction	**positive☐**	**negative ☐**	**☐**	**☐**	
Mandibula	**positive☐**	**negative ☐**	**☐**	**☐**	
Os hyoideum	**positive☐**	**negative ☐**	**☐**	**☐**	
Ventral cervical fascia	**positive☐**	**negative ☐**	**☐**	**☐**	

Sternal fascia **positive☐ negative ☐**

Sternal intraosseous **positive☐ negative ☐**

Lig. sternopericardiaca **positive☐ negative ☐**

3) Visceral Structures **Restriction** **right left**

Cardia restriction **positive☐ negative ☐**

Kidney mobility **positive☐ negative ☐ ☐ ☐**

4) Cervical Spine Segment **Restriction right left**

(Cervical facet joints)

C0-C1 **positive☐ negative ☐ ☐ ☐**

C1-C2 **positive☐ negative ☐ ☐ ☐**

C2-C3 **positive☐ negative ☐ ☐ ☐**

C3-C4 **positive☐ negative ☐ ☐ ☐**

C4-C5 **positive☐ negative ☐ ☐ ☐**

C5-C6 **positive☐ negative ☐ ☐ ☐**

C6-C7 **positive☐ negative ☐ ☐ ☐**

C7-Th1 **positive☐ negative ☐ ☐ ☐**

5) Thoracic Spine Segment **Restriction right left**

Th1-Th2 **positive☐ negative ☐ ☐ ☐**

Th2-Th3 **positive☐ negative ☐ ☐ ☐**

Costa 1 **positive** ☐ **negative** ☐ ☐ ☐

Costa 2 **positive**☐ **negative** ☐ ☐ ☐

Costa 3 **positive**☐ **negative** ☐ ☐ ☐

Th12-L1 **positive**☐ **negative** ☐ ☐ ☐

6) Os sacrum **Restriction right left**

positive☐ **negative** ☐ ☐ ☐

7) Os coccygis **Restriction right left**

positive☐ **negative** ☐ ☐ ☐

anterior☐ **posterior** ☐

Protocol of Intervention

ID-Nr.:_____

At T(_____) on _____ the following regions/structures/ dysfunctions were treated:

1._____

2._____

3._____

4._____

5._____

6._____

7._____

Final Questionnaire

ID-Nr.:_____

Date_____ T_5 and T_{W6}

1) How would you rate the overall result of the treatment?

very good ☐ good ☐ satisfactory ☐ poor ☐

2) Were you happy with the organization of the study? YES ☐ NO ☐

Suggestions for improvement:

_____

_____

_____

3) Were you happy with the research center environment YES ☐ NO ☐

Suggestions for improvement:

_____

_____

_____

4) Did you feel that you received competent guidance from

the osteopath during the study? YES ☐ NO ☐

Suggestions for improvement:

_____

_____

_____

5) Are you interested in the results of the study? YES ☐ NO ☐

6) Would you take part in a follow up study in ca. 2 years? YES ☐ NO ☐

7) Would you seek osteopathic treatment for other illnesses YES ☐ NO ☐

8) Would you recommend osteopathy as a treatment

to friends? YES ☐ NO ☐

Chapter 10: Appendix E

Characteristics of Included Studies

Characteristics of Included Studies [in alphabetic order]

Study 1 Fryer, G., Alvizatos, J., and Lamaro, J. 2005

Titel: The effect of osteopathic treatment on people with sub-chronic and chronic neck pain

---

Type of Study: Pilot study

Intervention: Passive

Outcome: Pain intensity

Pain quality

Emotional well-being

Neck-specific functioning

Instruments: VAS

McGill Pain Questionnaire

McGill Pain Questionnaire

NDI

Time since injury: Sub-chronic

Number of participants: 17

Study 2 Bonk, A. D., Ferrari, R., Giebel, G. D., Edelmann, M. and Huser, R., 2000

Titel: Prospective, randomized, controlled study of activity vs. collar, and the natural history for whiplash injury

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

ROM

Instruments: VAS

Goniometer

Time since injury: Acute

Number of participants: 79

Study 3 Borchgrevink, G. E., Kaasa, A., McDonagh, D., Stiles, T. C., Haraldseth, O., Lereim, I., 1998

Titel: Acute treatment of whiplash neck sprain injury. A randomized trial of treatment during the first 14 days after a car accident

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: ROM

Pain intensity

Self perceived recovery

Instruments: Cybex

VAS

Likert-scale response 0-3

Time since injury: Acute

Number of participants: 201

Study 4 Brison, R. J., Hartling, L., Dostaler, S., Leger, A., Rowe, B. H., Stiell, I., Pickett, W., 2006

Titel: A randomized controlled trial of an educational intervention to prevent the chronic pain of whiplash associated disorders following rear-end motor vehicle collisions

---

Type of Study: Randomized clinical trial

Intervention: Active vs. usual care

Outcome: Pain intensity

Self perceived recovery

Instruments: Likert-scale response 0-5

Likert-scale response 0-5

Time since injury: Sub-chronic

Number of participants: 405

Study 5 Bronfort, G., Evans, R., Nelson, B., Aker, P. D., Goldsmith, C. H., Vernon, H., 2001

Titel: A randomized clinical trial of exercise and spinal manipulation for patients with chronic neck pain

---

Type of Study: Randomized clinical trial

Intervention: Active vs. Passive

Outcome: Pain intensity

Disability

Global functioning

ROM

Emotional well-being

Instruments: NRS 0-10

NDI

SF-36

Spine Motion Analyzer CA6000 Orthop.Systems Inc.

7 point scale

Time since injury: Chronic

Number of participants: 191

Study 6 Bunketorp, L., Lindh, M., Carlsson, J., Stener-Victorin, E., 2006

Titel: The effectiveness of a supervised physical training model tailored to the individual needs of patients with whiplash-associated disorders - a randomized controlled trial

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

Disability

Emotional well-being

ROM

Pain quality

Instruments: VAS 100 mm diary 2/day

PDI

TAMPA-scale 17 items

Goniometer

Painometer, Dola Health Syst. Baltimore

Time since injury: Acute-Chronic

Number of participants: 47

Study 7 Carroll, A., Barnes, M., Comiskey, C., 2006

Titel: A prospective randomized controlled study of the role of botulinum toxin in whiplash-associated disorder

---

Type of Study: Randomized clinical trial

Intervention: Passive vs. placebo

Outcome: Pain intensity

ROM

Disability

Emotional well-being

Instruments: VAS

Hoppenbrouwers M 2006

NDI Vernon-Mior Index

Beck Depression Inventory

Time since injury: Acute

Number of participants: 37

Study 8 Crawford, J. R., Khan, R. J., Varley, G. W., 2004

Titel: Early management and outcome following soft tissue injuries of the neck-a randomized controlled trial

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Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

ROM

Global functioning

Instruments: VAS

Sum of 6 directions(0-380)

10-point scale

Time since injury: Acute-chronic

Number of participants: 108

Study 9 Dehner, C., Hartwig, E., Strobel, P., Scheich, M., Schneider, F., Elbel, M., Kinzl, L., Kramer, M., 2009

Titel: Grade II whiplash inuries to the neck: what is the benefit for patients treated by different physical therapy modalities?

Type of Study: Randomized clinical trial

Intervention: Active vs. Passive

Outcome: Pain intensity

ROM

Instruments: VAS 100 mm

Goniometer

Time since injury: Acute

Number of participants: 70

Study 10 Evans, R., Bronfort, G., Nelson, B., Goldsmith, C. H., 2002

Titel: Two year follow up of a randomized clinical trial of spinal manipulation

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

Disability

Global functioning

Instruments: Likert-scale response 0-10

NDI

SF-36

Time since injury: Chronic

Number of participants: 191

Study 11 Fernández de las Peñas, C., Palomeque del Cerro, L., Fernández Carnero, J., 2004

Titel: Manipulative treatment vs conventionalphysiotherapy in whiplash injury

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

ROM

Instruments: VAS

Goniometer

Time since injury: Acute

Number of participants: 38

Study 12 Fernandez-de-las-Penas et.al., 2004

Titel: Dorsal manipulative in whiplash injury treatment

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain quality

Disability

Pain intensity

Instruments: McGill Pain Questionnaire

NDI

VAS

Time since injury: Acute

Number of participants: 12

Study 13 Ferrari, R., Rowe, B. H., Majumdat, S. R., Cassidy, J. D., Blitz, S., Wright, S. C., Russell, A. S., 2005

Titel: Simple educational intervention to improve the recovery from acute whiplash

---

Type of Study: Randomized Clinical Trial

Intervention: Usual care vs. Passive

Outcome: ROM

Pain intensity

Instruments: Goniometer

Likert-scale response 0-2

Time since injury: Acute

Number of participants: 112

Study 14 Fialka, V., Preisnger, E., Bohler, A., 1989

Titel: Zur physikalischen Diagnostik und physikalischen Therapie der Distorsio columnae vertebralis cervicalis

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: ROM

Pain intensity

Instruments: Goniometer

Likert-scale response 0-2

Time since injury: Acute

Number of participants: 60

Study 15 Fitz-Ritson, D., 1995

Titel: Phasic exercises for cervical rehabilitation after whiplash trauma

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Disability

Instruments: NDI

Time since injury: Chronic

Number of participants: 30

Study 16 Foley-Nolan, D., Moore, K., Codd, M., Barry, C., O'Connor, P., Coughlan, R. J., 1992

Titel: Low energy high frequency pulsed electromagnetic therapy for acute whiplash injuries.

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

ROM

Self perceived recovery

Instruments: VAS

Likert-scale response 0-4

Likert-scale response 0-9

Time since injury: Acute

Number of participants: 40

Study 17 Gennis, P., Miller, L., Gallagher, E. J., Giglio, J., Carter, W., Nathanson, N., 1996

Titel: The effect oft soft cervical collars on persistent neck pain in patients with whiplash injury

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

Instruments: Likert-scale response 0-3

Time since injury: Acute

Number of participants: 196

Study 18 Giles, L. G., Muller, R., 2003

Titel: Chronic spinal pain: a randomized clinical trial comparing medication, acupuncture, and spinal manipulation

---

Type of Study: Randomized Clinical Trial

Intervention: Passive vs. passive

Outcome: Pain intensity

Disability

Global functioning

ROM

Instruments: VAS

Oswestry Questionnaire

NDI

SF-36

VAS

Time since injury: Chronic

Number of participants: 115

Study 19 Scholten-Peeters, G. G., Verhagen, A. P., Neeleman-van der Steen, C. W., Hurkmans, J. C., Wams, R. W., Oostendorp, R. A., 2003

Titel: Randomized clinical trial of conservative treatment for patients with whiplash-associated disorders: Considerations for the design and dynamic treatment protocol

---

Type of Study: Randomized clinical trial

Intervention: Active vs. advice

Outcome: Pain intensity

Global functioning

ROM

Emotional well-being

Disability

Instruments: VAS

SF-36

WBQ, VAS

NDI, DIP

Time since injury: Acute

Number of participants: Not calculated

Study 20 Hurwitz, E. L., Morgenstern, H., Harber, P., Kominski, G. F., Yu, F., Adams, A. H., 2002

Titel: A randomized trial of chiropractic manipulation and mobilization for patients with neck pain: Clinical outcomes from the UCLA neck-pain study

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Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

Global functioning

Disability

Instruments: NRS 0-10

SF-36

NDI

Time since injury: Acute

Number of participants: 336

Study 21 Irnich, D., Behrens, N., Molzen, H., Konig, A., Gleditsch, J., Krauss, M., Natalis, M., Senn, E., Beyer, A., Schops, P., 2001

Titel: Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain

---

Type of Study: Randomized clinical trial

Intervention: Passive vs. placebo acupuncture

Outcome: Pain intensity

ROM

Global functioning

Instruments: VAS

SF-36

Time since injury: Chronic

Number of participants: 177

Study 22 Kaiser, A., Kastner, R., Gietz, R., 2003

Titel: Studie zur osteopathischen Behandlung der Residualformen des Schleudertraumas

---

Type of Study: Clinical trail

Intervention: Passive

Outcome: Emotional well-being

Pain intensity

Neck specific functioning

Global functioning

Instruments: DIPS

VAS 1-10

NPAD Neck Pain and Disability Scale

SF-36

Time since injury: Chronic

Number of participants: 42

Study 23 Kongsted, A., Qerama, E., Kasch, H., Bendix, T., Bach, F. W., Korsholm, L., Jensen, T. S., 2007

Titel: Neck collar, "Act-as-usual" or active mobilization for whiplash injury?

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

Disability

General functioning

ROM

Instruments: NRS 1-10 Box scale

Copenh.NFDS 15 items

SF-36

Performance Attainment Ass.Roseville MN

Time since injury: Acute

Number of participants: 458

Study 24 Lamb, S. E., Gates, S., Underwood, M. R., Cooke, M. W., Ashby, D., Szczepura, A., Williams, M. A., Williamson, E. M., Withers, E. J., Mt Isa, S., Gumber, A., Mint Study Team, 2007

Titel: Managing injuries of the neck trial (MINT): design of a randomized controlled trial of treatment for whiplash associated disorders

---

Type of Study: Randomized clinical trial

Intervention: Active vs. advice

Outcome: Disability

Global functioning

Emotional well-being

Instruments: NDI

SF12

5 point Liker scale

Time since injury: Acute

Number of participants: 24

Study 25 MacDonald, R. S., Bell, C. M., 1990

Titel: An open controlled assessment of osteopathic manipulation in nonspecific back pain

---

Type of Study: Clinical trial

Intervention: Passive

Outcome: Pain intensity

Instruments: VAS

Time since injury: Chronic

Number of participants: 95

Study 26 McKinney, L. A., Dornan, J. O., Ryan, M., 1989

Titel: The role of physiotherapy in the management of acute neck sprains following road-traffic accidents

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive vs. advice

Outcome: Pain intensity

ROM

Instruments: VAS 1-10

Goniometer

Time since injury: Acute

Number of participants: 71

Study 27 Mealy, K., Brennan, H., Fenelon, G. C., 1986

Titel: Early mobilisation of acute whiplash injury

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

ROM

Instruments: VAS 1-10

Goniometer

Time since injury: Acute

Number of participants: 61

Study 28 Oliveira, A., Gevirtz, R., Hubbard, D., 2006

Titel: A psycho-educational video used in the emergency department provides effective treatment for whiplash injuries

---

Type of Study: Randomized clinical trial

Intervention: Passive vs. usual care

Outcome: Disability

Emotional well-being

Pain intensity

Instruments: SMFA

Questionnaire

VRS (verbal rating scale)

Time since injury: Chronic

Number of participants: 126

Study 29 Ottosson C, Pettersson H, 2007

Titel: Recovery after minor traffic injuries: A randomized controlled trial

---

Type of Study: Randomized clinical trial

Intervention: Non-treatment

Outcome: Recovery

Disability

Emotional well-being

Instruments: Question (yes/no)

SF-36

HAD

PTSD

Time since injury: Acute

Number of participants: 127

Study 30 Pennie, B. H., Agambar, L. J., 1990

Titel: Whiplash injuries: A trial of early management

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

ROM

Instruments: VAS

Goniometer

Time since injury: Acute

Number of participants: 135

Study 31 Provinciali, L., Baroni, M., Illuminati, L., Ceravolo, M. G., 1996

Titel: Multimodal treatment to prevent the late whiplash syndrome

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

ROM

Instruments: VAS

Likert-scale response 0-4

Time since injury: Acute

Number of participants: 60

Study 32 Richter, M., Ferrari, R., Otte, D., Kuensebeck, H.W., Blauth, M., Krettek, C., 2004

Titel: Correlation of clinical findings, collision parameters, and psychological factors in the outcome of whiplash associated disorders

---

Type of Study: Clinical trial

Intervention: Passive

Outcome: Pain intensity

Global functioning

Emotional well-being

Instruments: VAS

SF-36

CES-D, IES

Time since injury: Acute

Number of participants: 43

Study 33 Rosenfeld, M., Gunnarsson, R., Borenstein, P., 2000

Titel: Early intervention in whiplash-associated disorders

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: ROM

Pain intensity

Instruments: Inclinometer

VAS

Time since injury: Acute

Number of participants: 97

Study 34 Rosenfeld, M., Seferiadis, A., Carlsson, J., Gunnarsson, R., 2003

Titel: Active intervention in patients with whiplash-associated disorders improves longterm prognosis

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: ROM

Pain intensity

Instruments: Inclinometer

VAS

Time since injury: Acute

Number of participants: 102

Study 35 Rosenfeld, M., Seferiadis, A., Gunnarsson, R., 2006

Titel: Active involvement and intervention in patients exposed to whiplash trauma in automobile crashes reduces costs

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: ROM

Pain intensity

Instruments: Inclinometer

VAS

Time since injury: Acute

Number of participants: 97

Study 36 Schellingerhout, J.M., Verhagen, A.P., Heymans, M.W., Pool, J.J., Vonk, F., Koes, B.W., Wilhelmina, de Vet H.C., 2006

Titel: Which subgroups of patients with non-specific neck pain are more likely to benefit from spinal manipulation therapy, physiotherapy or usual care?

Type of Study: Randomized clinical trial

Intervention: Passive vs. usual care

Outcome: Recovery

Pain intensity

Instruments: 7-point ordinal Likert Scale

NRS 0-10

Time since injury: Chronic

Number of participants: 329

Study 37 Schmitt, M. A., van Meeteren, N. L., de Wijer, A., Helders, P. J., Graaf, Y., 1996

Titel: Functional health status in subjects after a motor vehicle accident, with emphasis on whiplash associated disorders

---

Type of Study: Prospective cohort study

Intervention: No intervention

Outcome: ROM

Pain intensity

Instruments: NBQ, SF-36, NDI.

NRS 0-10

Time since injury: acute

Number of participants: min 100

Study 38 Schnabel, M., Ferrari, R., Vassiliou, T., Kaluza, G., 2004

Titel: Randomised controlled outcome study of mobilization compared with collar therapy for whiplash injury

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

Disability

Instruments: VAS

VAS

Time since injury: Acute

Number of participants: 200

Study 39 Scholten-Peeters, G. G., Neeleman-van der Steen, C. W., van der Windt, D. A., Hendriks, E. J., Verhagen, A. P., Oostendorp, R. A., 2006

Titel: Education by general practitioners or education and exercises by physiotherapists for patients with whiplash-associated disorders?

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

Instruments: VAS, PDI

Time since injury: Acute

Number of participants: 80

Study 40 Schwerla, F., Bischoff, A., Nurnberger, A., Genter, P., Guillaume, J.P., Resch, K.L., 2008

Titel: Osteopathic treatment of patients with chronic non-specific neck pain: A randomised controlled trial of efficacy

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

Global functioning

Neck specific functioning

Instruments: NRS 0-10

SF-36

Time since injury: Sub-chronic

Number of participants: 41

Study 41 Söderlund, A., Lindberg, P., 2001

Titel: Cognitive behavioral components in physiotherapy management of chronic whiplash associated disrobers

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

ROM

Instruments: NRS, PDI

Goniometer

Time since injury: Sub-chronic

Number of participants: 33

Study 42 Soderlund, A., Olerud, C., Lindberg, P., 2000

Titel: Acute whiplash-associated disorders (WAD): The effects of early mobilisation and prognostic factors in long-term symptomatology

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: ROM

Pain intensity

Disability

Instruments: Goniometer

VAS, PDI

SES

Time since injury: Acute

Number of participants: 59

Study 43 Stewart, M. J., Maher, C. G., Refshauge, K. M., Herbert, R. D., Bogduk, N., Nicholas, M., 2007

Titel: Randomized controlled trial of exercise for chronic whiplash-associated disorders

---

Type of Study: Randomized clinical trial

Intervention: Advice

Outcome: Pain intensity

Disability

Global functioning

Emotional well-being

Instruments: VAS 1-10 box scale

NDI

SF-36

DASS Scale range 0-42 score

Time since injury: Sub-chronic-chronic

Number of participants: 134

Study 44 Thuile, Ch, Walzl, M., 2002

Titel: Evaluation of electromagnetic fiels in the treatment of pain in patients with lumbar radiculopathy or the whiplash syndrome

---

Type of Study: Randomized clinical trial

Intervention: Passive

Outcome: Pain intensity

ROM

Instruments: Likert-scale response 0-10

Goniometer

Time since injury: Chronic

Number of participants: 92

Study 45 Vassiliou, T., Kaluza, G., Putzke, C., Wulf, H., Schnabel, M., 2006

Titel: Physical therapy and active exercises - An adequate treatment for prevention of late whiplash syndrome? Randomized controlled trial in 200 patients

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

Disability

Instruments: NRS

NRS

Time since injury: Acute-chronic

Number of participants: 200

Study 46 Vendrig, A. A., van Akkerveeken, P. F., McWhorter, K. R., 2000

Titel: Results of a multimodal treatment program for patients with chronic symptoms after a whiplash injury of the neck

---

Type of Study: Clinical trial

Intervention: Active

Outcome: Pain intensity

Painful signs

Global functioning

Emotional well-being

Instruments: VAS 0-100

Pain drawing

QBPDS (Quebeck Back Pain Disability Scale)

MMPI-2 (Minnesota mulitphasic peronality inventory-2)

Time since injury: Chronic

Number of participants: 26

Study 47 Vikne, J., Oedegaard, A., Laerum, E., Ihlebaek, C., Kirkesola, G., 2007

Titel: A randomized study of the sling exercise treatment vs traditional physiotherapy for patients with chronic whiplash-associated disorders with unsettled compensation claims

---

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

Disability

Emotional well-being

ROM

Instruments: VAS

Roland & Morris disability questionnaire (29)

HSCL (25 item)

Cervical measurement system (32)

Time since injury: Chronic

Number of participants: 214

Study 48 Walker M.J., Boyles R.E., Young B.A., Strunce J.B., Garber M.B., Whitman J.M., Deyle G., Wainner R.S., 2008

Titel: The effectiveness of manual physical therapy and exercise for mechanical neck pain

---

Type of Study: Randomized clinical trial

Intervention: Active vs. passive

Outcome: Pain intensity

Disability

Instruments: VAS 100 mm MCID of 12±3 mm

NDI

Time since injury: Acute

Number of participants: 94

Study 49 Woodhouse, A., Vasseljen, O., 2008

Titel: Altered motor control patterns in whiplash and chronic neck pain

---

Type of Study: Case control study

Intervention: Non-treatment

Outcome: ROM

Pain intensity

Instruments: 3D motion tracking system (Fastrak)

NRS

Time since injury: Chronic

Number of participants: 173

Study 50 Cassidy, J. D., Carroll, L. J., Cote, P., Frank, J., 2007

Titel: Does multidisciplinary rehabilitation benefit whiplash recovery?: results of a population-based incidence cohort study

---

Type of Study: Cohort

Intervention: Active

Outcome: Pain intensity

Emotional well-being

Instruments: Likert-scale response 0-10

Questionnaire

Time since injury: Chronic

Number of participants: 6021

Study 51 Holm, L.W., Carroll, L.J., Cassidy, J., Skillgate, E., Ahlbom, A., 2008

Titel: Expectations for recovery important in the prognosis of whiplash injuries

---

Type of Study: Prospective cohort study

Intervention: Non treatment

Outcome: Disability

Pain intensity

Emotional well-being

Instruments: PDI ranges from 0-70

NRS 0-10

(HADS) Hospital Anxiety a.Depression Scale, (IES) Impact of Event Scale

---

Time since injury: Acute-chronic, Sub-chronic

Number of participants: 132

Study 52 Prushansky, T., Handelzalts, S., Pevzner, E., 2006

Titel: Performance of cervical motion in chronic whiplash patients and healthy subjects

---

Type of Study: Reproductibility study

Intervention: Non-treatment

Outcome: Pain intensity

Disability

Instruments: VAS 0-10 cm mechanic slide ruler

NDI

Time since injury: Chronic

Number of participants: 101

Study 53 Sterling, M., Jull, G., Kenardy, J. 2006

Titel: Physical and psychological factors maintain long-term predictive capacity post-whiplash injury

---

Type of Study: Prospective cohort study

Intervention: Non-treatment

Outcome: ROM

Pain intensity

Emotional well-being

Disability

Instruments: Motion tracking devise (Fasstrak USA)

Electric digital algometer Somedic AB,Farsta, Schweden

GHQ-28, TSK Tampa Scale of Kinesophobia, IES Impact of Events

Motion tracking devise (Fasstrak USA)

Time since injury: Chronic

Number of participants: 65

Study 54 Stewart, M. J., Maher, C. G., Refshauge, K. M., Herbert, R. D., Bogduk, N., Nicholas, M., 2007

Titel: Responsiveness of Pain and Disability Measures for Chronic Whiplash

---

Type of Study: Cohort

Intervention: Active vs. advice

Outcome: Pain intensity

Disability

Disability

Instruments: NRS 0-10 box scale (over last 24 h)

NDI Neck Disability Index 10 items 6 statements

Copenhagen Scale 15 Items 3 response option

Time since injury: Chronic

Number of participants: 132

Study 55 Yang, X., Cote, P., Cassidy, J. D., Carroll, L., 2007

Titel: Association between body mass index and recovery from whiplash injuries

---

Type of Study: Cohort study

Intervention:

Outcome: Disability

Pain intensity

Global functioning

Instruments: NDI

VAS

SF-36

Time since injury: Chronic

Number of participants: 4,395

Study 56 Pinfold, M., Niere, K. R., O'Leary, E. F., Hoving, J. L., Green, S., Buchbinder, R., 2004

Titel: Validity and internal consistency of a whiplash-specific disability measure

---

Type of Study: Evaluation study

Intervention: Non-treatment

Outcome: Disability

Disability

Instruments: WDQ, Whiplash disability Questionnaire

13 Items Scores NRS O-10

Time since injury: Sub-chronic

Number of participants: 83

Study 57 Willis, C., Niere, K. R., Hoving, J. L., Green, S., O'Leary, E. F., Buchbinder, R., 2004

Titel: Reproducibility and responsiveness of the Whiplash Disability Questionnaire

---

Type of Study: Evaluation study

Intervention: Non-treatment

Outcome: Neck specific functioning

Instruments: WDQ 3 Measure Points over 1 Month

Time since injury: Acute-chronic

Number of participants: 63

Study 58 Schmitt, M. A., van Meeteren, N. L., de Wijer, A., Helders, P. J., Graaf, Y., 2008

Titel: Functional health status in subjects after a motor vehicle accident, with emphasis on whiplash associated disorders: design of a descriptive, prospective inception cohort study

---

Type of Study: Study Protocol for a inception cohort study

Intervention: Active

Outcome: Pain intensity

Disability

Global functioning

Neck specific functioning

Instruments: NRS 1-10 Box scale

Bournemouth Questionnaire

SF-36

NDI

Time since injury: Chronic

Number of participants: 200

Study 59 Côté, P., Cassidy, J., Carette, S., Boyle, E., Shearer, H., Stupar, M., Ammendolia, C., Van Der Velde, G., Hayden, J., Yang, X., Van Tulder, M., Frank, J., 2008

Titel: Protocol of a randomized controlled trial of the effectiveness of physician education and activation versus two rehabilitation programs for the treatment of Whiplash-associated Disorders: The University Health Network Whiplash Intervention Trial (Dec 2008)

Type of Study: Randomized clinical trial

Intervention: Active

Outcome: Pain intensity

Disability

Global functioning

Emotional well-being

Instruments: NRS 0-10

WDQ

SF-36

CES-D

Time since injury: Acute-chronic

Number of participants: 444