

**OPEN THE BOX –  
AN EMPIRICAL RESEARCH CONCERNING  
THE EVALUATION OF THE BLACK-BOX-MODEL IN THE  
OSTEOPATHIC MEDICINE**

Master Thesis for obtaining the academic degree

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in the study programme Osteopathy

submitted by

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## ABSTRACT

Susanne Müller

Open the box – An Empirical Research concerning the Evaluation of the Black-Box-Model in the Osteopathic Medicine

**Objectives:** Execution of a quantitative evaluation of randomized controlled trials (RCTs) regarding osteopathic manipulative treatment (OMT) in order to identify experts for interviews to obtain their advice on respective data collection forms and RCTs.

**Method:** A systematic review was made by searching the literature until January 2014 using: PUBMED, CINAHL, CCTR, PEDRO, JAOA and IJOM. Multiple search terms were applied. The inclusion criteria were RCTs of detailed OMT that had adult participants, pregnancy was excluded.

**Results:** Initial searches revealed 493 papers, 459 were excluded and 34 papers were subject to the final analysis.

**Summary:** Since 1998 publications of RCTs regarding OMT are available. In 1/3 of the RCTs the number of participants ranges between 11 and 20, and duration of treatment is around 30 minutes. The OMT included structural, visceral and cranial osteopathy. The center of expertise is the Osteopathic Research Center in Texas and the Kirksville College of Osteopathic Medicine.

**Interviews:** RCTs shall assess the efficacy of OMT. Available data collection forms can be reviewed and adapted for new studies. Reasons to use a form are availability, adaptability, previous experiences and consistency. Good forms are simple, truthful and completed within a few minutes. Data shall be stored in electronic databases. OMT shall not be limited and include cranial and visceral osteopathy, however, due to funding purposes compromises may be necessary.

**Conclusion:** Research within the osteopathic medicine is already in place since the foundation. There are centres of expertise. An exchange of information with experts is possible.

### **Keywords:**

Systematic review, osteopathic manipulative treatment, data collection form

## ABSTRACT

Susanne Müller

“Open the box” – eine empirische Forschungsarbeit betreffend der Auswertung des “Black-Box-Modells” in der Osteopathie

**Ziele:** Durchführung einer quantitativen Auswertung von randomisierten kontrollierten Studien (RCTs) über osteopathische manipulative Behandlung (OMT) zwecks Identifikation von Experten für Interviews, um Ihren Rat bezüglich Datensammelformulare und RCTs zu erhalten.

**Methode:** Eine systematische Sichtung erfolgte mittels Literatursuche bis Jänner 2014 anhand von: PUBMED, CINAHL, CCTR, PEDRO, JAOA und IJOM. Mehrere Suchbegriffe wurden verwendet. Die Einschlusskriterien waren: RCTs von detaillierten OMT mit erwachsenen Teilnehmern, Schwangere waren ausgenommen.

**Ergebnisse:** Die ursprüngliche Suche ergab 493 Artikel, 459 wurden ausgeschlossen und 34 Studien wurden zur endgültigen Analyse herangezogen.

**Resümee:** Seit 1998 sind Veröffentlichungen von RCTs bezüglich OMT verfügbar. 1/3 aller RCTs hatte zwischen 11 und 20 Teilnehmern und die Behandlungsdauer betrug ungefähr 30 Minuten. Die OMT beinhaltete strukturelle, viszerale und cranio-sacrale Osteopathie. Kompetenzzentren sind das “Osteopathic Research Center” in Texas und das “Kirksville College of Osteopathic Medicine”.

**Interviews:** RCTs sollen die Wirksamkeit von OMT feststellen. Verfügbare Datensammelformulare können für neue Studien überprüft und adaptiert werden. Gründe für die Verwendung eines Formulars sind die Verfügbarkeit, die Anwendbarkeit, die gemachte Erfahrung und die Beständigkeit. Gute Formulare sind einfach, wahrheitsgemäß und sollten innerhalb weniger Minuten ausgefüllt sein. Die Daten sollten in elektronischen Datenbanken gespeichert werden. Die OMT soll nicht limitiert werden und viszerale und cranio-sacrale Osteopathie beinhalten, jedoch können aus finanziellen Gründen Kompromisse notwendig sein.

**Abschließende Bemerkung:** Forschung innerhalb der Osteopathie gibt es bereits seit der Gründung. Es gibt Kompetenzzentren. Ein Informationsaustausch mit Experten ist möglich.

**Schlüsselwörter:**

systematische Sichtung, osteopathische manipulative Behandlung, Datensammelformular

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*Osteopathy is a Science.*

*An osteopath must be a man of reason and prove his talk by his work. He has no use for theories unless they are demonstrated. (Still, 1910, p.10)*

## **1 Introduction**

As written in his book “Osteopathy Research and Practice” already in 1910 Andrew Taylor Still was aware of the fact that osteopathic medicine has to be verifiable and reproducible, in order to be recognized as a profound science. Every theory within the osteopathic medicine has to be subject to evidence. Consequently the osteopathic profession has supported research since its inception and a research institute in the early 1900s was founded (Patterson, 2011, p. 1021).

In the context of research within the osteopathic medicine the basic concept of osteopathic medicine has to be considered. The concept can be summarized with the first paragraph of the Kirksville consensus declaration, written in 1953: Osteopathy, or osteopathic medicine, is a philosophy, a science and an art. Its philosophy embraces the concept of the unity of body structure and function in health and disease. Its science includes the chemical, physical and biological sciences related to the maintenance of health and the prevention, cure and alleviation of disease. Its art is the application of the philosophy and the science in the practice of osteopathic medicine and surgery in all its branches and specialties. The consensus declaration can be summarized into the 4 tenets of osteopathic medicine:

1. The body is a unit.
2. The body possesses self-regulatory mechanisms.
3. Structure and function are reciprocally interrelated.
4. Rational treatment is based on an understanding of body unity, self-regulatory mechanisms, and the interrelationship of structure and function (Earley & Luce, 2010).

In 1999 Caroline Stone published in her book the “Science in the Art of Osteopathy” the following specificities regarding the osteopathic treatment in case of sickness: By reflecting on a broader number of parameters for health, practitioners should appreciate more possible etiologies for the ill-health of a patient, thus allowing more courses of treatment and management to emerge for that patient. Because 'circumstances' are by their nature very variable, the healthcare planners and providers must organize an adaptable system. Man does not live in an isolated bubble, and Dubois illustrated the problems this causes when he went on to say: *A perfect policy of public health could be conceived for colonies of social ants or bees whose habits have become stabilized by instincts. Likewise it would be possible to devise for a herd of cows an ideal system of husbandry with the proper combination of stables and pastures. But, unless man became robots, no formula can ever give them permanently the health and happiness symbolized by the contented cow, nor can their societies achieve a structure that will last for millennia. As long as mankind is made up of independent individuals with free will, there cannot be any social status quo. Men will develop new urges, and these will give rise to new problems, which will require ever new solutions. Human life implies adventure, and there is no adventure without struggles and dangers.* (Dubois, 1979). In this sense, it is likely that, in order to achieve freedom to pursue their goals, most people may require help on several different levels, and also be required to help themselves. It may also mean that what helped them at one stage is not necessarily going to help them at another time or in another situation. A broad, flexible and interchangeable healthcare model is required to constantly adapt to this idea of shifting healthcare needs. Within this framework, it is unlikely that the same treatment will be as successful for all people suffering the same disease process; and individual assessment and management is called for. Osteopaths certainly subscribe to the opinion that treatment must be individually tailored to each person who presents for care. (Even in similar cases, the treatments are not the same, which makes it a difficult method of practice to investigate using double-blind randomly controlled clinical studies, for example.). At this point, it can be appreciated that one cannot simply give the same treatment to each person and expect the same outcomes. This is why each application of osteopathy is so different, and explains why some observers of osteopathy, who do not come from the same perspectives of health and function, are often confused by this individualistic approach within osteopathy (Stone, 1999, p. 7).

Already in 1996 under consideration of scientific aspects Sackett et al. defined Evidence Based Medicine as “the conscientious, explicit, and judicious use of current best evidence in making decisions about care of individual patients”.

Confirming the requirements of evidence based medicine Norman Gevitz stated in an article in the March 2001 issue of the *Journal of the American Osteopathic Association*: Osteopathic medicine must be “researched and demonstrated.” It must show where and to what extent its distinctive approach to healthcare has value. To do so would increase its visibility and recognition not only to the scientific community but also to its patients and the public at large. For osteopathic medicine to move forward, it must be evidence based. The studies that can provide this evidentiary foundation can only come from within the profession. It is the absolute responsibility of this profession to provide the researchers and resources to accomplish this goal and, as a result, ensure the future of osteopathic medicine (Gevitz, 2001).

The quest for evidence based medicine seemingly pervades all of modern clinical practice. Evidence-based medicine involves using research data to enhance the diagnosis and treatment of clinical disorders. Somatic dysfunction and osteopathic manipulative treatment are two unique aspects of osteopathy that will benefit from a greater emphasis on scientific evidence (Licciardone, 2008).

In an editorial from Janine Leach issued in the *International Journal of Osteopathic Medicine* in 2008, she summarized this controversial situation as follows: The evidence-based medicine today seems to have regrettably polarized the osteopathic profession. The words “research” and “evidence” seem to conjure up for some a nightmare vision of the profession being swallowed up into a single manual therapy profession, comprising an army of white-coated technicians robotically performing set treatment protocols for specific symptom pictures based on scientific evidence! At the other extreme are those whose nightmare is the use of patient-centered techniques such as cranial osteopathy, for which there is no plausible biological model and an absence of scientific evidence of effect, despite positive clinical experience and patient feedback. Research may seem a dry, dusty and rule-based discipline but its findings can investigate and support the subtler aspects of holistic practice which embraces the art of palpation, the therapeutic relationship and the mysteries of the body’s own healing powers. Moreover, evidence-based medicine is not a straitjacket on individual practice, scientific evidence is only one piece of the jigsaw of information gathered and synthesized by a practitioner while interacting with a patient. Evidence and research need not polarize the profession. Andrew Taylor Still managed to embrace both poles. He was a true researcher of his day, always questioning traditional views, searching for the truth, keenly observing and testing new ideas. He was also deeply aware of the mysteries of life, the human spirit, magnetism and emotions.

Perhaps his vision can help to lead us to a new vision for osteopathy as a discipline of the twenty-first century, can help us to avoid becoming either fossilized in blind adherence to tradition or technical slaves to scientific evidence (Leach, 2008).

Evidence and research need not polarize the profession. Andrew Taylor Still managed to embrace both poles. He was a true researcher of his day, always questioning traditional views, searching for the truth, keenly observing and testing new ideas. He was also deeply aware of the mysteries of life, the human spirit, magnetism and emotions. Perhaps his vision can help to lead us to a new vision for osteopathy as a discipline of the twenty-first century, can help us to avoid becoming either fossilized in blind adherence to tradition or technical slaves to scientific evidence. But, the challenge for osteopaths is how do we evolve a model of practice that embraces the holistic aspects as well as utilizing scientific evidence (Leach, 2008)?

Only 2011 also Jonathan R. Kirsch raised his concerns in a letter under the title: Are Clinical Protocols for Osteopathic Manipulative Procedures Truly “Osteopathic”? Osteopathic manipulative treatment is defined as the “therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction.” American Osteopathic Association (AOA) protocols for the use of osteopathic manipulative treatment state that the “diagnosis must be specific.” Once a diagnosis is made, the osteopathic physician “determine(s) the appropriate techniques and treatment.” Furthermore, an evaluation and management service code requires a “history, examination, and medical decision making,” all of which must be documented in the medical record. Thus, by definition, osteopathic manipulative treatment is directed toward removing the somatic dysfunctions that are inhibiting the body's function and self-healing mechanisms. Furthermore he examined each of the tenets of osteopathic medicine as they relate to standardized clinical protocols for osteopathic manipulative treatment:

1. The body is a unit; the person is a unit of body, mind, and spirit. The first part of this tenet notes that the body is a unit, meaning that the body's structure and systems function together as a unit. Structure and function interact and are unified through myriad relationships and mechanisms, and in some cases, the real source of the patient's problem is anatomically distant from the area prompting the complaint. Although there are many parts to the body, “the osteopathic physician refrains from selecting any part above the whole.”

2. The body is capable of self-regulation, self-healing, and health maintenance. Certain osteopathic manipulative treatment protocols support the self-healing mechanisms through the use of manipulative procedures that correct somatic dysfunction or assist the autonomic or lymphatic systems. However, an osteopathic manipulative treatment protocol may not address the areas of the somatic dysfunctions—whether primary or secondary—that are most inhibiting to the patient's self-regulatory mechanisms.
3. Structure and function are reciprocally interrelated. This tenet addresses the interaction of the musculoskeletal system with the physiologic systems of the body. The tenet broadly states that the structure of the body affects its function, and the function of the body affects the structure. As noted by DiGiovanna et al, "As structure governs function, similarly, abnormal structure brings about dysfunction." Clinical protocols for osteopathic manipulative treatment procedures will certainly affect the musculoskeletal system.
4. Rational treatment is based upon an understanding of the basic principles of body unity, self-regulation, and the interrelationship of structure and function. Clinical protocols for osteopathic manipulative treatment procedures face a challenge in adhering to this tenet. By their very nature, standardized protocols are not able to meet the specific clinical needs of a patient because patients cannot be standardized. Protocols cannot fully address a patient's body unity because they are not based on the patient's physical examination or medical history. Protocols cannot fully address the structure-function tenet because they are not necessarily aimed at the key structural issues involved in each case. Protocols cannot fully assist the patient's self-healing mechanisms and abilities because they do not adequately address the structure and function of the body as a unit.

And finally Jonathan R. Kirsch drew the conclusion that the application of standardized clinical protocols for osteopathic manipulative treatment procedures may not be consistent with personalized treatment in osteopathic medicine that is customized for each patient and his or her specific dysfunctions. Breaking down each of the elements in the overall clinical approach to osteopathic manipulative treatment may be akin to trying to separate out the ingredients of a therapeutic herb in order to discover which ingredient is the active one. By isolating individual osteopathic manipulative treatment techniques from a comprehensive osteopathic approach, the techniques may cease to be osteopathic treatment at all (Kirsch, 2011).

In his response Michael Patterson pointed out that breaking down osteopathic manipulative treatment into parts for study is similar to separating out the ingredients of a therapeutic herb. Although in some herbal remedies there may be interactions among ingredients that are necessary for the total effect, in many other herbal remedies, a single “active” (i.e., most dramatically effective) ingredient has been found. A few examples of such herbal remedies are quinine, atropine, and curare. These substances were all initially used in their whole forms as herbal remedies before the major, active ingredient in each was isolated, purified, and processed into an important medication. Osteopathic manipulative treatment obviously consists of many components— such as touch, patient-physician interactions, and specific movements— all of which combine to produce the final result. Although it is important to examine the efficacy of the total treatment, it is also important to study the effects of the individual components so that the total effect can be fully understood. Both treatment and technique studies are necessary to maintain the uniqueness of osteopathic medicine. The distinctions between these 2 study types and the limitations of each must be clearly recognized and spelled out. Furthermore Michael Patterson agreed that assessments of effectiveness of osteopathic manipulative treatment be of osteopathic manipulative treatment as it is practiced. However, technique studies are not studies of osteopathic manipulative treatment, but only parts of it. By clearly recognizing this distinction, technique studies can be effective in helping to understand the totality of osteopathic practice according to osteopathic philosophy and, in that way, help to maintain the distinctiveness of osteopathic medicine (Patterson, 2011).

Finally also Degenhardt and Stoll (2011) argued in the book “Foundation of Osteopathic Medicine” in the chapter “Research priorities in Osteopathic Medicine” that for many clinical conditions, an osteopathic manipulative treatment prescription will include a variety of techniques intended to address different elements of the disease’s pathophysiology and will be selectively tailored in response to a given patient’s palpated specific somatic dysfunction. According to osteopathic principles and practices, an osteopathic researcher would likely hypothesize that the greatest therapeutic effect would occur when osteopathic manipulative treatment is utilized in this individualized, pragmatic, and holistic fashion. On the surface, this method seems inconsistent with best research practices, which dictate that interventions in clinical research trials must be standardized. However, on closer examination and with a better understanding of osteopathic manipulative treatment, it becomes apparent that a somewhat individualized approach using multiple techniques in multiple body regions is most appropriate and even critically necessary for quality osteopathic manipulative treatment research at this stage of its development (Degenhardt & Stoll, 2011, p. 1048).

According to all the information available in the World Wide Web and in osteopathic literature from the past until now discussions are still going on regarding randomized controlled trials of osteopathic manipulative treatment. Controversial point of views are available within the community of osteopath, therefore the questions are raised that in case of randomized controlled trials of osteopathic manipulative treatment how do experts within the field of research in the osteopathic medicine deal with this requirements and what compromises are necessary and what about the respective documentation?

### **1.1 The “Black-Box”**

As just mentioned the osteopathic concept does not only depend on techniques and “osteopathic” methods but also on principles and philosophy. The classification in structural, visceral and cranial techniques is for didactic and systematic use, which will become a treatment unit through osteopathic principles and philosophy. Up to now this unit is the common basis for scientifically prepared osteopathic papers to investigate the effectiveness of the osteopathic medicine as “black-box” (Dräger, 2009).

The “black-box” design is typically not only designed for the osteopathic medicine but for all kinds of traditional medicine as well. In this context the World Health Organization (2000) issued “General Guidelines for Methodologies of Research and Evaluation of Traditional Medicine” including the following definition of the “black-box” design: This means that the treatment and all of its components are delivered as they would be in the usual clinical situation. In this type of study, no component of the treatment “package” is isolated and studied independently. This allows the effectiveness of traditional medicine to be determined either within its own theoretical framework or within that of conventional medicine.

In this regard the interest was raised to investigate published trials within the osteopathic medicine in the aspect of holistic osteopathic manipulative treatment to open and analyze the “black-box”. Afterwards to identify experts in the field of osteopathic research in order to get in contact with them for their feedback on their documentation processes of the osteopathic manipulative treatment and finally to obtain their treatment protocol for trials within the osteopathic medicine.

## 2 Background

As one of the key elements of osteopathic care, manipulative treatment should be the subject of increasing amounts of research in the profession. In research aimed at investigating the usefulness of manipulative treatment, there is much confusion about proper research methodology. However, the researcher approaching osteopathic manipulation as an independent variable must decide which of the following is to be evaluated: a treatment or manipulative technique, osteopathic manipulative treatment, or osteopathic health care. Depending on the aspect of manipulation to be studied, different experimental designs will be employed (Patterson, 2011, p. 1027).

It is important to note that there are basically two types of studies of osteopathic manipulation: (1) technique studies, and (2) studies of osteopathic manipulative treatment. In a technique study, one or more specific osteopathic manipulative procedures are utilized for each patient. Technique studies are valuable and necessary to determine the specific effects of well-specified and circumscribed manipulations on a target problem (Patterson, 2002).

A study of osteopathic manipulative treatment, however, is designed to make use of the full range of manipulative techniques to treat a targeted problem - depending on the clinician's findings as a result of a thorough physical examination of the patient. Osteopathic manipulative treatment studies are guided by the patient's condition and response to treatment, which then determine the techniques used (Patterson, 2002).

Osteopathic theory and practice holds that the full treatment of an individual by an osteopathic physician entails an interaction between the physician and the patient that is not static but dynamic, changing from treatment to treatment and instant to instant as the treatment progresses. The physician responds to the dynamic changes in the patient's function; the patient responds to the attitudes and touch of the physician. The treatment is not a prearranged set of movements and thrusts given to each patient, but an ongoing stimulus/response synergism between the physician and patient, with the patient's response guiding the actions of the physician. In this case, the manipulation cannot be predetermined or prescribed by the research protocol but must "go with the flow" in response to the reactions of both physician and patient. The manipulative treatment is properly a "black box."



The physician/patient interaction determines what manipulative treatment is performed. The physician is free to do what is deemed best for the interaction. Because one of the basic axioms of osteopathy is that each person responds differently to stress and treatment, this freedom of interaction cannot be removed from the physician without changing the research to a technique investigation. To investigate manipulative treatment rather than a manipulative technique, manipulative treatment must be used (Patterson, 2011, p. 1028).

Once the difference between these two basic types of research on manipulation is realized, many of the other problems associated with investigating manipulation can be much more easily resolved. Both types of research are valuable and valid. Research on techniques gives information on specific techniques; research on treatment gives information on what the osteopathic physician does in practice. Both are necessary and essential for the future of the profession. Their differences must be recognized and appreciated for appropriate studies to be designed (Patterson, 2011, p. 1028).

## **2.1 Pragmatic Trial**

The health sciences community has spent enormous resources during the past decades on discovering and evaluating interventions, e.g., treatments, surgical procedures, and diagnostic and prognostic tests. During this process, robust interventional experiments (trials) have been developed and used to control for the numerous biases (systematic errors) that can infiltrate observational studies. Clinical trials, especially randomized controlled trials, have been the main tool used by the health sciences community to test and evaluate interventions (Patsopoulos, 2011).

The 'randomized controlled trial' is the mainstay of health research and is designed to determine the extent to which a given intervention 'works' by quantifying clinical benefits and harms. It takes attendance at just a few professional meetings to encounter criticism of randomized controlled trials as failing to adequately represent the patients, disorders and treatment approaches that are typically encountered in osteopathic practice (Moran, 2013).

Such critiques are, in some cases entirely appropriate and valid, but the generalization is frequently asserted that ‘randomized controlled trials are not appropriate for osteopathy’ and are often outright dismissed as ‘reductionism typical of biomedicine and big pharma’ or similar outbursts (Moran, 2013).

The concern of whether trials produce results applicable to everyday practice was raised many decades ago. Schwartz and Lellouch, back in 1967, coined the terms “explanatory” and “pragmatic” to differentiate trials. The term explanatory was used to describe trials that aim at evaluating the efficacy of an intervention in a well-defined and controlled setting, whereas the term pragmatic was used for trials designed to test the effectiveness of the intervention in a broad routine clinical practice. The explanatory trial is the best design to explore *if and how an intervention works*, and the whole experiment is designed in order to control for all known biases and confounders, so that the intervention's effect is maximized. Usually the intervention under examination is compared with a placebo or with another active treatment (Patsopoulos, 2011).

Explanatory trials investigate cause and effect relationships and are performed under strictly controlled conditions with the intent of minimizing bias to answer questions of efficacy – to what extent can the treatment work under ideal conditions? Specific decisions made by researchers at the design stage of explanatory trials mean that the relevance to clinical practice is purposefully compromised (Moran, 2013).

The pragmatic trial, on the other hand, is designed to test interventions in the full spectrum of everyday clinical settings in order to maximize applicability and generalizability. The research question under investigation is *whether an intervention actually works in real life*. The intervention is evaluated against other ones (established or not) of the same or different class, in routine practice settings. Pragmatic trials measure a wide spectrum of outcomes, mostly patient-centered, whereas explanatory trials focus on measurable symptoms or markers (clinical or biological) (Patsopoulos, 2011).

Pragmatic trials have characteristics intended to be representative of normal practice. The goal is to investigate benefits or harms under normal practice conditions. Usually there are few constraints made on criteria for inclusion as the goal is to study a spectrum of people who would normally receive the treatment (Moran, 2013).

A particularly distinctive aspect of pragmatic trials of particular relevance for osteopathy is that treatment can be delivered with flexibility and can accommodate the unique circumstances of individual patients. It is quite conceivable that treatment packages can be designed that can represent various forms of osteopathic practice and would fully incorporate the patient-centered care that lies at the heart of osteopathic care (Moran, 2013).

Since most results from explanatory trials fail to be broadly generalizable, the “pragmatic design” has gained momentum. Like any other concept, pragmatic trials are not free of limitations. However, the whole idea of applicable and generalizable research is very appealing and of benefit to the health sciences community. Sensitizing policy makers, practitioners, and even patients, and making them part of the research culture is a positive step. But should explanatory trials cease to exist? A trial can be designed to have some aspects that are more pragmatic than explanatory, and vice versa, but some trials must be as explanatory as possible. New interventions and identification of cause-effect relationships will always need experiments with high internal validity. Even the results of pragmatic trials will include many post-hoc exploratory analyses, which will require in turn explanatory trials to verify them. Thus, in terms of absolute numbers there will always be far more explanatory trials than pragmatic ones, with many trials lying in the continuum between them. Pragmatic trials are not here to replace the existing explanatory ones, rather to complement those (Patsopoulos, 2011).

As a consequence of the afore mentioned information osteopathic manipulative treatment applied in a holistic aspect as randomized controlled trial will also be considered as pragmatic trial.

### 3 Objectives

The systematic review of osteopathic manipulative treatments applied in randomized controlled trials aims to focus on the quantitative collection and analysis of the evidence and applicability. It should assess

- locations which issued randomized controlled trials of osteopathic manipulative treatment
- years of publication of randomized controlled trials of osteopathic manipulative treatment
- number of participants of randomized controlled trials of osteopathic manipulative treatment
- duration of osteopathic manipulative treatment applied in line with a randomized controlled trial
- and details of osteopathic manipulative treatment in line with a randomized controlled trial

Furthermore locations which are regularly involved in research and from which in line with the search results of the systematic review have issued at least 5 or more randomized controlled trials of osteopathic manipulative treatment will be considered as center of expertise in this master thesis. From each of these centers of expertise one person who issued more than 10 articles in PUBMED in the field of osteopathic medicine and also has published one randomized controlled trial concerning osteopathic manipulative treatment shall be contacted as expert in order to obtain feedback on randomized controlled trials of osteopathic manipulative treatment and relevant documentation.

Since the focus of the systematic review is a quantitative analysis, also for the determination of experts the quantitative criteria will be taken into consideration. If possible a gender distribution would be preferable.

## 4 Research Questions and Hypotheses

This raises the interest in the following research questions in order to understand the situation regarding osteopathic manipulative treatment in line with a randomized controlled trial.

The systematic review is intended to provide the following information:

- How many randomized controlled trials concerning detailed osteopathic manipulative treatment in the osteopathic medicine have been published until now and which year through the World Wide Web?
- Based on published randomized controlled trials regarding osteopathic manipulative treatment what is the situation concerning: number of participants, length of treatment and osteopathic manipulative treatment details applied?
- Where are centers of expertise regarding randomized controlled trials concerning osteopathic manipulative treatment in the osteopathic medicine?
- Can experts be identified in order to contact them and ask for their experiences in documenting osteopathic manipulative treatment regarding randomized controlled trials?
- Is it possible to obtain data collection forms from the experts as first reference including their respective feedback on the forms?

The respective hypotheses for this work are derived from the research questions assuming the following:

- There are randomized controlled trials available in the osteopathic medicine applying holistic osteopathic manipulative treatment that consequently experts can be defined.
- There are already data collection forms available, in order to document the osteopathic manipulative treatment in line with a randomized controlled trial.

## **5 Systematic Review**

For the systematic review it was necessary to review respective databases and e-journals in osteopathic medicine concerning published randomized controlled trials of osteopathic manipulative treatment (OMT) in order to extract them for a thorough analysis.

Furthermore research centers of expertise in the field of osteopathic manipulative treatment have to be identified in order to select experts from these locations as partner for the interview.

### **5.1 Time of Research**

The literature was searched until January 2014. No restriction was made as to the starting point of the search.

### **5.2 Literature Search**

The search strategy for this internet review followed the recommendation of the book “Foundations of Osteopathic Medicine” to use the National Library of Medicine via the search engine PUBMED, the Journal of the American Osteopathic Association and further public libraries. (Patterson, 2011)

Consequently a comprehensive search was conducted for relevant randomized controlled trials, utilizing four databases relevant to both conventional and complementary medical literature.

The following databases were included in the search: Cumulative Index to Nursing and Allied Health Literature (CINAHL); Cochrane Controlled Trials Register (CCTR) Physiotherapy Evidence Database (PEDRO) and PUBMED.

Furthermore also two e-journals were included in the search: International Journal of Osteopathic Medicine (IJOM) and Journal of the American Osteopathic Association (JAOA).

In addition, a selected hand search was made in case of those randomized controlled trials with the most participants confirming that the randomized controlled trials in line with osteopathic manipulative treatment are fully covered.

### **5.3 Identification of Search Terms**

All the search terms for this review have been chosen in agreement with the “Wiener Schule für Osteopathie”.

Multiple search terms were used. Search terms included the following keywords:

- "Osteopathic care" AND trial OR
- Osteopath\* AND "pragmatic trial" OR
- "Osteopathic manual treatment" AND trial OR
- "Osteopathic manipulative treatment" AND trial OR
- "Osteopathic treatment" AND trial.

Since the term “randomized controlled trial” is not included in all the studies but sometimes it is called pragmatic trial or even clinical trial, as mentioned in the beginning, in order to allow the maximum number of hits the term “trial” was used on its own.

Based on these above listed search terms 493 items in total were downloaded for research purposes. Details of the results are available in the appendix.

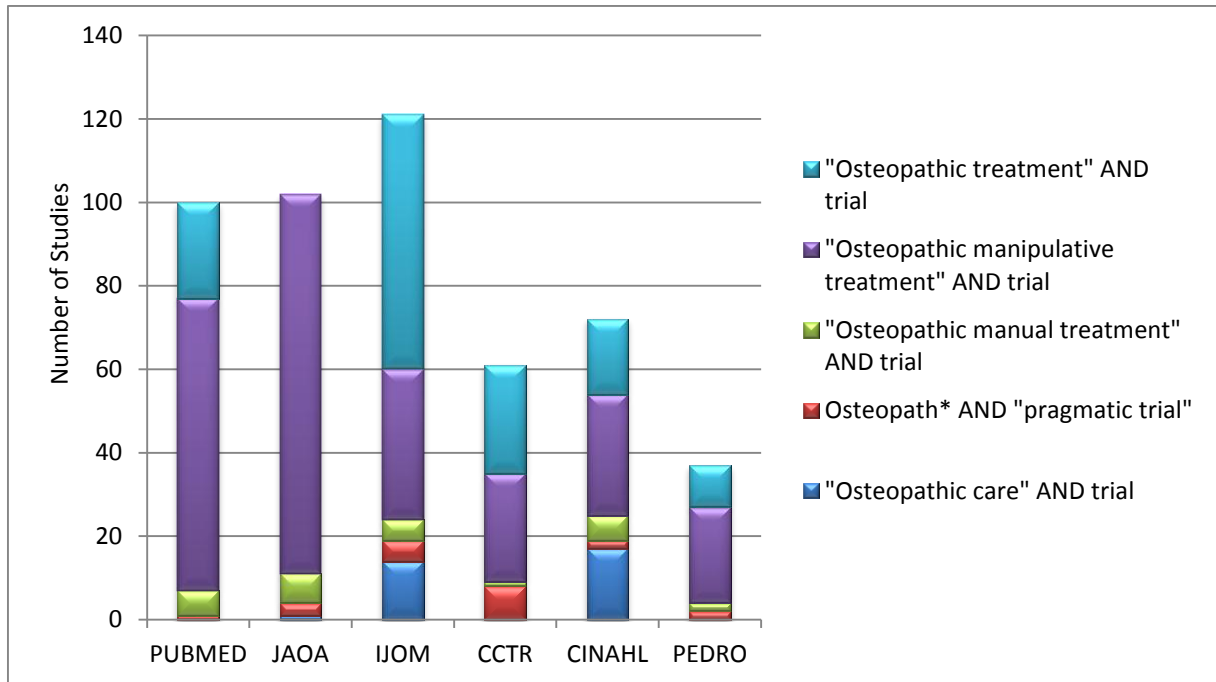


Figure 1: Search Results per term and source of data

From all the databases and e-journals IJOM produced the most results with 121 articles followed by JAOA 102 and PUBMED 100. The remaining data sources had considerably less scores: CINAHL 72, CCTR 61 and PEDRO 37.

The highest success rate in PUBMED (70 out of 100) and JAOA (91 out of 102) had the search term: "Osteopathic manipulative treatment" AND trial. IJOM had the highest hits with the search term: "Osteopathic treatment" AND trial (61 out of 121), this term however had no search results in JAOA.

The search term "Osteopathic care" AND trial did not provide any articles in PUBMED, CCTR and PEDRO.



## 5.4 Exclusion Criteria

All downloads have been reviewed and the following items were excluded, since they did not meet the qualification as pragmatic clinical trial of osteopathic manipulative treatment:

- Letter, Text, Editorial
- Pregnancy, Infants: All studies related to pregnancy since the osteopathic manipulative treatment techniques are limited- according to a randomized controlled trial made by Licciardone et al. (2010) during pregnancy high velocity and low amplitude techniques are prohibited because of the increasing ligamentous laxity that occurs in late pregnancy. The cranial technique known as compression of the fourth ventricle is also prohibited on theoretical grounds that it may potentially induce premature labor. Furthermore also the application of visceral techniques are limited. Also in case of children, a special gentle treatment is required considering the growing organism. Consequently due to these exceptions both groups were excluded from the overview.
- Systematic/Other Review: Other reviews include i.e. Cost reviews
- Technique Review: as mentioned above, are a different type of treatment
- Only Abstracts: For some older trials and also randomized controlled trials in line with a Master's degree, the details of the study have not been available in the World Wide Web.
- No osteopathic manipulative treatment details: Studies which did not provide any detail of the osteopathic manipulative treatment applied, since they tailored the osteopathic manipulative treatment to suit the needs of the individual.

According to this catalogue of criteria the final overall flowchart looks as follows:

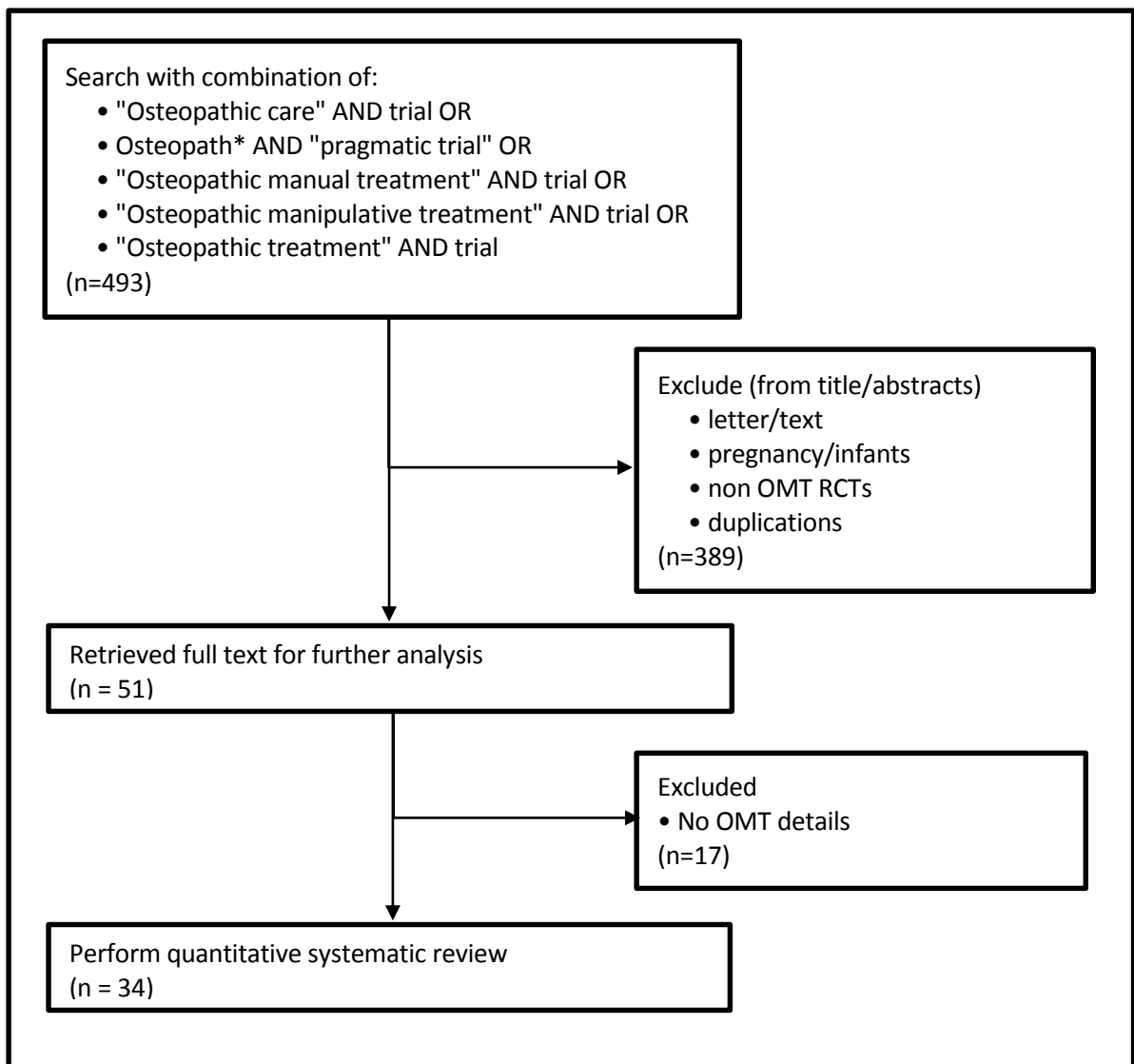


Figure 2: Flowchart of paper selection

Afterwards the whole overview is distributed accordingly between the individual data sources:

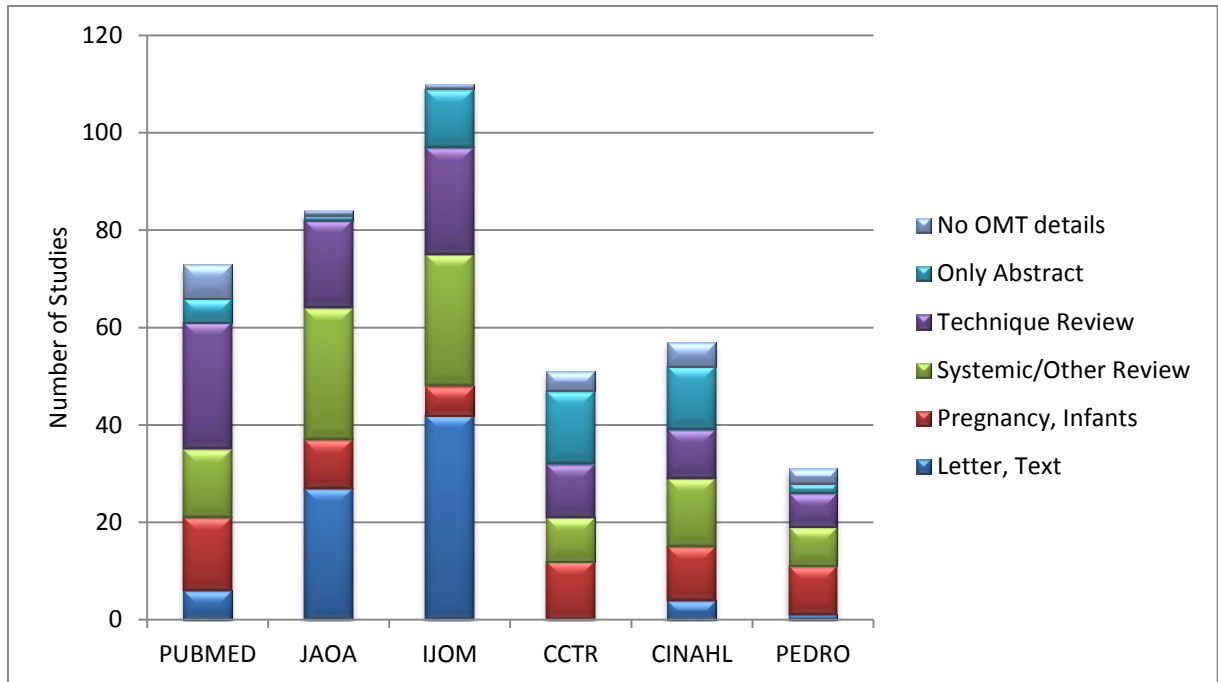


Figure 3: Exclusion Criteria per source of data

According to the criteria listed above in the first round in total 406 items had to be excluded.

The highest portion of excluded items was under the section Letter, Text or Editorial since 42 item of IJOM had to be excluded. JAOA had 27, PUBMED listed 8, CINAHL 4 and PEDRO only 1. Solely CCTR did not provide any Letter, Text or Editorial.

Concerning hits related to pregnancy or infants PUBMED had 15 items listed. CCTR had 12 and CINAHL 11. In case of JAOA and PEDRO 10 items were excluded. IJOM only published 6 of them.

The search in PUBMED produced 26 techniques reviews followed by IJOM with 22 and JAOA with 18. CCTR listed only 11 and CINAHL 10. PEDRO had only 7 respective downloads.

27 item in JAOA and IJOM were excluded because of systematic and other reviews. CINAHL and PUBMED had 14 respective exclusions, CCTR 9 followed by PEDRO with 8.

CCTR had 11 hits for which only abstracts have been available in the World Wide Web, 4 of them have been counted twice. CINAHL had 13 and IJOM 12. PUBMED had only 5 hits for which no abstract is available and PEDRO only 2 followed by IJOM with 1

In reviewing the research regarding osteopathic manipulative treatment details 5 hits in PUBMED did not provide any osteopathic manipulative treatment details and 2 were double listed. Consequently in total 7 studies were taken out. CINAHL had 5 hits, CCTR 4 and PEDRO 3. JAOA and IJOM both had only 1 study listed which did not provide osteopathic manipulative treatment details.

Consequently in total 406 items had to be excluded, headed by IJOM with 110 out of 121. In case of JAOA 84 were taken out. PUBMED followed with 73. CINAHL had 57 and CCTR 51. From PEDRO 31 items were eliminated.

### 5.5 Included Studies

Upon exclusion in total from all the data sources 87 randomized controlled trials remained.

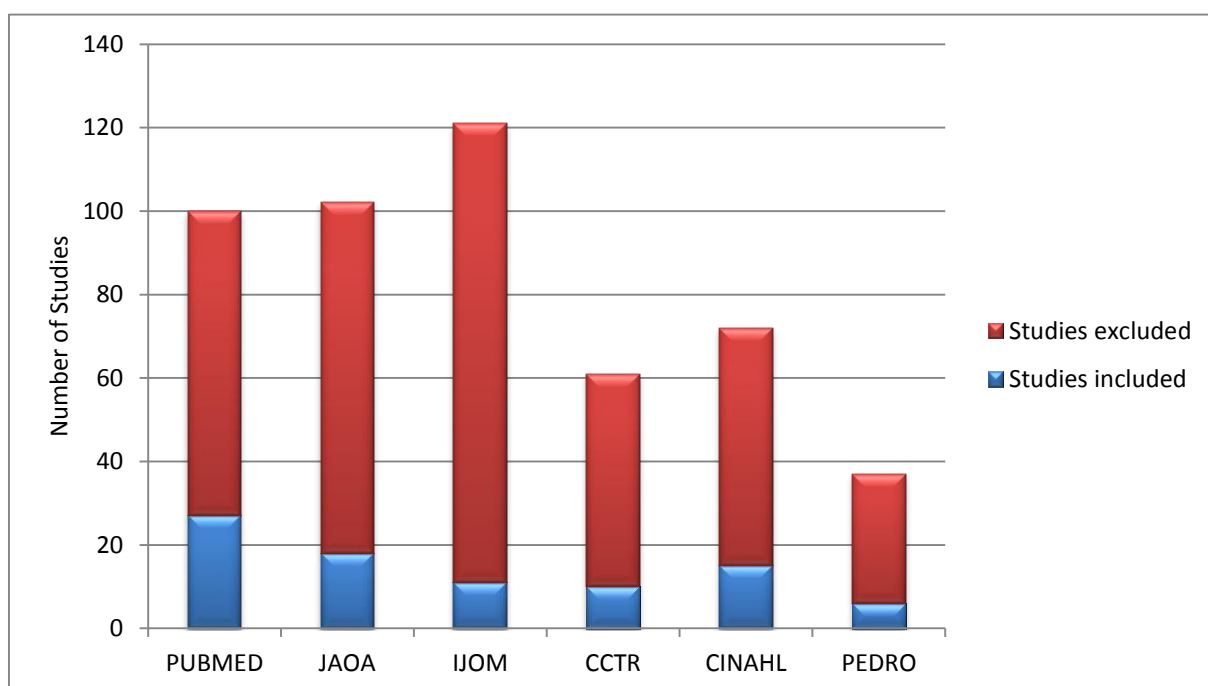


Figure 4: Included versus excluded Studies

From PUBMED 27 studies were included. From JAOA 18 studies have been subject to a further review, from CINAHL 15 and from IJOM 11. From PEDRO only 6 studies remained.

As last step in the study selection of the systematic review double entries in the different databases were eliminated. For this purpose PUBMED was taken as reference.

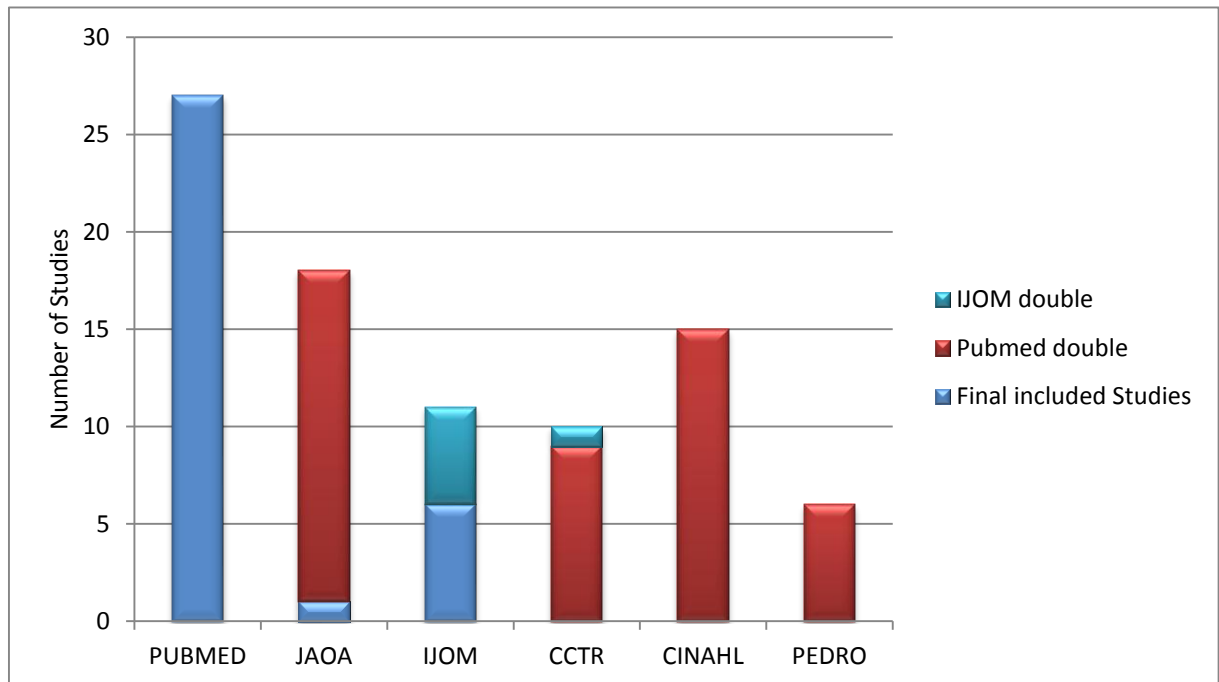


Figure 5: Final included Studies

All studies from CINAHL and PEDRO were already included in the download of PUBMED. From JAOA only one of 27 studies was not published in PUBMED. Also in case of CCTR 9 of 10 studies were also available in PUBMED and the remaining one was also published in IJOM. In the search IJOM produced 11 studies from which 5 have been eliminated as double entries. None of the data results from IJOM were mentioned in PUBMED.

Finally, 27 studies from PUBMED were considered, one from JAOA and 6 from IJOM. Thus a total of 34 studies remained for a further deeper quantitative review.

## 5.6 Data Extraction

The following list presents all studies for the systematic review, sorted by the year of publication, including also the name of authors:

**Table 1: List of Studies**

Year	Title	Authors
No. 1 2013	Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial	Licciardone JC, Minotti DE, Gatchel RJ, Kearns CM, Singh KP.
No. 2 2013	The effect of osteopathic manipulative treatment on postoperative medical and functional recovery of coronary artery bypass graft patients.	Wieting JM, Beal C, Roth GL, Gorbis S, Dillard L, Gilliland D, Rowan J.
No. 3 2013	Use of the SMART Balance Master to quantify the effects of osteopathic manipulative treatment in patients with dizziness.	Fraix M, Gordon A, Graham V, Hurwitz E, Seffinger MA.
No. 4 2012	A randomized, controlled trial of osteopathic manipulative treatment for acute low back pain in active duty military personnel.	Cruser dA, Maurer D, Hensel K, Brown SK, White K, Stoll ST.
No. 5 2012	Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study.	Snider KT, Snider EJ, Johnson JC, Hagan C, Schoenwald C.
No. 6 2012	Osteopathic manipulative treatment in obese patients with chronic low back pain: a pilot study	Vismara L, Cimolin V, Menegoni F, Zaina F, Galli M, Negrini S, Villa V, Capodaglio P.
No. 7 2012	Efficacy of osteopathic manipulative treatment for low back pain in euhydrated and hypohydrated conditions: a randomized crossover trial.	Parker J, Heinking KP, Kappler RE.
No. 8 2012	The effect of osteopathic manual therapy on the vascular supply to the lower extremity in individuals with knee osteoarthritis: A randomized trial	Wendy M. Jardine a,*, Carol Gillis b,d, Derek Rutherford
No. 9 2011	Effects of comprehensive osteopathic manipulative treatment on balance in elderly patients: a pilot study	Lopez D, King HH, Knebl JA, Kosmopoulos V, Collins D, Patterson RM.
No. 10 2011	Impact of osteopathic manipulative treatment on secretory immunoglobulin a levels in a stressed population	Saggio G, Docimo S, Pilc J, Norton J, Gilliar W.

No. 11 2011	Osteopathic manipulative treatment is effective on pain control associated to spinal cord injury	Arienti C, Daccò S, Piccolo I, Redaelli T.
No. 12 2011	Muscle fatigue in chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) and its response to a manual therapeutic approach: A pilot study	Raymond N. Perrin, Jim David Richards, V. Pentreath, David F. Percy
No. 13 2010	Osteopathic manipulative treatment and vertigo: a pilot study.	Fraix M.
No. 14 2010	Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial.	Noll DR, Degenhardt BF, Morley TF, Blais FX, Hortos KA, Hensel K, Johnson JC, Pasta DJ, Stoll ST.
No. 15 2010	Can osteopathy help women with a history of hypothyroidism and musculoskeletal complaints? Outcome of a preliminary, prospective, open investigation	Maria Sonberg, Brenda Mullinger*, De´van Rajendran
No. 16 2009	Chronic prostatitis/chronic pelvic pain syndrome. Influence of osteopathic treatment - a randomized controlled study	Marx S, Cimniak U, Beckert R, Schwerla F, Resch KL.
No. 17 2008	Immediate effects of osteopathic manipulative treatment in elderly patients with chronic obstructive pulmonary disease.	Noll DR, Degenhardt BF, Johnson JC, Burt SA.
No. 18 2008	The effect of Osteopathic Treatment on Chronic Constipation – A Pilot Study	Rebecca Brugman, Kylie Fitzgerald, Gary Fryer
No. 19 2007	Role of osteopathic manipulative treatment in altering pain biomarkers: a pilot study.	Degenhardt BF, Darmani NA, Johnson JC, Towns LC, Rhodes DC, Trinh C, McClanahan B, DiMarzo V.
No. 20 2006	A comparison of selected osteopathic treatment and relaxation for tension-type headaches	Anderson RE, Seniscal C.
No. 21 2005	Hemodynamic effects of osteopathic manipulative treatment immediately after coronary artery bypass graft surgery.	O-Yurvati AH, Carnes MS, Clearfield MB, Stoll ST, McConathy WJ.
No. 22 2005	Cannabimimetic effects of osteopathic manipulative treatment.	McPartland JM, Giuffrida A, King J, Skinner E, Scotter J, Musty RE.
No. 23 2005	Preoperative intravenous morphine sulfate with postoperative osteopathic manipulative treatment reduces patient analgesic use after total abdominal hysterectomy.	Goldstein FJ, Jeck S, Nicholas AS, Berman MJ, Lerario M.
No. 24 2005	Intramuscular ketorolac versus osteopathic manipulative treatment in the management of acute neck pain in the emergency department: a randomized clinical trial.	McReynolds TM, Sheridan BJ.

No. 25 2005	The effect of osteopathic treatment on people with chronic and sub-chronic neck pain: A pilot study	Gary Fryer, Jarrod Alvizatos, Joshua Lamaro
No. 26 2005	The effect of osteopathy in the treatment of chronic low back pain – a feasibility study	L. Kirk, M. Underwood, L. Chappell, M. Martins-Mendez, et al.
No. 27 2004	A randomized controlled trial of osteopathic manipulative treatment following knee or hip arthroplasty.	Licciardone JC, Stoll ST, Cardarelli KM, Gamber RG, Swift JN Jr, Winn WB.
No. 28 2004	Effectiveness of a sham protocol and adverse effects in a clinical trial of osteopathic manipulative treatment in nursing home patients.	Noll DR, Degenhardt BF, Stuart M, McGovern R, Matteson M.
No. 29 2003	Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial.	Licciardone JC, Stoll ST, Fulda KG, Russo DP, Siu J, Winn W, Swift J Jr.
No. 30 2002	Osteopathic manipulative treatment in conjunction with medication relieves pain associated with fibromyalgia syndrome: results of a randomized clinical pilot project.	Gamber RG, Shores JH, Russo DP, Jimenez C, Rubin BR.
No. 31 2001	Adjunctive osteopathic manipulative treatment in women with depression: a pilot study.	Plotkin BJ, Rodos JJ, Kappler R, Schrage M, Freydl K, Hasegawa S, Hennegan E, Hilchie-Schmidt C, Hines D, Iwata J, Mok C, Raffaelli D.
No. 32 2000	Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia	Noll DR, Shores JH, Gamber RG, Herron KM, Swift J Jr.
No. 33 2000	Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation.	Burton AK, Tillotson KM, Cleary J.
No. 34 1998	Effect of osteopathic manipulative treatment of length of stay for pancreatitis: a randomized pilot study.	Radjeski JM, Lumley MA, Cantieri MS.

The finally remaining 34 trials have been reviewed and analyzed in detail in order to get a picture of the current randomized controlled trials in osteopathic medicines which have been published until January 2014. The detailed overview is available in the appendix.



### 5.6.1 Country of Origin

First of all the data was reviewed regarding their country of origin.

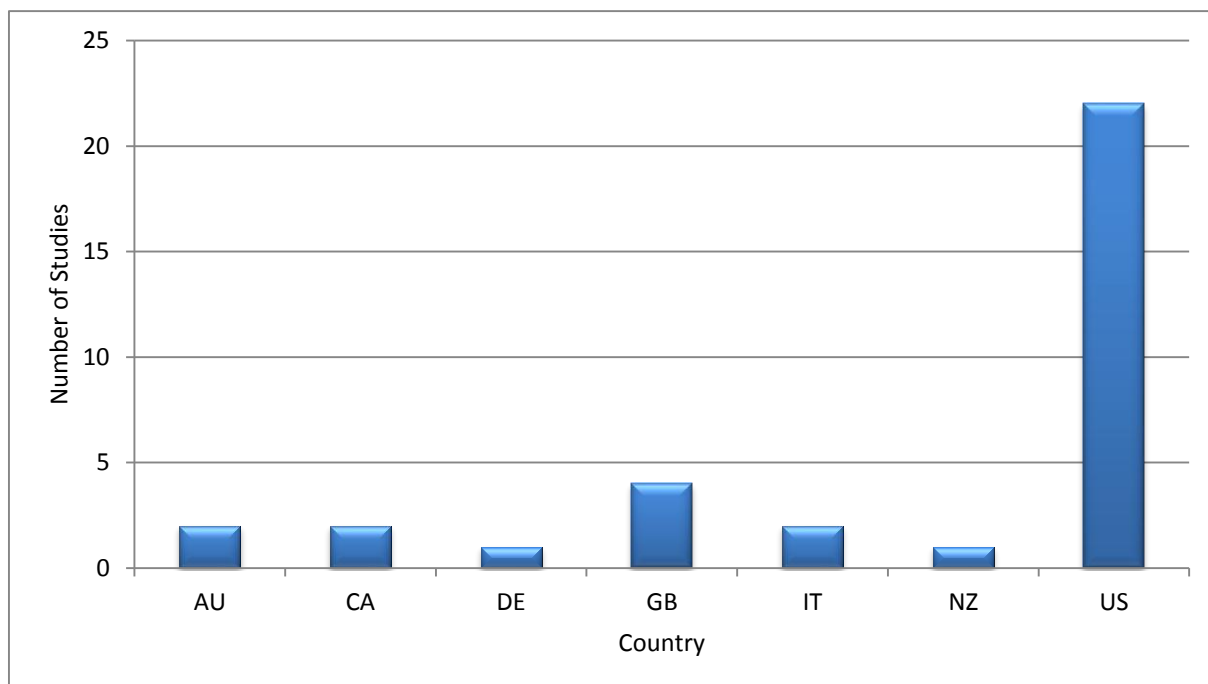


Figure 6: Country of Origin

In the context of search Germany (DE) and New Zealand (NZ) published one study, Australia (AU), Canada (CA) and Italy (IT) published two studies each, Great Britain (GN) four and 22 out of the 34 were made in the United States of America (US), representing 64.7% of all relevant published randomized controlled trials regarding osteopathic manipulative treatment.

In a further review of the studies published in the United States of America it is worth mentioning that 7 of the randomized controlled trials were made by “The Osteopathic Research Center, University of North Texas Health Science Center” and 5 were executed by the “Kirksville College of Osteopathic Medicine”. The remaining 10 are spread over the country.

### 5.6.2 Year of Publication

Starting already with 1998 randomized controlled trials in line with osteopathic manipulative treatment could be extracted out of the World Wide Web.

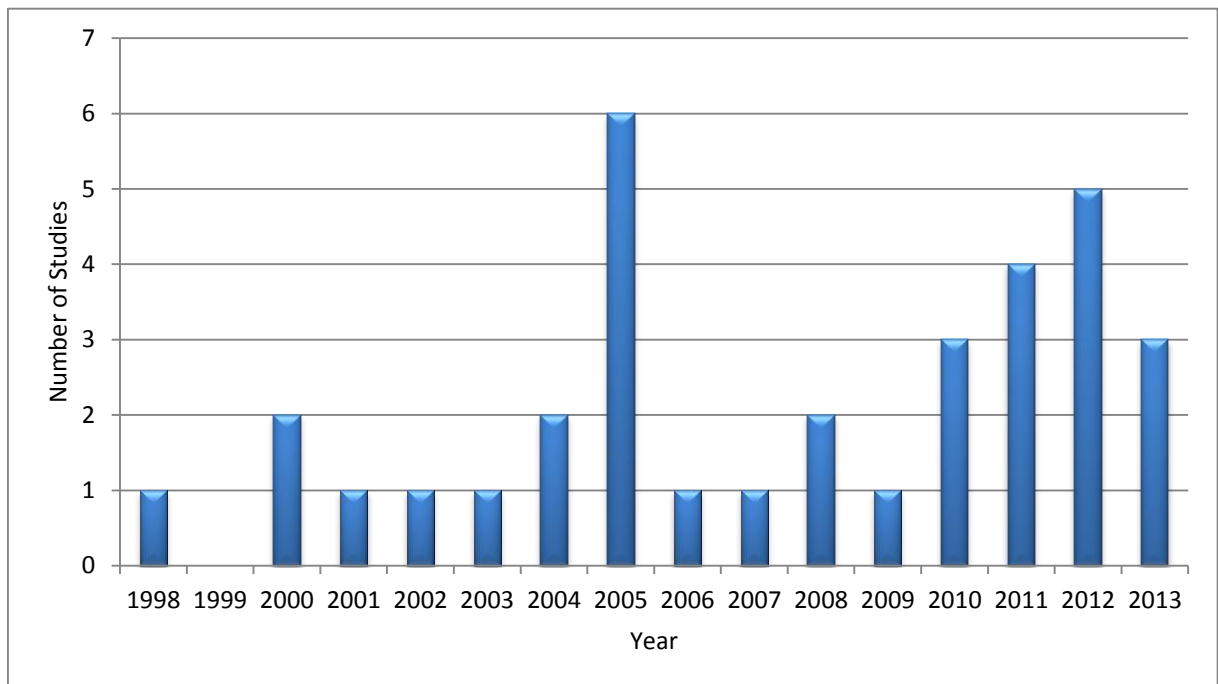


Figure 7: Year of Publication

On average every year 2.125 randomized controlled trials applying osteopathic manipulative treatment were published. In addition, it is recognizable that since 2010 the number of publications ranges above the average

### 5.6.3 Duration of Treatment

Only 27 out of 34 publications mentioned the duration of treatment.

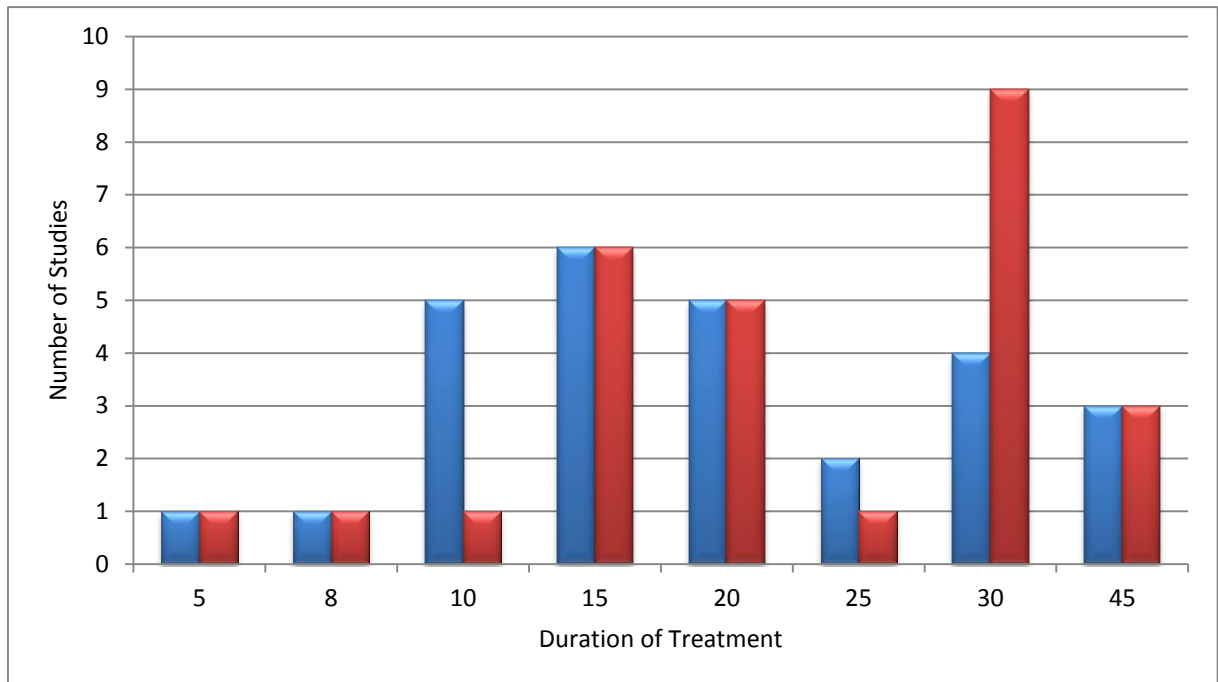


Figure 8: Duration of Treatment (blue: minimum, red: maximum)

In analyzing the duration of treatment the timeframe varies very widely between the different trials. It starts with 5 minutes and goes up to 45 minutes. However in 9 out of 27 the maximum duration was 30 minutes, which represents 1/3 of the trials.

#### 5.6.4 Number of Participants

Although there are already two randomized controlled trials available with more than 400 participants, however, the majority of trials, i.e. 11 out of 34, had between 11 and 20 participants.

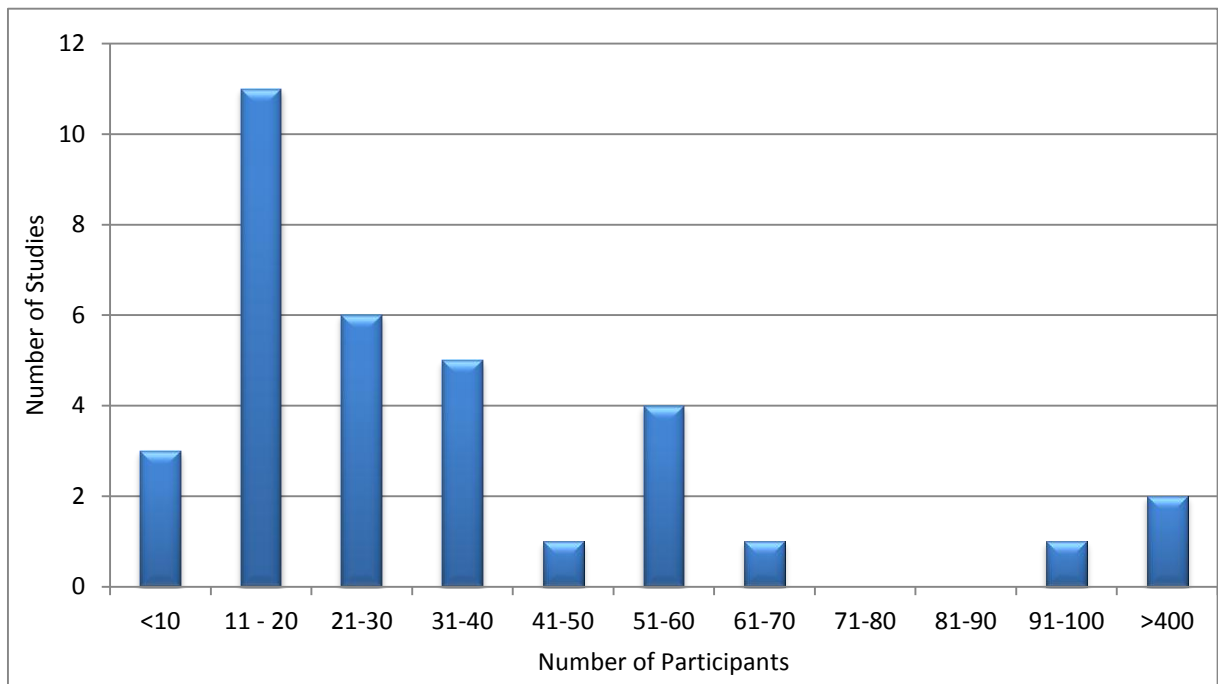


Figure 9: Number of Participants

### 5.6.5 Osteopathic Manipulative Treatment

All different kinds of osteopathic manipulative treatment were applied in the randomized controlled trials.

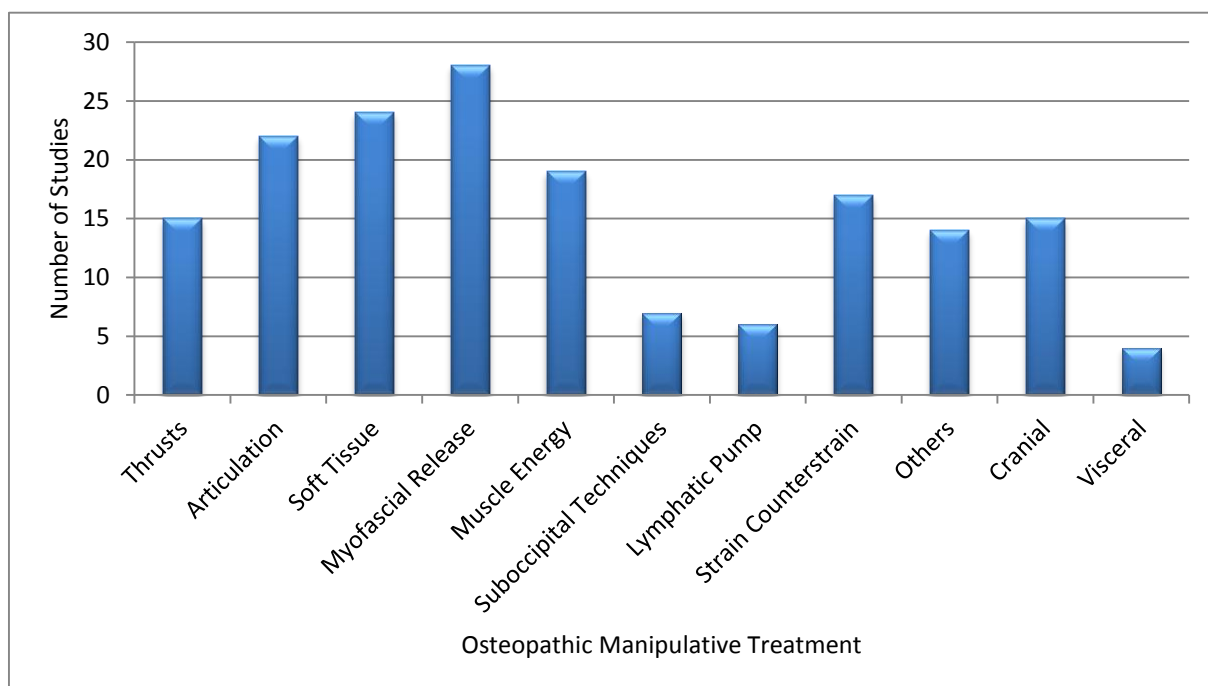


Figure 10: Osteopathic Manipulative Treatment

All areas have been covered, the majority of treatments were on the structure. Particularly myofascial release was applied in 28 out of 34 trials, but also cranial osteopathy and visceral osteopathy were parts of treatments. Others included the following techniques: balanced ligamentous tension, Chapman's reflexes, effleurage, Galbraeth technique, positioning release, myofascial tenderpoints, paraspinal inhibition, pectoral traction, release of Sibson fascia, rhythmic lifting of back, unwinding, inhibition and functional techniques.

## **5.7 Summary of the Systematic Review**

Since 1998 publications of randomized controlled trials regarding holistic osteopathic manipulative treatment are regularly conducted and available in the World Wide Web. 34 osteopathic manipulative treatment trials have been subject to a thorough review regarding: number of participants, length of treatment and treatment methods applied. Often the number of participants ranges between 11 and 20. The duration of treatment is in the majority of cases around 30 minutes. The osteopathic manipulative treatment included structural, visceral and cranial osteopathy. The centers of expertise are located in the USA especially in the Osteopathic Research Center, University of North Texas Health Science Center and the Kirksville College of Osteopathic Medicine.

As a result of the systematic review the first three research questions have been answered accordingly.

## **6 Interview**

In the second part the aim was to get feedback from experts in the field of randomized controlled trials involving osteopathic manipulative treatment regarding documentation of the treatment.

### **6.1 Identification of Experts**

The systemic review identified the Osteopathic Research Center, University of North Texas Health Science Center and the Kirksville College of Osteopathic Medicine as the centers of expertise

After consulting with the “Wiener Schule für Osteopathie”, Mrs. Snider from the Kirksville College of Osteopathic Medicine and Mr. Licciardone from the Osteopathic Research Center, University of North Texas Health Science Center were chosen as contacts.

### *6.1.1 Mrs. Karen T. Snider*

Mrs. Snider not only works in the Department of Osteopathic Manipulative Medicine, at the A.T. Still University of Health Sciences in Kirksville, but also was one of the authors who published 2012 the randomized controlled trial: “Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study.” This study was very interesting because it also included not only structural but also visceral aspects which have been really rare in the USA up to now as reflected in the systematic review. Furthermore 15 articles are listed under her name when searching in PUBMED by author, which qualifies her as expert in osteopathic research. In addition, her research interest according to the university’s home page covers a wide range of topics associated with Osteopathic Manipulative Medicine (Snider, 2014).

The following email was sent to Mrs. Snider as request for the interview:

**Table 2: Initial email to Mrs. Snider**

Dear Mrs. Snider,

I'm from Austria and currently in the process of writing my master thesis in osteopathic medicine at the Wiener Schule für Osteopathie (Vienna School of Osteopathy). The topic of my master thesis is: "Open the Box – An empirical research concerning the evaluation of the Black-Box-Model in the Osteopathic Medicine".

In the first step I did a systematic review within several databases and osteopathic journals to identify clinical trials which applied holistic osteopathic manipulative treatments. After this process I analyzed the collected data, concerning author and author location, which techniques have been applied, how long was the treatment duration and number of participants.

In line with this analysis Kirksville College of Osteopathic Medicine has turned out to publish several clinical trials.

Now as second step based on the findings I would like to make interviews with leading experts in the field of clinical trials within the osteopathic medicine. In this connection your study "Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study" was very interesting for me. Consequently it would be a great pleasure if you personally or one of your team would be open to make an **interview with me via Skype**, which would be recorded for purpose of the master thesis only and afterwards included in the thesis accordingly.

In this interview questions are concerning the documentation of the osteopathic manipulative treatment in line with a clinical trial (i.e. if there are any standard forms, experiences with the documentation, advantages/, disadvantages of your form used).

Furthermore I kindly ask you for a **copy of your preferred treatment form** of the osteopathic manipulative treatment in line with a clinical trial.

I would be really pleased, if there is the possibility to arrange for an appointment via Skype.

In case this is absolutely impossible for you, would you agree to complete the interview in writing?

I'm looking forward to your reply.

Kind regards, Susanne Müller

Wiener Schule für Osteopathie - Vienna, Austria

Already after a few days Mrs. Snider provided the osteopathic manipulative treatment data collection form of her study:



**Table 3: OMT Data Collection Form**

<b>OMT and LT Group Data Collection Form</b> <small>(Original format courtesy of Mount Clemens General Hospital)</small>													
<b>Date:</b>				<b>Evaluating Physicians Name:</b>									
<input type="checkbox"/> LT Group - protocol not performed				<b>Reason:</b>									
<input type="checkbox"/> OMT Group – Protocol not performed													
Region Evaluated	Degree			Specifics of Major Somatic Dysfunctions			Treatment Method (Circle)	Comments	Response				
	0	1	2	TTC	Te	A/R			R	I	U	W	
Head							DIR- ART / ME / MFR / HVLA						
							IND- CS / MFR / CR						
Neck							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Thoracic	T1-4							DIR- ART / ME / MFR / HVLA					
								IND- CS / BLT / VIS / MFR					
								DIR- ART / ME / MFR / HVLA					
IND- CS / BLT / VIS / MFR													
	T5-9							DIR- ART / ME / MFR / HVLA					
								IND- CS / BLT / VIS / MFR					
								DIR- ART / ME / MFR / HVLA					
IND- CS / BLT / VIS / MFR													
	T10-12							DIR- ART / ME / MFR / HVLA					
								IND- CS / BLT / VIS / MFR					
								DIR- ART / ME / MFR / HVLA					
IND- CS / BLT / VIS / MFR													
Lumbar							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Sacrum							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / CR						
Innominate							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Hip							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Low extremity							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Upper extremity							DIR- ART / ME / MFR / HVLA						
							IND- CS / BLT / MFR						
Ribs	R or L							DIR- ART / ME / MFR / HVLA					
								IND- CS / BLT / MFR					
Abdomen							DIR- ART / ME / MFR						
							IND- CS / BLT / VIS						
<b>Physician's evaluation of subject prior to treatment:</b> First Visit <input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Unchanged <input type="checkbox"/> Worse <input type="checkbox"/>								Required physical exam includes evaluation of cervical, thoracic, lumbar, sacrum, innominates, ribs, and abdomen. Physicians are expected to treat all significant somatic dysfunction.					
<b>Treating Physician's Signature:</b>													
<b>Supervising Physician's Signature (If applicable):</b>													
<b>Additional Comments:</b>													
TTC : TISSUE TEXTURE CHANGES      DIR : DIRECT                      IND : INDIRECT                      MFR- MYOFASCIAL RELEASE A/R : ASYMMETRY/RESTRICTION      ART : ARTICULATORY              CS : COUNTERSTRAIN              CR : CRANIAL TE : TENDERNESS                      ME : MUSCLE ENERGY              HVLA – HIGH VELOCITY LOW AMPLITUDE BLT- BALANCED LIGAMENOUS TENSION													

In addition she also provided a first feedback on the form:

**Table 4: Response from Mrs. Snider**

The main disadvantage of the OMT data collection form is the lack of documentation of specific somatic dysfunction findings such as T5 flexed sidebent right and rotated right. We opted for simple documentation of TART elements - tenderness, tissue texture abnormalities, asymmetry and restricted range of motion. This is essentially the same form as that used in the MOPSE pneumonia study.

Furthermore she agreed to take part in the interview however due to issues of time-restraint a verbal personal interview was not possible. Consequently the decision was made to send the interview questions via email under consideration of the information already received from her.

#### *6.1.2 Mr. John C. Licciardone*

Mr. Licciardone, is the Executive Director of the Osteopathic Research Center at the Texas College of Osteopathic Medicine. He was one of the authors in three randomized controlled trials in the field of osteopathic manipulative treatment, which are also included in the systematic review. Until January 2014 he published a total of 77 articles in PUBMED. Thus he is an expert in the field of osteopathic research.

The following email was sent to Mr. Licciardone as request for the interview:

**Table 5: Initial email to Mr. Licciardone**

Dear Mr. Licciardone,

I'm from Austria and currently in the process of writing my master thesis in osteopathic medicine at the Wiener Schule für Osteopathie (Vienna School of Osteopathy). The topic of my master theses is: "Open the Box – An empirical research concerning the evaluation of the Black-Box-Model in the Osteopathic Medicine".

In the first step I did a systematic review within several databases and osteopathic journals to identify clinical trials which applied holistic osteopathic manipulative treatments. After this process I analyzed the collected data, concerning author and author location, which techniques have been applied, how long was the treatment duration and number of participants.

In line with this analysis "The Osteopathic Research Center" in Texas has turned out to publish the majority of clinical trials.

Now as second step based on the findings I would like to make interviews with leading experts in the field of clinical trials within the osteopathic medicine. In this connection it would be a great pleasure if you personally or one of your team would be open to make an interview with me via Skype, which would be recorded for purpose of the master theses only and afterwards included in the thesis accordingly..

In this interview the questions are concerning the documentation of the osteopathic manipulative treatment in line with a clinical trial (i.e. if there are any standard forms, experiences with the documentation, advantages/, disadvantages of your form used).

Furthermore I kindly ask you for a copy of your preferred treatment form of the osteopathic manipulative treatment in line with a clinical trial.

I would be really pleased, if there is the possibility to arrange for an appointment via Skype.

In case this is absolutely impossible for you, would you agree to complete the interview in writing?

I'm looking forward to your reply.

Kind regards, Susanne Müller

Wiener Schule für Osteopathie, Vienna, Austria

A few days later Mr. Licciardone replied that he is open to take part in the interview but also in his case due to various reasons a personal interview was not possible. Consequently the interview questions were also sent to him via email.

## 6.2 Interview Questionnaire

The initial questionnaire was put together in cooperation with the “Wiener Schule für Osteopathie”. These questions were sent to Mr. Licciardone:

1. According to your experience what are the reasons to go for an OMT trial approach?
2. Which form do you use at your research center to document the OMT in a trial? Is this a standard form or especially created for each research?
3. What are the reasons to use this form in an OMT trial?
4. What do you think are the advantages of this form?
5. What do you think are the disadvantages of this form?
6. What does this form cover?
7. Is there also a section included for the “Visceral” and “Cranial” Osteopathy? If one of them is missing please let me know why?
8. How long does it take to complete the form?
9. What happens with the OMT data?
10. Which further investigation is done on the OMT data after collection?
11. In a lot of trials OMT is limited to a certain part of the body and also to a certain group of techniques – What do you think about this?
12. Please provide me with a copy of your preferred form.

Since Mrs. Snider already provided the OMT data collection form which she used for her study consequently the questions were adjusted according to the form received.

1. According to your experience what are your reasons to go for an OMT trial approach?
2. The form you have used to document the OMT in the trial was created for the MOPSE Pneumonia study in the first instance and now also used for the “Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study” – Is this form now a standard for future OMT trials?
3. Why did you use this form?
4. What do you think have been the advantages of this form?

5. What do you think have been the disadvantages of this form?
6. For the visceral Osteopathy only “Abdomen” is mentioned for treatment no further details (i.e. Large intestine, small intestine) – why?
7. There is nothing mentioned regarding the Cranial Osteopathy – why?
12. If you do have a new form available maybe you could also send it to me?

The questions 8 to 11 have been the same.

### 6.3 Details of the Answers

The final interview questionnaires were sent to the two experts on March 21<sup>st</sup>, 2014 and their answers returned on April 14<sup>th</sup> and 16<sup>th</sup>, 2014 already. Both provided their answers via email as agreed.

According to Flick (2007) the assessment of the interviews with experts analyzes and compares the content of the interview and the know-how of experts. In order to analyze the interviews the method of qualitative content analyses according Mayring (2008) was chosen (Bacher & Horwath, 2011).

Question 1:

Mrs. Karen T. Snider	Mr. John C. Licciardone
According to your experience what are your reasons to go for an OMT trial?	According to your experience what are the reasons to go for an OMT trial approach?
<i>I treat a large number of elderly people and have found over the years that manipulation vastly improves their quality of life. Individuals in the nursing home are often unable to go to an outpatient clinic for osteopathic manipulation so by bringing the treatment to them in their environment in the nursing</i>	<i>Randomized controlled trials are needed to definitively assess the efficacy of OMT because they are the best methodological approach to ensure that the therapeutic benefits of OMT are truly related to OMT as opposed to other factors such as placebo</i>

<i>home, we hope to see improvement in their health and quality of life within the nursing home environment and to keep them out of the hospital.</i>	<i>effects, “regression to the mean,” and attention to the patient.</i>
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Mrs. Snider’s answer related to the reasons to apply osteopathic manipulative treatment in her study and by applying osteopathic manipulative treatment she hoped to see improvement in the health and quality of life within the nursing home environment and to keep the patients out of the hospital. Consequently the use of osteopathic manipulative treatment should have a positive effect on the elderly people. Mr. Licciardone summarized that randomized controlled trials shall assess the efficacy of osteopathic manipulative treatment and exclude other factors such as placebo effects, “regression to the mean,” and attention to the patient.

Question 2:

Mrs. Karen T. Snider	Mr. John C. Licciardone
The form you have used to document the OMT in the trial was created for the MOPSE pneumonia study in the first instance and now also will be used for the preventative osteopathic manipulative treatment in the elderly nursing home resident. Is this form now a standard for future OMT trials?	Which form do you use at your research center to document the OMT in a trial? Is this a standard form or especially created for each research?
<i>This form was useful for both the MOPSE and the nursing home studies. However, future forms really need to be formed around the information that needs to be collected.</i>	<i>We generally use the Outpatient Osteopathic SOAP Note Form to document somatic dysfunction. Each study generally has its own specific form to document the OMT treatment protocol. We have different forms for each study because the treatment protocol generally varies from study to study.</i>

In case of Mrs. Snider it was possible to use one form for two studies. Mr. Licciardone confirmed that generally the Outpatient Subjective, Objective, Assessment, Plan (SOAP) Note Form is used and in addition specific osteopathic manipulative treatment protocols are prepared. So this means that available forms can be reviewed for new studies, but have to be adapted accordingly in order to collect the needed information.

Question 3:

Mrs. Karen T. Snider	Mr. John C. Licciardone
Why did your use this form?	What are the reasons to use this form in an OMT trial?
<i>We used this form because it was readily available and was easily adaptable for the nursing home study. We had not had a lot of feedback on the positives or negatives of the form and we were all familiar with it.</i>	<i>Using such forms helps to ensure and document that the OMT was delivered consistently to all patients throughout the study.</i>

Reasons to use a certain form for an osteopathic manipulative treatment trial are availability, adaptability of the form, also previous experiences and consistency. The answers have been complementary.

Question 4:

Mrs. Karen T. Snider	Mr. John C. Licciardone
What do you think the advantages of this form are?	What do you think are the advantages of this form?
<i>The advantages are it is relatively simple to complete the information provided.</i>	<i>In addition to my response to #3 above, the form may be used to acquire data to verify that the OMT was delivered according to the protocol. Also, other secondary hypotheses may potentially be addressed using data from the form.</i>

Advantages of good forms are simplicity, truthfulness and also further information is available, and also in this question the answers can be summarized to understand the whole situation.

Question 5:

Mrs. Karen T. Snider	Mr. John C. Licciardone
What do you think have been the disadvantages of this form?	What do you think are the disadvantages of this form?
<i>The disadvantage of the form was that you had to fill out individual named somatic dysfunctions such as T2 flexed, sidebent right, rotated right by hand. We are currently using electronic medical record that allows us to just click boxes for this sort of diagnosis, which would likely be much better for data collection in the future.</i>	<i>The investigators and each OMT provider must be trained to reliably and validly administer or complete the form for all patients in the study. In addition to initial “fidelity training,” this requires periodic “booster training” sessions throughout the study.</i>

Disadvantages of forms as noted are the lack of details in the form and also the reliability of the administrators of the form. To overcome the lack of details electronic medical records shall be used for data collection. In order to ensure well-educated administrators initial and regular trainings session throughout the study are obligatory. Both have made their experiences with their forms and consequently both answers have to be considered as valid.

Question 6 and 7:

Although at the first view question 6 and 7 seem to be different however these questions are intended to understand the part of visceral and cranial osteopathy in the US.

Mrs. Karen T. Snider	Mr. John C. Licciardone
For the visceral osteopathy part of abdomen is mentioned for treatment, no further details, large intestines, small intestines...why?	What does this form cover?
<i>Currently just like the head, cervical, thoracic, lumbar, sacrum, pelvis, lower extremity and</i>	<i>The form is basically a check list with instructions. It covers the “required” OMT</i>



<p><i>upper extremity, abdomen is a somatic dysfunction region as defined by ICD9. It was up to the individual physician to mark a specific area that was treated just as in the other body areas where they needed to mark any specific dysfunctions that were treated.</i></p>	<p><i>techniques that must be used (except if contraindicated), and includes space to document "optional" OMT techniques if they are also allowed by the protocol.</i></p>
<p>There is no mention regarding cranial osteopathy...why?</p>	<p>Is there also a section included for the "Visceral" and "Cranial" Osteopathy? If one of them is missing please let me know why?</p>
<p><i>Cranial osteopathy is an approach to manipulation rather than individual techniques. Within cranial osteopathy there is a wide variety of techniques including direct, indirect, balanced ligamentous tension, balanced membranous tension, engagement, exaggeration, disengagement, and articular. These sorts of categories of techniques are utilized throughout the body. However, understanding that cranial often means a specific group of techniques rather than an individual technique, the abbreviation CR is put at the end of the head and sacrum treatment method columns.</i></p>	<p><i>Visceral and cranial osteopathy are not specifically included among the OMT techniques that are "required" for our low back pain studies because they are not commonly reported as treatment techniques used by osteopathic physicians in the USA to treat low back pain. However, they are sometimes used and documented as "optional" techniques for low back pain in our studies.</i></p>

Both agreed that cranial osteopathy as well as visceral osteopathy shall always be considered in an osteopathic manipulative treatment, even if not required within the original design of the study the techniques shall always be considered as optional for the treatment. Consequently this requirement has to be reflected in the documentation form accordingly. Both answers are homogenous and confirm that osteopathic manipulative treatment also include cranial and visceral osteopathy.

Question 8:

Mrs. Karen T. Snider	Mr. John C. Licciardone
How long does it take to complete the form?	
<i>Usually about 3 minutes.</i>	<i>Our treatment sessions generally last about 15 minutes; however, it should not take longer than a minute or two to complete the form.</i>

Completing the form shall be possible within a very short period of time, one to three minutes as certified in Mrs. Sniders study. The two experts agree on this point.

Question 9 and 10:

Mrs. Karen T. Snider	Mr. John C. Licciardone
What happened to the OMT data?	What happens with the OMT data?
<i>There was a student physician who had been working on compiling it and she had hoped to submit it for publication on the types of techniques used. However, she didn't finish her project before she left town so currently the data is waiting for somebody who is interested in compiling it and publishing it.</i>	<i>It is entered into a study database.</i>
Was there any further investigation on the OMT data?	Which further investigation is done on the OMT data after collection?
<i>See #9</i>	<i>The data are used to assess the study hypotheses and form the basis for the primary study publication. In some cases, secondary (unplanned) analyses are also performed and yield additional publications. Sometimes, the data are used to plan and estimate sample size for future studies.</i>

Ideally collected data shall be stored in databases to allow further analyses and others to use them for comparison and further studies. Unfortunately not always everything is possible. However, in any case the data is available in paper format. Basically both experts agree.

Question 11:

Mrs. Karen T. Snider	Mr. John C. Licciardone
In a lot of trials, OMT is limited to a certain part of the body and also a certain group of techniques. What do you think of this?	
<p><i>OMT trials limited to certain techniques are “technique” studies. However, we were not interested in the effectiveness of a specific technique but rather the effectiveness of an entire treatment as would be typically done for an individual. Individual treatments when applied to a patient usually encompass a wide variety of techniques based on the skill and the experience of the physician and the tolerance of the patient. This protocol was meant to simulate what realistically occurs during a clinical encounter.</i></p>	<p><i>In the current “disease” model, it is almost impossible to receive research funding or to publish articles unless there is a specific disease condition (e.g., pneumonia) or at least an important symptom (e.g., low back pain) that is the focus of the study. There are pros and cons about whether the studies should be strict “efficacy” trials based on a rigid treatment protocol in highly selected patients, or if they should be less restrictive “pragmatic” trials. In the latter, all (or almost all) patients with the condition of interest would be eligible and all (or almost all) treatment techniques would be allowed. Our studies tend to be hybrids which have elements of both the efficacy and pragmatic approaches.</i></p>

Mrs. Snider clearly stated that in case of randomized controlled trials of osteopathic manipulative treatment the treatment shall not be limited to certain techniques. Mr. Licciardone firstly mentioned that also the funding of research is important and for this purpose a specific disease or symptom has to be the focus of the study, whether all or only a restricted set of techniques is allowed may depend on the argumentation. His studies tend to be hybrids which have elements of both the efficacy and pragmatic approaches.

Question 12:

Mrs. Karen T. Snider	Mr. John C. Licciardone
If you do have a new form available, maybe you can send it to me?	Please provide me with a copy of your preferred form
<i>I do not have a new form available at this point in time. From this point forward we will likely use electronic medical records then data mine from what has been recorded. We are currently using the NextGen electronic medical records which has a somatic dysfunction template that we created here in Kirksville.</i>	<i>The Outpatient Osteopathic SOAP Note Form (available through the American Academy of Osteopathy) is our preferred form for documenting somatic dysfunction (using the musculoskeletal table) and can also be used for treatment. The entire family of osteopathic SOAP Note Forms may be viewed at <a href="http://bit.ly/1m2XdCU">http://bit.ly/1m2XdCU</a>.</i>

At the Kirksville College of Osteopathic Medicine electronic records will be used for data recording. At the Osteopathic Research Center, University of North Texas Health Science Center the “Outpatient Osteopathic SOAP Note Form” is still used for treatment, a copy of this form is attached below:

**Table 6: Outpatient SOAP Note Form**

### Outpatient Osteopathic SOAP Note Form

Office of: \_\_\_\_\_

Patient's Name: \_\_\_\_\_ Sex:  Male  Female  For office use only: \_\_\_\_\_

Date: \_\_\_\_\_ Age: \_\_\_\_\_

Vital Signs: B/P \_\_\_\_\_ Pulse \_\_\_\_\_ Respir. \_\_\_\_\_ Temp. \_\_\_\_\_ Wt. \_\_\_\_\_ Ht. \_\_\_\_\_

**S** CC: \_\_\_\_\_

HPI: \_\_\_\_\_

ROS/PFSH: \_\_\_\_\_

Meds: \_\_\_\_\_

**O** \_\_\_\_\_

Level of GMS: \_\_\_\_\_  
 2 • 1-5 elements  
 3 • 6+ elements  
 4 • 2+ from each of 6 areas  
 5 • 12+ elements in 2+ areas  
 6 • 2+ elements from each of 9 areas

Methods Used to Examine: T-  A-  R-  passive  T-  active  T-

Severity Scale:  No SD or background (BG) levels  Obvious TART (esp. R and T), +/- symptoms  
 More than BG levels, minor TART  Key lesions, symptomatic, R and T stands out

Region Evaluated	Severity				Somatic Dysfunctions and Other Systems <small>MS / SNS / PNS / LYM. / CV / RESP. / GI / FAS. / etc.</small>	OMT		Treatment Method <small>(Circle Treatment Methods Used)</small>	Response			
	0	1	2	3		Yes	No		R	I	U	W
Head	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cervical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thoracic T1-4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
T5-9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
T10-12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lumbar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sacrum/Pelvis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pelvis/Innom.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extremity lower	R	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extremity upper	R	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ribs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abd./Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	ART / BLT / CR / CS / DIR / FPR / HVLA IND / INR / LAS / ME / MFR / ST / VIS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

**A** 1. \_\_\_\_\_ 3. \_\_\_\_\_  
 2. \_\_\_\_\_ 4. \_\_\_\_\_

**P**

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

Meds: \_\_\_\_\_ PT: \_\_\_\_\_

Exercise: \_\_\_\_\_ Other: \_\_\_\_\_

Nutrition: \_\_\_\_\_

Minutes spent with patient:  10  15  25  40  60  >60 Follow-up:  1  2  3  4  6  8  11  12 Units:  Days  Wk.  Mo.  Yr.  PRN

Signature of the examiner: \_\_\_\_\_

03MX2M.PCX SSWAK 5/98 Funded under a grant from the AOA Bureau of Research ©American Academy of Osteopathy

## 6.4 Summary of the Answers

As a first step the question was if there are centers of expertise in case of osteopathic research from which experts can be contact for an interview.

Centers of expertise are locations which are regularly involved in research and according to the search results of the systematic review have issued at least 5 or more randomized controlled trials of osteopathic manipulative treatment. From each of these centers of expertise one person who issued more than 10 articles in PUBMED in the field of osteopathic medicine and also published one randomized controlled trial concerning osteopathic manipulative treatment shall be contacted as expert in order to obtain feedback on randomized controlled trials of osteopathic manipulative treatment and respective documentation. If possible a gender distribution would be preferable.

According to the systematic review two locations in the USA appeared as center of expertise: the Osteopathic Research Center, University of North Texas Health Science Center and the Kirksville College of Osteopathic Medicine. Consequently Mrs. Karen T. Snider from the Kirksville College of Osteopathic Medicine and Mr. John C. Licciardone from the Osteopathic Research Center, University of North Texas Health Science Center were selected as partners for the interview.

Both have been invited independently for interviews, which were made via email according to their responses.

Finally it can be summarized that randomized controlled trials shall assess the efficacy of osteopathic manipulative treatment and exclude other factors such as placebo effects, "regression to the mean," and attention to the patient. For the purpose of documentation available forms can be reviewed for new studies, but have to be adapted accordingly in order to collect the needed information. Reasons to use a certain form for an osteopathic manipulative treatment trial are availability, adaptability of the form, also previous experiences and consistency. Advantages of good forms are simplicity, truthfulness and also that further information is available.

Disadvantages of forms as noted are the lack of details in the form and also the reliability of the administrators of the form. To overcome the lack of details electronic medical records shall be used for data collection. In order to ensure well-educated administrators initial and regular trainings session throughout the study are obligatory. Cranial osteopathy as well as visceral osteopathy shall always be considered in an osteopathic manipulative treatment, even if not required within the original design of the study the techniques shall always be considered as optional for the treatment. Thus this requirement has to be reflected in the documentation form. Completing the form shall be possible within a very short period of time. Ideally collected data shall be stored in databases to allow further analyses and others to use them for comparison and further studies. Mrs. Snider clearly stated that in case of randomized controlled trials of osteopathic manipulative treatment the treatment shall not be limited to certain techniques. Mr. Licciardone, however, mentioned that also the funding of research is important and for this purpose a specific disease or symptom has to be the focus of the study, whether all or only a restricted sets of techniques are allowed may depend on the argumentation. His studies tend to be hybrids which have elements of both the efficacy and pragmatic approaches. At the Kirksville College of Osteopathic Medicine electronic records will be used for data recording in the future. At the Osteopathic Research Center, University of North Texas Health Science Center the “Outpatient Osteopathic SOAP Note Form” is still used for treatment.

Furthermore both experts provided data collection forms to document the osteopathic manipulative treatment applied in a pragmatic trial for further review.

In analyzing the answers provided on the basis of the interview questionnaires it is remarkable that most of the answers are similar and sometimes the information can be recognized as supplementary in order to fully understand the situation. Only in one point a discrepancy is remarkable: Mrs. Snider clearly states that osteopathic manipulative treatments shall not be limited to certain techniques, while Mr. Licciardone allows some flexibility and compromises due to funding and specific argumentation.

## 7 Discussion

This systemic review of randomized controlled trials of osteopathic manipulative treatment was only done to receive quantitative data on the studies executed, however, no detailed quality review of the extracted studies were made regarding results and reliability. Consequently quality scores for all the selected randomized controlled trials are subject to further reviews.

Only very few studies from Europe were included in this systematic review. This may be due to the fact that the search was done in English only and no further languages were applied as search options. Furthermore there may be also additional databases available in different languages. This also is subject to further reviews.

Due to the lack of European studies no experts from Europe were identified as expert for the purposes of the interview. Although their input would have been interesting in the same manner.

Also the interviews have been only written questionnaires in lieu of verbal contacts as intended initially so information may be missing.

However, in addition to all the data analysed and also the information received this master thesis has shown that experts within the osteopathic medicine can be identified and are available and an exchange of information is possible. This is a first step and maybe further steps can be made for future cooperation.



## 8 Conclusion

The present systematic review provides an overview of studies in medical databases and osteopathic e-journals analyzing holistic pragmatic trials in osteopathic medicine. The currently available studies on this topic are homogenous.

The interviews also have shown that the requirements of an osteopathic manipulative treatment randomized controlled trial include structural, cranial and visceral osteopathy. Data collection forms are available but may be individually designed according to the study. Past experiences of documentation forms have shown that simple forms which are easy and quick to complete are favored. Training for the administrators is beneficiary to increase the quality of the documentation. Ideally all data shall be stored in electronic databases to allow further analyses. Both interview partners independently provided homogenous feedback, confirming that the understanding of documenting osteopathic manipulative treatment in a randomized controlled trial is the same, however due to funding purposes and specific designs of the randomized controlled trial hybrids, having elements of both the efficacy and pragmatic approach may be the solution.

In summary it can be stated that research within the osteopathic medicine is already conducted since the foundation. There are centres of expertise in place, for the time being mainly in the US. However, this master thesis has shown, that an exchange of information with experts is possible, even when they are abroad.

## 9 References

- Anderson, R.E., & Seniscal, C. (2006). A comparison of selected osteopathic treatment and relaxation for tension-type headaches. *Headache*, 46, 1273-1280. doi: 10.1111/j.1526-4610.2006.00535.x \*
- Arienti, C., Daccò, S., Piccolo, I., & Redaelli, T. (2011). Osteopathic manipulative treatment is effective on pain control associated to spinal cord injury. *Spinal Cord*, 49, 515-519. doi: 10.1038/sc.2010.170. \*
- Bacher, J., Horwath, I. (2011), *Einführung in die Qualitative Sozialforschung, Teil 1*. Retrieved from [http://www.jku.at/soz/content/e94921/e95830/e202629/e202930/SkriptTeil1ws11\\_12\\_ger.pdf](http://www.jku.at/soz/content/e94921/e95830/e202629/e202930/SkriptTeil1ws11_12_ger.pdf)
- Brugman, R., Fitzgerald, K., & Fryer G. (2010). The effect of Osteopathic Treatment on Chronic Constipation – A Pilot Study. *International Journal of Osteopathic Medicine*, 13, 17-23. doi:10.1016/j.ijosm.2009.10.002 \*
- Burton, A.K., Tillotson, K.M., & Cleary, J.. (2000). Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation. *European Spine Journal*, 9, 202-207. Retrieved from <http://www.ncbi.nlm.nih.gov> \*
- Cruser, d.A., Maurer, D., Hensel, K., Brown, S.K., White, K., & Stoll, S.T. (2012). A randomized, controlled trial of osteopathic manipulative treatment for acute low back pain in active duty military personnel. *Journal of Manual & Manipulative Therapy*, 20, 5-15. doi: 10.1179/2042618611Y.0000000016. \*
- Degenhardt, B.F., Darmani, N.A., Johnson, J.C., Towns, L.C., Rhodes, D.C., Trinh, C., ...DiMarzo, V. (2007) Role of osteopathic manipulative treatment in altering pain biomarkers: a pilot study. *Journal of the American Osteopathic Association*, 107, 387-400. Retrieved from <http://www.jaoa.org> \*
- Degenhardt, B.F., & Stoll, S.T. (2011). Research Priorities in Osteopathic Medicine. In A. Chila (Ed.), *Foundation of Osteopathic Medicine* (pp. 1039-1051). Philadelphia, PA: Lippincott Williams & Wilkins, a Wolters Kluwer business.

- Dräger, K. (2009). *DÄGO-Stellungnahme zur „Wissenschaftlichen Bewertung der Osteopathie“ durch die BÄK*. Retrieved from <http://www.osteopathie.de/de-news-vodnews---1261041900.html>
- Earley, B.E., & Luce, H. (2010). An Introduction to Clinical Research in Osteopathic Medicine. *Primary Care: Clinics in Office Practice*, 37, 49-64. doi: 10.1016/j.pop.2009.09.001
- Fraix, M. (2010). Osteopathic manipulative treatment and vertigo: a pilot study. *Journal of the American Academy of Physical Medicine and Rehabilitation*, 2, 612-618. doi: 10.1016/j.pmrj.2010.04.001. \*
- Fraix, M., Gordon, A., Graham, V., Hurwitz, E., & Seffinger, M.A. (2013). Use of the SMART Balance Master to quantify the effects of osteopathic manipulative treatment in patients with dizziness. *Journal of the American Osteopathic Association*, 113, 394-403. Retrieved from <http://www.jaoa.org> \*
- Fryer, G., Alvizatos, J., & Lamaro, J. (2005). The effect of osteopathic treatment on people with chronic and sub-chronic neck pain: A pilot study *International Journal of Osteopathic Medicine*, 8, 41-48. doi:10.1016/j.ijosm.2005.03.001\*
- Gamber, R.G., Shores, J.H., Russo, D.P., Jimenez, C., & Rubin, B.R. (2002). Osteopathic manipulative treatment in conjunction with medication relieves pain associated with fibromyalgia syndrome: results of a randomized clinical pilot project. *Journal of the American Osteopathic Association*, 102, 321-325. Retrieved from <http://www.jaoa.org> \*
- Gevitz, N. (2001). Researched and demonstrated: inquiry and infrastructure at osteopathic institutions. *Journal of the American Osteopathic Association*, 101, 174-179. Retrieved from <http://www.jaoa.org>
- Goldstein, F.J., Jeck, S., Nicholas, A.S., Berman, M.J., & Lerario, M. (2005). Preoperative intravenous morphine sulfate with postoperative osteopathic manipulative treatment reduces patient analgesic use after total abdominal hysterectomy. *Journal of the American Osteopathic Association*, 105, 273-279. Retrieved from <http://www.jaoa.org> \*

- Jardine, W.M., Gillis, C., & Rutherford, D. (2013). The effect of osteopathic manual therapy on the vascular supply to the lower extremity in individuals with knee osteoarthritis: A randomized trial. *International Journal of Osteopathic Medicine*, 15, 125-133. doi:10.1016/j.ijosm.2012.07.001 \*
- Kirk, L., Underwood M., Chappell L., & Martins-Mendez, M. (2005). The effect of osteopathy in the treatment of chronic low back pain – a feasibility study. *International Journal of Osteopathic Medicine*, 8, 5–11 doi: 10.1016/j.ijosm.2004.08.001 \*
- Kirsch, J.R. (2011). Are Clinical Protocols for Osteopathic Manipulative Procedures Truly “Osteopathic”? *Journal of the American Osteopathic Association*, 111, 322-347. Retrieved from <http://www.jaoa.org>
- Leach, J. (2008). Towards an osteopathic understanding of evidence. *International Journal of Osteopathic Medicine*, 11, 3-6. doi:10.1016/j.ijosm.2008.01.002
- Licciardone, J.C., Stoll, S.T., Fulda, K.G., Russo, D.P., Siu, J., Winn, W., & Swift, J.Jr. (2003). Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial. *Spine*, 28, 1355-1362. \*
- Licciardone, J.C., Stoll, S.T., Cardarelli, K.M., Gamber, R.G., Swift, J.N.Jr., & Winn, W.B. (2004). A randomized controlled trial of osteopathic manipulative treatment following knee or hip arthroplasty. *Journal of the American Osteopathic Association*, 104, 193-202. Retrieved from <http://www.jaoa.org> \*
- Licciardone, J.C. (2008). Educating osteopaths to be researchers – what role should research methods and statistics have in an undergraduate curriculum? *International Journal of Osteopathic Medicine*, 11, 62–68. doi: [10.1016/j.ijosm.2008.03.003](https://doi.org/10.1016/j.ijosm.2008.03.003)
- Licciardone, J.C. (2010). Osteopathic Manipulative Treatment of Back Pain and Related Symptoms during Pregnancy: A Randomized Controlled Trial. *American Journal of Obstetrics & Gynecology*, 202, 43.e1-43.e8. doi: [10.1016/j.ajog.2009.07.057](https://doi.org/10.1016/j.ajog.2009.07.057)
- Licciardone, J.C., Minotti, D.E., Gatchel, R.J., Kearns, C.M., & Singh, K.P. (2013). Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial, *The Annals of Family Medicine*, 11, 122–129. doi: 10.1370/afm.1468\*

- Lopez, D., King, H.H., Knebl, J.A., Kosmopoulos, V., Collins, D., & Patterson, R.M. (2011). Effects of comprehensive osteopathic manipulative treatment on balance in elderly patients: a pilot study. *Journal of the American Osteopathic Association*, 111, 382-388. Retrieved from <http://www.jaoa.org>\*
- Marx, S., Cimniak, U., Beckert, R., Schwerla, F., & Resch, K.L. (2009). Chronic prostatitis/chronic pelvic pain syndrome. Influence of osteopathic treatment - a randomized controlled study. *Der Urologe*, 48, 1339-1345. doi: 10.1007/s00120-009-2088-z. \*
- McPartland, J.M., Giuffrida, A., King, J., Skinner, E., Scotter, J., & Musty, R.E.. (2005). Cannabimimetic effects of osteopathic manipulative treatment. *Journal of the American Osteopathic Association*, 105, 283-291. Retrieved from <http://www.jaoa.org> \*
- McReynolds, T.M., & Sheridan, B.J. (2005). Intramuscular ketorolac versus osteopathic manipulative treatment in the management of acute neck pain in the emergency department: a randomized clinical trial. *Journal of the American Osteopathic Association*, 105, 57-68. Retrieved from <http://www.jaoa.org> \*
- Moran, R. (2013), Recognising patient-centred care in clinical trials of osteopathy – towards a more pragmatic approach. *International Journal of Osteopathic Medicine*, 16(2), 65-67. doi:10.1016/j.ijosm.2013.04.003
- Noll, D.R., Shores, J.H., Gamber, R.G., Herron, K.M., & Swift, J.Jr. (2000). Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia. *Journal of the American Osteopathic Association*, 100, 776-782. Retrieved from <http://www.jaoa.org>
- Noll, D.R., Degenhardt, B.F., Stuart, M., McGovern, R., & Matteson, M. (2004). Effectiveness of a sham protocol and adverse effects in a clinical trial of osteopathic manipulative treatment in nursing home patients. *Journal of the American Osteopathic Association*, 104, 107-113. Retrieved from <http://www.jaoa.org> \*
- Noll, D.R., Degenhardt, B.F., Johnson, J.C., & Burt, S.A. (2008) Immediate effects of osteopathic manipulative treatment in elderly patients with chronic obstructive pulmonary disease. *Journal of the American Osteopathic Association*, 108, 251-9. Retrieved from <http://www.jaoa.org> \*

- Noll, D.R., Degenhardt, B.F., Morley, T.F., Blais, F.X., Hortos, K.A., Hensel, K., Johnson, J.C.,...Stoll, S.T. (2010). Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial. *Osteopathic Medicine and Primary Care*, 19, 4-2. doi: 10.1186/1750-4732-4-2. \*
- O-Yurvati, A.H., Carnes, M.S., Clearfield, M.B., Stoll, S.T., & McConathy, W.J. (2005). Hemodynamic effects of osteopathic manipulative treatment immediately after coronary artery bypass graft surgery. *Journal of the American Osteopathic Association*, 105, 475-481 Retrieved from <http://www.jaoa.org> \*
- Parker, J., Heinking, K.P., & Kappler, R.E. (2012). Efficacy of osteopathic manipulative treatment for low back pain in euhydrated and hypohydrated conditions: a randomized crossover trial. *Journal of the American Osteopathic Association*; 112, 276-284. Retrieved from <http://www.jaoa.org> \*
- Patterson, M.M. (2002). Editor's Message: "Techniques" versus "treatment" in osteopathic manipulation. *Journal of the American Osteopathic Association*, 102, 375. Retrieved from <http://www.jaoa.org>
- Patterson, M.M. (2011). Foundation of Osteopathic Medical Research. In A. Chila (Ed.), *Foundation of Osteopathic Medicine* (pp. 1021-1038). Philadelphia, PA: Lippincott Williams & Wilkins, a Wolters Kluwer business.
- Patterson, M.M. (2011). Response. *Journal of the American Osteopathic Association*, 111(5), 347-348. Retrieved from <http://www.jaoa.org>
- Patsopoulos, N.A., (2011). A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience*, 13(2), 217–224. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed>
- Perrin, R.N., Richards, J.D., Pentreath, V., & Percy, D.F. (2011). Muscle fatigue in chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) and its response to a manual therapeutic approach: A pilot study. *International Journal of Osteopathic Medicine*, 14, 96-105, doi:10.1016/j.ijosm.2010.12.002 \*

- Plotkin, B.J., Rodos, J.J., Kappler, R., Schrage, M., Freydl, K., Hasegawa, S., Hennegan, E.,...Raffaelli, D. (2001). Adjunctive osteopathic manipulative treatment in women with depression: a pilot study *Journal of the American Osteopathic Association*, 101, 517-523. Retrieved from <http://www.jaoa.org>\*
- Radjeski, J.M., Lumley, M.A., & Cantieri, M.S. (1998). Effect of osteopathic manipulative treatment of length of stay for pancreatitis: a randomized pilot study. *Journal of the American Osteopathic Association*, 98, 264-272. Retrieved from <http://www.jaoa.org> \*
- Sackett, D.L., Rosenberg, W.M.C., Muir Gray, J.A., Haynes, R.B., & Scott Richardson, W. (1996). Evidence based medicine: what it is and what it isn't. *British Medical Journal*, 312, 71-72. doi: <http://dx.doi.org/10.1136/bmj.312.7023.71>
- Saggio, G., Docimo, S., Pilc, J., Norton, J., & Gilliar, W. (2011). Impact of osteopathic manipulative treatment on secretory immunoglobulin a levels in a stressed population. *Journal of the American Osteopathic Association*, 111, 143-147. Retrieved from <http://www.jaoa.org> \*
- Snider, K.T., Snider, E.J., Johnson, J.C., Hagan, C., & Schoenwald, C. (2012). Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study. *Journal of the American Osteopathic Association*, 112, 489-501. Retrieved from <http://www.jaoa.org> \*
- Snider, K.T. (2014). *Faculty and Staff*. Retrieved from [http://www.atsu.edu/kcom/faculty\\_staff/bios/Snider-K-Bio.htm](http://www.atsu.edu/kcom/faculty_staff/bios/Snider-K-Bio.htm)
- Sonberg, M., Mullinger, B., & Rajendran, D. (2010). Can osteopathy help women with a history of hypothyroidism and musculoskeletal complaints? Outcome of a preliminary, prospective, open investigation. *International Journal of Osteopathic Medicine*, 13, 11-16, doi:10.1016/j.ijosm.2009.07.001 \*
- Still, A.T. (1910). *Osteopathy Research and Practice*. Kirksville, MO: Author. Retrieved from <http://www.archive.org/details/osteopathyresear00stilia>
- Stone, C. (1999). *Science in the Art of Osteopathy – Osteopathic Principles and Practice*, Cheltenham, UK: Stanly Thornes

- Vismara, L., Cimolin, V., Menegoni, F., Zaina, F., Galli, M., Negrini, S.,...Capodaglio, P. (2012). Osteopathic manipulative treatment in obese patients with chronic low back pain: a pilot study. *Manual Therapy*, 17, 451-455. doi: 10.1016/j.math.2012.05.002. \*
- Wieting, J.M., Beal, C., Roth, G.L., Gorbis ,S., Dillard, L., Gilliland, D., & Rowan, J. (2013). The effect of osteopathic manipulative treatment on postoperative medical and functional recovery of coronary artery bypass graft patients. *Journal of the American Osteopathic Association*, 113, 384-393. Retrieved from <http://www.jaoa.org> \*
- World Health Organization. (2000). *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*, Retrieved from [http://whqlibdoc.who.int/hq/2000/WHO\\_EDM\\_TRM\\_2000.1.pdf](http://whqlibdoc.who.int/hq/2000/WHO_EDM_TRM_2000.1.pdf)

\* All References marked with an asterisk (\*) have been included in the systematic review.



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## 12 Abbreviations

AOA	American Osteopathic Association
AU	Australia
CA	Canada
CCTR	Cochrane Controlled Trials Register
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DE	Germany
GB	Great Britain
IJOM	International Journal of Osteopathic Medicine
IT	Italy
JAOA	Journal of the American Osteopathic Association
OMT	Osteopathic Manipulative Treatment
PEDRO	Physiotherapy Evidence Database
RCTs	randomized controlled trials
SOAP	Subjective, Objective, Assessment, Plan
US	United States of America

## 13 Appendices

### 13.1 Total Breakdown

<b>Search Terms</b>	<b>PUBMED</b>	<b>JAOA</b>	<b>IJOM</b>	<b>CCTR</b>	<b>CINAHL</b>	<b>PEDRO</b>	<b>Total</b>
"Osteopathic care" AND trial	0	1	14	0	17	0	32
Osteopath* AND "pragmatic trial"	1	3	5	8	2	2	21
"Osteopathic manual treatment" AND trial	6	7	5	1	6	2	27
"Osteopathic manipulative treatment" AND trial	70	91	36	26	29	23	275
"Osteopathic treatment" AND trial	23	0	61	26	18	10	138
<b>TOTAL</b>	<b>100</b>	<b>102</b>	<b>121</b>	<b>61</b>	<b>72</b>	<b>37</b>	<b>493</b>
<b>Included / Excluded</b>	<b>PUBMED</b>	<b>JAOA</b>	<b>IJOM</b>	<b>CCTR</b>	<b>CINAHL</b>	<b>PEDRO</b>	<b>Total</b>
Studies included	27	18	11	10	15	6	87
Studies excluded	73	84	110	51	57	31	406
<b>Total</b>	<b>100</b>	<b>102</b>	<b>121</b>	<b>61</b>	<b>72</b>	<b>37</b>	<b>493</b>
<b>Studies excluded</b>	<b>PUBMED</b>	<b>JAOA</b>	<b>IJOM</b>	<b>CCTR</b>	<b>CINAHL</b>	<b>PEDRO</b>	<b>Total</b>
Letter, Text	6	27	42	0	4	1	80
Pregnancy, Infants	15	10	6	12	11	10	64
Systemic/Other Review	14	27	27	9	14	8	99
Technique Review	26	18	22	11	10	7	94
Only Abstract	5	1	12	15	13	2	48
No OMT details	7	1	1	4	5	3	21
<b>Total</b>	<b>73</b>	<b>84</b>	<b>110</b>	<b>51</b>	<b>57</b>	<b>31</b>	<b>406</b>
<b>Studies included</b>	<b>PUBMED</b>	<b>JAOA</b>	<b>IJOM</b>	<b>CCTR</b>	<b>CINAHL</b>	<b>PEDRO</b>	<b>Total</b>
Studies included	27	18	11	10	15	6	87
Pubmed double		17		9	15	6	47
IJOM double			5	1			6
<b>Final included Studies</b>	<b>27</b>	<b>1</b>	<b>6</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>34</b>

## 13.2 Details of Studies 1 - 17

#	Year	Title	Country	Thrusts	Articulation	Soft Tissue Stretching	Myofascial Release / Stretching	Muscle Energy / Isometric muscle activation	Suboccipital	Lymphatic Pump	Strain Counterstrain	Others	Cranial	Viszeral	Min. Treatment duration in minutes	Max. Treatment duration in minutes	Total Participants
1	2013	Osteopathic manual treatment and ultrasound therapy for chronic low back pain: a randomized controlled trial	US	Yes	Yes	Yes, kneading & Pressure	Yes	Yes				Myofascial Tenderpoints			15	15	455
2	2013	The effect of osteopathic manipulative treatment on postoperative medical and functional recovery of coronary artery bypass graft patients.	US		Rib Raising	Yes	Thoracic Inlet		Yes						8	8	53
3	2013	Use of the SMART Balance Master to quantify the effects of osteopathic manipulative treatment in patients with dizziness.	US	Yes			Yes	Yes			Yes	BLT	Yes				16
4	2012	A randomized, controlled trial of osteopathic manipulative treatment for acute low back pain in active duty military personnel.	US	Yes	Yes	Yes	Yes	Yes			Yes						63
5	2012	Preventative osteopathic manipulative treatment and the elderly nursing home resident: a pilot study.	US		Rib Raising, Hip & Shoulder	Yes	Diaphragm & Thoracic Inlet		Suboccipital Release			paraspinal inhibition		Yes	10	15	21
6	2012	Osteopathic manipulative treatment in obese patients with chronic low back pain: a pilot study	IT	Yes			Yes						Yes		45	45	19
7	2012	Efficacy of osteopathic manipulative treatment for low back pain in euhydrated and hypohydrated conditions: a randomized crossover trial.	US	Yes	Yes	Yes	Yes	Yes			Yes				30	30	19
8	2012	The effect of osteopathic manual therapy on the vascular supply to the lower extremity in individuals with knee osteoarthritis: A randomized trial	CA					Yes					Yes				30
9	2011	Effects of comprehensive osteopathic manipulative treatment on balance in elderly patients: a pilot study	US			Yes	Yes	Yes	occipitoatlantal & condylar decompression		Yes	Myofascial Tenderpoints	Yes		25	30	40
10	2011	Impact of osteopathic manipulative treatment on secretory immunoglobulin A levels in a stressed population	US		Rib raising				occipitoatlantal release	Yes					20	20	25
11	2011	Osteopathic manipulative treatment is effective on pain control associated to spinal cord injury	IT			Yes	Yes				Yes		Yes		45	45	47
12	2011	Muscle fatigue in chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) and its response to a manual therapeutic approach: A pilot study	GB	Yes	Yes	Yes						Effleurage	Yes		30	30	9
13	2010	Osteopathic manipulative treatment and vertigo: a pilot study.	US				Yes	Yes			Yes	BLT					18
14	2010	Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial.	US		Rib raising	Yes	Diaphragm & Thoracic Inlet		suboccipital decompression	Yes					15	15	406
15	2010	Can osteopathy help women with a history of hypothyroidism and musculoskeletal complaints? Outcome of a preliminary, prospective, open investigation	GB		Yes	Yes	Yes					Chapman's reflexes	Yes				18
16	2009	Chronic prostatitis/chronic pelvic pain syndrome. Influence of osteopathic treatment - a randomized controlled study	DE	Yes	Yes	Yes	Yes	Yes			Yes		Yes	Yes	45	45	35
17	2008	Immediate effects of osteopathic manipulative treatment in elderly patients with chronic obstructive pulmonary disease.	US		Rib raising	Yes	Diaphragm & Thoracic Inlet		suboccipital decompression	Yes		Pectoral Traction			20	20	35

### 13.3 Details of Studies 18 - 34

#	Year	Title	Country	Thrusts	Articulation	Soft Tissue Stretching	Myofascial Release / Stretching	Muscle Energy / Isometric muscle activation	Suboccipital	Lymphatic Pump	Strain Counterstrain	Others	Cranial	Viszeral	Min. Treatment duration in minutes	Max. Treatment duration in minutes	Total Participants
18	2008	The effect of Osteopathic Treatment on Chronic Constipation – A Pilot Study	AU	Yes	Yes	Yes	Yes	Yes			Yes			Yes	30	30	6
19	2007	Role of osteopathic manipulative treatment in altering pain biomarkers: a pilot study.	US		Yes	Yes		Yes			Yes				20	25	20
20	2006	A comparison of selected osteopathic treatment and relaxation for tension-type headaches	CA		Yes	Yes	Yes	Yes			Yes	Unwinding, Inhibition, Functional	Yes				26
21	2005	Hemodynamic effects of osteopathic manipulative treatment immediately after coronary artery bypass graft surgery.	US		Rib raising		Sternum & Diaphragm		occipitoatlantal decompression			Release of Sibson Fascia	BLT		25	30	29
22	2005	Cannabimimetic effects of osteopathic manipulative treatment.	NZ	Yes	Yes		Yes	Yes							20	20	31
23	2005	Preoperative intravenous morphine sulfate with postoperative osteopathic manipulative treatment reduces patient analgesic use after total abdominal hysterectomy.	US			Yes	Yes					Rhythmic lifting of back			10	10	39
24	2005	Intramuscular ketorolac versus osteopathic manipulative treatment in the management of acute neck pain in the emergency department: a randomized clinical trial.	US	Yes		Yes		Yes							5	5	58
25	2005	The effect of osteopathic treatment on people with chronic and sub-chronic neck pain: A pilot study	AU	Yes	Yes	Yes		Yes			Yes						17
26	2005	The effect of osteopathy in the treatment of chronic low back pain – a feasibility study	GB	Yes	Yes	Yes	Yes	Yes							30	30	9
27	2004	A randomized controlled trial of osteopathic manipulative treatment following knee or hip arthroplasty.	US	Yes		Yes	Yes	Yes			Yes		Yes		10	30	60
28	2004	Effectiveness of a sham protocol and adverse effects in a clinical trial of osteopathic manipulative treatment in nursing home patients.	US		Yes & Rib raising		Yes & Diaphragm, anterior thoracic inlet	Yes		Yes	Yes	paraspinal inhibition			15	15	14
29	2003	Osteopathic manipulative treatment for chronic low back pain: a randomized controlled trial.	US	Yes		Yes	Yes	Yes			Yes		Yes		15	30	91
30	2002	Osteopathic manipulative treatment in conjunction with medication relieves pain associated with fibromyalgia syndrome: results of a randomized clinical pilot project.	US			Yes	Yes	Yes			Yes		Yes		15	30	24
31	2001	Adjunctive osteopathic manipulative treatment in women with depression: a pilot study.	US				Yes	Yes		Yes	Yes	Galbraeth Technique, Posit. Release	Yes		20	20	17
32	2000	Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia	US		Rib Raising	Cervical Muscle	Diaphragm, anterior thoracic inlet			Yes		bilateral paraspinal inhibition	Condylar decompression		10	15	58
33	2000	Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation.	GB	Yes	Yes	Yes									15	15	20
34	1998	Effect of osteopathic manipulative treatment of length of stay for pancreatitis: a randomized pilot study.	US		Yes		Yes				Yes			Yes - Abdominal tenderpoints	10	20	14
		Total	34	15	22	24	28	19	7	6	17	14	15	4	27	27	34