Osteopathic Treatment of Female Incontinence

A Systematic Review

by

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Approval Page

This Thesis Proposal was submitted by Hösele Klaus, whose committee was composed of the persons indicated below. It was submitted to the Dean of the Post-graduate School of Osteopathic Clinical Research and approved in partial fulfillment of the requirements for the degree of Master of Science in Osteopathic Clinical Research at A.T. Still University of Health Sciences.

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Abstract

Osteopathic Treatment of Female Incontinence

Background:

Incontinence differs from other health problems in so far that it deals with a strongly tabooed ailment. The quality of life for those affected is often significantly limited. Urinary incontinence is seen as a common problem worldwide and is present in all cultures. Women are considerably more frequently affected than men.

Objective:

What can a conservative treatment such as osteopathy do for female incontinence?

Methods: Search strategies

The most important databases utilized were MEDLINE, COCHRANE LIBRARY, Osteopathic Research Web as well as the reference lists of the articles included. The survey period of the data ranges from 1999 to 2009.

Selection criteria

The purpose of the search was mainly published randomized controlled studies and studies in waiting list design, as well as clinical studies.

Data collection and data analysis

For the quality assessment of studies, there are already numerous published checklists in circulation. The CONSORT Statement, PRISMA-Statement, as well as the risk of bias tool from the Cochrane back group (FURLAN). The risk of bias tool from the Cochrane back group (FURLAN) was applied for this study.

Results:

In total, 6 studies were included in the evaluation, 4 RCT studies and 2 controlled clinical studies (CCT). One of the RCT study was with 22 (11/11) participants, relatively small and included a questionnaire which was not validated. One RCT study with 24 (12/10) seems to me to be carried out with too few participants, but the questionnaires used were validated. The remaining 4 studies had sufficient participants and validated target parameters.

Conclusion:

The studies included provide promising and suggestive evidence that the osteopathic treatment of female incontinence can achieve a reduction of the symptoms associated with incontinence problems.

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Chapter 1: Introduction

1.1. Background

1.2. Epidemiology and causes of urinary incontinence

Incontinence appears to be a growing problem in our society. The subject of incontinence differs from other health problems in that incontinence deals with a medical complaint that bears a strong taboo, and is rarely spoken about in public.

The quality of life is considerably impaired for those affected. Urinary incontinence is seen worldwide as a common problem and appears in all cultures. Women are notably more often affected than men. (Minassian, Drutz, & Al-Badr, 2003)

1.3. Definition of „Incontinence“ as stated by the ICS

In 2002, the International Continence Society (ICS) issued the following new definition (Abrams et al., 2002):

„Urinary incontinence is an involuntary loss of urine which is objectively demonstrable and a social or hygienic problem.”

This definition as well as the detailed article (Abrams et al. 2002) from The Standardization Committee of the ICS is available on the Internet, at the address, www.icsoffice.org.

The International Continence Society (ICS) differentiates in its description of the various levels of urinary incontinence, in that under certain circumstances, the same medical terms were used.

Therefore, urinary incontinence can be, depending on the level of description, as follows:

- a symptom
- a clinical condition
- an illness (an affliction, a condition)

To further differentiate the various symptoms of incontinence, the ICS has proposed a classification which distinguishes the following forms.

Definition of Urinary Incontinence

1. Stress incontinence (stress urinary incontinence)
2. Overactive bladder syndrome (OAB)

3. Urinary incontinence associated with chronic urinary retention
4. Mixed urinary incontinence
5. Extra urethral urinary incontinence
6. Other (neurogenic) forms

Stress Incontinence (Stress Urinary Incontinence)

Synonym: Stress Incontinence, Sphincter Incompetence

Stress, in this situation, refers purely to the mechanical pressure. A better, but less commonly used term for this form of incontinence is therefore the expression stress incontinence.

In general, any mechanical stress which leads to an increase in pressure in the abdomen can cause a stress urinary incontinence. An involuntary loss of urine arises as a result of physical exertion, for example, when lifting and carrying, but also when sneezing or coughing. Stress incontinence is the predominant form of incontinence in (younger) women. It is due to a functional weakness of the urinary tract (caused by a defective shutter function of the detrusor - detrusor instability. This form of incontinence is often associated with a weakened pelvic floor, for example, as a result of childbirth.

Overactive Bladder Syndrome (Overactive Bladder OAB)

Synonym: Urge and Stress Incontinence, Irritable Bladder

„An overactive bladder is urinary urgency, with or without urge incontinence, which is usually accompanied with increased urinary frequency and nocturia without the presence of an infection or other illness." (ICS definition)

Generally, the overactive bladder syndrome (OAB) represents a complex combination of symptoms:

The main symptom is a sudden, unavoidable urinary urgency that can only be suppressed with great difficulty. This symptomatic form of incontinence is found in the German literature, under the term "irritable bladder". (Reuter et al. 1990)

Consequently, this can lead to pollakiuria (frequency urgency syndrome) or nocturia. The urge to urinate can occur without the loss of urine ("OAB dry"). The urge urination can lead to the passing of water (urination) or even to wetting ("OAB wet").

Information regarding the definition

Since the definition is based only on the symptoms of an overactive bladder, it

is not necessarily identical with a demonstrable urodynamic detrusor activity (it covers also the sensory urge symptomatic under the old nomenclature).

Urodynamically, according to latest deliberations, a distinction is drawn between an “overactive detrusor” and “incontinence due to an overactive detrusor”.

Urinary Incontinence associated with chronic urinary retention

Chronic urinary retention describes a condition that is characterized by a non-painful bladder with large amounts of residual urine. Patients with these problems may be incontinent. The resulting loss of urine which occurs in this case is then referred to as chronic urinary retention and incontinence is replaced with the former term of overflow incontinence.

Chronic urinary retention sets itself apart from the acute retention, which is described as painfully palpable or as percutaneous bladder in a patient who cannot empty the bladder.

Mixed Urinary Incontinence

Mixed urinary incontinence or mixed incontinence, which show both the symptoms of OAB as well as those of the stress and respectively stress incontinence are (according to the ICS definition) defined as incontinence.

Extra Urethral Urinary Incontinence

The symptom of a continuous loss of urine often indicates this form of urinary incontinence.

- Loss of urine, which by-passes the urethra or as the case may be, the urethral sphincter
- Extra urethral incontinence occurs as a result of loss of urine through other channels other than the urethra, either through a congenital dysfunction, an abnormality of the urethra opening or through the development of a fistula.

Other (neurogenic) Forms

Synonym: Unconscious Incontinence, Reflex Incontinence,
Overflow Incontinence, Extra Urethral Incontinence,
Nocturnal Enuresis (Nocturnal Bedwetting)

Unconscious incontinence is not accompanied by urinary urgency. At the point in time when the loss of urine takes place, it is not perceived consciously.

Reflex incontinence occurs when the nerve tracts or nerve centers, which are

responsible for the arbitrary control of the bladder, are defective or fail (for example: Paraplegia, MS Multiple Sclerosis).

The bladder empties itself by reflex, without the individual having the urge to urinate. In most cases however, there remains additional residual urine indicating an incomplete drainage of the bladder.

Overflow incontinence occurs when the pressure in the overfilled bladder is higher than the closing pressure of the sphincter muscle.

The causes of overflow incontinence are weak bladder muscle or an obstacle that hinders the drainage of urine. Sometimes both causes are found simultaneously.

Nocturnal bedwetting (nocturnal enuresis) indicates the involuntary loss of urine during sleep. From the age of approximately 5 years, nocturnal enuresis is considered to be a cause for concern. However, in the course of the child's maturity, these symptoms disappear by themselves.

Particularly common are stress- or stress incontinence and AOB as well as a mixed form of both. (Niederstadt, Gaber, & Füsgen, 2007)

Classification of Urinary Incontinence (according to Ingelman-Sundberg)

Ingelman-Sundberg and Stamey carried out a classification of urinary incontinence which allowed the evaluation of the severity of urinary incontinence based on differing levels of physical stress. (Dannecker, Friese, Stief, & Bauer, 2010)

Grade 1 Loss of urine when coughing, sneezing, laughing, straining or when lifting heavy objects

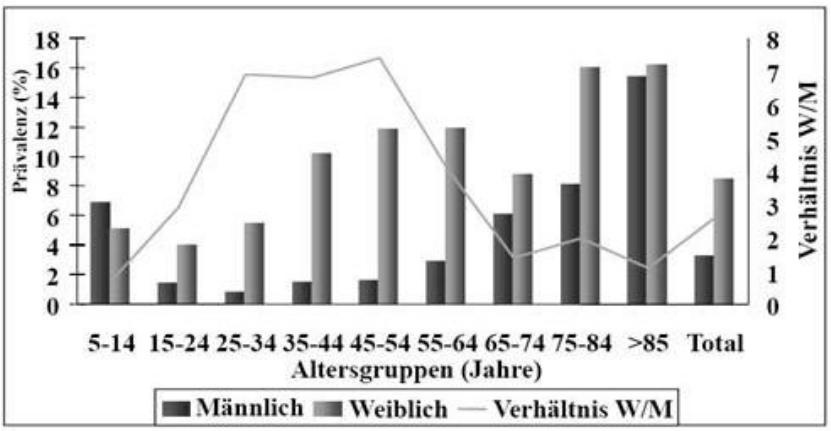
Grade 2 Loss of urine when the body position changes: getting up, sitting down or when walking

Grade 3 Permanent urination, incontinence when lying down

1.4. Prevalence und Incidence of Urinary Incontinence

Findings regarding the prevalence of urinary incontinence were predominantly based on interviews, even though these were carried out using different methods and for different target groups.

Gender Differences in Urinary Incontinence



1. Thomas TM, *Prevalence of urinary incontinence. Br Med J 1980 Nov 8;281(6250):1243-5*

Table 1 Prevalence of urinary incontinence (Männlich = male; Weiblich = female; Verhältnis W/M = ratio female to male; Altersgruppen (Jahre) = age groups (years) (Thomas, Plymat, Blannin, & Meade, 1980)

The prevalence of the disease is approximately 31% -63%. Postmenopausal women are more frequently affected. (Peschers et al. 2003)

The frequency of incontinence as a disease increases with age.

In women aged between 30 – 40 years old, it is 15%.

In women aged between 40 – 50 years old, it is 25%

And in women over the age of 50 years, over 60% are afflicted.

Purely numerically, the figures from the studies relating to prevalence show that the urinary incontinence is already a public health issue of enormous significance.

In the EPINCONT study, the grade of severity for all forms of incontinence increased with age.

There are few studies available regarding the incidence of urinary incontinence, that is to say, the occurrence of "new cases" per year. These studies show highly different findings. (Robert Koch Institute, Issue 39 Urinary Incontinence, 2007)

The American NOBEL Programme (National Overactive Bladder Evaluation Programme) includes an extensive prevalence study for overactive bladder in the United States.

The study covers the period from November 2000 – January 2001.

- 17,231 households were contacted
- 5,204 questionnaires were completed

- 4,160 control checks
- 1,044 cases were evaluated

Conclusions:

More than 33 million overactive bladders (OAB) afflicted persons (16.6% of the population)

63% without urinary incontinence ("OAB dry),

37% with urinary incontinence ("OAB wet")

OAB represents a significant impairment of health related quality of life, even for people without urge incontinence (Stewart et al., 2003).

Due to the high level of morbidity, urinary incontinence also represents a high burden on the healthcare system. In the year 1995, approximately $26.3 billion were required in the USA, for the treatment of urinary incontinence and its complications.

Similarly, in 1993, Sweden spent 2% of the total cost of the public healthcare system, approximately € 11 billion for incontinence treatment.

It is also foreseeable that as a result of the population growth, with its increase of elderly people requiring treatment, that incontinence disorders and related financial burdens will increase.

1.5. Treatment of Urinary Incontinence

The treatment of urinary incontinence depends on the symptoms and the therapy requested by the patients. According to the pathophysiology of the various forms of urinary incontinence, conceptual thinking is apparent. Nevertheless, depending on the psychological distress of the patient, the therapy concept should be tailored to the patient in each individual case. Conservative therapy for stress and urge incontinence is aimed at extending the miction intervals and the associated increase in functional bladder capacity.

As for specific therapies for the treatment of urinary incontinence, there are three main categories to choose from:

1. Modified behavioral techniques including physical therapy
2. Medication therapy
3. Surgical procedures

Modified Behavioral Techniques

As treatment or in therapy trials, modified behavioral techniques and physical

therapies come into consideration for many patients with urinary incontinence.

Toilet training

Under the concept of toilet training, various behavioral interventions are summarized.

In the international and German speaking areas, there is currently no standardized nomenclature for the various forms of toilet training. In the AWMF guideline No. 084/001, the following terminology was used:

Scheduled Toileting (Fixed Emptying times FE, Timed voiding, Scheduled Toileting)

Individual discharge times (IE, Habit Training)

Prompted voiding

Bladder training (BT, Bladder Trill)

Toilet training at night

Physiotherapy – Pelvic Floor Exercises

Pelvic floor training exercises have already been widely used to improve bladder control by strengthening and exercising the muscles responsible for bladder control.

They are also known as sphincter muscle exercises or Kegel Exercises. A physiotherapeutic pelvic floor exercise is most likely an effective treatment for urinary incontinence. It can (like all other behavior modifying methods) be used for stress incontinence, urge incontinence and mixed incontinence.

Vaginal Cones

The training with the help of vaginal weights (Vaginal Cones) is probably similarly effective as pelvic floor exercises. (Herbison, Plevnik, & Mantle, 2000)

Electrical Stimulation of the Pelvic Floor

Electrical stimulation is a method which uses electrical impulses to artificially contract the pelvic floor muscles. Electrical stimulation for urinary incontinence is probably comparably as effective as the pelvic floor training and the use of vaginal cones. (Herbison et al. 2000)

Sacral blockade

The sacral blockade represents another therapeutic option for urge

incontinence. The principle therapeutic effect of this therapy is to inject a local anesthetic in the S2 – S4 region to decrease the parasympathetic bladder innervations.

Alternative Therapy Methods

Last but not least, Complementary Medicine should be specifically mentioned for women with urge incontinence.

Phytotherapy (Herbal medicine), Homeopathy and the Traditional Chinese Medicine (TCM) such as acupuncture (Emmons & Otto, 2005) have in recent years been scientifically investigated and in various studies have shown results through which its beneficial impact and side effects profile can be seen.

Biofeedback

Biofeedback is a method for targeted behavioral training, which can be applied for the treatment of incontinence.

The "evidence" for the effectiveness of biofeedback for urinary incontinence is relatively good. However, the question is, whether the method is more effective than the pelvic floor training without feedback support. (Bo, Talseth, & Holme, 1999)

Following the recommendations of the International Consultation of Incontinence 2005, the prevalence of the pelvic floor training with biofeedback compared to the training without biofeedback is not documented.

Magnet Stimulation Therapy

One conservative form of therapy for urine and faecal incontinence is the magnet stimulation therapy which was developed in the USA in June 1988 and introduced in the Aachener University Clinic in 2001.This is a useful addition to the conservative therapy. It is free from side effects and the patient does not associate it with the insertion of an electrode, used during the conventional vaginal or anal electro stimulation therapy.

The patient sits fully clothed on the therapy chair and is treated with frequencies of 10 Hz and 50 Hz during sessions lasting between 20 – 30 minutes. The patient clearly feels the muscles contracting as a result of these impulses. This therapy takes place twice a week, over a 6 week period.

In particular, women who lose urine when they cough, sneeze, laugh or during sporting activities, yet do not want to undergo an immediate operation, benefit from a magnet stimulation therapy. The majority of these patients do not sufficiently stretch

their pelvic floor muscles or they do so, but incorrectly.

A magnet stimulation treatment may also be worthwhile for patients who suffer from an overactive bladder, sudden urgent need to urinate and frequent urination.

Aids and Appliances

Particularly in cases of patients suffering from a middle to a progressive form of incontinence, an appropriate treatment with incontinence aids and appliances is necessary, to enable them to continue an active social life and of course, prevent damage to the skin.

Aids for Incontinence care are classified as follows:

- Aids/appliances attached to the body

(For example: Absorbent: panty liners and pads, protective underwear, penis sheath as a condom urinal)

- Mobile body aids (Urine bottles, bed sheets/mattress covers, bedpans)

(Physical distance aids)

- Aids to help you fit in your social environment

(Raised toilet seats, assistance grips/handles, toilet stools)

In every case, the aim is to conduct an appropriate consultation with those affected and to test if they are able to cope with the products offered.

Medication Therapy (Pharmacotherapy)

Medication (drugs) is a fundamental part in the overall concept of incontinence therapy. It begins with the omission of drugs (E.g. alpha-blockers, diuretics, calcium antagonists, anticonvulsants, antihistamines, psychotropic drugs). These drugs increase or support an incontinence problem. Food supplements such as cranberry juice are also supported in the medication therapy.

For Stress Incontinence

In the case of stress incontinence, continence is rarely achieved through a drug therapy. Under these circumstances, it would be more a combination of physical therapy measures (pelvic floor exercises and pelvic floor stimulation) and pharmacological therapy

Serotonin, noradrenaline re-absorption inhibitor and alpha 1 adrenergic are used to increase the urethral closure pressure and to reduce the episodes of

incontinence by up to 64%.

Alpha sympathomimetics and estrogens are amongst the substances with a broader application for stress incontinence. The treatment with alpha sympathomimetics should lead to a toning of the smooth muscle in the area of the neck of the bladder. However the limiting factors of this therapy are the side effects, a rate of up to 40%. As such, tachycardia, arrhythmia, the onset of angina pectoris seizures as well as hyperglycaemia are included.

These treatments are contraindicated in patients with arterial hypertension, coronary heart disease, tachycardia arrhythmia, myocardial infarction, hyperthyroidism, renal insufficiency and narrow angle glaucoma (acute angle closure glaucoma).

There is an indication for an estrogen treatment in stress incontinence with all its mixed forms accompanied with signs of an estrogen deficiency. The contraindications are a result of the potential side effects of estrogen replacement therapy: vaginal bleeding, endometrial and cervical cancers, breast cancer and thromboembolism. Application restrictions exist for liver disease, migraine, angina pectoris and congenital disorders of lipid metabolism.

Based on the current studies, it seems justified to hold a trial test treatment with estrogens over a limited period of time, i.e. 4 – 6 weeks, in the case of stress and mixed incontinence, with simultaneously existing atrophic symptoms.

Overactive Bladder Syndrome (OAB)

Urge incontinence, which belongs to the symptom complex of OAB, is effectively treated by pharmacotherapy. Regardless of the underlying etiology and the measurement of the urodynamic characteristics detectable as sensory or motor, in urge incontinence, a reduction of the detrusor contractibility could be achieved through a range of pharmaceutical drugs. These include the anticholinergics, antispasmodics, the myotropic and tricyclic antidepressants. In the clinical, geriatric practice; calcium channel blockers, beta adrenergic agents, prostaglandin synthesis inhibitors and anti diuretic DDAVP (Desmopressin) do not play a role.

The anticholinergic drugs are still considered to be the gold standard. According to the DEGAM guidelines No. 5, a positive recommendation of the prescription is mentioned. The side effects of anticholinergics can be explained by the parasympathetic side effects of the substances affecting other Organ Systems.

These include the eye (mydriasis, increased intraocular pressure), the gastro-intestinal tract (dry mouth, nausea, constipation), the cardiovascular system (tachycardia), the urogential tract (residual urine) and for tertiary amines, the central nervous system (agitation, confusion, delirium).

Additionally, there are contraindications of the anticholinergic medication in those with narrow angle glaucoma, mechanical stenosis of the gastro-intestinal tract, tachycardic arrhythmias, myasthenia gravis and residual urine.

In 2004 and 2005, a number of new pharmaceutical drugs (or as the case may be, well known substances) were admitted in Germany. Currently, various antimuscarinic agents are available for the treatment of Overactive Bladder: Solifenacin, Darifenacin (new anticholinergics), Tolterodin, Trospium Chloride, Oxbutinin and Duloxetine. All substances are, due to the improved tolerance of retarding formulations, available in Germany. A transdermal form of application was developed for Oxybutinin. The effectiveness of Oxybutinin is well documented. Tolterodin is seen as an alternative for those who are intolerant to Oxybutinin.

Other (neurogenic) Forms

Synonym: Unconscious Incontinence, Reflex Incontinence, Overflow Incontinence, Extra Urethral Incontinence (Overflow Incontinence in other forms).The same treatment strategies apply for reflex incontinence and OAB. Drug therapy for overflow incontinence depends on the etiology of residual urine.

The injection of botulinum toxin into the detrusor musculature proves to be a valuable and safe treatment of detrusor hyperraflexia and reflex incontinence in patients with neurogenic bladder dysfunction and also by severe form of OAB. Ninety-five percent became continent, and could significantly reduce or discontinue oral anticholinergics.

To achieve an effective therapy with a paralysis of the bladder for at least a period of 9 months, a dose of 300 units of Botox® has been tried and tested. The improvement of the urodynamic parameters were in compliance with the clinical continence and with the subjective satisfaction of the patient.

Certain medications (drugs) can have an adverse impact on the continence (anti psychotic drugs, diuretics, antihypertensives).Recent studies showed that a hormone treatment with conjugated estrogens, alone or in combination with progesterone is not a useful treatment for urinary incontinence in post-menopausal

women. It seems rather to increase the risk of Incontinence and to aggravate the symptoms. (Brown et al., 1996; Hendrix et al., 2005)

The frequency of drug usage has shown a marked increase in recent years.

The Drug Report 2005 warns that the spasmolytic anticholinergic drugs only offer a limited therapeutic effect. The report comes to the conclusion that non pharmacological methods should be the first choice therapy for incontinence. A combination of behavioral therapy and medication seems to be more successful than the sole implementation of a single therapeutic measure in the treatment of overactive bladder (urge incontinence).

Table 2 German Drug Report 2005

Active Agent	MDD (in Millions)	Cost per MDD (in €)	Cost (in Million €)
Oxybutynine	8.4	1.00	8.4
Tolterodine	22.0	1.87	41.1
Trospiumcloride	28.7	1.23	35.3
Propiverine	10.3	1.59	16.4
Solifenacine	2.0	1.61	3.2
Duloxetine	.6	2.52	1.5
Total	**72.1**	**1.47**	**106.0**

(Schwabe U, Paffrath D (2006) Arzneiverordnungsreport 2005. Springer, Heidelberg): Prescriptions of urological spasmolytics within the German Social Security System in 2004; MDD = mean daily doses

Surgical Treatment Procedures (Invasive Therapy)

The surgical techniques used in Germany for the treatment of incontinence are the Burch colposuspension and abdominal surgery according to Marshall-Marchetti-Krantz.(Niederstadt, Gaber, & Füsgen, 2007) The Burch colposuspension seems, according to most studies, to deliver the best long term results. With these two operational techniques, the bladder floor and urethra can be lifted via access through the abdominal wall. (Houfflin-Debarge, Cosson, Querleu, & Crepin, 1999)

Furthermore, in Germany, the Stamey operation is also used. In this case, the urethra and bladder floor will be lifted. This is achieved by an endoscopic access through the abdominal and vaginal wall.

Likewise, the commonly used anterior colporrhaphy, also known as vaginal ruffles, brings the bladder and urethra back into the normal anatomical position by realigning the supporting tissues which have divided and moved.

Slings for sling operations are made out of plastic or autologous materials, are placed around the urethra from behind, to support and lift it. Access is achieved jointly through the abdominal and vaginal wall. The new surgical techniques using tension bands (tension free vaginal tape TVT) are very promising. TVT procedure was first described by Ulmsten 1996. It has become one of the first most popular procedures worldwide for the treatment of female stress urinary incontinence.

Meanwhile, the initial data are available that document the results from such operations after 5 years, demonstrating they are comparable with traditional surgical techniques.

Trans Obturator Tape (TOT) by Delorme 2001 advocated the transobturator route. TOT was associated with a high success rate, no bladder injury and few preoperative complications in women with SUI.

Conclusion TVT versus TOT:

The TOT procedure seems to be safer (fewer complications) and more cost effective (shorter OP time, no need for intraoperative cystoscopy) than the original TVT procedure. Meanwhile, the initial data is available that documents that the results from such operations after 5 years, are comparable with traditional surgical techniques.

Long-term results after TVT-deposit (91.1 months mean follow-up time)

81.3% cure

16.3% significant improvement

1.3% treatment success

(C.G. Nilson et al. IUGA 2003)

1.6. Objective

Against this background, it seems sensible to investigate the relevance of non-invasive non-drug strategies in the treatment of female incontinence, in particular the potential of an osteopathic approach to the problem by means of a systematic review of the literature and by a qualitative (and, if possible, quantitative) pooling and evaluation of the results of suitable clinical trials.

Chapter 2: Methods

A systematic review is a scientific article, in which certain studies are identified, their quality is assessed and their results are summarized according to scientific methods. Currently, there are few medical journals in which no systematic reviews (review articles) are found. Review articles summarize scientific knowledge on a particular topic from a collection of individual studies. The systematic review gives the reader a quick overview of the topics of interest. They can keep up-to-date without having to work through all of the practical relevant individual studies.

Carefully prepared systematic reviews of medical literature are complete research studies on their own. They identify certain studies to assess their quality, and summarize their results using scientific methods. Systematic reviews differ from traditional review articles (narrative reviews) mainly through focused questioning, prospective planning and a degree of transparency in the literature search, selection and assessment. Subjectivity is largely eliminated and there is more accurate determination of the effect of the treatment.

2.1. Criteria for Considering Studies for this Review

2.1.1. Types of studies

Only randomized clinical studies (RCT) or controlled clinical studies (CCT) or clinical studies (CT) were included. Only studies in German or English language were included. Only studies after 1999 were included.

2.1.2. Types of participants

Inclusion criteria of the participants were

- Female and at least 18 years old
- A diagnosed female incontinence

Exclusion criteria were

- Neurologic disorders
- Tumors
- Pregnancy

2.1.3. Types of intervention

Only those studies were taken into consideration whose effect size could be

assigned to an osteopathic treatment. If used, co-interventions also had to be carried out in the control group as a measure.

2.1.4. Types of outcome measure

Until today no consistent measurement exists for urinary incontinence. So the review has no restriction in outcome measurements and includes different measurements like daily miction diary (MTB), residual urine (ultrasound), residual urine (PAD Test) and different questionnaires.

2.2. Search methods for Identification of studies

2.2.1. Electronic searches

A systematic literature search on urinary incontinence and osteopathic treatment was done from June 2009 to July 2010 in the following electronic databases:

MEDLINE
EMBASE
COCHRANE LIBRARY
(Cochrane Incontinence Group of clinical Trials)
SCIENCEDIRECT
DIMDI
(German Institute for Medical Documentation and Information)
OSTMED DR
OSTEOPATHIC RESEARCH WEB
PEDro
(Physiotherapy Evidence Database)
Springer, Thieme and Elsevier Verlagsdatenbank
Medscape

2.2.2. Searching other resources

This search was supplemented by an internet search with Google and in the register of studies by the Academy for Osteopathy (AFO). A manual search in the reference lists of all relevant papers which are not listed in the electronic database was carried out. Likewise, using internet resources, a search of osteopathic studies and degree dissertations was carried out in various osteopathic schools in Germany,

Belgium, France, Switzerland, Austria, England and America, i.e., Sutherland College, The German Osteopathic College (DOK), The International Academy of Osteopathy (IAO), Kirksville College of Osteopathic Medicine (KCOM), Ecole Suisse d'Ostéopathie (Swiss School of Osteopathy), The British School of Osteopathy (BSO).

Internet services of the Association of Scientific Medical Societies in Germany (http://www.uni-duesseldorf.de/WWW/AWMF/awmfmap and http://www.awmf-leitlinien.de/), The Medical Center Quality Assurance (http://www.leitlinien.de/), the German Society for General Medicine (http://www.degam.de/), the German Society for Urology (http://dgu.springer.de/index.html), the Society for Incontinence Aid (http://www.gih.de/.htm), the German Society for Gynaecology and Obstetrics (via the AWMF Membership website: http://www.uni-duesseldorf.de/WWW/AWMF/ membfram.htm), the Agency for Healthcare Research and Quality (http://www.ahrq.gov/). The American National Guideline Clearing House (http://www.guidelines.gov) has also been included. The complete search strategy is listed in Appendix A.

2.3. Data collection and data analysis

The reviewer conducted citation identification, study selection and data extraction and analysis. For the data extraction and the comparison process a PICO form was used. According to the German Cochrane Center, the PICO scheme is defined as an alternative scheme for formulating a clinical question on the impact of interventions: patient, intervention, comparative intervention (comparison) and target parameters (outcome).

In addition to that a separate data form was created which includes all the primary and secondary outcome data (see Appendix B).

With Review Manager 5 (Cochrane collaboration) standardized mean differences with 95% confidence intervals (SMD; 95% CI) for continuous data were calculated for 4 studies.

2.4. Assessment of risk of bias tool in included studies

A systematic review has to take into consideration the four major systematic errors that could have an influence on the internal validity. Internal validity means the

extent to which the results of the study are free from bias.

- Selection bias
- Performance bias
- Detection bias
- Attrition bias

Bias is defined as an error where the „true„ effect of an intervention or exposure is either over or under estimated. According to the principles of the Cochrane Institute, the systematic assessment of literature includes:

1. Are the results valid? (Internal validity)
2. Overview: Catchwords for quality assessment of various studies
3. What are the results?
4. Are the results important and applicable (external validity)

Checklists for the methodology of studies guarantees transparency, in order to show how study design can possibly transform criteria so that the results will be attributed to whatever has been examined (internal validity). There are no strict guidelines for the use of risk of bias assessment in systematic reviews. The internal validity of the studies has been examined with the „Method Guidelines for Systematic Reviews“ of the Cochrane Back Review Group (CBRG), (Furlan, Pennick, Bombardier, & van Tulder, 2009). Eleven of twelve criteria were used in 65% and ten of twelve criteria were used in 18% of the CBRG reviews. The internal validity criteria are related to selection bias (criteria 1, 2, 9), performance bias (criteria 3, 4, 10, 11), attrition bias (criteria 6, 7), and detection bias (criteria 5, 12).

A description of the evaluation with the „risk of bias tool“ by the Cochrane Collaboration as well as the criteria of the Cochrane Back Review Group are listed in Appendix C.

Chapter 3: Results

3.1. Identification of the results

After completion of the intensive search, a total of 13 potentially relevant clinical trials could be identified. Seven of the studies were excluded (Lerma, 2008; Sussman, 2007; Lonsway, 2000; Fingerman, 2000; Kowalczyk, 2000; Wiggins, 2000; Hughes, 1999). Four of these studies constitute treatment reports and two studies, surveys and one study included a literature review.

A total of six studies could be included into this systematic review. Four of them were RCT's (Ringkamp, Rodriquez 2009; Gerhardt, Montag, 2005, Gabriel 2006, Brix 2007), and two were controlled intervention studies in the waiting list design (Eckmann, Karen, Mertens 2005; Osenstätter, Ernst 2002).

3.1.1. Excluded studies

The study of Lerma (2008) contained an osteopathic treatment report on recurring urinary tract infections. Osteopathic findings showed somatic dysfunctions in the thoracic region, lumber and pelvic area. The treatment plan included medical treatment, the intake of Ciprofloxacin 500 mg x 14 days (antibiotics), and behavioral training such as sex education lessons regarding sexually transmitted diseases, prevention and increased fluid intake.

One osteopathic manipulative treatment (OMT) was carried out, with two additional treatments after an interval of 1 week. The patient experienced a significant relief of her symptoms within 48 hours after the first OMT. The urine culture showed initial high levels of Escherichia coli bacteria. However, after administration of antibiotics and OMT treatment, the urine culture was free from bacteria.

The study of Sussman (2007) showed a treatment report regarding the basic medical care for an overactive bladder (OAB). Treatment options for the therapy of overactive bladder include both non pharmacological and pharmacological therapies. Characteristics of antimuscarinic drugs, including three new drug therapies, have been reviewed and should help optimize the therapy options, particularly for older patients.

(See Appendix E)

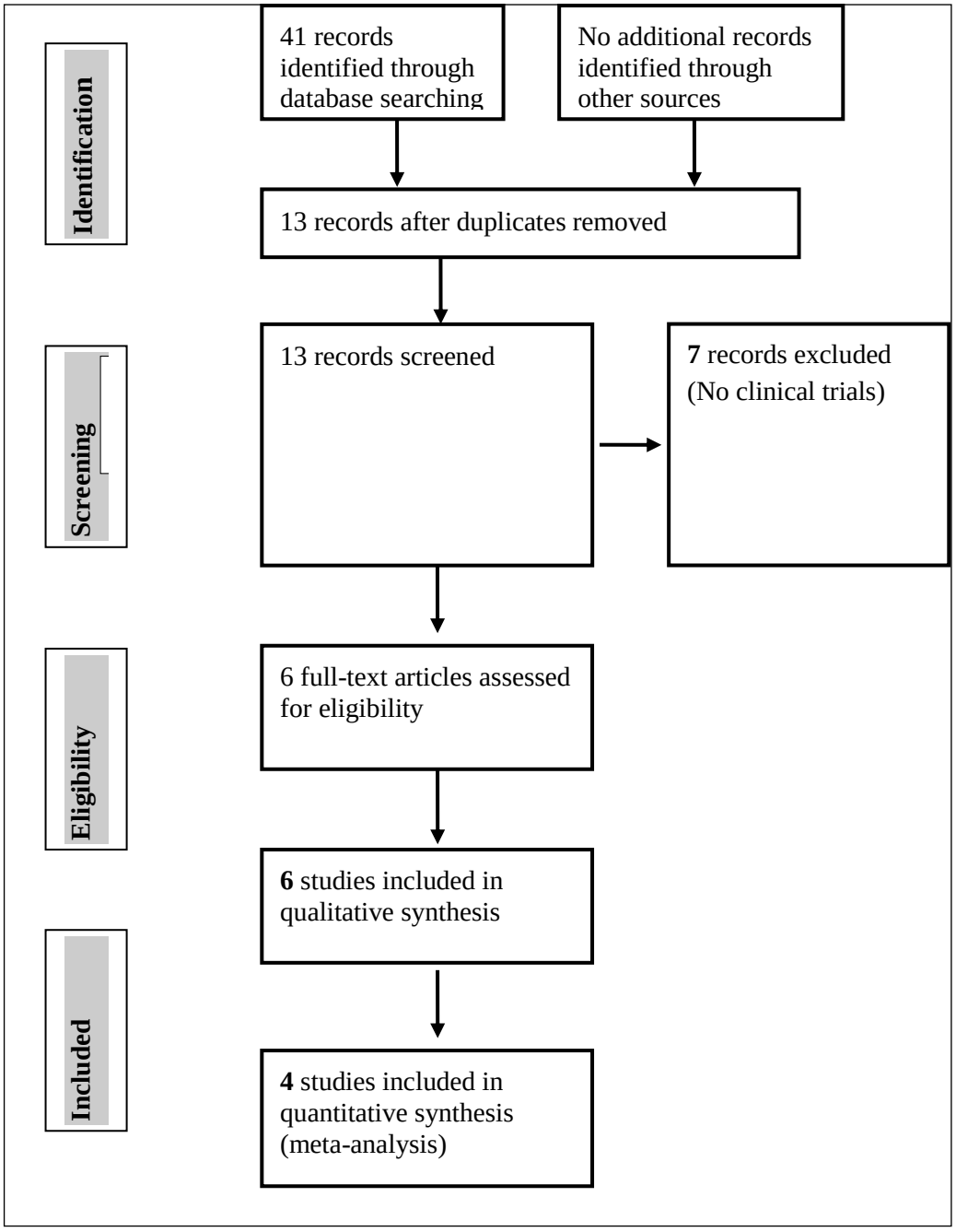


Figure 1: Flowchart study selection "osteopathic treatment by female incontinence"

The flow of information is based on the recommended diagram of the PRISMA statement (Moher, Liberati, Tetzlaff, Altman, & The Prisma Group, 2009)

The study of Fingerman (2000) showed a treatment report of a 36 year old woman with multiple sclerosis who suffered urinary incontinence due to an overactive bladder (OAB). Treatment with anticholinergic drugs was carried out. No therapy approaches with conservative treatment methods, for example OMT, were shown.

The study of Lonsway (2000) showed surgical and medical treatment options for urge incontinence. The author presented the research findings of literature regarding the basic medical care in treating urge incontinence. The listed treatment options are medical therapy, biofeedback, electro-stimulation as well as surgical intervention.

The study of Kowalczyk (2000) showed a clinical evaluation with patients who suffered from an overactive bladder (OAB). In the first phase of the treatment, the author described oral drug therapy for OAB.

The study of Wiggins (2000) dealt via a survey with osteopathic considerations in the treatment of adult patients with urinary incontinence. The purpose of this study was to survey 200 osteopaths. These osteopaths were randomly interviewed using a four part questionnaire relating to general information, treatment approach, specialist knowledge, level of confidence pertaining to the treatment with the topic of urinary incontinence.

The study of Hughes (1999) dealt with the identification of the most important issues in osteopathic approach to the treatment of urinary incontinence. Nine qualified osteopaths were interviewed. These osteopaths subjectively believed that they had experience in the treatment of patients with the symptoms of urinary incontinence.

Table: 3 Overview of included clinical trials with urinary incontinence Part 1

Author / Year Country	**Ringkamp 2009 Germany**	**Gerhardt 2005 Germany**	**Gabriel 2006 Austria**
Study design	RCT	RCT	RCT
Aim of the Study	The influences of osteopathic treatment on females with voiding dysfunction	To evaluate whether osteopathic treatment in addition to standard therapy of "pelvic floor muscle training" can significantly improve the overall quality of life of women suffering from UI* as a result of an injury to the perineum during delivery.	Treatment of UI* (stress incontinence) at a descencus of vagina and bladder.
Reported inclusion /Exclusion criteria /Dropouts	+ / + Dropouts reported	+ / + Dropouts reported	+ / + Unsure
No. of treatments / Period	5 / 10 weeks	4 / 12 weeks	3 / 4-6 weeks
Measurement	Questionnaire AUSAI SF 36 Residual urine	Questionnaire "Kings Health Questionnaire" (KHQ)	Questionnaire "Quality of Life" (QLF) University of Freiburg
Number of patients/ Age /	47 / Ø 48	60 / Ø 37,5	24 / (data not coherent) Ø ?
Number of pts Intervention / Control	a. 24 b. 23	a. 30 b. 30	a. 12 b. 10
Randomized / Blind (Patients) /	+ / No	+ / No	+ ** No
Intervention Control	a. OMT b. No treatment	a. OMT + PFMT*** b. PFMT***	a. OMT b. Placebo
Reported Results	"Five osteopathic treatments over a period of 10 weeks led to clinically relevant positive changes of urological symptom severity level of women suffering from voiding dysfunction".	OMT "had a clinical relevant influence on the symptom-specific quality of life of women with UI following an injury of the perineum".	"A significant improvement of stress incontinence of urine could be achieved by osteopathic techniques".

*** UI = Urinary incontinence**

**** Randomization procedure not explained**

***** PFMT = Pelvic floor muscle training**

Table 3: Overview of included clinical trials with urinary incontinence Part 2

Author / Year Country	**Ernst 2002 Germany**	**Alberts 2005 Germany**	**Brix 2007 Austria**
Study design	CCT	CCT	RCT
Aim of the Study	The influences of osteopathic treatment on females with urge incontinence and the combination of urge and stress incontinence.	The influence of osteopathic treatment to the severity code of symptoms of voiding dysfunction in women.	To determine if a pelvic floor training program, supported by biofeedback and supplemental OMT could lessen the symptoms of stress incontinence.
Reported inclusion / Exclusion criteria / Dropouts	+ / + Dropouts reported	+ / + No dropouts	+ / + No dropouts
No. of treatments / Period	3 / 4-6 weeks	3 / 6 weeks	3 / 6 weeks
Measurement	Questionnaire "Journal of the American Geriatric Society" (JAGS)	Questionnaire "Kings Health Questionnaire" (KHQ)	Private Questionnaire (not validated)
Number of patients/ **Age /**	29 / Waiting list design Ø 53	45 / Waiting list design Ø 46	22 /
Number of patients Intervention / Control	a. 25 b. 25	a. 45 b. 45	a. 11 b. 11
Randomized / Blind (Patients) /	-/ No	-/ No	+ ** No
Intervention Control	a. OMT b. No treatment	a. OMT b. No treatment	a. OMT + Biofeedback + PFMT*** B. Biofeedback + PFMT***
Reported Results	"...high significant improvement by osteopathic treatment for stress and urge incontinence"	"...a high significant improvement of the severity code of the urological symptoms by only 3 osteopathic treatments..."	"...no significant improvement in symptoms brought about by the osteopathic treatments..."

*** UI = Urinary incontinence**

**** Randomization procedure not explained**

***** PFMT = Pelvic floor muscle training**

3.1.2. Included studies

The study carried out by Ringkamp and Rodriquez (2009) treated 47 patients aged between 19 – 82 years diagnosed with a urological bladder emptying dysfunction (BES). An external randomized trial was carried out with an intervention group of 24 patients and a control group of 23 patients.

The intervention group was examined with ultrasound to measure rest urine and received 3 osteopathic treatments. In addition, they were required to fill out a questionnaire from the American Urological Association Symptom Index and the short form health survey with 36 questions (AUASI and SF-36) and were asked to keep a cystitis diary.

It was noted that a dropout occurred in the intervention group and also in the control group. The "intention to treat analysis" was performed. This study lasted a total period of 32 weeks.

The study of Gerhardt and Montag (2005) treated 60 patients aged between 18 – 45 years with stress or urge incontinence (OAB) after vaginal delivery with episiotomy or perineal laceration. The randomized trial was carried out externally in an intervention group and control group, each with 30 patients.

The intervention group received 4 osteopathic treatments combined with pelvic floor exercises (PFMT), and conducted a miction diary (MTB) in addition to completing a questionnaire (KHQ, 1993). It was noted that 2 dropouts occurred in the intervention group. An „intention to treat analysis" was performed. The study period lasted 12 weeks.

The study of Gabriel (2006) treated 24 patients with stress incontinence. Randomization was carried out in an intervention group with 12 patients and a control group of 10 patients.

Within a period of 15 minutes, both groups had to carry out the following activities:

- drink 500 ml of water
- complete a questionnaire QLF
- perform a PAD Test 30 minutes later
- walk for 2 minutes
- climb and go down stairs for 2 minutes
- stand up from a sitting position (x) 15 times

- cough strongly x 15
- run on the spot for 1 minute
- jump up and down for 30 seconds
- pick up something from the floor x 10
- perform movements that possibly cause loss of urine x 20
- wash hands with warm running water
- complete a questionnaire again (QLF University of Freiburg with 26 questions)

The intervention group received 3 osteopathic treatments over a period of 4 – 6 weeks combined with a questionnaire and PAD test. The control group received 3 placebo treatments and completed a questionnaire QLF and conducted a PAD test. In the control group, 2 dropouts were reported. There was no "intention to treat analysis". The study period lasted approximately 4-6 weeks.

The study of Brix (2007) treated 22 patients with stress incontinence grade I-II (out of 3 grades), all patients were postmenopausal and had experienced at least one pregnancy/birth. There was no age restriction and the group selection was by randomization. The intervention group with 11 patients received 3 osteopathic treatments every two weeks, as well as 6 biofeedback treatments once a week. The 7th biofeedback treatment was administered after a 4 week break. Finally a questionnaire, that was not validated, was completed. The control group with 11 patients also received 6 Biofeedback treatments once a week. The 7th biofeedback treatment was given after a 4 week break. Ultimately the same questionnaire, which was used in the intervention group, was completed. The study period lasted approximately 11 weeks.

The study of Osenstätter and Ernst (2002) treated 29 patients with stress or urge incontinence between the ages of 18 – 70 years. It was an intervention study with untreated observation periods (waiting list design). The patients received 3 osteopathic treatments every 1 – 2 weeks, then 4 weeks of rest. After the break, they completed the questionnaire from the Journal of the American Geriatrics Society (JAGS, SF 36 specially modified for incontinence).

After admission in the study, there were 4 dropouts. Therefore, the study was continued with 25 patients. There was no “intention to treat analysis” carried out. The study period lasted 12 weeks.

The study of Alberts, Eckmann and Mertens (2005) treated 45 patients with an average age of 45.9 years who were suffering from bladder emptying syndrome

(BES). It was an intervention study with an untreated observation phase (waiting list design). After admission in the study, there was a six week waiting period, or control period, after which 3 treatments in approximately 14 day intervals were carried out.

The symptoms were recorded by means of the questionnaire from the American Urological Association Symptom Index (AUASI). After 14 days, the participation of the patients in this study ended. They used the validated German translation patronized by the World Health Organization (WHO, 1994). There were no dropouts reported. The study period lasted 12 weeks.

3.2. Evaluation of the included studies

The assessment of the methodological quality of clinical trials is complex and often complicated by the variety of possible factors. These range from the design of the study followed by the implementation and data analysis through the interpretation of the results.

3.2.1. Description of the summary of Outcomes (primary and secondary outcomes measures)

Descriptive results of the target parameters:

In the study of Ringkamp and Rodriquez (2009) based on the primary outcome of the AUASI (American Urological Association Symptom Index Score), a progressive, positive development was found in an increasing number of osteopathic treatments. These results were evident after the first follow-up which took place 22 weeks later.

The secondary target parameter, the 8 scale profile of the pain questionnaire (SF-36), showed a significant improvement at the end of 22 weeks, in the area of "vitality" and "pain".

In the evaluation of the residual urine, which was also a secondary target parameter, the authors described a weakness in the setting of the study designs. There should have been a second measurement of residual urine in the control group. Therefore the control group was only measured at the beginning of the study. Therefore, in all areas of primary and secondary target parameters, significant results were achieved. Consequently, this substantiates the hypothesis that the osteopathic intervention can bring some relief in the severity of the symptoms and improve the quality of life.

There were two drop outs reported in the control group; one patient did not fulfill the inclusion criteria (minimum age 18 years) and the other patient became seriously ill after the sixth week.

In the study of Gerhardt and Montag (2007) for the primary target parameter (King Health Questionnaire 1993 (KHQ)), the total score could only be calculated from 40 out of 60 patients. In the intervention group, there was a significant improvement in the symptoms related to the quality of life. In the control group, only a small improvement could be achieved. The direct comparison between both groups did not reveal any statistical significance.

Through the randomization, a homogenous distribution between the two groups was achieved. The assessment of 9 individual items revealed a significant difference only in the area of "restrictions in the daily activities" In the secondary target parameter, "number of daily toilet habits", no improvement was recorded in the intervention nor in the control group.

The KHQ is comprised of 9 items. The item "personal relationships" was only completed by 40 patients. Incomplete data were interpreted as "missing values." A significant difference was determined for the single item "restriction of daily activities" ($p = 0.007$).

With osteopathic dysfunction, there are often dysfunctions in the area of the pelvis, lumbar region, head joint and cervicothorakaler area and connecting systems. In the visceral system, there were disorders in the urogential tract. In the cranial-sacral system, there were often disorders of the temporal bones, the zygomaticum bone and the temporomandibular joint (TMJ).

There were 2 drop outs reported in the intervention group: a patient became pregnant during the study; a further patient did not make contact despite repeated requests. This study showed an increase in the effectiveness of osteopathic treatment in conjunction with pelvic floor exercises.

In the study of Gabriel (2006), the questionnaire „Quality of life"(Qol) from the University of Freiburg was selected as a target parameter. The questionnaire consisted of two parts. The first part contained questions about subjective assessment of bladder function and the second part was focused on questions relating to daily life. The next target parameter was the measurement of the residual urine using the PAD test. In this study, there were no specifically assigned primary or secondary target parameters.

In the intervention group, 11 out of 12 people achieved an improvement in the amount of residual urine using the PAD test. In the control group with 10 people, there was almost no change in the amount of residual urine (PAD test).

With the target parameter questionnaire “Qol” Part 1, the interventions group achieved a subjective improvement compared with the control group. In Part 2, a significant improvement in the intervention group was achieved in the areas of daily routine such as going shopping and doing the housework. In Part 2, no clear improvement could be achieved by the control group.

In the study of Brix (2007), it was difficult to locate a target parameter. A questionnaire was used, only once at the end of the treatment. It was completed by the intervention group and the control group. However, this questionnaire was not validated.

There were only 2 questions, “How much have their symptoms improved?” and “How often during the 4 week break have they trained on their own and conducted the pelvic floor exercises?” In the evaluation of the first written question, no significant improvement could be achieved in the intervention group nor the control group ($p = 0.258$).To increase the focus of the test, a new category (at least an improvement) was established which also demonstrated a lack of significance ($p = 0.2966$).

In the evaluation of the second question (“How often have they been training their pelvic floor muscles on their own during the 4 week break?”), likewise, no significant change was found ($p = 1$). Furthermore, the result of the test in the category (“at least somewhat trained”) was increased. Again there was no significant Change ($p = 0.6109$).The hypothesis of this study could not be clearly identified.

The study of Alberts, Eckmann, and Mertens (2005) applied as primary target parameter, the questionnaire AUASI (American Urological Association Symptom Index Score) in order to document the improvement of the severity of the symptoms. As a secondary target parameter, the osteopathic dysfunction was determined by means of the osteopathic findings sheet.

This deals with a controlled clinical study with waiting list design. In the so called waiting time (W0 to W6), no significant changes were found by the evaluation of the AUASI. In the period of intervention (W6 to W12), marked significant changes were found ($p = 0.000$).

The secondary target parameters, "osteopathic findings sheet", showed a range

of noticeable, frequent disorders. These were referred to as dysfunction of the thoracic diaphragm, visceral facial region and stresses of the pelvic floor.

Subsequently, it was also clear that the aim of the study to achieve an improvement in the severity of the symptoms associated with bladder emptying dysfunction with osteopathic treatment was accomplished.

In the study of Ernst and Osenstätter (2002), the questionnaire JAGS (Journal of the American Geriatric Society) with Part 1 and 2 as primary target parameter was used. As a secondary target parameter, the reduction of the osteopathic findings was included. The questions were answered using a scale similar to the Likert Scale of 1 – 6 to measure reactions.

Between the times P1 (admission – waiting time) and P2 (the start of the treatment period), no significant change could be detected in any of the criteria of the questionnaire. Between the period P2 (start of the treatment period) and P3 (follow up phase), a highly significant improvement was determined ($p = 0.001$), except under the criteria "sexual activity" of the questionnaire. The characteristics in Part 1 of the questionnaire were related to general activities, travel, physical activities, feelings, relationships and sexual activity.

The evaluation of the Part 2 questionnaire showed no significant differences in results in P1 as well as P2. However, in contrast, in phase P2 and P3, there was a highly significant difference detected ($p = 0.001$).

Under the criteria "stress", three questions were answered and under the criteria "urge", 8 questions. The total score of the questionnaire Part 2 amounted to $p = 0.00008$.

The following abnormalities were found in the evaluation of the secondary target parameter. The dysfunction of the parietal system in the area of the sacrum, dysfunction in the area TH 10, L1, L2-L4, cervicothorakaler area, as well as in the visceral-ligamentous system.

Four drop-outs were reported. The patients completed their participation in the study after the first appointment (initial examination, filling out questionnaire). Therefore 25 participants were evaluated.

The hypothesis was confirmed that osteopathic treatment for urge incontinence and the combination of stress and urge incontinence achieved improvement.

3.2.2. Quality score (Checklist according to Cochrane Back Group Risk of Bias Tool)

Assessment of Risk of Bias in Included Studies

Checklists for the methodology of studies guarantee the transparency, in order to show how study design can possibly transform criteria so that the results will be attributed to whatever has been examined (internal validity). There are no strict guidelines for the use of risk of bias assessment in systematic reviews.

The internal validity of the studies about nonspecific back pain in this review has been examined with two different tools. One is the examination according to the criteria, recommended by the „Method Guidelines for Systematic Reviews“of the Cochrane Back Review Group (CBRG), (Furlan, Pennick, Bombardier, & van Tulder, 2009). This 12-point system is a compilation of former guidelines of the CBRG (van Tulder, Furlan, Bombardier, & Bouter, 2003), the evaluation checklist of nonpharmacological trials (CLEAR NPT) (Boutron et al., 2005) as well as comments from the „Cochrane Handbook of Reviews and Interventions“(Higgins & Green, 2008). Eleven of twelve criteria were used in 65% and ten of twelve criteria were used in 18% of the CBRG reviews. The internal validity criteria are related to selection bias (criteria 1, 2, 9), performance bias (criteria 3, 4, 10, 11), attrition bias (criteria 6, 7), and detection bias (criteria 5, 12).

Generally speaking, overview studies, which assign points for the fulfillment of single „quality criteria“ and conclude with a summarized scale, should be used with some caution (Kunz, Khan, Kleijnen, & Antes, 2009; McCarthy et al., 2008). This is why it is suggested to additionally use the Cochrane Collaboration’s „risk of bias tool” for the methodical evaluation of the studies.

The „risk of bias tool“ is suggested by the Cochrane Collaboration, which is eager to compose, update and circulate systematic overview studies in the medical field (Higgins & Green, 2008). It provides a clear illustration of essential markers on the methodology of the implemented study. The „risk of bias tool“ is therefore explicitly not to be mistaken for some kind of score list. The column „description“ promotes the transparency of the methodological evaluation as does the CBRG checklist, which lists the study according to their points.

A description of the evaluation with the „risk of bias tool“ by the Cochrane Collaboration as well as the criteria of the Cochrane Back Review Group are listed in

Appendix C.

Table 4 Risk of bias of the included studies

	Randomization?	Allocation concealed?	Patient blinding	Care provider blinding?	Outcome assessor blinding?	Drop-outs acceptable?	Analyzed in allo-cated group ?	Free of selective outcome report.?	Similar baseline?	Co-intervention avoided?	Compliance acceptable?	Similar timing?
Study	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Ringkamp 2009	Yes	No	No	No	No	Yes	Yes	Yes	?	Yes	Yes	No
Gerhardt 2005	Yes	No	No	No	No	Yes	Yes	Yes	?	Yes	Yes	Yes
Gabriel 2006	?	No	No	No	No	Yes*	Yes	Yes	?	Yes	Yes	Yes
Ernst 2002	No	No	No	No	No	Yes	Yes	Yes	?	Yes	Yes	No
Alberts 2005	No	No	No	No	No	Yes	Yes	Yes	?	Yes	Yes	Yes
Brix 2007	?	No	No	No	No	Yes	Yes	Yes	?	Yes	Yes	Yes

Sources of Risk of Bias

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

*drop-out rate under 20% but drop-outs not described
(According to (Furlan, Pennick, Bombardier, & van Tulder, 2009)

3.2.3. Results of the Meta-Analysis

Four studies used some sort of an incontinence questionnaire as an outcome. Three studies report a statistically significant superiority of the osteopathic treatment over the respective control intervention, one study (Gerhard 2007) fails to reach the level of significance. The diamond in table five (as well as the total SMD and its 95% confidence interval) shows that pooling of the data of all four studies clearly and statistically significantly favors the osteopathic treatment over the control interventions.

Since marked heterogeneity was observed between the four studies, probably not least resulting from conceptual and structural differences between the different assessment instruments used, a variety of sensitivity analyses were undertaken, the results of which are depicted in tables 6 to 9. While heterogeneity differs markedly depending on the inclusion or exclusion of studies using particular questionnaires, there still remains a clear tendency into the same direction, reaching the level of significance in two of the four sensitivity analyses (tables 6 and 7).

Table 5
Forest Plot: Osteopathic Treatment of Female Incontinence
Outcome: Incontinence Questionnaires AUASI, KHQ /PAD-Test

	Treatment			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Alberts 2005	-9.98	0.82	45	0.31	0.22	45	22.8%	-16.99 [-19.57, -14.42]
Gabriel 2006	-67.04	30.35	12	0.3	9.72	10	25.3%	-2.76 [-4.00, -1.53]
Gerhardt 2007	-14	11.8	30	-7.6	11.5	30	26.0%	-0.54 [-1.06, -0.03]
Ringkamp 2009	-8.8	4.4	24	-0.1	2.9	22	25.9%	-2.27 [-3.03, -1.52]
Total (95% CI)			**111**			**107**	**100.0%**	**-5.30 [-8.72, -1.89]**

Heterogeneity: Tau² = 11.60; Chi² = 160.18, df = 3 (P < 0.00001); I² = 98%
Test for overall effect: Z = 3.04 (P = 0.002)

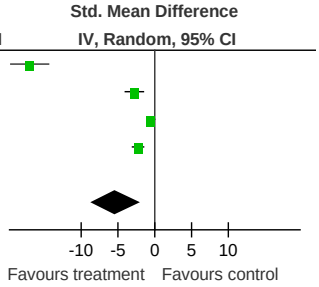


Table 6
Forest Plot: Osteopathic Treatment of Female Incontinence
Outcome: Incontinence Questionnaires AUASI, KHQ

	Treatment			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Alberts 2005	-9.98	0.82	45	0.31	0.22	45	31.2%	-16.99 [-19.57, -14.42]
Gabriel 2006	-67.04	30.35	12	0.3	9.72	10	0.0%	-2.76 [-4.00, -1.53]
Gerhardt 2007	-14	11.8	30	-7.6	11.5	30	34.5%	-0.54 [-1.06, -0.03]
Ringkamp 2009	-8.8	4.4	24	-0.1	2.9	22	34.3%	-2.27 [-3.03, -1.52]
Total (95% CI)			**99**			**97**	**100.0%**	**-6.26 [-10.79, -1.74]**

Heterogeneity: Tau² = 15.37; Chi² = 156.65, df = 2 (P < 0.00001); I² = 99%
Test for overall effect: Z = 2.71 (P = 0.007)

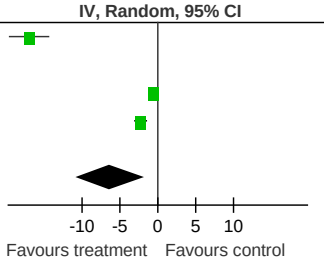


Table 7
Forest Plot: Osteopathic Treatment of Female Incontinence
Outcome: Incontinence Questionnaires AUASI, /PAD-Test

	Treatment			Control				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Alberts 2005	-9.98	0.82	45	0.31	0.22	45	0.0%	-16.99 [-19.57, -14.42]	
Gabriel 2006	-67.04	30.35	12	0.3	9.72	10	27.3%	-2.76 [-4.00, -1.53]	
Gerhardt 2007	-14	11.8	30	-7.6	11.5	30	0.0%	-0.54 [-1.06, -0.03]	
Ringkamp 2009	-8.8	4.4	24	-0.1	2.9	22	72.7%	-2.27 [-3.03, -1.52]	
Total (95% CI)			**36**			**32**	**100.0%**	**-2.41 [-3.05, -1.76]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.44, df = 1 (P = 0.51); I² = 0%
Test for overall effect: Z = 7.33 (P < 0.00001)

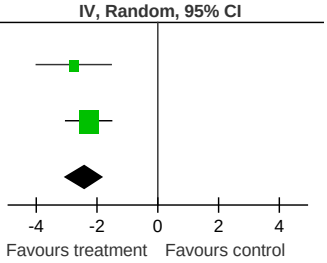


Table 8
Forest Plot: Osteopathic Treatment of Female Incontinence
Outcome: Incontinence Questionnaires AUASI, KHQ

	Treatment			Control				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Alberts 2005	-9.98	0.82	45	0.31	0.22	45	49.7%	-16.99 [-19.57, -14.42]	
Gabriel 2006	-67.04	30.35	12	0.3	9.72	10	0.0%	-2.76 [-4.00, -1.53]	
Gerhardt 2007	-14	11.8	30	-7.6	11.5	30	50.3%	-0.54 [-1.06, -0.03]	
Ringkamp 2009	-8.8	4.4	24	-0.1	2.9	22	0.0%	-2.27 [-3.03, -1.52]	
Total (95% CI)			**75**			**75**	**100.0%**	**-8.72 [-24.84, 7.40]**	

Heterogeneity: Tau² = 134.44; Chi² = 151.07, df = 1 (P < 0.00001); I² = 99%
Test for overall effect: Z = 1.06 (P = 0.29)

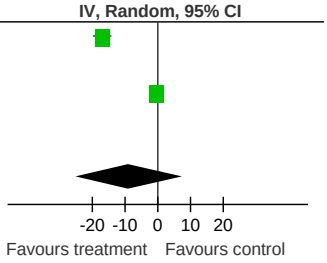
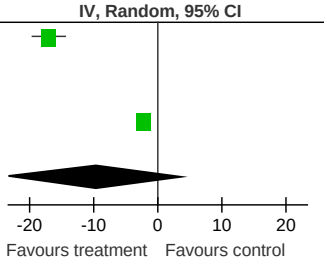


Table 9
Forest Plot: Osteopathic Treatment of Female Incontinence
Outcome: Incontinence Questionnaires AUASI

	Treatment			Control				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Alberts 2005	-9.98	0.82	45	0.31	0.22	45	49.6%	-16.99 [-19.57, -14.42]	
Gabriel 2006	-67.04	30.35	12	0.3	9.72	10	0.0%	-2.76 [-4.00, -1.53]	
Gerhardt 2007	-14	11.8	30	-7.6	11.5	30	0.0%	-0.54 [-1.06, -0.03]	
Ringkamp 2009	-8.8	4.4	24	-0.1	2.9	22	50.4%	-2.27 [-3.03, -1.52]	
Total (95% CI)			**69**			**67**	**100.0%**	**-9.58 [-24.01, 4.84]**	

Heterogeneity: Tau² = 107.40; Chi² = 115.81, df = 1 (P < 0.00001); I² = 99%
Test for overall effect: Z = 1.30 (P = 0.19)



Chapter 4: Discussion

4.1 Discussion of Background

The International Incontinence Society (ICS) defines incontinence as "involuntary loss of urine" that is measurable and of such a magnitude that it causes hygienic and social problems.

Although this subject has received more attention from the medical field during the last decade, incontinence is still, even today, a taboo subject for many patients. For this reason, it is not easy to recognize an existing urinary incontinence amongst those affected and to treat it.

The selection of modified behavioral techniques for treating incontinence is large. The emphasis is on physical therapy (PFMT), toilet training, biofeedback and electrical stimulation therapy. Although these measures are very time consuming and require a high level of compliance for both the patient and the physician, they provide an effective treatment option.

If the above mentioned treatments are unsuccessful, then medication and surgical treatments should be taken into consideration. The large number of medication studies, their development and widespread publications, readily create the impression that medication treatment alone is successful and is, for example, superior to the manual treatment.

It is quite possible that in the therapeutic routine, medication is prescribed too quickly. However, the opposite method could also be successful. Numerous drugs promote incontinence (eg: alpha blockers, diuretics, calcium antagonists, antiepileptic drugs, antihistamines, psychotropic drugs). However, this requires that the attending physician is aware of the complete amount of prescribed medication taken and that this is reflected in his treatment plan.

4.2 Discussion of the Methods and Results

Classical search strategies are based on the information contained in the large databases Medline and Embase. During recent years, the Cochrane Library has been recommended as an additional source. For the current review, the search performed in these data banks was not successful.

The results were significantly better in osteopathic specific data sources such

as the Osteopathic Research Web or the Academy of Osteopathy. The studies included in this review are, without exception, from the German speaking regions. This may have something to do with the fact that the visceral osteopathy is more deeply rooted in the German and also in the Austrian osteopathy than for example, in the USA, Australia or Great Britain. The studies used have all been derived over last 8 years. It appears as if osteopathy has only just discovered the clinical picture of female incontinence in the recent years.

In the studies, various questionnaires were used in the appraisal of the findings, for example, the questionnaires of the American Urological Association Symptom Index Score (AUASI), SF-36, Kings Health (KHQ), Quality of life (QLF University Freiburg) and one published in the Journal of the American Geriatric Society (JAGS). (See Table 10 for a summary of these questionnaires.)

Table 10 Overview of the primary and secondary outcomes measures

Authors	Year	Primary outcomes measures	Secondary outcomes measures
Ringkamp C., Rodriquez B.	2009	Questionnaire AUASI (American Urological Association Symptom Index Score)	Questionnaire SF-36 Residual urine
Gerhardt K., Montag G.	2005	Questionnaire KHQ (Kings Health Questionnaire)	Daily visit to the toilet (miction diary, MTB) Loss of urine
Gabriel R.	2006	Questionnaire QLF (Quality of life)	PAD Test (check the weight of the PADs)
Osenstätter H., Ernst H.	2002	Questionnaire JAGS (Journal of the American Geriatric Society) modified SF-36 for incontinence problems	Reduction of the symptoms of incontinence
Eckmann B., Mertens B., Karen A.	2005	Questionnaire AUASI (American Urological Association Symptom Index Score)	Reduction of osteopathic dysfunction
Brix S.	2007	Not specifically defined (subjective improvement of incontinence problems)	Not specifically defined (subjective improvement of incontinence problems)

According to the AWMF Guideline Urinary incontinence No. 084/001 (AWMF online Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften), up until now, no consistent symptom, or assessment instrument

for the quality of life, has been established in Germany for urinary incontinence.

In principle, there are three types of incontinence assessment instruments found in the medical literature:

- Symptom questionnaires
- General Quality of Life assessments
- Diagnosis related to Quality of Life assessments

The application of the symptom questionnaire is multifunctional. It can be used in order to standardize an incontinence anamnesis, collection of incontinence symptoms, differentiation of the forms of incontinence, assessment of incontinence severity, as well as in studies on the possible evidence of improvement of symptoms in the context of an intervention.

Symptom questionnaires and quality of life assessments, as well as the clinical studies, highlight the different aspects of incontinence. They are therefore suitable to convey an overall impression of the patient. However, it also means that the changes in the symptom case history of the patient can be displayed differently.

While the AUASI, for example, uses 7 questions to classify the direct symptoms of Urinary Incontinence, KHQ and JAGS predominantly measure the subjective assessment of incontinence in various areas of life.

In the six studies found by searching the osteopathic literature, osteopathic treatment was carried out four times on its own as an intervention procedure, and twice in combination with pelvic floor exercises and biofeedback (see table 5). Both methods deal with the standard procedures in the conservative treatment of incontinence. (See Table 11 for a listing of the studies.)

Table 11 Intervention and control procedures in the included studies

Study	**Intervention**		**Control**
Ringkamp 2009	Osteopathic Treatment	versus	No treatment
Gerhardt 2005	Osteopathic Treatment + PFMT		PFMT
Gabriel 2006	Osteopathic Treatment		Placebo
Ernst 2002	Osteopathic Treatment		No treatment
Alberts 2005	Osteopathic Treatment		No treatment
Brix 2007	Osteopathic Treatment + Biofeedback		Biofeedback

Osteopathic treatment in combination with the pelvic floor exercises achieved significantly better results than the control group whose treatment consisted only of pelvic floor exercises. However, the use of osteopathic treatment in combination with biofeedback versus biofeedback treatment alone was not given. Here, the results were almost the same. Nevertheless, it must be noted in the evaluation, that a self-developed questionnaire was used which was not validated and furthermore, only contained 2 questions.

Of the two questions, only the first one ("To what extent have your symptoms improved?") aims to understand the condition of the subjects, whereas the second question asked for information regarding their training habits ("How often during the interim four week break have your trained the pelvic floor muscles by yourself?").

In this study, neither primary nor secondary target parameters were defined, only a general subjective improvement of incontinence problems was covered.

Self-developed questionnaires, in particular, those that are poorly constructed and inadequately designed, are, for the collection of study findings, neither useful nor necessary. All the more so because there are many different validated questionnaires for incontinence in existence. It is extremely unfortunate if due to an unsuitable monitoring instrument, the assessment of the findings cannot be presented convincingly, as in the study from Brix.

In three studies, the osteopathic treatment was compared to the untreated control group and in one case against a placebo. Urinary incontinence in women is an extremely well studied disease. The information obtained from the untreated control group, permits an assessment about the natural course of the illness. However, it raises the question, whether or not this is really necessary with such a well defined disease.

For the treatment of patients, it would be more important to know how effective an osteopathic treatment is in comparison to or in addition to a conservative standard therapy.

A patient, who is concerned about health, will not be able to choose between numerous treatments procedures. It would therefore be more meaningful, purely to measure procedures of complementary medicine such as osteopathic treatment compared to the existing standard procedures.

Similar considerations apply equally to a placebo (non specific laying on of hands) in the control group. Surprisingly, none of the studies provided sufficient data

which would have indicated that the most important factors that could influence incontinence (eg: age, BMI, number of births) did not significantly differ from each other in the intervention and control groups. It can therefore also not be determined whether the randomization was successful with the four included RCTs or if a selection bias existed.

In the studies, there was no separation between the therapist and the person who compiled the findings. If the therapist also records the results of the subject, then it is easily possible to change or enhance the results. It may be that the subject, as a result of the presence of the therapist, cannot give unbiased feedback and therefore the treatment findings are not adequately documented. To prevent any speculation and a detection bias, the documentation of the findings of the treatment should always be carried out separately and by a person that is not involved in the treatment.

In this context, the fact that the studies included were invariably carried out without financial support possibly plays a role. Students conducted the work in order to obtain a training certificate. This course of action may have been solely incorporated for financial reasons, to carry out much of the necessary work of the therapists themselves.

However, one should be aware of the possible bias of the study findings as a result of this situation. Furthermore it must be realized that the design of the study itself has to change in order to adapt to the quality requirements, defined in all tools which are important for assessing bias.

Without exception, all studies point to weaknesses in the blinding tests and experience a downgrading (OR devaluation) in the risk of bias tool from the Cochrane Back Group (points 2, 3, and 4).This raises the inevitable question of whether the osteopathic studies have weaknesses in study design that can be measured with the risk of bias tool.

Or alternatively, whether the risk of bias tool from the Cochrane Back Group sets standards that are more suitable to assess the internal validity in terms of a "efficacy study", rather than in terms of a study that focuses on daily therapeutic routine (effectiveness study).

For an efficacy study whose aims were the effect (or outcome) of a specific intervention, blinding tests and concealment in the course of the study were indispensable. This is because every non-specific factor would lead to a distorted collection of the specific effects (outcomes, responses, reactions).

However, in effectiveness study in which the objective of the study is the effectiveness of a treatment under daily conditions, concealment and blinding tests are counterproductive. This is because hardly any patient goes to a therapist simply for an unknown treatment technique.

It would be highly preferable if the scientific discussions would be conducted more strongly in this context to achieve a more fundamental agreement between the development of study designs and their assessment with risk of bias tools.

4.3 Discussion of the Results of the Meta-Analysis

In this review, a meta-analysis was carried out with 4 of the 6 included studies. The authors of the remaining two studies were personally approached, yet did not respond or could not provide appropriate additional data to include either of the two studies in the meta-analysis.

As a primary parameter, the questionnaires used were the AUASI, KHQ and the PAD-Test. The Forest plot showed a statistically significant overall result in favor of osteopathic treatment. The overall effect size clearly favors the osteopathic intervention with -5.30 (95% confidence interval -8.72 to -1.52).

Although the four studies included show statistically significant values in favor of the osteopathic treatment in the individual calculations, a Chi^2 of 160 (F=98%) clearly indicates substantial heterogeneity of the data. Based on the information available, it can only be speculated whether this may be, e.g., attributed to conceptual differences in the outcome instruments or structural differences of the different study populations. The sensitivity analysis including the two studies using the AUASI Questionnaire, also exhibited a high level of heterogeneity was observed (see Table 9), may advocate the latter.

The sensitivity analysis shows (see Tables 7 and 8) that the consistency of the results between the study from Gabriel and Ringkamp, despite different measurement tools, is very high (I^2 with 0%) whereas the results of the Alberts and Gerhardt study lie relatively wide apart from each other and exhibit an I^2 of 99%. One reason could be that in the study from Alberts, the osteopathic treatment was carried out with an untreated group as controls.

However, in the study from Gerhardt, the intervention group was treated with pelvic floor exercises and osteopathic treatment, and in comparison, the control group was treated only with pelvic floor exercises. Of the four studies, the study by Gerhardt

is the only one that showed an alternative intervention. However, it was the study which showed only weak superiority of the osteopathic intervention.

However, the heterogeneity of the data cannot be purely explained by the situation that there are treated and untreated control groups. It seems sensible to assume that pooling of different study designs, different procedures in the intervention and control group as well as different measurement tools which weigh particular aspects of the symptomatology differently, may account for the apparent heterogeneity of the data.

The statistical analysis shows the inherent problems of the current lack of a clear standard, and, therefore the use of different measurement instruments more clearly than in the qualitative evaluation.

4.4 Conclusion

These existing studies, apart from one exception (Brix, 2007), point to a statistically significant improvement of the symptoms associated with female incontinence through an osteopathic treatment.

In four out of six studies, the osteopathic intervention was compared to an untreated comparison group, or to a placebo (sham) group.

The findings of this systematic review and meta-analysis are very promising and encouraging to conduct larger, rigorous osteopathic intervention studies. Future studies should compare the osteopathic treatment with either established standard procedures or “no treatment” in the control groups, representing the two most prevalent “real life situations” for patients suffering from the condition.

Unlike placebo or sham controlled studies, which are appropriate to scrutinize the extent of the effect of particular osteopathic techniques, blinding of patients and therapists to the treatment option does not seem to be of core relevance. However, evaluator blinding should always be assured. This would also comply with recommendations of the Cochrane Collaboration.

In addition to the findings concerning the effectiveness of the osteopathic approach to the problem, this review demonstrates the disadvantage of the lack of a commonly accepted and widely used standard outcome instrument – and the need to develop and/or establish such a standard.

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Appendix A

Search Strategy

Results of searched Databases

1.	PubMed	4
2.	Cochrane	1
3.	Science Direct	2
4.	Osteopathic Research Web 2000	11
5.	AFO (Germany)	4
6.	IAO (Belgium)	2
7.	JAOA (USA)	8
8.	SAOM (Switzerland)	1
OSTMED-DR		8

Results total:	**41**
Excluded studies:	**7**
Included studies:	**6**

Results of the internet research:

Search results:

a) „Incontinence“

b) „Osteopathic treatment“

c) “Incontinence AND osteopathic treatment“(osteopathic medicine)

1. PubMed:

a) Term searched „urinary incontinence“	27524	hit
b) Term searched „osteopathic treatment“	2189	hit
c) „urinary incontinence AND osteopathic treatment“	4	hit

1. Nemett 2008
2. Amostegui 2004
3. Fingermann 2000
4. Ravetz 1999

2. Cochrane:

a) Term searched „urinary incontinence“	6076	hit
b) Term searched „osteopathic treatment“	6076	hit
c) „urinary incontinence AND osteopathic treatment“	1	hit

1. Nemett 2008

3. Science Direct:

a) Term searched „urinary incontinence“ 29685 hit

b) Term searched „osteopathic treatment“ 4227 hit

c) „urinary incontinence AND osteopathic treatment“ 102 hit

1. Gerhardt/Montag 2008
2. Nemett 2008

4. Osteopathic Research Web:

a) Term searched „urinary incontinence“ 6 hit

b) Term searched „osteopathic treatment“ 206 hit

c) „urinary incontinence AND osteopathic treatment“ 0 hit

1. Brix 2007
2. Gabriel 2006
3. Gerhardt/Montag 2008
4. Wiggins 2000
5. Hughes 1999
6. Bergmann 1998
7. Keating/Miller/Schulte 1988
8. Browning 1987
9. Kargl 2008 Eneuresis
10. Klougart/Leboeuf 1997
11. Gruenberg/James 1985

5. AFO:

a) Term searched „urinary incontinence“ 1 hit

b) Term searched „osteopathic treatment“ hit

c) „urinary incontinence AND osteopathic treatment“ 4 hit

1. Ernst/Osenstätter 2002
2. Alberts/Eckmann/Mertens 2005
3. Gerhardt/Montag 2007
4. Ringkamp/Rodriquez 2009

6. IAO: 2 hit

1. Müller 1998
2. Otremba 2005

7. JAOA

a) Term searched „urinary incontinence“ 121 hit

b) term searched „osteopathic treatment“ 828 hit

c) „urinary incontinence AND osteopathic treatment“ 8 hit

1.	Novi	2008	
2.	Tettambel	2005	
3.	Sussmann	2007	
4.	Novi	2009	fecal
5.	Fingermann/Finkelstein	2000	
6.	Schober	2009	
7.	Tettambel	2007	
8.	Ronak	2010	Eneuresis

8. SAOM (Schweiz) 1 hit

1.	Bartu	1997	Eneuresis

9. OstMed Dr.

a) Term searched „urinary incontinence“ 160 hit

b) Term searched „osteopathic treatment“ 9324 hit

c) „urinary incontinence AND osteopathic treatment“ 136 hit

1.	Lerma	2008	
2.	Novi/Joseph	2008	Op Techniques
3.	Sussmann	2007	
4.	Farley	1999	male
5.	Baumann	1994	1994
6.	Kowalcyzek	2000	
7.	Fingermann	2000	
8.	Lonsway	2000	

10. Clinical Trials gov.

a) Term searched „urinary incontinence“ 448 hit

b) Term searched „osteopathic treatment“ 59 hit

c) „urinary incontinence AND osteopathic treatment“ 3 hit

3 work in preparation

11. National Guideline Clearinghouse

a) Term searched „urinary incontinence“	94	hit
b) Term searched „osteopathic treatment“	36	hit
c) „urinary incontinence AND osteopathic treatment“	0	hit

Appendix B

Characteristics of included studies

Characteristics of included clinical trials with urinary incontinence Part 1

Author / Year Country	**Ringkamp 2009 Germany**	**Gerhardt 2005 Germany**	**Gabriel 2006 Austria**
Study design	RCT	RCT	RCT
Aim of the Study	The influences of osteopathic treatment on females with voiding dysfunction	To evaluate whether osteopathic treatment in addition to standard therapy of "pelvic floor muscle training" can significantly improve the overall quality of life of women suffering from UI* as a result of an injury to the perineum during delivery.	Treatment of UI* (stress incontinence) at a descencus of vagina and bladder.
Reported inclusion / Exclusion criteria / Dropouts	+ / + Dropouts reported	+ / + Dropouts reported	+ / + Unsure
No. of treatments / Period	5 / 10 weeks	4 / 12 weeks	3 / 4-6 weeks
Measurement	Questionnaire AUSAI SF 36 Residual urine	Questionnaire "Kings Health Questionnaire" (KHQ)	Questionnaire "Quality of Life" (QLF) University of Freiburg
Number of patients/ **Age /**	47 / Ø 48	60 / Ø 37,5	24 / (data not coherent) Ø ?
Number of patients Intervention / Control	a. 24 b. 23	a. 30 b. 30	a. 12 b. 10
Randomized / Blind (Patients) /	+ / No	+ / No	+ ** No
Intervention Control	a. OMT b. No treatment	a. OMT + PFMT*** b. PFMT***	a. OMT b. Placebo
Reported Results	"Five osteopathic treatments over a period of 10 weeks led to clinically relevant positive changes of urological symptom severity level of women suffering from voiding dysfunction".	OMT "had a clinical relevant influence on the symptom-specific quality of life of women with UI following an injury of the perineum".	"A significant improvement of stress incontinence of urine could be achieved by osteopathic techniques".

*** UI = Urinary incontinence**

**** Randomization procedure not explained**

***** PFMT = Pelvic floor muscle training**

Characteristics of included clinical trials with urinary incontinence Part 2

Author / Year Country	**Ernst 2002 Germany**	**Alberts 2005 Germany**	**Brix 2007 Austria**
Study design	CCT	CCT	RCT
Aim of the Study	The influences of osteopathic treatment on females with urge incontinence and the combination of urge and stress incontinence.	The influence of osteopathic treatment to the severity code of symptoms of voiding dysfunction in women.	To determine if a pelvic floor training program, supported by biofeedback and supplemental OMT could lessen the symptoms of stress incontinence.
Reported inclusion / Exclusion criteria / Dropouts	+ / + Dropouts reported	+ / + No dropouts	+ / + No dropouts
No. of treatments / Period	3 / 4-6 weeks	3 / 6 weeks	3 / 6 weeks
Measurement	Questionnaire "Journal of the American Geriatric Society" (JAGS)	Questionnaire "Kings Health Questionnaire" (KHQ)	Private Questionnaire (not validated)
Number of patients/ **Age /**	29 / Waiting list design Ø 53	45 / Waiting list design Ø 46	22 /
Number of patients Intervention / Control	a. 25 b. 25	a. 45 b. 45	a. 11 b. 11
Randomized / Blind (Patients) /	-/ No	-/ No	+ ** No
Intervention Control	a. OMT b. No treatment	a. OMT b. No treatment	a. OMT + Biofeedback + PFMT*** B. Biofeedback + PFMT***
Reported Results	"...high significant improvement by osteopathic treatment for stress and urge incontinence"	"...a high significant improvement of the severity code of the urological symptoms by only 3 osteopathic treatments..."	"...no significant improvement in symptoms brought about by the osteopathic treatments..."

*** UI = Urinary incontinence**

**** Randomization procedure not explained**

***** PFMT = Pelvic floor muscle training**

Appendix C

Criteria for a Judgment of "Yes" for the Sources of Risk of Bias

1	Was the method of randomization adequate? A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.
2	Was the treatment allocation concealed? Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
3	Was the patient blinded to the intervention? This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
4	Was the care provider blinded to the intervention? This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful
5	Was the outcome assessor blinded to the intervention? Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or: –for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes" –for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination –for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome –for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes" –for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data
6	Was the drop-out rate described and acceptable? The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).
7	Were all randomized participants analyzed in the in the group to which they were

	allocated? All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
8	Are reports of the study free of suggestion of selective outcome reporting? In order to receive a "yes", the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
9	Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
10	Were co-interventions avoided or similar? This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.
11	Was the compliance acceptable in all groups? The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.
12	Was the timing of outcome assessment similar in all groups? Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

Appendix D

Outcomes and Measurement in the included studies

Study No. 1 Ringkamp/Rodriquez 2009					
Primary outcomes measures: AUASI					
Secondary outcomes measures: SF-36 residual urine					
Characteristics		Intervention group (n = 24)	Control group (n = 22)	Difference of the average values. (95% CI)	p Value
Age		44.9 ±18.5	51.5 ±16.9	6.6 (-4 to 17.1)	0.22
AUASI		15.5±5.3	14.5 ±5.3	1.1 (-2.1 to 4.2)	0.49
SF-36 (somatically)		47.3 ± 8.9	14.5 ±5.3	0.3 (-4.9 to 4.4)	0.92
SF-36 (psychical)		42.9± 10.1	46.2 ± 9.3	3.3 (-2.5 to 9.0)	0.26
Residual urine (ml)		147.3± 61.5	109.6± 47.2	37.7 (-5 to 70.5)	0.03
Inter-group comparison					
AUASI		-8.8 ± 4.4	-0.1 ± 2.9	-8.7 (-10.9 to -6.4)	< 0.005
SF-36 (somatically)		3.9 ± 6.0	-0.2 ± 2.8	4.1 (1.3 to 7.0)	0.005
SF-36 (psychical)		5.1 ± 6.4	-0.9 ± 4.3	6.0 (2.8 to 9.3)	0.001
Intra-group comparison					
AUASI	input value	15.6 ± 5.3	14.5 ± 5.3		
	end value	6.8 ± 4.8	14.4 ± 4.5		
MW (95% CI)		-8.8 (-10.7 to 6.9)	-0.1 (-1.4 to 1.1)		
p Value		< 0.005	0.83		
SF-36 (somatically)	input value	47.3 ± 8.9	47.0 ±6.5		
	end value	51.2 ± 8.0	46.8 ± 6.9		
MW (95% CI)		3.9 (1.9 to 6.5)	-0.2 (-1.5 to 1.1)		
p Value		0.004	0.73		
SF-36 (psychical)	input value	42.9 ± 10.1	46.2 ± 9.3		
	end value	48.1 ± 8.8	45.3 ± 9.3		
MW (95% CI)		5.1 (2.5 to 7.8)	-0.9 (-2.8 to 1.0)		
p Value		0.001	0.34		

Study No. 2 Gerhardt/Montag				
Primary outcomes measures : KHQ				
Secondary outcomes measures: Daily visit to the toilet (Miction diary. MTB). Loss of urine. daily used PAD`s				
Characteristics	Intervention group (n = 30). 2 Dropouts	Control group (n = 30)	Difference of the average values. (95% CI)	p Value
Age	37.8 ±4.5	37.1 ±4.6	(-3.1 to 1.6)	0.53
BMI	22.7±3.0	22.6 ±2.9	(-1.6 to 1.4)	0.90
Number of births	1.9± 0.9	1.9 ± 0.8	(-0.5 to 0.4)	0.88
Number of the tear of the perineum	1.6± 0.9	1.7± 0.8	(-0.3 to 0.5)	0.75
KHQ	(n=20)	(n=20)		
	34.1 ± 14.0	31.4 ± 14.5	(-11.8 to 6.4)	0.56
Inter-group comparison (Total score)	(n=20)	(n=16)		
KHQ	-15.0 ± 13.6	-9.5 ± 13.1	(-3.7 to 14.6)	0.24
KHQ (with the use of missing values)	(n=30)	(n=30)		
	-14.0 ±11.8	-7.6 ±11.5	(0.3 to 14.4)	0.04
Intra-group comparison (Total score)	(n=20)	(n=16)		
KHQ input value	34.1 ± 14.0	31.3 ± 15.5		
end value	19.1 ± 12.9	21.7 ± 7.9		
MW Wert (95% CI)	(8.6 to 21.4)	(2.6 to 14.6)		
p Value	<0.0005	0.011		
Intra-group comparison	(n=30)	(n=30)		
KHQ input value	31.5 ± 12.1	31.0 ± 12.6		
end value	17.6 ± 11.4	23.4 ± 8.9		
MW (95% CI)	(9.5 to 18.4)	(3.3 to 11.9)		
p Value	< 0.0005	0.001		

Study No. 3 Gabriel						
Primary outcomes measures : QLF (University Freiburg. special for urinary incontinence)						
Secondary outcomes measures : PAD Test (check the weight of the PADs)						
Characteristics	Intervention group (n = 12)		Control group (n = 10). 2 Dropouts		Difference of the average values. (95% CI)	p Value
PAD Test	**change in Gramm / %**		**change in Gramm / %**			
Subject 1	-5.1 g	-83.6 %	1.2 g	5.9 %		
Subject 2	2.0	9.1	-1.6	-8.7		
Subject 3	-6.1	-22.3	-0.9	-3.0		
Subject 4	-9.0	-64.3	-0.8	-4.3		
Subject 5	-0.9	-90.0	0.2	18.2		
Subject 6	-1.1	-78.6	-0.2	-12.5		
Subject 7	-0.6	-60.0	0.6	4.7		
Subject 8	-0.9	-81.8	-4.3	-10.2		
Subject 9	-14.9	-80.01	0.3	9.4		
Subject 10	-20.0	-81.3	0.2	3.6		
Subject 11	-6.3	-80.8				
Subject 12	-7.9	-90.8				
Average value	-5.9	-67.0	-0.5	0.3		
Minimum value	-20.0	-90.8	-4.3	-12.5		
Maximum value	2.0	9.1	1.2	18.2		
Standard deviation	6.5	30.4	1.6	9.7		
Median value	-5.6	-80.5	0.0	0.3		
Inter-group comparison					u-Test = 8.0	0.0003

Study No. 4 Ernst/Osenstätter				
Primary outcomes measures: Questionnaire JAGS (Journal of the American Geriatric Society). modified SF-36(urinary incontinence problems)				
Secondary outcomes measures : Reduction of the symptoms of incontinence				
Characteristics	Patients (n = 25)	p Value	p Value	Difference of the average values. (95% CI)
Alter				52.92
		P1 – P2	**P2 – P3**	
Questionnaire of incontinence Part I		(Recording – Treatment)	(Treatment – Follow up)	
		(0-4 weeks)	(4-12 weeks)	
1. general activities		0.22733	0.00025	
2. travel		0.12589	0.00044	
3. physical activities		0.43305	0.00236	
4. feelings		0.64352	0.00040	
5. relationship		0.50675	0.02801	
6. Sexual Function		0.29451	0.52937	
7. Total-Score		0.2586	0.00006	
Questionnaire of incontinence Part II				
1. Urge incontinence		0.26594	0.00019	
2. Stress incontinence		0.26594	0.00068	
3. Total-Score		0.58292	0.00008	

Study No. 5 Alberts/Eckmann/Mertens					
Primary outcomes measures : AUASI (American Urological Association Symptom Index)					
Secondary outcomes measures : osteopathic dysfunction					
Characteristics	Patients (n = 45)	start Waiting time	finish waiting-time	Difference of the average values. (95% CI)	p Value
Age				45.9	
AUASI total				19.1 ± 5.9	
AUASI storage				7.9 ± 3.7	
AUASI emptying				11.3 ± 4.1	
		Waiting time 0 Weeks	**Waiting time 6 Weeks**		
AUASI total		19.11	19.42	-0.76 ± 0.14	0.172
AUASI storage		7.91	7.93	-0.40 ± 0.45	0.916
AUASI emptying		11.31	11.49	-0.24 ± 0.60	0.400
		Waiting time 6 Weeks	**Waiting time 12 Weeks**		
AUASI total		19.42	9.44	8.33 ± 11.63	0.000
AUASI storage		7.93	4.33	-4.43 ± 2.77	0.000
AUASI emptying		11.49	5.11	5.12 ± 7.64	0.000
Comparison of waiting time and treatment time		**Waiting time**	**Treatment time**		
AUASI total		0.31	-9.98	-12.04 ± -8.53	0.000
AUASI Storage		0.02	-3.60	-4.54 ± -2.70	0.000
AUASI emptying		0.18	-6.38	-7.95 ± -5.15	0.000

Study No. 6 Brix				
Primary outcomes measures: not specifically defined. (subjective improvement of incontinence problems)				
Secondary outcomes measures: not specifically defined. (subjective improvement of incontinence problems)				
Characteristics	Intervention group (n = 11)	Control group (n = 11). 2 Dropouts	Difference of the average values. (95% CI)	p Value
Questionnaire not valid				
Question 1				0.258
Modified question 1				0.2966
Question 2				1.0
Modified question 2				0.6109

Appendix E

Overview of the excluded studies

Table 12 Study overview of the excluded studies

Author	Title	Year	Study-design	Target parameter - notes
Wiggins. F. (GB)	Urinary incontinence-the silent suffers	2000	Survey Questionnaire	The study dealt via a survey with osteopathic considerations in the treatment of adult patients with urinary incontinence.
Hughes. L. (GB)	Identifying key issues in the osteopathic approach to urinary incontinence	1999	Survey Questionnaire	The study dealt with the identification of the most important issues in osteopathic approach to the treatment of urinary incontinence.
Kowalczyk. J. (USA)	Office evaluation of the patient with an overactive urinary bladder	2000	Case report	The study showed a clinical evaluation with patients who suffered from an overactive bladder (OAB).
Sussman. D. (USA)	Overactive Bladder: Treatment options in Primary Care Medicine	2007	Case report	The study showed a treatment report regarding the basic medical care for an overactive bladder (OAB).
Lonsway. J.M. (USA)	Surgical and medical treatment options for urge incontinence	2000	Literature research	The study showed surgical and medical treatment options for urge incontinence.
Fingerman. J.S. (USA)	The overactive bladder in multiple sclerosis	2000	Case report	The study showed a treatment report of a 36 year old woman with multiple sclerosis who suffered urinary incontinence due to an overactive bladder (OAB).
Lerma. C. (USA)	An osteopathic Approach to Visceral Disease: A case of Recurrent Urinary Tract Infection	2008	Case report	The study contained an osteopathic treatment report on recurring urinary tract infections

Appendix F

Questionnaires AUASI
JAGS (part 1and part 2)

Questionnaire from the study of Ernst and. Osenstätter (2002)

INKONTINENZ-FRAGEBOGEN I. ID-NR: _____

Wie oft wurden Sie in den letzten 4 Wochen Urinverlust und/oder Blasenprobleme bei folgenden Aktivitäten beeinträchtigt?

1. Bei Arbeiten im Haus oder Garten

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

2. Bei Arbeiten außerhalb des Hauses

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

3. Wenn Gäste zu Besuch kommen

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

4. Bei längerem Gehen

Nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

5. Bei gesellschaftlichen Aktivitäten außerhalb des Hauses

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Wie oft wurden Sie in den letzten 4 Wochen Urinverlust und/oder Blasenprobleme gestört wenn Sie das Haus verlassen haben?

6. Wenn Sie unterwegs und unsicher sind ob Toiletten vorhanden sind

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

7. Beim Besuch von Veranstaltungen (Konzerts- Kino- Kirche)

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

8. Bei Fahrten die weniger als 1 Stunde von zu Hause dauern

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

9. Wenn Sie einen ganzen Tag von zu Hause weg sind

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	

10.Wenn Sie mehrere Tage von zu Hause weg sind

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Wie oft wurden sie in den letzten 4 Wochen Urinverlust und/oder Blasenprobleme gestört in Verbindung mit folgenden Übungsaktivitäten

11.schnelles Gehen

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

12.Laufen. Joggen oder Aerobic

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

13.Beim Benützen von Heimfahrrädern oder Trainingsgeräten (Fitness-Studio)

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

14.Bei Hobbysportarten wie Schwimmen. Skifahren oder Tennis

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Wie oft hat ihr Urinverlust und/oder Blasenproblem in den letzten 4 Wochen folgende Gefühle bei ihnen hervorgerufen?

15.Zornig oder ängstlich

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

16.Unangenehm oder beschämend

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

17.Beeinträchtigung der Weiblichkeit

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

18.Mangelnde Attraktivität

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

19.Fehlendes Selbstvertrauen

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Wie oft hat ihr Urinverlust und/oder Blasenproblem in den letzten 4 Wochen folgende Gefühle bei ihnen hervorgerufen?

20.Hilflosigkeit

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

21.Isolation

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

22.Mangel an Selbstwertgefühl

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Wie oft werden Sie durch Urinverlust und/oder Blasenproblem die letzten 4 Wochen beeinträchtigt in Bezug auf

23.Ihre Freunde

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

24.Ihre Familie

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

25.Ihren Freund oder Partner

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

26.Ihre Kinder

nie	selten	manchmal	ziemlich oft	sehr oft	immer

□ □ □ □ □ □

Viele Frauen sagen dass der Urinverlust bzw. Blasenprobleme ihr sexuelles Leben beeinträchtigt

27.Bedeutet das Problem ein Ende der sexuellen Aktivität?

ja

□ wenn **ja**. somit ist für Sie der Fragebogen beendet!

nein

□ wenn **nein: wie oft beeinträchtigt der Urinverlust bzw. Blasenproblem folgende Aspekte ihres sexuellen Lebens**

28.die Fähigkeit zu entspannen und Sex zu genießen

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

29.einen Orgasmus zu haben

nie	selten	manchmal	ziemlich oft	sehr oft	immer
□	□	□	□	□	□

Inkontinenz-Fragebogen II ID - NR:

Die folgenden Symptome wurden von Frauen beschrieben. die Blasenprobleme und Erfahrungen mit Urinverlust haben. Bitte beschreiben Sie. welche Symptome Sie haben und wie stark Sie diese beeinträchtigen.

1. Müssen Sie Ihre Blase häufig entleeren?
□ ja □ nein (bitte beantworten sie Frage 2)
wenn **ja** wie oft werden Sie dadurch belästigt?

nicht im geringsten	wenig	mäßig	stark
	4-5 mal	6-8 mal	10 mal
□	□	□	□

2. Haben Sie einen starken Drang ihre Blase zu entleeren?
□ ja □ nein
wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

3. Haben Sie Schwierigkeiten Urin zu halten?
□ ja □ nein
wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

4. Verlieren Sie überhaupt Urin?
□ ja □ nein
wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

5. Besteht ein Zusammenhang zwischen Urinverlust und Harndrang?
□ ja □ nein
wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

6. Besteht ein Zusammenhang zwischen Urinverlust und körperlicher Aktivität – Husten und/oder Niesen ?
□ ja □ nein
wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

7. Haben sie Urinverlust. der nicht in Zusammenhang mit Harndrang und körperlicher Aktivität steht?

□ ja □ nein

wenn **ja** wie stark belästigt es Sie?

nicht im geringsten	wenig	mäßig	stark
□	□	□	□

8. Müssen Sie nachts Wasser lassen?

nein	wenig	mäßig	stark
□	□	□	□

9. Haben Sie unkontrollierten nächtlichen Harnabgang?

nein	wenig	mäßig	stark
□	□	□	□

10. Wenn Sie Harndrang verspüren. müssen sie dann sofort zur Toilette oder können sie noch abwarten?

ich kann länger warten	kann 15 min. warten	kann5 min. warten	muss sofort gehen
□	□	□	□

11.Verlieren sie auf dem Weg zur Toilette Urin?

nein	wenig	mäßig	stark
□	□	□	□

Überlegen Sie bitte durch welche der abgefragten Probleme von Ziff. 1 – 11 Sie sich am meisten betroffen fühlen. Notieren Sie bitte nur den für Sie wichtigsten Punkt:

Datum Ort

Unterschrift

Questionnaire of the study by Ringkamp and Rodriquez 2009 and the study of Alberts. Eckmann and Mertens 2005

AUASI Fragebogen

Datum : ID-NR. :

Bitte jeweils die Antwort pro Frage ankreuzen, die Ihre Symptome beschreibt. Die Angaben beziehen sich auf die letzten 4 Wochen

	niemals	seltener als in einem von fünf Fällen	seltener als in der Hälfte der Fälle	Ungefähr in der Hälfte der Fälle	in mehr als der Hälfte der Fälle	fast immer
1. Wie oft hatten Sie das Gefühl, dass Ihre Blase nach dem Wasserlassen nicht ganz entleert war? 2. Wie oft mussten Sie innerhalb von 2 Stunden ein zweites Mal Wasser lassen?	0	1	2	3	4	5
3. Wie oft mussten Sie beim Wasserlassen mehrmals aufhören und wieder neu beginnen?	0	1	2	3	4	5
4. Wie oft hatten Sie Schwierigkeiten, das Wasserlassen hinauszuzögern?	0	1	2	3	4	5
5. Wie oft hatten Sie einen schwachen Strahl beim Wasserlassen	0	1	2	3	4	5
6. Wie oft mussten Sie pressen oder sich anstrengen, um mit dem Wasserlassen zu beginnen? 7. Wie oft sind Sie nachts aufgestanden, um Wasser zu lassen?	kein mal 0	ein mal 1	zwei mal 2	drei mal 3	vier mal 4	fünf mal 5

Summe aller Punkte:

was bedeuten diese Punkte?

0-7 Punkte: Die Symptome werden als mild eingestuft.

8-19 Punkte: Die Symptome werden als mäßig eingestuft.

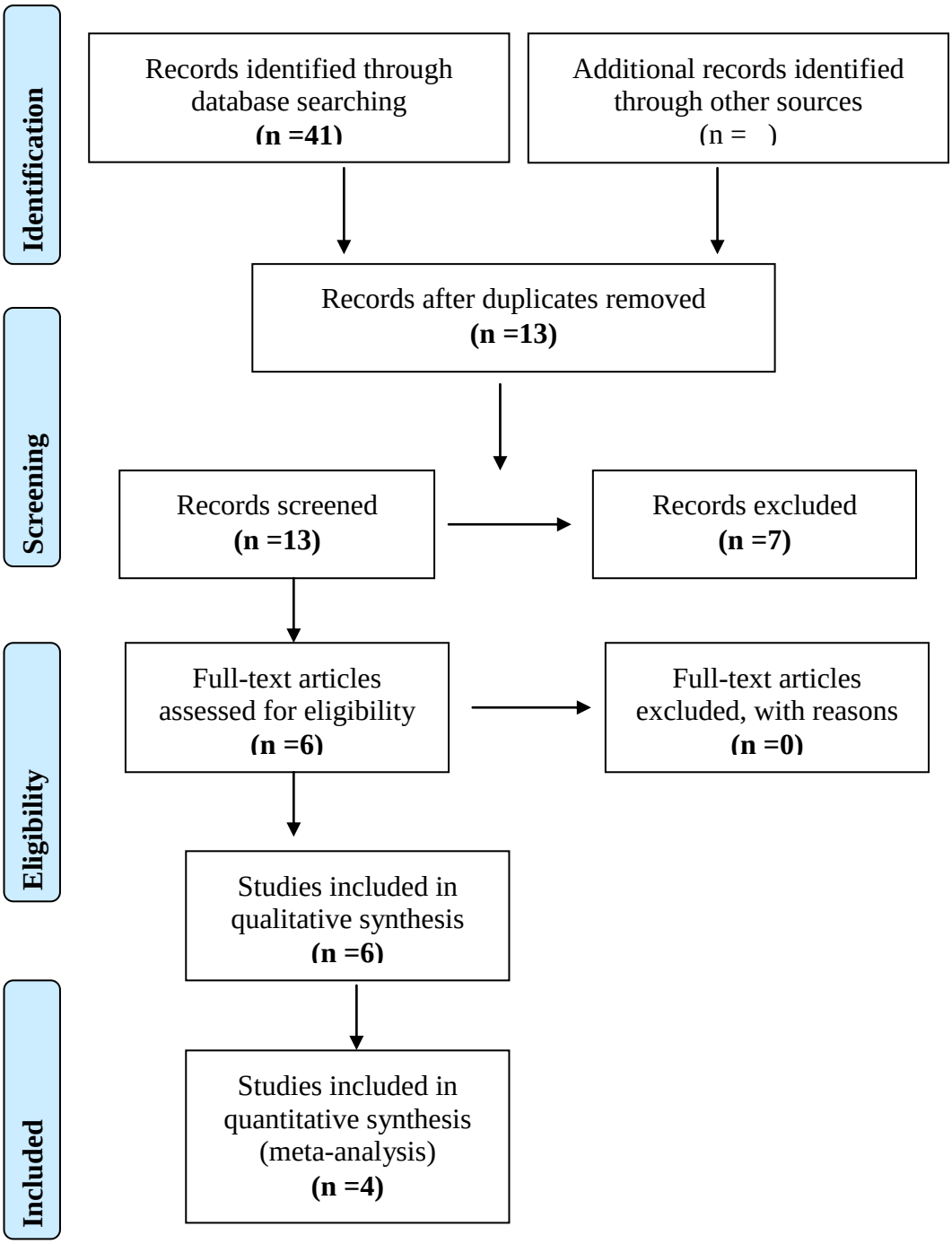
20-35 Punkte: Die Symptome werden als schwerwiegend eingestuft.

Dieser Fragebogen kann von Ihrem Arzt auch verwendet werden, um entweder die Entwicklung innerhalb eines bestimmten Zeitraumes zu beobachten oder auch um Sie gezielt an bestimmte Behandlungsmöglichkeiten heranzuführen. Ebenso kann der Fragebogen Hinweise auf das Ansprechen auf bestimmte Behandlungen geben.

Appendix G

PRISMA Flow Diagram and PICO schema of the included osteopathic studies

PRISMA 2009 Flow Diagram



PICO schema of the included osteopathic studies

Ref.Nr.: **01**
Autor: **Ringkamp. Rodriquez**
Titel: **Osteopathische Behandlung von Frauen mit Blasenentleerungsstörungen**
Jahr: **2009**

Patients	47 Patienten (Alter 19-82. im Mittel 48 Jahre) mit einer urologisch diagnostizierten Blasenentleerungsstörungen (BES). Einschlußkriterien sind Frauen mit mind. 18 Jahre alt und AUASI Klassifizierung >/=7 aufweisen. gesamte Studienzeit 32 Wochen **Randomisierung extern** (telefonisch durch Bad Elster. Prof. Dr. Resch) **I= Interventionsgruppe** (mit 24 Patienten 5x Osteo im Abstand von 2 Wochen) **II= Kontrollgruppe** (mit 23 Patienten unbehandelt. aber erhielten 1x Osteo im Anschluss aus ethischem Gesichtspunkt)
Intervention	**I = Interventionsgruppe** Sonographische Restharnmessung in WX. Follow up in W22. W32 (3x) Osteo in W0-W2-W4-W6-W8 (5x) Ausfüllen von AUASI und SF-36 in W0-W6-W10-W22-W32 (5x) Führen eines Zystitis Tagebuch in W2-W4-W4-W6-W8-W10-W22-W32 (8x) **II = Kontrollgruppe** Sonographische Restharnmessung in WX. (1x) Ausfüllen von AUASI und SF-36 in W0-W6 (2x) Führen eines Zystitis Tagebuch in W0-W6 (2x) Nach W6 1x Osteo
Comparator	Interventionsgruppe mit 5x Osteo + 3x Restharnbestimmung + 5x AUASI und SF-36 + 8x Zystitis Tagebuch führen **versus** Kontrollgruppe mit 1x Restharnbestimmung + 2x AUASI und SF-36 + 2x Zystitis Tagebuch führen
Outcomes	Intention to treat Analyse vorgenommen Studienabbrecher werden nach der Methode „Last Oberservation Carried Forward“ (LOCF) behandelt
	1 Dropout in der Interventionsgruppe und 1 Dropout in der Kontrollgruppe (Gründe beschrieben)

Ref.Nr.: **02**
Autor: **Gerhardt. Montag**
Titel: **Osteopathische Behandlung von Frauen mit Harninkontinenz nach Verletzung des Perineums unter der Entbindung**
Jahr: **2005**

Patients	60 Patienten (Alter 18-45. im Mittel 37.5 +- 4.5 Jahre) mit Stress- oder Dranginkontinenz (OAB). Einschlußkriterien sind vaginale Entbindung mit Episiotomie oder Dammriss. **Randomisierung extern** (telefonisch bei Statistikerin). BMI unter 33 **I= Interventionsgruppe** (mit 30 Patienten 4x Osteo+MTB+PFMT+KHQ im Abstand von 3 Wochen) **II= Kontrollgruppe** (mit 30 Patienten und MTB+PFMT+KHQ)
Intervention	beide Gruppen erhalten 4 Termine zur Einweisung PFMT. primärer Zielparameter ist Lebensqualität KHQ von 1993 (3 Teile-21 Fragen). in den 12 Wochen 4x Anleitung PFMT **I = Interventionsgruppe** 1. Termin (osteopathische Behandlung erläutert. Ablauf und Erklärung der PFMT. MTB. 4 Sitzungen werden vereinbart). 2.Termin (1.Osteo. PFMT. MTB. KHQ). 3. Termin (2.Osteo. PFMT. MTB) 4.Termin (3.Osteo. PFMT. MTB). 5. Termin (4.Osteo. PFMT. MTB). 6.Termin (KHQ. MTB). **II = Kontrollgruppe** 1.Termin (Anamnese. Erklärung KHQ. MTB). 2.Termin (KHQ. MTB. PFMT). 3.Termin (MTB. PFMT). 4.Termin (MTB. PFMT). 5. Termin (MTB. PFMT). 6.Termin (KHQ. MTB)
Comparator	Interventionsgruppe mit 4x Osteo + MTB + PFMT + KHQ **versus** Kontrollgruppe mit MTB + PFMT + KHQ
Outcomes	Intention to treat Analyse vorgenommen p= 0.007 bei Einschränkungen der täglichen Aktivitäten bei KHQ (Gesamtscore) IG p<0.0005 (h.s). KG p=0.011 (s.). Intervergleich p=0.24 (n.s) beim Intergruppenvergleich keine signifikante Verbesserung
	2 Dropouts in der Interventionsgruppe (Gründe beschrieben) Keine einheitliche Begriffe wie IV bzw. KG gewählt KHQ persönliche Beziehung nur von 40 Patienten ausgefüllt Bei konfirmatorischen Analyse sinkt die Zahl der auswertbaren Patienten auf 46 (IG 20/KG 16) MTB (tägliche Toilettengänge) keine Veränderung in beiden Gruppen

Ref.Nr: **03**
Autor: **Gabriel**
Titel: **Treatment of urinary incontinence (stress-incontinence of urine) at a descencus of vagina and bladder;**
Jahr: **2006**

Patients	24 TN Frauen mit Stressinkontinenz. Einschlußkriterium (Stufe I) Ausschlusskriterium sind Frauen mit Dranginkontinenz Testgruppe mit 12 TN und Kontrollgruppe mit 10 TN **randomisierte Studie** mit 3 osteopathischen Behandlungen im Zeitraum von 4-6 Wochen
Intervention	Beide Gruppen mussten vorher folgendes durchführen: 500 ml Wasser innerhalb 15 min trinken. QLF ausfüllen. 30 min später PAD Test. 2 min Spaziergang. 2 min Klettern-Treppe hinunter gehen. 15x Aufstehen vom Sitzen. 15x energisch Husten. 1 min auf der Stelle laufen. 30 sec. Auf und ab Springen. 10x etwas vom Boden aufheben. 20x Bewegungen durchführen. die evtl. Urin verlieren lassen. Hände waschen unter warmen. fließenden Wassers. QLF 26 Fragen beantworten I = Testgruppe mit 12 TN 3x Osteo (innerhalb 4-6 Wochen) + QLF (Uni Freiburg mit 16 Fragen) + PAD Test II = Kontrollgruppe mit 10 TN 3x Placebobehandlung (innerhalb 4-6 Wochen) + QLF + PAD Test
Comparator	Testgruppe mit 3x Osteo + QLF + PAD Test **versus** Kontrollgruppe mit 3x Placebo Behandlung + QLF + PAD Test
Outcomes	Testgruppe von 12 TN. bei 11 TN eine deutliche Verbesserung bei Urinverlust (von 0.6-20 g)
	2 Drop outs (nicht beschrieben warum?) Keine Intention-to-Treat (ITT) Analyse durchgeführt

Ref.Nr.: **04**
Autor: **Osenstätter. Ernst**
Titel: **Osteopathische Behandlung der Drang- und der Kombination aus Drang- und Stressinkontinenz bei Frauen**
Jahr: **2002**

Patients	29 Patienten mit Stress- und Dranginkontinenz und Kombination S+D Alter 18-70 Jahre. MW 52.92 Jahre. Median 55 Jahre **keine Randomisierung. sondern Waiting List Design** (Interventionsstudie mit unbehandelter Beobachtungsphase) Vorliegen einer ärztlichen Diagnose Verwendung von 3 verschiedenen Fragebögen: allgemeiner Eingangsfragebogen zweiteiliger JAGS Fragebogen(SF 36 speziell für Inkontinenz modifiziert) allgemeiner Abschlussfragebogen 3x Osteo Abstand 8-14 Tage pro Behandlung + 4 Wochen Pause + JAGS Fragebogen
Intervention	1. Termin: Osteo-US 1 + Einverständniserklärung + JAGS + 4 Wochen Pause Bei Osteo-US 16 Test. davon müssen 10 Tests positiv sein(EK) 2. Termin: US 2 + JAGS + Osteo 1 + 3. Termin: nach 8-14 Tagen Osteo 2 4. Termin: nach 8-14 Tagen Osteo 3 + Abschlussuntersuchung 5. Termin: Follow up nach 4 Wochen + JAGS + Abschlussfragebogen Es wurden von 29 TN wurden 25 TN behandelt(Ernst 11/Osenstätter 14)
Comparator	entfällt
Outcomes	Auswertung nach Wilcoxon Test(für JAGS. 25 von 29 TN) Klassifizierung 16% Dranginkontinenz und 84% Kombination von Drang-und Stressinkontinenz Zwischen 1. und 2. Termin ohne Osteo keinen signifikanten Unterschied. d.h. ohne Behandlung(Osteo) auch keine Verbesserung Zwischen T2 und T3 außer Merkmal sexuelle Aktivität(Nr. 6) hochsignifikante Verbesserung JAGS Teil I(Nr.1-5) p=0.001. JAGS Teil II(Nr.1-3) p=0.001
	Drop outs 4 von 29 TN nach dem 1.Termin (Gründe beschrieben) JAGS Fragebogen evtl. zu differenziert zu beantworten. einfacher zu beantworten z.B. Verbesserung nach VAS? Beantwortung JAGS I (Nr.6) sexueller Teil zu persönlich? TN Anzahl evtl. zu gering?

Ref.Nr.: **05**
Autor: **Alberts. Eckmann. Mertens**
Titel: **Der Einfluss der osteopathischen Behandlung auf Blasenentleerungsstörungen bei Frauen.**
Jahr: **2005**

Patients	**nicht randomisierte Studie im Waiting-List-Design** (Interventionsstudie mit unbehandelter Beobachtungsphase) mit 6-wöchiger behandlungsfreier Zeit. gefolgt von 3 osteopathischen Behandlungen 45 TN Behandlungen von 3 verschiedenen Osteopathen (A.E.M) durchgeführt
Intervention	3x Osteo in Anstand von 14 Tagen Fragebogen von American Urological Association Symptom Index Score (AUASI)
Comparator	entfällt
Outcomes	Der Schweregrad der Symptomatik BES verbesserte sich zwischen Beginn und Ende der Behandlung (p=0.001 CI=8.33/11.63) Auch der direkte Vergleich Wartezeit/ Interventionszeit zeigte eine hohe statistisch signifikante Verbesserung (p=0.000) Sowohl Speicherungs- als auch Entleerungssymptomatik verbesserten sich analog.
	Keine Drop outs

Ref.Nr.: **06**
Autor: **Brix Susanne**
Titel: **Osteopathische Behandlung bei Stressinkontinenz in Kombination mit Biofeedback**
Jahr: **2007**

Patients	22 Patienten mit Stressinkontinenz Grad I-II(von 3 Graden). es gibt keine Altersbegrenzung (alle nach Menopause und 1x Entbindung).**Gruppierung war zufällig geschehen (Randomisierung?)** Die Studienteilnehmerinnen werden von einer Gynäkologin speziell ausgewählt Ausschlußkriterien sind: neurologische Erkrankungen. Totaloperationen. Krebserkrankungen. Chemotherapie und Hormoneinnahmen beide Gruppen erhalten 7x Biofeedbackbehandlungen/PFMT und Fragebogen **I= Interventionsgruppe** (mit 11 TN 3x Osteo Abstand 14 täglich +6x Biofeedback 1x wöchentlich. 7. Biofeedback nach 4 Wochen Pause) **II= Kontrollgruppe** (mit 11 TN 7x Biofeedback und Fragebogen 6x Biofeedback 1x wöchentlich. 7. Biofeedback nach 4 Wochen Pause)
Intervention	beide Gruppen erhalten 7x Biofeedbackbehandlungen **I= Interventionsgruppe** (mit 11 TN 3x Osteo Abstand 14 täglich +6x Biofeedback 1x wöchentlich. 7. Biofeedback nach 4 Wochen Pause und zum Abschluss einen Fragebogen ausfüllen) **II= Kontrollgruppe** (mit 11 TN 7x Biofeedback 6x Biofeedback 1x wöchentlich. 7. Biofeedback nach 4 Wochen Pause und zum Abschluss einen Fragebogen ausfüllen)
Comparator	Interventionsgruppe mit 3x Osteo + 7x Biofeedback/PFMT **versus** Kontrollgruppe mit 7x Biofeedback/PFMT und Fragebogen
Outcomes	Auswertung Biofeedback/PFMT erfolgte nach mehrfaktorielle Varianzanalyse „MANOVA“ Der Faktor Gruppe hat keinen signifikanten Einfluss auf die Daten (F1= 1.72; p= 0.1946). „Post-Hoc Test“ verwendet signifikanter Unterschied zwischen der 1. und der 7. (letzten) Sitzung sichtbar (p= 0.037). Allerdings wird kein signifikanter Unterschied zwischen der 6. und der 7. (letzten) Sitzung entdeckt (p= 0.96). Der Faktor „subjektive Verbesserung“ ist eine Rangskala (Fragebogen) Die Kontingenztafelanalyse hat ergeben. dass kein signifikanter Anstieg in der subjektiven Verbesserung festgestellt werden konnte (p >= 0.258).
	Keinen validen Fragebogen verwendet. nur 2 Fragen über subjektive Verbesserung. Die Studie zeigt keinen signifikanten Unterschied zwischen der Test- und der Kontrollgruppe aufgrund der **geringen Anzahl der Versuchspersonen** Keine Dropouts