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Bachelorarbeit

What is the effect of sensory feedback training on chronic low back pain?

A systematic review.

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Abstract

Study design: Systematic review and qualitative narrative synthesis.

Objective: To evaluate if sensory feedback training (SFT) decreases the outcomes pain and function.

Summary of Background Data: The studies that were integrated have used different kind of sensory feedback training.

Methods: A systematic search was performed on the databases MEDLINE, PubMed, CINAHL and Embase, and was completed by screening the references of the records. Randomised controlled trials comparing SFT with other interventions, no treatment or sham therapy in patients with chronic low back pain were included. The outcomes for pain and function were extracted and analysed qualitatively.

Results: The search revealed 42 records of which 6 fulfilled the inclusion criteria. These studies included 7 groups that, after having received SFT, all show a decreasing effect for pain and function, 3 groups fulfil the minimal clinically important difference (MCID), whereas there is one in the compared groups.

Conclusion: Although the SFT groups reported a reduction in pain and function, the results were either not significant or did not correspond to the MCID. Study limitations render firm conclusions unsafe.

Keywords: chronic low back pain, physiotherapy, sensory feedback training, tactile stimulation, systematic review.

1 Introduction

In contemporary society, chronic pain such as chronic low back pain (CLBP) are major concerns in health care (Chou, Huffman, 2007 and Van Tulder, Koes, Malmivaara, 2006). The prevalence of chronic pain is estimated at 16% in Denmark and 18% in Sweden (Harker, Reid, Bekkering, Kellen, Bala, Riesma, Worthy, Misso and Kleijnen, 2012). The total costs resulting from low back pain (LBP) in Switzerland are estimated at about 7.4 billion Euros annually according to INTERPHARMA (2007, quoted from Luomajoki, 2010, p. 2).

On current reckoning, it is assumed that the management of pain and disability (therefore also for CLBP) should address five factors: the physical dysfunction, beliefs about back pain, distress, social interactions and the illness behaviour (Waddell, 2004). Training with sensory feedback could be an interesting approach to treat certain physical dysfunctions.

Training with sensory feedback, such as tactile discrimination (Moseley, Zalucki and Wiech, 2008) and sensorimotor retraining (Wand, O'Connell, Di Pietro and Bulsara, 2011), to treat chronic pain are new approaches which are based on theories integrating the idea of central affection of the neural system (Wand, Parkitny, O'Connell, Luomajoki, McAuley, Thacker and Moseley, 2011). These therapies focus on the treatment of the changed cortical reorganization, observed in chronic pain patients (Flor, Denke, Schaefer and Grüsser, 2001). However, such treatments have not been fully developed, nor tested (Wand et al. 2011). This systematic review (SR) focuses on the effect of such therapies based on sensory feedback whose effects are measured by the parameters of pain intensity and physical function.

1.1 Theoretical Background

1.1.1 Cortical changes in chronic low back pain

Wand et al. (2011), Moseley (2006) and McCabe, Haigh and Ring (2003) emphasise that patients suffering from CLBP show similar neurochemical, structural and functional changes of the brain as it has previously been observed with phantom limb pain (Knecht, Henningsen, Hohling, Elbert, Flor and Pantev, 1998) and chronic regional pain syndrome (Maihofer, Handwerker, Neundorfer and Birklein, 2004).

A subgroup of the functional changes are alterations in the cortical representation of the physical body parts, in the present case the representation of the back in the primary somatosensory cortex (Flor et al., 2001 and Wand et al., 2011), commonly described as “cortical reorganization” (Flor, Braun, Elbert and Birbaumer, 1997).

Such changes are thought to be one of the main reasons for both coexisting disturbed sensory perception and pain when treated with the current training approaches (Wand et al., 2011). These current training approaches have focused on diagnoses and treatments, which Robinson and Apkarian (2009, quoted from Wand et al., 2011, p. 536) call “end organ dysfunctions”. According to Wand et al. (2011), there are ongoing studies that try to find an approach in order to train not just the end organ, but also the brain. However, whether these cortical changes are the cause for the coexisting problems in CLBP has not been demonstrated yet (Apakarian, Baliki and Geha, 2009). Wand et al. (2011) reviewed the structural and functional changes of the brain in chronic back pain patients and describe with citations from various studies that cortical changes have been observed, but that there is still leaking evidence whether this is the cause for the coexisting problems. They also emphasize that the processes involved in these cortical changes are not studied in low back pain as deep as those related to other chronic painful disorders and that the approach to do so is still in its “infancy”.

1.1.2 Sensory feedback training

Sensory feedback training (SFT) has not yet been defined for CLBP treatment approaches. Moreover, because there is not a large number of studies that expected this type of sensory feedback in this new field, the kind of training should not form an obstacle, but it must be in accordance with the following principles. In general, the stimulus should not just be a stimulation of the affected area (or of another body part) but also include an active perception (discrimination component) of the treated person, what hereinafter will be referred to as feedback of the patient. Moseley et al. (2008) have developed a training for chronic limb pain, which involved the recognition of the location and the type of the stimuli. This can be combined with differently localized sensory stimuli and their localization, such as “localization training” introduced by Wand et al. (2011), and will be called “sensory feedback training”

(SFT) in the present SR. Furthermore, the recognition of the stimulus type may be integrated as well.

1.2 Objectives

The objectives of the present SR are to determine the effects of SFT on CLBP compared to no treatment, placebo or sham therapy, other therapies as well as the addition of SFT to other therapies.

1.3 Hypothesis

H0: Sensory feedback training (SFT) is not more effective for the relief of pain intensity for CLBP patients than general exercise, passive treatments or no treatment.

2 Method

For the structuration of this SR, the *CRD's guidance for undertaking reviews in health care* (Centre for Reviews and Dissemination, 2009) and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins and Green, 2008) have been used as supporting tools. As this work is a bachelor thesis and the review group is limited to one author, it is not possible to cover the complete proceeding that is recommended in the Cochrane Handbook.

2.1 Study selection

2.1.1 Types of studies

Only randomised controlled trials (RCT) in full text have been included in this SR. The deadline for the search was end of September 2014. As it is a new approach there has not been met a time limit into the past.

2.1.2 Types of participants

The participants have to be adult (18 years or older) and match with the following criteria:

- chronic pain in the low back
- no nerve root pain, no specific pathology
- not pregnant
- no coexisting major medical disease
- no spinal surgery in the last 12 months
- no contraindications to general exercise training

2.1.3 Types of interventions and comparisons

The included studies relied on SFT that was either applied by manual work, machines or other tools used to employ sensory inputs. These inputs should be applied on the painful or another part of the body. The main unit (more than 50% of the training time) of the training program applied in the study should be SFT consisting of active perception of the stimulated body part.

The abovementioned interventions should be compared with control groups; other common exercise treatments, placebo and sham therapy, passive treatment (such as ultrasound or electrotherapy) as well as SFT added to other therapies.

2.1.4 Types of outcome measures

There are many different outcome measures, which are important for LBP patients: symptoms, daily functioning, well-being, work disability and satisfaction (Deyo, Battie, Beurskens, Bombardier, Croft, Koes, Malmivaara, Roland, Von Korff, Waddell, 1998).

The primary outcome measure based on the section symptom (Deyo et al, 1998) was self-reported pain intensity. As there are different types of tools, such as the visual analogue scale (VAS), the numerical rating scale (NRS) or the pain rating index (PRI), to measure these outcomes, there was only restriction imposed: the method must have been validated. The secondary outcome is deduced from the section of daily functioning (Deyo et al. 1998) and more generally summarized in function and can be documented by any tool that has been validated and focuses on physical functioning.

2.1.5 Search methods for the identification of relevant studies

One investigator (SK) searched the medical databases MEDLINE, PubMed, cinahl and Embase, and narrowed the results to English and German literature. A second researcher (CB) accompanied the process. The following keywords were applied in the search: randomised controlled trial, chronic pain, back, low back, lower back, lumbar spine, lumbar column, sensory feedback, sensory training, sensory motor training, sensory motor feedback, feedback training, discrimination training, tactile stimulation, perceptive rehabilitation, tactile discrimination. The keywords have also been combined by using the Boolean operators “AND” and “OR” (see appendix I for full strategy).

2.2 Data collection and analysis

2.2.1 Study selection

Firstly, all the findings (records) of the search on the different databases were compiled (identification) and duplicates were removed. The references of the records (n=28) have been screened to identify other potentially relevant literature and were then added to the records. Then, in the screening process, all the records obviously

not corresponding to the inclusion criteria were removed. In a second phase, the same procedure was applied to the remaining records (n=10) by screening their full text articles in order to check whether all the inclusion criteria were met and therefore the text were eligible for the present SR. Reasons for exclusion have been noted (see appendix). All studies meeting the inclusion criteria were then included in the present SR (n=6).

2.2.2 Methodological quality assessment (Risk of Bias assessment)

The included studies were rated using the PEDro (Physiotherapy Evidence Database) tool for the risk of Bias assessment. This tool has been tested and approved as reliable by Maher, Sherrington, Herbert, Moseley and Elkins (2003). Two investigators (SK, NS) independently assessed the methodological quality of the included studies. After that, the assessments were compared and a consensus was found in order to get a final score. The cases that needed a consensus are marked as such.

According to the Centre for Evidence-Based Physiotherapy at the University of Sydney and their survey (Moseley, Herbert, Sherrington and Maher, 2002) the cut-off of a study to be ranged of moderate to high quality was set by 5/10 by the PEDro scale.

2.2.3 Clinical relevance

One investigator (SK) evaluated the clinical relevance using the five questions recommended by Shekelle, Andersson and Bombardier (1994) and the Updated Method Guidelines by van Tulder, Furlan and Bombardier (2003):

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

2.3 Analysis

The primary analyses, defined a priori, were:

- SFT compared to no treatment or sham therapy
- SFT compared to another intervention
- SFT added to an intervention compared to the intervention without SFT

Due to the expected clinical diversity of the studies (different training approaches) included in this SR, it has been decided to analyse the findings using a qualitative narrative synthesis approach instead of a quantitative synthesis approach with statistical analysis like meta-analysis. *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins et al., 2008) recommends not using a meta-analysis in a review if the studies are too different to be combined. Alternatively, Higgins et al., (2008) recommend for this case the narrative analyse, which has to be well structured and understandably documented in order to make this subjective method (rather than the statistical one) comprehensible.

For structuring the narrative synthesis of the present SR, the *CRD's guidance for undertaking reviews in health care* (Centre for Reviews and Dissemination, 2008, p. 48) has been used as a guidance:

> The general framework consists of four elements:
>
> - Developing a theory of how the intervention works, why and for whom
> - Developing a preliminary synthesis of findings of included studies
> - Exploring relationships within and between studies
> - Assessing the robustness of the synthesis

This framework is completed with a range of practical tools and techniques. The guidance recommends choosing the appropriate tools and techniques in accordance with the review. The development of the theory and the resulting hypothesis can be found in the introduction. Textual description, transforming data into a common measure (see also section 2.3.1) and tabulation of the outcome measures are essential to a summary that is as objective as possible. Additionally, this framework

has been completed by combining it with a general framework for qualitative and quantitative analysis recommended in *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins et al., 2008, p. 244). These four questions were integrated in the section “Exploring relationships within and between studies” in order to give it a reasonable structure. Especially in a narrative synthesis approach is it of high importance to assess critically the robustness of the synthesis. Therefore, it has been decided to integrate the section “Reflecting critically on the synthesis process” and “Asssessing the robustness of the synthesis” in order to demonstrate its limitations, followed by the “Discussion” part. Finally, the aim of this SR is to determine the effects of sensorimotor feedback training on CLBP and to draw a conclusion and possible implications for both practice and research.

Figure 1 shows the detailed framework that has been chosen for the present SR.

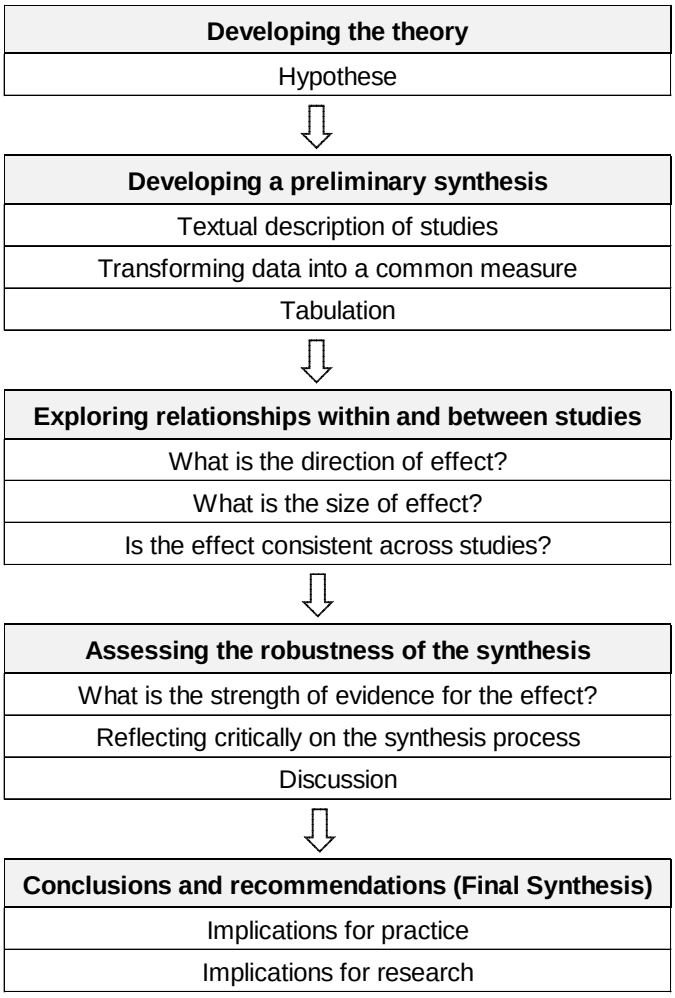

Figure 1: Detailed framework chosen for the present SR.

2.3.1 Minimal clinically important differences of the outcome measures

As there are different outcome measures to rate pain and function, these were scaled for each outcome measure from 0 to 100 units as proposed by Hayden, van Tulder, Malmivaara and Koes (2005). Based on the current literature on Minimal clinically important differences (MCID), we considered that an 20-unit (/100) improvement in pain (Salaffi, Stancati, Silvestri, Ciapetti and Grassi, 2004 and Ostelo, Deyo, Stratford, Waddell, Croft, Von Korff, Bouter and de Vet, 2008) and a 10-unit (/100) improvement in functioning (Bombardier, Hayden and Beaton, 2001, Ostelo et al., 2008)) should be considered as the limit (minimal change).

3 Results

3.1 Flow diagram

The search revealed 28 findings of which 18 have been excluded on the base of records. The 10 remaining studies have been screened in full text and 4 were excluded based on our criteria. Reasons of exclusion are given in the appendix II. Therefore, 6 studies are included in this SR. One study (Vetrano et al., 2013) included two groups, which have received SFT, and the control group was therefore an intervention group in this SR. The groups of the other 5 studies have been integrated originally.

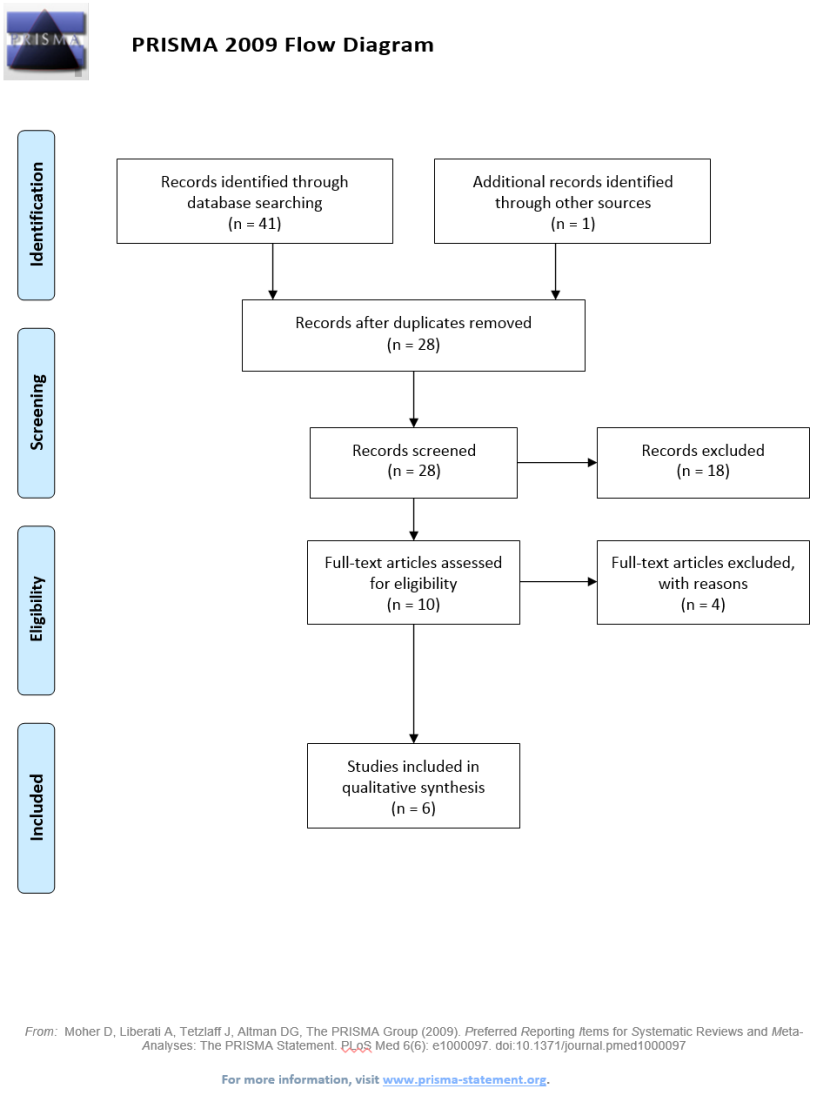

Figure 2: Flow diagram

3.2 Preliminary synthesis

3.2.1 Textual description of studies

Barker et al. (2008)

Methods	- Single-blinded, randomised controlled, non-inferiority trial - Setting: Physiotherapy Department at the Nuffield Orthopaedic Centre NHS, Oxford, United Kingdom - Informed consent: yes - Ethics approval: yes
Participants	60 patients have been recruited, referred to a Physiotherapy Department with the a diagnosis of CLBP **Inclusion criteria:** - >18 years - diagnosed CLPB lasting for a minimum of 3 months **Exclusion criteria:** - patients with leg pain - current transcutaneous electrical nerve stimulation (TENS) users - patients which might be harmed by either of the treatment modalities (This was based on the warnings and precautions for the use of TENS, namely patients with a pacemaker, damaged or broken skin, malignancy, poorly enervated areas and spinal infection.) It was not mentioned for all the inclusion criteria whether they were met or not (f.ex. surgery)
Interventions	**1) FairMed (intervention group)** The FairMed device has been used for this group. This device consists of two components: a hand held controller as subject interface and an array including 16 vibrating stimulation points which can be placed on the lumbar spine. These vibrating points can be activated separately and the user than interacts with the controller indicating which point has been stimulated. The device than responds whether the answer is correct or incorrect (it is not mentioned whether the point is stimulated again if the answer is incorrect). Patients have been instructed to use the device for 30-minutes-sessions. **2) TENS (control group)** For the TENS group, a portable TENS TPN 200 PLUS unit has been used, applying conventional TENS with parameters of 80 Hz and 100 µs. Patients were suggested to use the TENS as much and as often as required. There have been placed two surface electrodes (5cm × 5cm) at a distance of 5cm – 20cm to the painful area. The intensity has been adjusted in order to produce a tingling sensation, which would be approximately 2 – 3 times the sensory threshold. **Duration:** Intervention group: sessions of 30 minutes (not mentioned how often) / 3 weeks Control group: as often as required / 3 weeks
Outcomes	1) Pain: VAS (0 – 100mm) 2) Function: Oswestry disability index (ODI), (0-100) Levels of pain and function were assessed pre and post treatment **Analysis:** Levels of pain and function have been assessed at baseline and after 3 weeks, 6 weeks and 12 weeks (results after 6 and 12 weeks are not noted, neither mentioned in the result part).
Notes	- Funding: not reported

Hohmann et al. (2012)

Methods	- Randomised controlled pilot study - Setting: Department of Complementary and Integrative Medicine, Kliniken Essen-Mitte, Essen, Germany - Informed consent: yes - Ethics approval: not mentioned
Participants	42 participants were recruited using flyers and announcement on the institutional homepage. **Inclusion criteria:** - 18 – 75 years - CLBP for at least three consecutive months **Exclusion criteria:** - radicular pain - neurological symptoms suggesting a disc prolapse - vertebral column surgery less than 12 months prior to the study - chiropractic manoeuvre or infiltration at the area treated 4 weeks prior to the inclusion in the study - congenital deformation of the spine - insulin-dependent diabetes mellitus - dermatological diseases or skin changes at the treated area - Severe mental illness that required medication - a known tendency for haemorrhages - current anticoagulation or corticosteroid medication. It was not mentioned for all the inclusion criteria whether they were met or not (f.ex. pregnancy)
Interventions	**1) Intervention group:** The intervention consisted in a home training with a mechanical needle stimulation pad. This is a plastic mat consisting of 60 hexagonal discs, with 19 spikes each (see study for details). The participants were instructed to use this device daily at home during 14 days. Procedure: The patients had to press both feet on the above-described mat for 10 minutes while sitting on a chair (no detailed procedure). Afterwards it was recommended to put the needle stimulation pad on a soft surface, f.ex.the bed, and lie on the top of it with the uncovered painful part of the back. The participants were informed that the first 2 to 5 minutes could be painful and it was recommended to treat the painful area of the back for about 30 minutes (no detailed procedure). **2) Waiting list control group:** Received no therapy (no details available) They received the intervention too after having participated to this study (not documented). **Duration:** Daily treatment of 30 minutes was recommended / 14 days
Outcomes	1) Pain: NRS (0-10) 2) Function: ODI (0-100) 3) Mechanical detection threshold (not included in this SR) 4) Pressure pain threshold (not included in this SR) 5) Vibration detection threshold (not included in this SR) **Analysis:** The assessments were taken after the intervention had finished (14 days after the baseline assessment).
Notes	- Funding: supported by the Karl and Veronica Carstens Foundation Product information: Zhencidian pad, CMP Chinese Medical Products Trading GmbH, Austria

Morone et al. (2011)

Methods	- Randomised clinical study - Setting: outpatient academic hospital in Rome, Italy - Informed consent: yes - Ethics approval: yes
Participants	75 patients of an academic hospital have been recruited. **Inclusion criteria:** - 18 – 75 years - CLBP persisting for at least three months **Exclusion criteria:** - Acute LBP - pain due to a specific cause (e.g. fracture, spondylolisthesis, disc herniation and lumbar stenosis), scheduled back surgery, severe cognitive impairments, pregnancy, presence of concomitant rheumatologically, neurological, psychiatric, cardiological, respiratory, oncological diseases that could affect spine function or alter the perception of pain. It was not mentioned for all the inclusion criteria whether they were met or not (f.ex. surgery)
Interventions	**1) Surface perceptive group (intervention group)** The "Surface for Perceptive Rehabilitation" was developed as a therapeutic system with small latex cones which are fixed on a support surface. These cones, normally 100 are used; vary in dimension (height 3-8 cm, base diameter 2-4cm) and elasticity (capacity to change in volume from 20% up to 60%). They have been put in standardized order according to previous studies (unspecified) for the first session. The participants were lying supine on this cone surface which stimulated the body. After the first session the hyperaemia areas were documented and then the cone surface for the next session was adapted in order to get an improved symmetry between back and surface (not explained in detail). In the following sessions the patient underwent cognitive-perceptive rehabilitation to interact actively with the cone surface (training explained but not in details). Normally, a session lasted 45 minutes and began with relaxation (not written how long), then the patient performed active exercises, consisting of tactile and proprioceptive tasks with increasing difficulty. The exercises are listed in the study, but it is not mentioned in which order and dose they have been applied and according to which criteria the difficulty was increasing. **2) Back school program group (control group 1)** The Back school program group has been treated by an intensive intervention comprising theory lessons including anatomical, psychological and ergonomical knowledge. Pamphlets covering these topics as well as information for daily life, for example suggesting the correct posture at work, have been handed out. Nine session focused on exercises of breathing, stretching of trunk muscles, erector spine and abdominal reinforcement and postural exercises. The treatment is referenced to be based on *the Back schools for nonspecific low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group* (Heymans, van Tulder, Esmail, 2005), but the treatment is not explained in detail. **3) group with medical and pharmacological assistance only (control group 2)** The participants of the control group 2 received only medical and pharmacological assistance (as the other two groups) such as analgesics, miorelaxants and nonsteroidal anti-inflammatory drugs. **Duration:** Intervention group: 3 session (45 minutes) per week during 1 month Control group 1: 3 sessions per week during 4 weeks (approximately the same treatment duration as for the intervention group) Control group 2: no treatment
Outcomes	1) VAS (0-100mm) 2) McGill Pain Questionnaire (0-100) 3) ODI (0-100) 4) Waddell Disability Index (0-9) All measurements were recorded before treatment, at the end of the treatment, 12 and 24 weeks after. **Analysis:** Levels of pain and function have been assessed at baseline, post-treatment, after 12 weeks and after 24 weeks.
Notes	- Funding: received no specific grant from any funding scheme

Paolucci et al. (2012)

Methods	- RCT - Setting: academic hospital in Rome, Italy - Informed consent: yes - Ethics approval: yes
Participants	30 patients of an academic hospital have been recruited. Recruitment: not reported **Inclusion criteria:** - 18-75 years - diagnosed CLBP (back pain without any specific cause that lasts longer than 12 weeks) **Exclusion criteria:** - Acute LBP - pain due to a specific cause (e.g. fracture, spondylolisthesis, disc herniation and lumbar stenosis), scheduled back surgery, severe cognitive impairments, pregnancy; presence of concomitant rheumatological, neurological, psychiatric, cardiological, respiratory or oncological diseases that could affect spine function or alter the perception of pain. It was not mentioned for all the inclusion criteria whether they were met or not (f.ex. surgery, inclusion/exclusion for healthy control group)
Interventions	**1) Standard surface for perceptive rehabilitation (Su-Per) treatment** Same as Morone et al. (2011) **2) Back school group** Same as control group in Morone et al. (2011) **3) Healthy individuals as control group received no treatment** No intervention (not included in the SR) **Duration:** Intervention group: 3 sessions (45 minutes) per week during 1 month Control group: 3 sessions (45 minutes) per week during 1 month (approximately the same treatment duration as for the intervention group)
Outcomes	1) Stabilometric assessment (not integrated in this SR) 2) McGill Pain Questionnaire (range not mentioned. Pain rating index: 0 – 100) **Analysis:** Levels of pain have been assessed at baseline and at the end of the treatment.
Notes	- Funding: not reported

Ryan et al. (2014)

Methods	- pilot randomised controlled trial - Setting: NHS physiotherapy outpatient department within a UK hospital -Informed consent: yes -ethic approval: yes
Participants	Study invitations were sent to all potentially suitable individuals with CLBP (via mail) 24 patients have been recruited **Inclusion criteria:** - ≥ 18 years - pain duration ≥ 6 months - CLBP ≥6 months with/without leg pain **Exclusion criteria:** - not having an informal carer to assist the home training program - being unable to read English: therefore isolated persons and those not understanding English are not covered in this study It was not mentioned for all the inclusion criteria whether they were met or not (f.ex. surgery, pregnancy)
Interventions	The intervention- and the control group received three sessions (stimulation or acuity training) with a physiotherapist and followed their home training program with an informal carer. In addition, both groups had usual care physiotherapy (not reported in detail). **1) Tactile acuity training intervention (intervention group)** The Tactile acuity training intervention comprised two components: 3 blocks of 24 stimuli have been performed over approximately 24 minutes. a) Tactile acuity training: This training consisted of marking five or ten sites of the painful area which then have been randomly stimulated by a big or a small probe. The participant had to concentrate on the stimulus and tell which of the points was stimulated and which probe was used. If > 90% of the answers were correct, the marks were moved 10% closer to make the task more difficult. The same program was performed at home as part of the home training program. b) Graphaesthesia acuity training: Graphaesthesia acuity training consisted of a series of 60 letters of the alphabet which have been traced on the painful area by the clinician or the carer. They were about 1 inch high. The patient had to identify the letter and was given guided feedback. He or she was informed whether his/her answer was correct and if not, the letter was retraced and the patient was informed about the correct answer. **2) Tactile stimulation (sham group)** The placebo group (sham) received the same tactile stimulation as the intervention group, but they did not focus on the stimulus and therefore had no interaction with the carer. For the first treatment of the patient, the carer was invited to participate as well, in order to be taught about his role. The aim was that every patient received a total of 21 sessions of therapy, of which 3 sessions (intervention or placebo) were provided by the physiotherapist. Follow-up: is recorded. The intervention group lost 3 participants, Placebo lost 6 participants, which is quite a lot out of 24. **Duration:** Minimal duration: 21 days (21 sessions) Maximal duration: decided by the clinician providing the usual care
Outcomes	1) Pain: VAS (0 – 100mm) 2) Function: Rolland Morris disability index (RMDQ), (0 – 24) Levels of pain and function were assessed pre- and post-treatment **Analysis:** Levels of pain and function have been assessed at baseline and post-treatment.
Notes	- Funding: not reported In the tactile stimulation (sham) group, 6 patients were lost (for several reasons), which is half of this group's test persons, considering the group size of n=12.

Vetrano et al. (2013)

Methods	- Single-blind, RCT - Setting: outpatient academic hospital in Rome, Italy - Informed consent: yes - Ethics approval: yes
Participants	24 patients have been recruited with CLBP The recruited patients have consulted one the participating physicians from January to July 2011. **Inclusion criteria:** - 25-70 years - Established diagnosis of CLPB not attributable to a recognizable, known specific pathology (e.g. infection, neoplasisa, osteoporosis, fracture, structural deformity, inflammatory disorder – e.g. ankylosing spondylitis – radicular syndrome or cauda equina syndrome) for at least 12 weeks before the treatment - capable of completing questionnaires and of giving informed consent - a "wash-out" period of 12 weeks was required between any non-operative therapy and the inclusion in the study **Exclusion criteria:** - History of surgery on the spine and/or abdominal surgery, abdominal aortic aneurysm, presence of herniated lumbar disc, spondylosthesis, spinal stenosis, serious and severe scoliosis or kyphosis, previous osteoporotic fractures based, cancers, systematic rheumatic, cardiological, respiratory and neurological diseases, pregnancy and diagnosis of psychiatric disorders
Interventions	**1) Standard Su-Per treatment (intervention group 1)** Same as Morone et al. (2011) except for the duration which is 5min less per session. **2) Su-Per treatment without higher stimulus at the interspinous line (Intervention group 2 / control group)** Same as Group 1, but also more deformable cones in the midline. **Duration:** Intervention group: 3 session (40 minutes) per week during 1 month Control group: received the same dose of therapy as the intervention group.
Outcomes	1) Pain: VAS (0 – 100mm) 2) McGill Pain Questionnaire 3) ODI (0-100) All measurements were recorded before treatment, at the end of the treatment, 4 and 12 weeks after. **Analysis:** Levels of pain and function have been assessed at baseline, post-treatment, after 4 weeks and after 12 weeks.
Notes	- Funding: not reported

3.2.2 Methodological quality assessment (Risk of Bias)

PEDro scale	Barker et al. (2008)	Hohmann et al. (2012)	Morone et al. (2011)	Paolucci et al. (2012)	Ryan et al. (2014)	Vetrano et al. (2013)
Eligibility criteria specified	Yes	Yes	Yes	Yes	Yes	Yes
Random allocation	Yes	Yes	Yes	Yes	Yes	Yes
Concealed allocation	Yes	Yes	Yes	No	Yes	Yes
Similar groups at baseline	Yes	Yes	Yes	No	Yes	Yes
Blinding of subjects	No	No	No	No	No	No
Blinding of therapists	No	No	No	No	No	No
Blinding of assessors	Yes	No	Yes	No	No	Yes
Measure of one key outcome obtained for 85% of subjects	Yes	Yes	Yes	No	Yes	Yes
Intention-to-treat analysis	Yes	Yes	Yes	No	No	Yes
Between-group comparisons of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Point and variability measures of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Score	8	7	8	3	6	8

Table 1: PEDro scale

The methodological quality assessment revealed that all studies except Paolucci et al. (2012) have more than 5/10 points and are therefore ranged between moderate and high quality.

3.2.3 Clinical relevance

Clinical relevance assessment						
Studies	Patients	Inter-ventions	Relevant outcomes	Size of effect	Benefits and harms	Facts influencing the clinical relevance
Barker et al. (2008)	Y	N	N	N	Y	Patients: Surgery has not been an exclusion criteria and is not documented. Intervention is poorly described. Results 6 weeks and 12 weeks post-treatment are not integrated.
Hohmann et al. (2012)	N	N	Y	N	Y	Patients: Pregnancy has not been an exclusion criteria and is not documented, although 15 patients out of 21 were women. Intervention is poorly described.
Morone et al. (2011)	Y	Y	Y	Y	Y	Patients: Surgery has not been an exclusion criteria and is not documented.
Paolucci et al. (2012)	Y	Y	N	N	Y	Patients: Surgery has not been an exclusion criteria and is not documented. Function has not been measured in this study.
Ryan et al. (2014)	N	Y	Y	N	Y	Patients: Surgery and pregnancy have not been exclusion criteria and are not documented. In addition the ratio men / women is not documented.
Vetrano et al. (2013)	Y	Y	Y	Y	Y	All the inclusion / exclusion criteria have been met but there has been remarkably more women included in this study than men (see figure 5). Intervention 2 (Control group) received also a sensory feedback training.

Table 2: Clinical relevance assessment

The clinical relevance has revealed that there are some criteria, like surgery or pregnancy, which have not been specified enough to decide whether the patients in this SR are fully comparable to those that are seen in daily practice. There is a big variety about how the intervention took place and how the setting was in detail, which would limit the applicability of two treatments of the intervention groups (Barker et al., 2008 and Hohmann et al., 2012). For this SR, pain and function have been determined as clinically relevant outcomes, which have been poorly reported in Barker et al. (2008) for the post-treatment part. In the study of Paolucci et al. (2012)

function has not been measured at all. The size of the effect has been judged by the MCID for both pain and function and is shown in detail in table 4. No intervention of the included studies has potential harms for the treated persons. SFT such as the Su-Per treatment (Morone et al. (2011), Paolucci et al. (2012) and Vetrano et al. (2013)) require special equipment (costs not reported).

3.2.4 Transforming data into a common measure

The data of pain and function of the included studies have been transformed into a common measure, as mentioned in the method part. A table of the raw data can be found in appendix IV.

3.2.5 Study design, outcome measures and subgrouping

The following 3 tables give an overview of the results, with table 3 focusing on the study designs and the subjects. Table 4 provides the results at the outcomes of each study and shows the between-groups comparisons. In order to get an overview of all the groups included in this SR, table 5 completes this tabulation part by subgrouping them.

Study designs and subjects								
Study	Intervention groups program	n	m/w	age mean (SD)	Control groups program	n	m/w	age mean (SD)
Barker et al. (2008)	Fairmed	32	16 / 16	52.7 (10.7)	Tens	28	14 / 14	54.1 (12.5)
Hohmann et al. (2012)	Needle stimulation pad	21	6 / 15	47.0 (10.9)	Waiting list control group	21	7 / 14	64.5 (10.6)
Moronoe et al. (2011)	Su-Per treatment	25	4 / 21	52.7 (17.6)	Control group 1: Backschool program	25	9 / 16	55.4 (13.7)
					Control group 2: Waiting list control	25	9 / 16	57.9 (12.8)
Paolucci et al. (2012)	Su-Per treatment	15	-	55.5 (16.4)	Control group 1: Backschool program	15	-	62.1 (10.6)
					Control group 2: Healthy controls (no intervention)	15	-	59 (7.6)
Ryan et al. (2014)	Tactile acquity training	9	-	45 (17)	Sham group: tactile stimulation	6	-	46 (14)
Vetrano et al. (2013)	Su-Per treatment	10	2 / 8	52.6 (10.5)	In this systematic review, the control group is an intervention group			
	Su-Per treatment without higher Stimulation	10	3 / 7	52.2 (16.2)				

Legend: m/w = men / women, n = number of participants, SD = Standard Deviation,

Table 3: Study designs and subjects

Table 4: Outcomes and comparisons

Outcomes and comparisons

study	groups	pre		post		4 weeks post		12 weeks post		24 weeks post		change pre / post		between-group comparisons pre / post	
		pain	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**
		Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (SD) units	Mean (CI) units	Mean (CI) units		
Barker et al. (2008)	Intervention group Control group	63 (19) 66 (14)	40.8 (15.9) 42.8 (14.8)	55 (18) 59 (14)	40.2 (8.7) 41.9 (5.1)	-	-	-	-	-	-	- 8 (-15 to -1) - 7 (-13 to -1)	- 0.6 (-3.8 to 2.7) - 0.9 (-3.0 to 1.1)	1 unit difference not significant p = 0.83 *	- 0.3 units difference not significant p = 0.85 *
Hohmann et al. (2012)	Intervention group Control group	50 (23) 49 (19)	22.8 (14.5) 25.0 (13.9)	32 (22) 54 (19)	18.8 (14.6) 19.9 (10.9)	-	-	-	-	-	-	- 18 (*+) - 5 (*+)	- 4.0 (*+) - 5.1 (*+)	13 units difference **significant** CI: -23 (-32 to -13) p = <0.001	- 1.1 units difference not significant CI: 0.4 (-4.8 t 5.6) p = 0.878
Morone et al. (2011)	Intervention group Control group 1 Control group 2	60 (10) 70 (20) 70 (20)	34 (20) 26 (24) 24 (20)	40 (20) 60 (40) 80 (10)	16 (16) 16 (18) 22 (24)	-	-	50 (10) 50 (40) 80 (10)	16 (12) 12 (16) 26 (20)	50 (40) 40 (40) 70 (30)	20 (19) 10 (12) 26 (18)	**- 20 (*+)** - 10 (*+) - 10 (*+)	**- 18 (*+)** **- 10 (*+)** - 2 (*+)	10 units difference **significant** p = <0.001 * (Intervention group compared with control group 1 and control group 2)	8 / 16 units difference not significant p = 0.403 * (Intervention group compared with control group 1 and control group 2)
Paolucci et al. (2012)	Intervention group Control group	40 (15) 51 (32)	-	23 (14) 32 (13)	-	-	-	-	-	-	-	- 17 (*+) - 19 (*+)	-	- 2 units difference not significant p = 0.436 *	not measurable
Ryan et al. (2014)	Intervention group Control group	49 (19) 48 (31)	38.8 (27.5) 30.4 (12.9)	40.9 (27.8) 15.2 (14.5)	31.7 (31.7) 13.8 (14.1)	-	-	-	-	-	-	- 8.1 (*+) **- 32.8 (*+)**	- 7.1 (*+) **- 16.6 (*+)**	- 24.8 units difference not significant CI: 25.6 (-0.7 to 51.9) p = 0.056	- 9.5 units difference not significant CI: 2.2 (-1.6 to 6.0) p = 0.237
Vetrano et al. (2013)	Intervention group 1 Intervention group 2	75 (21) 50 (30)	28 (14.5) 24 (16)	50 (35) 30 (20)	12 (11) 10 (8)	40 (35) 30 (15)	12 (9) 10 (8)	20 (55) 20 (20)	7 (13.5) 4 (11)	-	-	**- 25 (*, p = 0.002)** **- 20 (*, p = <0.001)**	**- 16 (*, p = 0.003)** **- 14 (*, p = <0.003)**	5 units differnce not significant p = 0.179 *	2 units difference not significant p = 0.299 *

Legend: SD = Standard Deviation; p = p-value; CI = Confidence Intervall, * = no CI available, + = no p-value available, in bold print = fulfils the requirements of the MCID of this SR
Results of Ryan et al. (2014) have been calculated by the reviewer with the raw data.
All the data in this table have been transformed into common measure as mentioned in the method part.

Subgrouping				
sensory feedback training	**sensory feedback training added to another intervention**	**another intervention**	**sham**	**no treatment**
FairMed (Barker et al.)	no group	TENS (Barker et al.)	sham tactile acuity training (Ryan et al.)	Waiting list control group (Hohmann et al.)
Needle stimulation Pad (Hohmann et al.)		Back school program (Morone et al.)		Waiting list control group (Morone et al.)
Su-Per treatment (Morone et al.)		Back school program (Paolucci et al.)		
Su-Per treatment (Paolucci et al.)				
Tactile acuity training (Ryan et al.)				
Su-Per treatment (Vetrano et al.)				
without higher stimulus (Vetrano et al.)				

Table 5: Subgrouping of the included groups

The assessment tools for the outcome “self-reported pain intensity” which have been taken by the included studies are the VAS, NRS and the pain rating index (PRI), for details see appendix IV.

The primary outcome measure, based on the section symptom (Deyo et al, 1998), was self-reported pain intensity. As there are different types of tools, such as the visual analogue scale (VAS) or the numerical rating scale (NRS), in order to measure these outcomes, there was only one restriction imposed: the method must have been validated. The secondary outcome is deduced from the section of daily functioning (Deyo et al. 1998) and more generally summarized in function. It can be documented by any tool that has been validated and focuses on physical functioning.

3.3 Relationships within and between the studies

The search revealed just two studies with long-term (4, 12 and 24 weeks post-treatment) results of the outcomes and in one of the two, the intervention group received SFT. Therefore, the analysis in this SR focuses on the short-term effects (pre-post intervention).

3.3.1 Direction of the effect

Every intervention group shows a decrease in pain and less limitation in function. In the control groups (the one of Vetrano et al. (2013) excluded, as it is also a SFT) there is no consistent effect on pain. However, there has also been observed a decreasing effect concerning the limitation in function.

3.3.2 Size of the effect

The size of the effect varies between -25 and -8 units for pain and between -16 and -0.6 units for limitation in function, including all the groups of SFT. Three groups out of the seven that apply SFT do meet the criteria of a decrease of 20 units as MCID for pain.

Regarding the limit of 10 units set for MCID in function, there are three groups out of the seven that apply SFT which do meet our criteria.

3.3.2.1 Sensory feedback training versus no treatment

The two waiting list control groups are the only groups which have worsening values, with an increase in pain and on the level of function an improvement that is below the MCID. Their corresponding intervention groups show significant improvement in pain (Hohmann et al., pain, -23; 95% CI, -32 to -13, Morone et al., pain, p= <0.001) but not in function. However, just one intervention group fulfils the MCID.

3.3.2.2 Sensory feedback training versus sham therapy

Only one group received sham therapy, which has shown a decrease of about 32.8 units in pain and 16.6 in function, that are the highest values of all the included groups in this SR. This group has therefore been superior to its intervention group, which has been treated by a SFT (tactile acuity training), but there is no significant difference between the groups. In addition, the sham therapy group (n=6) and the sensory feedback group (n=9) were very small. It is important to mention that the content of the program for the group receiving sham therapy was the same as for the intervention group, except the fact that they were not asked to focus on the stimuli.

3.3.2.3 Sensory feedback training versus another intervention

Three groups have applied other interventions: one using TENS and the other two were back school programs. None of these groups met the criteria of the MCID for

pain, but one of the back school programs (Morone et al.) did in regard to function. Compared with the matching intervention group, in the study of Morone et al. has been observed one significant difference on the level of pain (p= <0.001). However, for the parameter function there has not been observed any significant difference within the three studies. In the long-term follow up, there is no significant difference between the groups. However, the results show that the back school group continues to improve in pain after the treatment and shows a MCID between post-treatment and 24 weeks after (not statistically tested in that study). On the level of function, it is difficult to compare the groups because the baseline of the intervention group was more disabled (although not significant, but a difference of 8 points). The intervention group and the back school program continue to have MCID compared to the baseline. After 24 weeks, the intervention group is more disabled whereas the back school program tends to improve (not significate) compared to post-treatment.

3.3.2.4 SFT versus SFT added to another intervention

There is no comparison possible because we did not find any RCT for this comparison.

3.4 Robustness of the synthesis

3.4.1 Strength of evidence for the effect

The strength of evidence for the findings has been judged using the *Levels of Evidence for Therapeutic Studies* (Burns, Rohrich, Chung, 2011). According to this classification, the strength of evidence of this SR is rated as 1B, which is the second highest level and requiring the criteria to include individual RCT.

It should be taken into account that the quality of the RCT is of great importance in order to get a more comprehensive strength of evidence. Of the 6 included studies, 5 are ranged of moderate to high quality (see results).

3.5 Reflecting critically on the synthesis process

Not all the directives of *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins et al., 2008) have been integrated into this SR, due to time restrictions and an understaffed review team. Nevertheless, the four most important contents have been integrated and form the general framework (see method) in order to give the analysis a scientific and structured approach.

The literature search has been restricted to four databases (MEDLINE, PubMed, cinahl and Embase) and was narrowed on English and German literature. We have not excluded any studies because of the language but this search strategy without searching on other databases might have led to the exclusion of important findings and therefore to language bias.

Although a definition of SFT has been implemented and the keywords for the search have been defined as precise as possible, it cannot be guaranteed that all the studies addressing SFT were included.

The inclusion and exclusion criteria vary considerably from study to study. In Vetrano et al. (2013), all the criteria have been integrated into the recruiting process of the participants, whereas in the other studies, the criteria surgery and/or pregnancy have not been documented (even though some studies do have integrated more female than male participants, see figure 5). These leaks of knowledge do increase the risk of Bias. Another point that needs to be mentioned is the determination of the exclusion criteria of having had a spinal surgery in the last 12 months and the critical analysis whether this timeframe is long enough to wash out possible bias.

The inclusion criteria “chronic pain in the low back” has not been specified, as there exist various definitions (Waddell, 2004). Nevertheless, a comparison of the definitions of each study revealed that all of them do meet the minimal duration of pain which has been defined to be at least 3 months (Waddell, 2004).

The included studies have been rated by the PEDro scale, which is a common tool in physiotherapy, but the recommended cut-off, which was set by 5/10 (Moseley et al., 2002), has not been validated and therefore a lack of validation.

In order to assess the measuring methods of the different studies included, the various assessments have been verified about their quality criteria. The assessment for documenting the outcome pain, which are VAS, NRS and PRI (scaled as VAS), are recommended for use in diagnosis and follow-up (Oesch, Hilfiker, Keller, Kool, Schädler, Tal-Akabi, Verra and Widmer Leu, 2006). For the second outcome in this SR, ODI and RMDQ have been taken as assessment tools, which have also been judged to be recommended for diagnosis and follow-up (Oesch et al., 2006).

The measurement tools for the two outcome measures varied among the studies and were finally all scaled in units (0 -100) in order to make them comparable. This is a common approach (Jacek and Kopec, 2000), but it has to be kept in mind that comparisons are not always based on the same tools.

Due to the heterogeneity of the included studies, no meta-analysis could be conducted and the narrative synthesis process that was chosen did not allow to making quantitative comparisons between the studies and limits, in order to get summarized results for the effects. On one hand, this leads to less biased results, but on the other hand to no estimation of a generalized effect is possible.

Another point which should be critically reflected is the integration of the *Levels of Evidence for Therapeutic Studies* (Burns et al., 2011), which evaluates the level of evidence only by the type of study but does not integrate the risk of bias and other criteria which would have been covered in greater detail by *the GRADE (*Grades of Recommendation, Assessment, Development and Evaluation Group) *approach* (Higgins et al., 2008). This approach is a very demanding process and has therefore not been applied in this SR.

4 Discussion

The aim of this SR was to determine what kind of effects of the SFT on CLBP can be measured concerning the outcomes pain and function. The collected data of the six included studies suggest that there is no conclusive evidence about the effectiveness of SFT in patients with CLBP. All the SFT included in this SR did report a reduction in pain and function but they were not consistent, because some were either not significant in comparison to the control group or even inferior to them and therefore conflicting to draw a conclusive recommendation for the short-term effect. It is also impossible to conclude something about the long-term effect of SFT. There is only one study covering this topic and the non-significant results are not in favour of the SFT.

In addition, study limitations make firmer conclusions unsafe. Various risks of bias have been detected in the PEDro analysis, whereas two categories of the list, namely the blinding of the subjects and the therapists, have not been achieved in any of the included studies. The opinion of the raters about the risk of bias did not always meet the appraisal of the PEDro criteria e.g. in Morone et al. (2011) the random allocation is poorly described, but following the PEDro guideline, it is specified well enough in order to give it the point. The sham therapy applied to the control group in Ryan et al. (2014) is fully in consent with the PEDro scale, but as it is controversial, the following section gives reasons why no point has be given. The patients received a sham tactile stimulation, which, according to the definition of this SR, is no SFT, because of the absence of perceptive interaction with the stimulus. However, the expectation of the patient being treated with stimuli on the back could lead to the impression that he/she is allocated to the intervention group. Hypothetically, it could also be expected that the patient focus on the stimuli even if they are not instructed to do so and in this case it would become a SFT. Alternatively the control group program could consist of physical activity or no treatment.

The search process revealed that there are not many studies covering the topic of SFT. In addition, all the included studies recruited only small groups of test persons, the smallest with about 6 participants and the biggest with about 32.

In the clinical relevance assessment it was mentioned that the Su-Per treatment (applied in four of the intervention groups) does require special equipment whose price is not reported but which surely means a special investment for the therapist and will not be applicable for the patient at home. This increases the dependency of the patient towards the therapist or an assistant person and does not allow the treatment to be integrated easily into the daily life, as it complicates the practicability.

Another risk of bias that needs to be mentioned is that the authors Barker et al. (2008) might benefit financially if the FairMed device would ever be marketed. This has been declared in their study. One of the three studies focusing on the Su-Per treatment mentions not to have received any financial support of any funding, but in none of the studies it is mentioned whether they would benefit financially in case the device would be marketed. The study focusing on the needle stimulation pad does not declare either whether there are any competing interests.

SFT is a very broad term which covers a lot of different therapies, such as all those that are mentioned in this SR. Therefore, comparisons between the studies are very difficult: first of all, the duration of the sessions and the treatments varied widely and were not always reported in detail. Second, a great heterogeneity about the type of intervention has been observed which ranged from self-dependent or with the help of a formal or informal carer up to a fully applied treatment by a health professional. Third, there were big differences in the level of activity during the different treatments as well, covering the whole spectrum from no integration of activity (needle stimulation pad) to SFT combined with physical activities (Su-Per treatment). And last but not least, each study had a different starting position and applied its own tools for the therapies.

In the majority of the studies, the patient lied on the back without visual feedback. Barker et al. (2008) used a prone position with a picture of the patients own back as an additional sensory input. In none of the studies were any discussions why the particular starting position had been chosen. On top of that, it has not been stated in the literature whether the starting positions have an impact on the perception of the low back.

Another issue is the fact that two interventions of SFT (Barker et al. (2008) and Hohmann et al. (2012)) and the TENS group (Barker et al. (2008)) have been applied at the patients' home by themselves. This seems to increase the practicability, because it allows the application of the intervention at home and therefore decreases the dependency towards the therapists. On the other hand, this leads to a reduced verification and quantification of the applied therapy, even stronger if no guidance is given about the frequency of the application.

Other studies, which did not meet the inclusion criteria of this SR, as the one with *Acupuncture applied as a sensory discrimination tool* (Wand et al., 2013), show a greater decrease in pain in applied acupuncture if sensory discrimination is optimised (36 units, SD = 20 units) compared to acupuncture where it is not. (28 units, SD = 25 units). This is a significant result (mean difference = 8 units, 95% CI: -14 to -3, $p = 0.011$) but it is relativised by the fact that the intervention group as well as the control group received both therapies, but in reversed order, and therefore both therapies had an impact in both groups. But still, this leads to the idea that acupuncture may offer a specific benefit if it is combined with sensory discrimination, which is a kind of SFT.

Another excluded study was one that used a single-case design and covered three participants, which used a sensorimotor retraining approach, consisting of a graded sensory and motor retraining (Wand et al., 2011). The decrease of pain (mean difference = 39.2 units, 95% CI: 15.6 to 6.27, $p < 0.001$) and disability (mean difference = 40.25 units, 95% CI: 17.6 to 62.6, $p < 0.001$) has to be interpreted with caution, due to the sample size. Nevertheless, it shows an interesting effect that goes in the same direction as all the sensory feedback groups included in this SR.

5 Conclusions and recommendations

5.1 Implications for practice

There is conflicting evidence from 6 trials (257 people) about whether SFT is more effective than another intervention, no treatment or sham therapy for patients with CLBP without neurological symptoms concerning the outcomes pain and function in the short-term.

Another essential criterion for a therapist to decide whether a treatment can be applied in daily life are the acquisition costs of the necessary materials, which, for example for the Su-Per treatment, are not reported. Furthermore, if the therapy is applied by another person it has to be kept in mind that this could evoke or enlarge the so called *illness behaviour of excessive help* (Waddell, 2004). The patient is then thought to have the tendency to make use of unnecessary assistance.

The tactile acuity training intervention is therefore a better intervention, as it requires only very simple tools, but on the other hand it does not show significant reductions of the two parameters. Related trainings like sensorimotor approaches (Wand et al., 2013) including SFT do show significant results, but have only been studied in case studies.

To sum up, it is too early to give general implications for practice, but SFT could be an interesting component of the management of the physical dysfunctions, which is one of the five factors to be addressed for the management of pain and disability, as described in the introduction.

5.2 Implications for research

The findings in this SR do show a moderate general effect, but in order to investigate this matter further, studies with sufficiently large intervention- and control groups and comprehensive inclusion and exclusion criteria (especially pregnancy) would be necessary. Many women suffer from temporary back pain during their pregnancy, but this seems not to have any lasting effect (Waddell, 2004).

As already mentioned in the discussion, the starting position that was chosen was lying on the back (except Wand et al. (2013) -> prone, and Barker et al. (2008) -> is not mentioned), but has not been evaluated. Therefore, for future research we

recommend to be aware of the starting position in both, the influence on pain and the impact on the results regarding functionality. Hypothetically, the position with the least pain could have the strongest learning effect, as there are less disturbing inputs for the brain. It might also have an influence whether the therapy is combined with visual sensory inputs (illustration of the back and the points stimulated). At the same time, it should be aspired to arrange/design the therapy as easily applicable in daily life as possible, without any gear that would cost too much to purchase. Like this, the patients' self-management can be enforced.

We further recommend a consequent description of the SFT, which enables to make the setting reproducible and more comparable to other interventions, taking into account the vast variety of interventions summed up as SFT. The description of the training should include precise data about the intervention time and the period in which the intervention has been applied. If sham therapy is applied to a control group, it should be critically analysed whether the sham intervention could also be considered as a kind of a SFT.

In a next step, it would be interesting to examine which components of the trainings offer the largest benefit.

In addition, it seems to be reasonable to aspire to make the treatment applicable at home and in daily life, in order to ensure that the patients do not depend on medical stuff and, if possible, not on an assistant person. If the study setting is applied by the patient at home, it should be assured that bias is kept low by giving clear guidance of the performance and quantity of the treatment sessions. Nevertheless, controllability remains difficult.

This SR raises the question whether SFT can change sensory organization in the brain and if yes, how long it might take to observe such a structural reorganization of the sensory cortex in the case of chronic pain. Such findings might explain why short-term effects are not significant.

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Figures

Tables

List of abbreviations

CI	Confidence Interval
CLBP	Chronic low back pain
FairMed	Device to deliver sensory discrimination training
GRADE	Grades of Recommendation, Assessment, Development and Evaluation Group
LBP	Low back pain
MCID	Minimal clinically important difference
NRS	Numerical rating scale
ODI	Oswestry disability index
PEDro	Physiotherapy Evidence Database
PRI	Pain rating index
RCT	Randomised controlled trial
RMDQ	Rolland Morris disability index
SFT	Sensory feedback training
Su-Per	Surface for perceptive rehabilitation
SR	Systematic Review
TENS	Transcutaneous electrical nerve stimulation
VAS	Visual analogue scale

Appendices

Appendix I

MEDLINE search strategy

1 randomized controlled trial (401018)

2 chronic pain (23871)

3 back (151918)

4 low back (25181)

5 lower back (3057)

6 lumbar spine (21239)

7 lumbar column (71)

8 3 or 4 or 5 or 6 or 7 (169419)

9 sensory feedback (1512)

10 sensory training (104)

11 sensory motor training (22)

12 sensory motor feedback (22)

13 feedback training (330)

14 discrimination training (640)

15 tactile stimulation (1689)

16 perceptive rehabilitation (5)

17 tactile discrimination (363)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (31369)

19 1 and 2 and 8 and 17 (5)

PubMed search strategy

1 randomized controlled trial (471989)

2 chronic pain (75690)

3 back (160606)

4 low back (36737)

5 lower back (16472)

6 lumbar spine (57358)

7 lumbar column (2584)

8 3 or 4 or 5 or 6 or 7 (206002)

9 sensory feedback (5351)

10 sensory training (1212)

11 sensory motor training (1764)

12 sensory motor feedback (2342)

13 feedback training (18982)

14 discrimination training (10764)

15 tactile stimulation (4878)

16 perceptive rehabilitation (96)

17 tactile discrimination (1431)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (39350)

19 1 and 2 and 8 and 18 (13)

CINAHL search strategy

1 randomized controlled trial (16325)

2 chronic pain (16369)

3 back (36932)

4 low back (11820)

5 lower back (1201)

6 lumbar spine (3049)

7 lumbar column (33)

8 3 or 4 or 5 or 6 or 7 (39002)

9 sensory feedback (146)

10 sensory training (77)

11 sensory motor training (37)

12 sensory motor feedback (7)

13 feedback training (436)

14 discrimination training (60)

15 tactile stimulation (162)

16 perceptive rehabilitation (4)

17 tactile discrimination (50)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (819)

19 1 and 2 and 8 and 17 (0)

20 randomized clinical study (5476)

21 controlled clinical trial (2353)

22 randomized controlled trials (27569)

23 1 or 19 or 20 or 21 (41234)

24 2 and 8 and 18 and 23 (1)

Embase search strategy

1 randomized controlled trial (459832)

2 chronic pain (127265)

3 back (208622)

4 low back (60577)

5 lower back (23152)

6 lumbar spine (62080)

7 lumbar column (3090)

8 3 or 4 or 5 or 6 or 7 (257475)

9 sensory feedback (2732)

10 sensory training (1799)

11 sensory motor training (2015)

12 sensory motor feedback (2824)

13 feedback training (14630)

14 discrimination training (8122)

15 tactile stimulation (8193)

16 perceptive rehabilitation (755)

17 tactile discrimination (3538)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (37961)

19 1 and 2 and 8 and 18 (22

Findings literature search			Search. 01. 10. 2014								
Nr.	Inclu-ded	Title	Authors	Published	Nr. of inclu-ded studies	Pain	Function	Raison of exclusion	Records excl.	Full-text article excl.	Nr. after dupli-cates removed
		pubmed (13 studies)									
1	Yes	Tactile acuity training for patients with chronic low back pain: a pilot randomised controlled trial.	Ryan C, Harland N., Drew B., Martin D.	2014	1	VAS	Rolland Morris Disability questionnaire				1
2	No	Acupuncture applied as a sensory discrimination training tool decreases movement-related pain in patients with chronic low back pain more than acupuncture alone: a randomised cross-over experiment.	Wand B., Abbaszadeh S., Smith A., Catley M., Moseley G.	2013				study is a randomized cross-over study		Y (1)	2
3	Yes	Perceptive rehabilitation of patients with non-specific chronic low back pain: the role of body midline. A randomized controlled trial.	Vetrano M., Pournajaf S., Vulpiani M., Santoboni F., Paolucci T., Spadini E., Ferretti A., Saraceni VM.	2013	2	VAS McGill pain questionnnaire	Oswestry Disability Index				3
4	Yes	The efficacy of a perceptive rehabilitation on postural control in patients with chronic nonspecific low back pain.	Paolucci T., Fusco A., Iosa M., Grasso M., Spadini E., Paolucci S., Saraceni V., Morone G.	2012	3	VAS McGill pain questionnnaire	Stabilometric Assessment				4
5	Yes	Efficacy of perceptive rehabilitation in the treatment of chronic nonspecific low back pain through a new tool: a randomized clinical study.	Morone G., Iosa M., Paolucci T., Fusco A., Alcuri R., Spadini E., Saraceni V., Paolucci S.	2011	4	VAS McGill pain questionnnaire	Oswestry Disability Index / Waddell Disability Index				5
6	No	Ankles back in randomized controlled trial (ABrCt): braces versus neuromuscular exercises for the secondary prevention of ankle sprains. Design of a randomised controlled trial.	Janssen K., van Mechelen W., Verhagen E.	2011				study about Ankles back - not about back	Y (1)		6
7	No	First non-contingent respiratory biofeedback placebo versus contingent biofeedback in patients with chronic low back pain: a randomized, controlled, double-blind trial.	Kapitza K., Passie T., Bernateck M., Karst M.	2010				respiratory feedback	Y (2)		7
8	No	Two psychological interventions are effective in severely disabled, chronic back pain patients: a randomised controlled trial.	Glombiewski J., Hartwich-Tersek J., Rief W.	2010				Cognitive-behavioural therapy and biofeedback		Y (2)	8
9	No	A walking programme and a supervised exercise class versus usual physiotherapy for chronic low back pain: a single-blinded randomised controlled trial. (The Supervised Walking In comparison to Fitness Training for Back Pain (SWIFT) Trial).	Hurley D., O'Donoghue G., Tully M., Moffett J., van Mechelen W., Daly L., Boreham C., McDonough S.	2009				walking programm		Y (3)	9
10	Yes	Treatment of chronic back pain by sensory discrimination training. A Phase I RCT of a novel device (FairMed) vs. TENS.	Barker K., Elliott C., Sackley C., Fairbank J.	2008	5	VAS	Oswestry Disability Index				10
11	No	Rationale, design, and baseline findings from a randomized trial of collaborative care for chronic musculoskeletal pain in primary care.	Dobscha S., Corson K., Leibowitz R., Sullivan M., Gerrity M.	2008				ongoing study: main study not found	Y (3)		11
12	No	EMG biofeedback training, relaxation training, and placebo for the relief of chronic back pain.	Stuckey S., Jacobs A., Goldfarb J.	1986				no active feedback training	Y (4)		12
13	No	EMG biofeedback used to reduce standing levels of paraspinal muscle tension in chronic low back pain.	Nouwen A.	1983				no active feedback training	Y (5)		13

Findings literature search (continued)											
Nr.	Inclu-ded	Title	Authors	Published	Nr. of inclu-ded studies	Pain	Function	Raison of exclusion	Records excl.	Full-text article excl.	Nr. after dupli-cates removed
		medline (5 studies)									
14	Yes	Perceptive rehabilitation of patients with non-specific chronic low back pain: the role of body midline. A randomized controlled trial.	Vetrano M., Pournajaf S., Vulpiani M., Santoboni F., Paolucci T., Spadini E., Ferretti A., Saraceni V.	2013	2	VAS McGill pain questionnnaire					3
15	Yes	Acupuncture applied as a sensory discrimination training tool decreases movement-related pain in patients with chronic low back pain more than acupuncture alone: a randomised cross-over experiment.	Wand B., Abbaszadeh S., Smith A., Catley M., Moseley G.	2013		NRS	most painful movement direction analysed				2
16	Yes	Efficacy of perceptive rehabilitation in the treatment of chronic nonspecific low back pain through a new tool: a randomized clinical study.	Morone G., Iosa M., Paolucci T., Fusco A., Alcuri R., Spadini E., Saraceni V., Paolucci S.	2011	4	VAS McGill pain questionnnaire					5
17	No	Ankles back in randomized controlled trial (ABrCt): braces versus neuromuscular exercises for the secondary prevention of ankle sprains. Design of a randomised controlled trial.	Janssen K., van Mechelen W., Verhagen E.	2011				study about Ankles back - not about back	Y (1)		6
18	Yes	Treatment of chronic back pain by sensory discrimination training. A Phase I RCT of a novel device (FairMed) vs. TENS.	Barker K., Elliott C., Sackley C., Fairbank J.	2008	5	VAS	Oswestry Disability Index				10
		cinahl (1)									
19	Yes	Efficacy of perceptive rehabilitation in the treatment of chronic nonspecific low back pain through a new tool: a randomized clinical study.	Morone G., Iosa M., Paolucci T., Fusco A., Alcuri R., Spadini E., Saraceni V., Paolucci S.	2011	4	VAS McGill pain questionnnaire	Oswestry Disability Index				5
		via references (1)									
20	Yes	The benefit of a mechanical needle stimulation pad in patients with chronic neck and lower back pain: two randomized controlled pilot studies.	Hohmann C., Ullrich I., Lauche R., Choi K., Ludtke R., Rolke R., Cramer H., Saha F., Rampp T., Michalsen A., Langhorst J., Dobos G., Musial F.	2012	6	NRS	Oswestry Disability Index				14
		Embase (22)									
21	No	A randomized controlled trial of hypnosis compared with biofeedback for adults with chronic low back pain	Tan G., Rintala D., Jensen M., Fukui T., Smith D., Williams W.	2014				poorly described and not "active" (biofeedback controlled group)		Y (4)	15
22	No	Effects of proprioceptive exercises for patients with chronic low back and neck pain: A systematic review	Mccaskey M., Schuster-Amft C., Wenderoth N., De Bruin E.	2014				no full text available because of congress work	Y (6)		16
23	Yes	Tactile acuity training for patients with chronic low back pain: A pilot randomised controlled trial	Ryan C., Harland N., Drew B., Martin D.	2014	1	VAS	Rolland Morris Disability questionnaire				1

Findings literature search (continued)											
Nr.	Inclu-ded	Title	Authors	Published	Nr. of inclu-ded studies	Pain	Function	Raison of exclusion	Records excl.	Full-text article excl.	Nr. after dupli-cates removed
24	No	Mind-body therapies for the self-management of chronic pain symptoms	Lee C., Crawford C., Hickey A., Buckenmaier C., Crawford P., Delgado R., Freilich D., Jonas W., May T., Petri R., Schoomaker E., Spevak C., Swann S., York A.	2014				no RCT not demanded subject	Y (7)		17
25	No	Nonpharmacologic, complementary, and alternative interventions for managing chronic pain in older adults	Hashefi M., Katz J., Reid M.	2013				not the same subje	Y (8)		18
26	Yes	Perceptive rehabilitation of patients with non-specific chronic low back pain: The role of body midline. A randomized controlled trial	Vetrano M., Pournajaf S., Vulpiani M., Santoboni F., Paolucci T., Spadini E., Ferretti A., Saraceni V.	2014	2	VAS McGill pain questionnnaire					3
27	Yes	The efficacy of a perceptive rehabilitation on postural control in patients with chronic nonspecific low back pain.	Paolucci T., Fusco A., Iosa M., Grasso M., Spadini E., Paolucci S., Saraceni V., Morone G.	2012	3	VAS McGill pain questionnnaire					4
28	Yes	Efficacy of perceptive rehabilitation in the treatment of chronic nonspecific low back pain through a new tool: a randomized clinical study.	Morone G., Iosa M., Paolucci T., Fusco A., Alcuri R., Spadini E., Saraceni V., Paolucci S.	2012	4	VAS McGill pain questionnnaire	Oswestry Disability Index				5
29	No	Ankles back in randomized controlled trial (ABrCt): Braces versus neuromuscular exercises for the secondary prevention of ankle sprains. Design of a randomised controlled trial	Janssen K., Van Mechelen W., Verhagen E.	2011				study about Ankles back - not about back	Y (1)		6
30	No	Movement control exercise versus general exercise to reduce disability in patients with low back pain and movement control impairment. A randomised controlled trial	Saner J., Kool J., De Bie R., Sieben J., Luomajoki H.	2011				not the same subject	Y (9)		19
31	No	What are the limits for targets in radiofrequency neurotomy?	Kvarstein G.	2011				not the same subject	Y (10)		20
32	No	First Non-Contingent Respiratory Biofeedback Placebo versus Contingent Biofeedback in Patients with Chronic Low Back Pain: A Randomized, Controlled, Double-Blind Trial	Kapitza K., Passie T., Bernateck M., Karst M.	2010				respiratory feedback	Y (2)		7
33	No	Assessment of a biofeedback program to treat chronic low back pain	Santaella Da Fonseca Lopes De Sousa K., Garcia Orfale A., Mara Meireles S., Roberto Leite J., Natour J.	2009				biofeedback training little part o the whole program	Y (11)		21
34	No	A walking programme and a supervised exercise class versus usual physiotherapy for chronic low back pain: A single-blinded randomised controlled trial. (The Supervised Walking in comparison to Fitness Training for Back Pain (SWIFT) Trial)	Hurley D., O'Donoghue G., Tully M., Moffett J., Van Mechelen W., Daly L., Boreham C., McDonough S.	2009				walking programm		Y (3)	9
35	No	Chronic back pain: What does biofeedback add to cognitive-behavioral treatment? A randomized controlled trial	Trapp K., Glombiewski J., Hartwich-Tersek J., Rief W.	2009				not the same subject	Y (12)		22
36	Yes	Treatment of chronic back pain by sensory discrimination training. A Phase I RCT of a novel device (FairMed) vs. TENS	Barker K., Elliott C., Sackley C., Fairbank J.	2008	5	VAS	Oswestry Disability Index				10

Findings literature search (continued)											
Nr.	Inclu-ded	Title	Authors	Published	Nr. of inclu-ded studies	Pain	Function	Raison of exclusion	Records excl.	Full-text article excl.	Nr. after dupli-cates removed
37	No	Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: A randomized trial	Ferreira M., Ferreira P., Latimer J., Herbert R., Hodges P., Jennings M., Maher C., Refshauge K.	2007				not the same subject	Y (13)		23
38	No	Clinical observation on Mchenzie mechanics principle plus ultrashort wave in treatment of lumbar and leg pain	Si R., Xiong C., Han D., Zhu F., Ning L., Zhang M.	2007				not the same subject	Y (14)		24
39	No	Mind-Body Therapies for the Management of Pain	Astin J.	2004				not the same subject	Y (15)		25
40	No	Radiofrequency lesions for the treatment of spinal pain	Wenger C.	1998				not the same subject	Y (16)		26
41	No	Behavioural rehabilitation of chronic low back pain: Comparison of an operant treatment, an operant- cognitive treatment and an operant-respondent treatment	Vlaeyen J., Haazen I., Schuerman J., Kole-Snijders A., Van Eek H.	1995				not the same subject	Y (17)		27
42	No	Perceived and actual control in EMG treatment of back pain	Biedermann H., McGhie A., Monga T., Shanks G.	1987				not the same subject	Y (18)		28
					n = 6				n = 18	n = 4	n = 28

total studies: n = 42
total studies (excluded doubles): n = 28
total studies excluded n = 22
total studies included n = 6

Appendix III

Methodological quality assessment (Risk of Bias assessment)

Rater 1 (Samuel Kälin)

PEDro scale	Barker et al. (2008)	Hohmann et al. (2012)	Morone et al. (2011)	Paolucci et al. (2012)	Ryan et al. (2014)	Vetrano et al. (2013)
Eligibility criteria specified	Yes	Yes	Yes	Yes	Yes	Yes
Random allocation	Yes	Yes	Yes	Yes	Yes	Yes
Concealed allocation	Yes	Yes	Yes	No	Yes	No
Similar groups at baseline	Yes	Yes	Yes	No	Yes	Yes
Blinding of subjects	No	No	No	No	Yes	Yes
Blinding of therapists	No	No	No	No	No	No
Blinding of assessors	Yes	No	Yes	No	Yes	Yes
Measure of one key outcome obtained for 85% of subjects	Yes	Yes	Yes	No	No	Yes
Intention-to-treat analysis	Yes	Yes	No	Yes	No	Yes
Between-group comparisons of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Point and variability measures of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Score	8	7	7	4	7	8

Rater 2 (Nicolas Siordilis)

PEDro scale	Barker et al. (2008)	Hohmann et al. (2012)	Morone et al. (2011)	Paolucci et al. (2012)	Ryan et al. (2014)	Vetrano et al. (2013)
Eligibility criteria specified	Yes	Yes	Yes	Yes	Yes	Yes
Random allocation	Yes	Yes	No	Yes	Yes	Yes
Concealed allocation	Yes	Yes	Yes	No	Yes	Yes
Similar groups at baseline	Yes	Yes	Yes	No	Yes	Yes
Blinding of subjects	No	No	No	No	No	No
Blinding of therapists	No	No	No	No	No	No
Blinding of assessors	Yes	No	Yes	No	No	Yes
Measure of one key outcome obtained for 85% of subjects	Yes	Yes	Yes	No	Yes	Yes
Intention-to-treat analysis	Yes	Yes	Yes	No	Yes	Yes
Between-group comparisons of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Point and variability measures of at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes
Score	8	7	7	3	7	8

Consensus

Not matching points	Comment
Morone et al. (2011): Random allocation	Random allocation is poorly described; therefore, rater 2 did not give the point. Following the PEDro guideline, the point has to be given.
Morone et al. (2011): Intention-to-treat analysis	Rater 1 criticised that the “Intention-to-treat” has already been mentioned in the method part. Because the intention-to-treat analysis has been carried out, the point has to be given.
Paolucci et al. (2012): Intention-to-treat analysis	No point given, due to the poor description of the drop-out procedure. It is not clear whether all patients have received the planned therapy.
Ryan et al. (2014): Blinding of subjects	The use of tools leads generally to the impression of being in the intervention group, therefore no blinding possible and no point given.
Ryan et al. (2014): Blinding of assessors	Because of the explicit mention of not having blinded the patients, the point has not been given. According to the PEDro guideline, the point could be given.
Ryan et al. (2014): Measure of one key outcome obtained for 85% of subjects	As the outcomes have not been measured at several points in time, the second part of the criteria does not have to be fulfilled. The point has to be given.
Ryan et al. (2014): Intention-to-treat analysis	The intention-to-treat analysis has not been performed in this study. rater 2 has not noticed the comment in the discussion part. The point is not given.
Vetrano et al. (2013): Concealed allocation	Randomisation has been described but not mentioned in detail in the study; rater 1 has not noticed that. That point has to be given.
Vetrano et al. (2013): Blinding of subjects	Blinding is in this kind of study design not feasible, due to the use of a tool that leads generally to the impression of being in the intervention group. Therefore, the point is not given.

Appendix IV

Outcomes: raw data													
		Parameter		pre		post		4 weeks post		12 weeks post		24 weeks post	
study	group	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**	**pain**	**function**
				Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Barker et al. (2008)	Intervention group Control group	VAS (0-10)	ODI (0-100)	6.3 (1.9) 6.6 (1.4)	40.8 (15.9) 42.8 (14.8)	5.5 (1.8) 5.9 (1.4)	40.2 (8.7) 41.9 (5.1)	-	-	-	-	-	-
Hohmann et al. (2012)	Intervention group Control group	NRS (0-10)	ODI (0-100)	5.0 (2.3) 4.9 (1.9)	22.8 (14.5) 25.0 (13.9)	3.2 (2.2) 5.4 (1.9)	18.8 (14.6) 19.9 (10.9)	-	-	-	-	-	-
Morone et al. (2011)	Intervention group Control group 1 Control group 2	VAS (0-10)	ODI (0-100)	6 (1) 7 (2) 7 (2)	34 (20) 26 (24) 24 (20)	4 (2) 6 (4) 8 (1)	16 (16) 16 (18) 22 (24)	-	-	5 (1) 5 (4) 8 (1)	16 (12) 12 (16) 26 (20)	5 (4) 4 (4) 7 (3)	20 (19) 10 (12) 26 (18)
Paolucci et al. (2012)	Intervention group Control group	PRI (0-100)	-	40 (15) 51 (32)	-	23 (14) 32 (13)	-	-	-	-	-	-	-
Ryan et al. (2014)	Intervention group Control group	VAS (0-100)	RMDQ (0-24)	49 (19) 48 (31)	9.3 (6.6) 7.3 (3.1)	40.9 (27.8) 15.2 (14.5)	7.6 (7.6) 3.3 (3.4)	-	-	-	-	-	-
Vetrano et al. (2013)	Intervention group Control group	VAS (0-10)	ODI (0-100)	7.5 (2.1) 5.0 (3.0)	28 (14.5) 24 (16)	5 (3.5) 3 (2)	12 (11) 10 (8)	4 (3.5) 3 (1.5)	12 (9) 10 (8)	2 (5.5) 2 (2)	7 (13.5) 4 (11)	-	-

Legend: SD = Standard Deviation, NRS = Numerical Rating Scale, ODI = Oswestry Disability Index, RMDQ = Rolland Morris Disability Index, PRI = Pain Rating Index, VAS = Visual Analogue Scale
Mean and SD for the post-treatment section has been calculated out of raw data for Ryan et al.

Number of words: 5923

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Eigenständigkeitserklärung

Ich erkläre hiermit, dass ich die vorliegende Arbeit selbständig, ohne Mithilfe Dritter und unter Benutzung der angegebenen Quellen verfasst habe.

24.04.2015 Samuel Kälin