

## Identification and description of controlled clinical trials published in Physiotherapy journals in Spain

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## **Abstract**

**Rationale and objectives** The quantity and quality of research in physiotherapy has increased exponentially during the past decades. However, retrieving publications associated with this field of research is difficult. The aim of this study is to identify and describe controlled clinical trials (CCT) published in Spanish physiotherapy journals using electronic and handsearching strategies.

**Method** Observational study through which we identified eligible journals in order to retrieve CCTs using electronic and handsearching strategies, as proposed by the Cochrane Collaboration. A descriptive analysis of the main characteristics of these CCTs was completed.

**Results** Seventy-eight CCTs were identified in 10 eligible journals, none of which were indexed in the major databases. 16.7% of the identified studies were multicentric. Traumatology and orthopaedics was the most studied field (33.3%) followed by neurology (15.4%). The most researched health problems were back pain (17.24%) fibromyalgia, arthrosis and stroke (6.8% each). Measured outcomes varied greatly, including pain control, functional mobility and quality of life. Most CCTs (64.1%) had a high risk of bias. **Conclusions** The number of CCTs published in Spanish physiotherapy journals is limited. Handsearching these journals is essential, since none is indexed in major databases. In general, the identified CCTs carry a high risk of bias.

## **Keywords**

evidence-based medicine, medical research, structured reviews

## Introduction

Ever since the first controlled clinical trial (CCT) on physiotherapy was published in 1930, the quality and quantity of publications on this field has grown exponentially [1–3]. Nowadays, if a search of CCTs on physiotherapy is conducted in PubMed, over 17 000 references will be retrieved. PEDro (Physiotherapy Evidence Database), an evidence-based physiotherapy database, also presents a significant increase in activity, doubling the number of CCTs and systematic reviews every three and a half years [4].

Evidence-based medicine is defined as ‘the conscious, explicit and judicious use of the best clinical evidence available to make decisions of the healing of patients’ [5]. Applied to physiotherapy, this approach is known as evidence-based physiotherapy [6]. Evidence-based physiotherapy enables a structured approach to research and practice in this field, improving the understanding of research methods, providing scientific support to clinical and managerial decision making, reducing the variability of interventions and facilitating access to more effective practices [1–7].

The best clinical evidence of the effect of a health care intervention is provided by CCTs [4,8]. It is imperative to base decision making not only on one’s own knowledge but also on the results of research projects, bearing in mind at all times that CCTs with an inadequate methodology may involve exaggerated estimates of the effects of interventions [9].

Evidence-based physiotherapy relies on having access to the entire body of evidence provided by CCTs, which is achieved with an electronic search of the available literature complemented with a handsearching strategy [10]. The former, which relies on electronic filters and keywords, presents low sensitivity and precision [11,12]. Handsearching of literature, which involves progressive, page-by-page examination of all issues of a given journal [10], is a tool that allows circumventing these shortcomings.

Several studies that aimed at identifying CCTs combining electronic and handsearching strategies conducted in anaesthesiology [13], general and internal medicine [14], and patient safety [15] journals

confirm these results. Through these projects, it has been found that the sensitivity of the electronic searches (proportion of all studies identified via electronic search over those identified via handsearch) does not exceed 69%, while the specificity (truly eligible studies among all those retrieved via the electronic search strategy) does not exceed 50%.

Nevertheless, access to clinical evidence and the time needed to scrutinize it are two key limitations that block the practice of evidence-based physiotherapy [10]. A survey in the UK and Australia shows that between 20% and 44% of physiotherapists reported difficulties to access scientific literature, and between 31% and 61% stated that they had no time to read scientific articles [16,17].

This study aimed to identify all CCTs conducted in physiotherapy and published in physiotherapy journals in Spain. Additionally, and in order to obtain a clearer picture of the strengths and challenges of research in physiotherapy, a description of the methodological aspects of CCTs identified was performed, including an assessment of potential risk of biases and quality of reporting results [18,19]. Lastly, the identified articles will be submitted for inclusion in the Cochrane Central Register of Controlled Trials (CRS).

## **Methods**

We conducted a descriptive observational study that consisted of two parts: identification of eligible journals and handsearching of CCTs with a corresponding descriptive and risk of bias analysis of the retrieved studies.

### **Identification of journals**

The first step of this study consisted of selecting the journals that were to be handsearched. Eligibility criteria included physiotherapy journals published in Spain that disseminate original research. Journals were identified through PubMed (MEDLINE), the Spanish Medical Index (IME), the National Catalogue of Periodicals in Spanish Health Science Libraries C-17 (edited by Centro de

Información y Documentación Científica (CINDOC), Latindex, Periodic, LILACS and SciELO. We excluded journals that do not publish original research and that focus instead on educational, promotional, or commercial contents.

### **Identifications of controlled clinical trials**

Handsearching of the identified journals was conducted following the guidelines provided by the Cochrane Collaboration. These state that each journal article must be carefully reviewed, including not only original articles but also other types of studies, letters to the editor, abstracts, and conference presentations. The recommended steps for handsearching a journal are: (1) reading the table of contents; (2) locating keywords in the title of the article (e.g. randomized, random, blinded, etc.); (3) reading the abstract; and (4) reading the methods section in the full text of the article. Handsearching of journals has to be performed retrospectively, starting backwards with the latest issue published. If no CCTs are identified in five consecutive years in a given journal, the handsearch can be stopped for that journal since it is assumed that no CCTs will be found from that point onward.

In line with the recommendation from the Cochrane Collaboration, each reviewer conducted a pilot test consisting of reviewing a volume of a journal that had been previously handsearched by experts in this field.

Furthermore, an electronic search was planned in PubMed (MEDLINE) in order to identify CCTs published in the eligible journals of this study and to compare results with those of the handsearching strategy.

### **Inclusion and exclusion criteria**

In order to be considered a CCT, and in line with the criteria proposed by the Cochrane Collaboration, a study had to

- 1 Compare treatments in humans.
- 2 Be prospective: interventions must have been planned before the study took place.

**3** Compare two or more physiotherapy treatments or interventions, one of which can be a no-treatment control group or a placebo. The interventions can be of any type: diagnostic, rehabilitative, educational, etc.

**4** Have a random method of allocation to treatment.

- Randomized CCTs: authors explicitly state that compared groups were formed by random assignment, generally describing the allocation method.

- Quasi-randomized CCTs: authors attempt to form intervention groups with similar characteristics. Methods to achieve this end include allocation by date of birth, day of the week or month of the year, even and odd numbers, medical record number, etc. We excluded articles that were references to or translations into Spanish of work published elsewhere.

Handsearching of journals was conducted individually. Two authors (MT and MS) verified that all potential CCTs identified were indeed eligible. Discrepancies were resolved by consensus or by consulting a third author (HP).

### **Data extraction**

In order to ensure that data were collected in an orderly and systematic fashion, a database was created to record each CCT identified and to track the progress of the project. A data collection logbook including all outcomes of interest was also developed.

An assessment of risk of bias (high/medium/low) of the identified CCTs was also conducted, using the tool provided by the Cochrane Collaboration for this purpose [20]. This instrument evaluates aspects of CCTs methodology such as random sequence generation, allocation concealment, blinding of patients or investigators, and reasons for missing data (if applicable). In addition, it was recorded whether the authors adhered to the CONSORT tool for non-pharmacological interventions (CONSORT-NPT tool) [18] when reporting the results of their research projects.

## Analysis

A descriptive analysis of the outcomes of interest was performed using SPSS version 17.0 (SPSS, Inc., Chicago, IL, USA).

## Results

Ten physiotherapy journals published in Spain were identified, none of which were indexed in PubMed (MEDLINE), CENTRAL, EMBASE or CINAHL. A total of 451 issues with 3775 articles were handsearched. Of these, 78 (2.07%) were CCTs (see Fig. 1, Table 1). Ten reviewers participated in this stage of the project.

The first CCT was published in 1980 in the journal *Rehabilitación* (Salvador E, Alvarado AG. La infiltración epidural en el tratamiento de las lumbalgias. *Rehabilitación*. 1980;14(2): 165–174.), which evaluated the efficacy of kinesiotherapy plus electrotherapy with and without lumbar spinal traction in low back pain. Thereafter, a progressive increase in the number of CCTs published was observed. The highest number of CCTs were published in 2011 (20.5% of all identified studies), followed by 2012 (19.2%). Between 2008 and 2012 alone, over 64% of the identified articles were published. Figure 2 shows the number of publications of CCTs per 5-year interval.

The journal with the most CCTs was *Rehabilitación*, with 28 CCTs representing 35.9% of the total, followed by *Fisioterapia* with 25 CCTs (32.1%). Most CCTs were conducted in one centre (65, 83.3%), whereas only 16.7% were multicentre. The most common settings were hospitals (28 CCTs, 35.9%), followed by universities (12 CCTs, 15.4%), others institutions (such as fitness centres, associations, etc.; 11 CCTs, 14.1%), physiotherapy centres (10 CCTs, 12.8%), nursing homes (6 CCTs, 7.7%) and primary care centres (4 CCTs, 5.1%). Regarding medical subspecialty, traumatology and orthopaedics was the most studied field (33.3%) followed by neurology (15.4%) (see Fig. 3).

Age of participants varied greatly, ranging from 13 to 80 with a mean of 82.3, but this variable was not reported in 34 CCTs, or 43.6% of the identified studies. In 59 CCTs (75.6%), the sex of participants was reported; for those that did, men accounted for 41.0% of the total (SD 29.4) compared to 59.1% of women.

The most studied health problems were back pain (cervical and low back pain; 17.24%) followed by fibromyalgia, arthrosis and stroke (6.8% each) spinal cord injuries, knee osteoarthritis and knee replacement (3.8% each; see Fig. 4). Nevertheless, the majority of the identified studies were performed on healthy subjects (focusing on the effects of electrotherapy, manual therapy or the effects of muscle strengthening).

The most common main outcome in the identified studies was pain control, followed by functional mobility, range of movement and quality of life. Measures used to evaluate outcomes are shown in Appendix S1 online (also available at the Iberoamerican Cochrane Centre website, <http://www.cochrane.es>).

Fifty-six (71.8%) of the identified CCTs reported total treatment duration. Most CCTs lasted a day or a period of 2–3 weeks (19.6%, 11 CCTs each), followed by 8 weeks (17.9%, 10 CCTs),

4 weeks (16.1% or 9 CCTs), 12 weeks (14.3% or 8 CCTs) and 12 weeks or more (12.5%, 7 CCTs; see Appendix S1 online, also available at the Iberoamerican Cochrane Centre website, <http://www.cochrane.es>).

Forty-eight CCTs (61.5%) reported number of sessions of physiotherapy intervention held weekly during the treatment period. 16 (20.5%) reported more than three sessions per week, another 16 (20.5%) conducted two or three sessions, and 16 (20.5%) with a single weekly session (or simply a single session). However, 30 RCTs (38.5%) did not report this information (see Appendix S1 online, also available at the Iberoamerican Cochrane Centre website, <http://www.cochrane.es>).

The duration of each session of physiotherapy intervention was not reported in 45 CCTs, representing (57.7%). Among those that did, 77.4% lasted less than one hour, 19.4% lasted between 1 and 2 hours, and 3.2% lasted over 2 hours (see Appendix S1 online, also available at the Iberoamerican Cochrane Centre website, <http://www.cochrane.es>). Follow-up of patients varied greatly, from less than 1 month (3 CCTs, 3.9%), to 1 month (9,

11.5%), 2–6 months (19, 24.4%), or over 6 months (2, 2.6%). This information was not reported in 45 CCTs 57.7%.



The quality of the included studies presented several shortcomings that are described in Table 2. A total of 27 of the identified studies (34.6%) were classified as randomized CCTs, whereas 51 were quasi-randomized (65.4%). Most CCTs had a high risk of bias (64.1%). A total of 61.5% did not generate the randomization sequence adequately and 67.9% did not conceal allocation of patients to treatments or interventions. Blinding was adopted by 36 CCTs, equivalent to 46.2% of the total. Regarding the CONSORT tool, two CCTs (2.6%) reported using it in the drafting of the report. Groups at the beginning of the study were comparable in 74.4% of the studies. In 65.4%, there was no missing relevant data. For the remaining studies, 24.4% specified reasons for such omissions, while 10.3% did not.

Concerning source of funding, 91.1% of authors did not specify whether they received funds to conduct their research. Of those that did, 6.4% received private funding compared to 2.6% who received public funding. Conflicts of interest were reported by 39.7% of authors.

Figure 5 provides a summary that allows assessing the overall risk of bias of the identified CCTs at a glance.

The electronic search conducted in PubMed (MEDLINE) retrieved 175 CCTs on physiotherapy conducted by authors affiliated to Spanish institutions. However, these studies were found either in journals published in other countries or in journals that did not focus exclusively on physiotherapy. These studies will be analysed in a future research project. It should be noted that since none of the journals handsearched in this study were indexed in PubMed, there was no overlap between the CCTs identified through both searches.

## **Discussion**

The main aim of this article was to identify and describe all the CCTs published in Spanish physiotherapy journals, to assess their methodological quality, and to, subsequently, incorporate them into CRS.

Despite an increase in physiotherapy research in recent years [1,3], the number of CCTs identified in Spanish physiotherapy journals is low. A total of 78 CCTs published between 1980 and 2012 were found, corresponding to an average of 2.4 CCTs per year.

Most CCTs were published in *Rehabilitación* (35.9%) and *Fisioterapia* (32.1%). Thus, these journals stand as leaders in the dissemination of research on physiotherapy in Spain.

Regarding researched health problems, back pain, including low back and cervical pain, was the condition that gathered the most attention from investigators. This was expected since, according to the Spanish National Health Survey in 2011–2012, back pain is one of the most common health ailments in the country [21], with a high impact on quality of life and sick leaves, and its corresponding effect on productivity [22]. Back pain is closely associated with body posture and a sedentary lifestyle, both of which can be targeted using physiotherapy interventions [23].

Another commonly addressed health issue was hypertension, which is also identified as a serious public health problem among adults in Spain [21]. Additionally, there was a marked interest on researching the effects of physiotherapy interventions on functional mobility of patients after a stroke.

However, there is a lack of studies that investigate the impact of physiotherapy intervention on other chronic diseases such as diabetes, obesity or hypercholesterolemia. In addition, and despite the fact that Spain is one of the countries with a higher proportion of elderly citizens [24], research on geriatric populations remains scant.

Most studies were conducted in hospitals. However, there was almost no research conducted on surgical patients, which is the most common reason for hospitalization in Spain [21]. It would therefore be of invaluable importance to research the effect of physiotherapy interventions on the recovery of post-surgical patients and on reducing costs associated with hospital stays.

Pain control and quality of life are the main outcome of interest in the identified studies. Physiotherapy interventions that address these variables can also have an effect on other conditions associated with chronic diseases, such as depression, insomnia and anxiety [25]. The lack of research on these variables highlights the need to include them in future studies, which would both broaden the

field of action of physiotherapy interventions and incorporate new tools to assess the efficacy of these interventions.

This study underlines the variety of interventions that physio-therapists implement treating patients. In addition, while over 40% of studies conducted two or more weekly sessions per intervention, in general, treatment period was short (3 months or less). This may be reflective of budgetary restrictions or that studies focused on short-term results.

The overall methodological quality of the included studies was low. In over 60%, the randomization sequence was not generated adequately and in 67.9%, this sequence was not concealed. As a result, the fact that a study is classified as randomized does not guarantee that it meets the methodological standards associated with this type of studies [23]. Additionally, 65.4% of CCTs were classified as quasi-randomized.

A method for masking physiotherapy interventions was reported by 46.2% of CCTs. This result is encouraging given the difficulties of blinding researchers or patients in this field. Most studies reported all the data they had planned to disseminate; when they did not, they provided reasons for such omissions. This good practice ensures transparency in the flow of patients throughout the study and decreases the chance of biased results.

Authors provided information on sources of funding in only seven CCTs (9.0%) compared with 71 CCTs (91.0%) that did not report any information on this matter. This finding is in line with García-Alamino et al. [23], who observed that, in a high percentage of cases, authors did not specify the source of funding for their studies. Likewise, there was no mention of potential conflicts of interest, or lack thereof, in over half of the CCTs identified.

Only two authors mentioned adhering to the CONSORT-NPT tool. Given the deficiencies in the reporting of results in the identified CCTs, it is essential to promote the dissemination of this tool among physiotherapists, which will undoubtedly have a positive impact on the quality of their publications.

One of the major strengths of this study is the large number of documents reviewed, a total 451 numbers published in 10 journals (until 31 December 2012). Handsearching – always in accordance with the criteria of the Cochrane Collaboration – was systematic and exhaustive for all volumes and supplements, including letters to the editor, abstracts, conferences and monographs.

The CCTs identified in this study would not have been retrieved through an electronic search in PubMed (MEDLINE), as the reviewed journals were not indexed in this database. This is further evidence of the limitations of searches conducted exclusively electronically [21] and the invaluable role of handsearching to identify CCTs, especially those reported as abstracts, letters to the editor or reported in languages other than English [22].

One possible limitation of this study is that the review of journals was conducted individually and without corroboration from another author, which might have resulted in eligible CCTs being discarded. However, the possibility of false positives was minimized since the 78 identified CCTs were verified by at least two of the authors. In addition, this paper focused only on Spanish physiotherapy journals and excluded international publications. Future studies currently underway at the Iberoamerican Cochrane Centre will focus on Latin American physiotherapy journals and on journals that publish physiotherapy original research articles indexed in bibliographic databases.

For future research, similar studies could be carried out in international publications, which would permit a wider analysis of the current status of research in the field of physiotherapy. It would also be interesting to consider other types of study designs to assess the effect of health interventions, such as systematic reviews, as well as to expand this work to fields that are closely associated with physiotherapy, such as osteopathy.

In conclusion, the number of physiotherapy CCTs published in the identified Spanish journals is limited. Handsearching these journals is essential for the identification of such CCTs, as eligible Spanish physiotherapy journals are not indexed in PubMed (MEDLINE).

Most studies investigated the effect of physiotherapy interventions on back pain, fibromyalgia, arthrosis and stroke, assessing outcomes such as pain control, functional mobility and quality of life.

These studies, however, were conducted on healthy patients in a majority of cases and had short follow-up periods.

In general, the identified CCTs carry a high risk of bias. Therefore, it is recommended that authors adhere to the CONSORT-NPT tool and to standard recommendations to reduce risk of bias when conducting CCTs and to improve the quality of future research.

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## Tables

Journal (revision period)	No. of revised articles	No. of CCTs found	% of total CCTs
■ Cuestiones de Fisioterapia (2003–2012)	154	14	17,9
■ Fisioglobal: La revista científica Iberoamericana del Método Mézières y terapias globales (2008–2011)	24	0	0
■ Fisioterapia (1985–2012)	895	25	32,1
■ Fisioterapia al día (2003–2012)	92	1	1,3
■ Fisioterapia y calidad de vida (2008–2012)	67	0	0
■ Medicina de Rehabilitación (1999–2004)	167	1	1,3
■ Rehabilitación (1975–2012)	2157	28	35,9
■ Revista científica del colegio de fisioterapeutas de Catalunya (2011–2012)	13	1	1,3
■ Revista de Fisioterapia (Guadalupe) (2007–2011)	61	0	0
■ Revista Iberoamericana de Fisioterapia y Kinesioterapia (1998–2011)	145	8	10,3
<b>TOTAL:</b>	<b>3775</b>	<b>78</b>	<b>100</b>

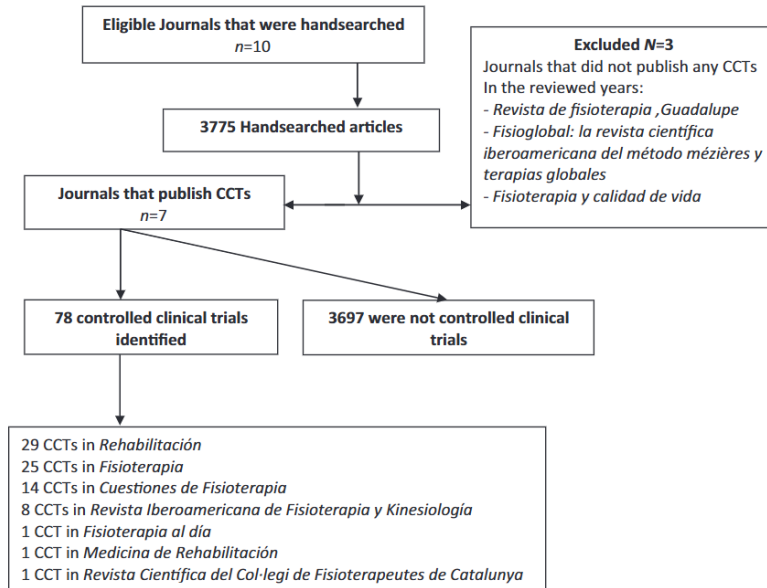
**Table 1** Identified journals and Clinical Controlled Trials found

**Table 2** Methodological quality of identified studies

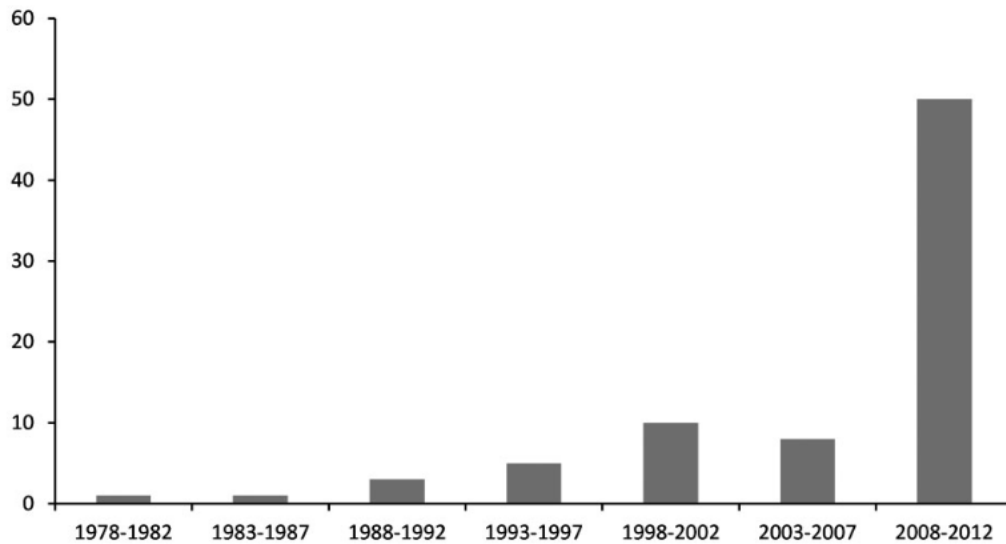
Category	<i>n</i>	%
Funding		
Public	2	2,6
Private	5	6,4
Not reported	71	91,0
Conflicts of interest		
Reported	31	39,7
Not reported	47	60,3
Risk of bias		
Low	6	7,7
Moderate	22	28,2
High	50	64,1
Comparable groups at study beginning		
Yes	58	74,4
No	3	3,8
Not reported	17	21,8
Adequate randomization		
Yes	25	32,1
No	48	61,5
Not reported	5	6,4
Assignment concealment		
Yes	13	16,7
No	53	67,9
Not reported	12	15,4
Blinding		
Yes	36	46,2
No	34	43,6
Not reported	8	10,3
Reasons for missing data		
Yes	19	24,4
No	2	2,6
Not applicable	51	65,4
Not reported	6	7,7
Use of CONSORT recommendations		
Yes	2	2,6
No	76	97,4

**Table 2** Methodological quality of identified studies

## Figures



**Figure 1** Journals and CCTs eligibility flow chart



**Figure 2** Number of CCTs published in 5-year intervals

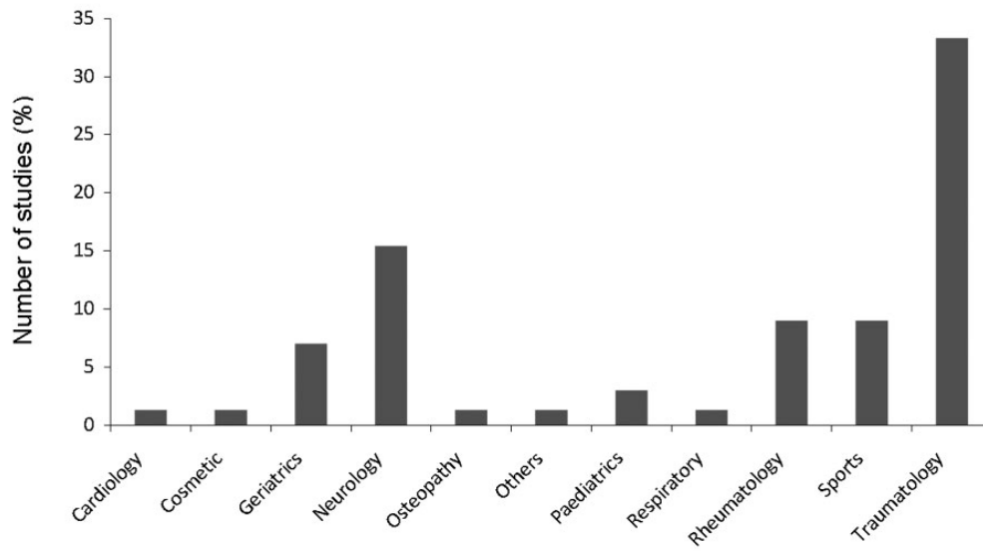


Figure 3 Medical subspecialty

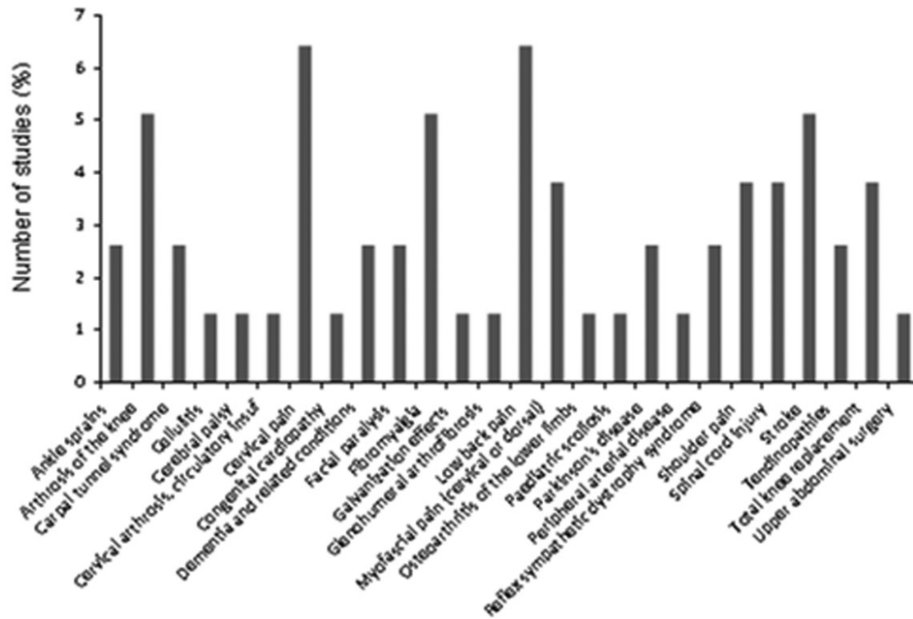
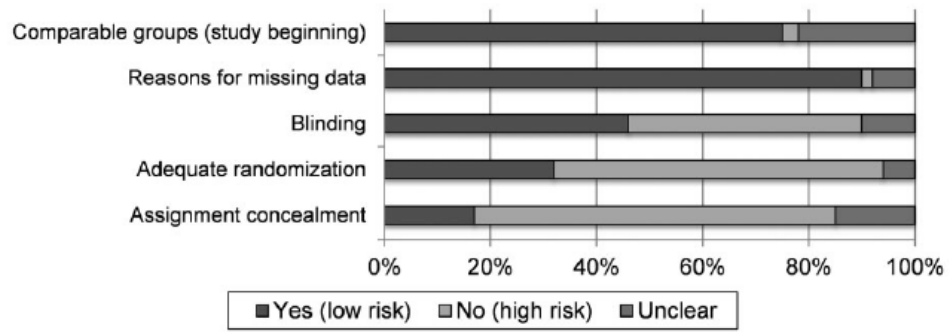


Figure 4 Researched health problem



**Figure 5** Risk of bias summary