Chiropractic Treatment of Pregnancy-Related Low Back Pain: A Systematic Review of the Evidence

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Abstract

Objective: This study systematically reviewed the published evidence regarding chiropractic care, including spinal manipulation, for pregnancy-related low back pain (LBP).

Methods: A multimodal search strategy was conducted, including multiple database searches along with reference and journal hand searching. Studies were limited to those published in English and in a peer-reviewed journal or conference proceeding between January 1982 and July 2007. All study designs were considered except single case reports, personal narratives, and qualitative designs. Retrieved articles that met the inclusion criteria were rated for quality by using a validated and reliable checklist.

Results: Six studies met the review's inclusion criteria in the form of 1 quasi-experimental single-group pretest-posttest design, 4 case series, and 1 cross-sectional case series study; their quality scores ranged from 5 to 14 of 27. All of the included studies reported positive results for chiropractic care of LBP during pregnancy. Outcome measure use between the studies was inconsistent as were descriptions of patients, treatments, and treatment schedules.

Conclusions: Results from the 6 included studies showed that chiropractic care is associated with improved outcomes in pregnancy-related LBP. However, the low-to-moderate quality of evidence of the included studies preclude any definitive statement as to the efficacy of such care because all studies lacked both randomization and control groups. Given the relatively common use of chiropractic care during pregnancy, there is need for higher quality observational studies and controlled trials to determine efficacy. (J Manipulative Physiol Ther 2008;31:447-454)

Key Indexing Terms: *Pregnancy; Chiropractic; Manipulation, Spinal; Low Back Pain; Public Health*

Pregnancy is a common time for women to experience back pain. Studies show that between 50% and 80%[1-5] of pregnant women suffer from low back pain (LBP) during their pregnancy. Back pain during pregnancy may commence as early as the 12th week, although the fifth through seventh months are cited as the most common period for onset of back pain.[5] A previous history of back pain, back pain during a prior pregnancy, multiparity, and advancing age are the most commonly named risk factors.[1,2,5,6]

Back pain during pregnancy can be significant in terms of intensity and resulting disability. Stapleton et al[7] found that 35.5% of 1120 South Australian women had at least moderately severe back pain during 1 or more of their pregnancies. Gutke et al[8] found that, of 189 subjects with pregnancy-related LBP, 29% had clinically important Oswestry or Visual Analog Scale (VAS) scores, whereas 56% had clinically important Oswestry and VAS scores. As part of their study, Sihvonen et al[6] had 32 pregnant women with preexisting LBP and 21 pregnant women with no previous history of back pain complete VAS and Oswestry Low Back Disability questionnaires at 20 and 36 weeks of gestation. The VAS scores went from 5.86 to 9.21 mm in the previous back pain group and from 0 to 14.67 mm in the group with no previous back pain. The Oswestry scores went from 5.14 to 7.79 in the previous back pain group and from 0 to 5.67 in the previously pain free group.

Stapleton et al[7] reported that 48.9% of their subjects with back pain did not seek any treatment for their pain. This number is lower than other reports that have indicated that between 68% and 85% of pregnant women with back pain during pregnancy have not sought care, one potential explanation being that many patients attribute the back pain as being a normal part of pregnancy.[3,4] Over two thirds of

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Table 1. *Review selection criteria*

Inclusion criteria	Exclusion criteria
Patients must have LBP during their pregnancy, patients may have another comorbid or related musculoskeletal condition such as hip or groin pain, etc.	Patients do not have LBP during their pregnancy.
Study must be on pregnant patients or must answer questions relating to their pregnancy (or pregnancies).	Studies that focus on postpartum LBP or back pain in other nonpregnant patients.
Treatments administered by a qualified chiropractor.	Treatments not administered by a qualified chiropractor, ie, performed by a medical doctor or physical therapist, etc.
Papers written in English.	Papers not written in English.
Published between January 1982 and July 2007.	Published before 1982.
Prospective or retrospective studies including RCTs, controlled clinical/quasi-experimental trials, cohort, case control, case series, and survey designs.	Personal narratives, qualitative, or single case report (n = 1) designs.
Study must use some outcome measure for determining the effect of chiropractic care on the amount of LBP experienced by the subjects.	Studies looking only at the effect of chiropractic care on labor or delivery times, without an evaluation of change in pain levels.
Published in peer-reviewed journal or conference proceedings/abstracts.	Published in non–peer-reviewed journal.

Stapleton et al's 1120 subjects (68%) continued to have recurrent LBP after their pregnancies, further highlighting the importance of this problem as it raises concern about the pain becoming chronic and inherently more difficult to resolve.[7] Skaggs et al[2] reported that, of the 15% of pregnant women in their study who received some form of care for their pregnancy-related LBP, only 10% were satisfied with the symptom relief they obtained. This highlights the importance of finding efficacious treatments for pregnancy-related LBP.

Numerous treatments have been advocated for back pain during pregnancy, including exercise (such as encouraging maintenance of fitness as much as possible), use of proper ergonomics, heat and cold therapy, relaxation exercises, rest as needed, patient education on avoiding aggravating factors and encouraging relieving activities, joint mobilization, stretching, massage, acetaminophen (or other pain relieving medications), acupuncture, and chiropractic.[4,5] One systematic review found randomized controlled trials supporting the use of physiotherapy, acupuncture, and pregnancy-specific exercises in particular.[4] Two reviews of chiropractic care for LBP during pregnancy exist.[9,10] Those reviews did not evaluate the literature for quality, and only 1 database (Medline) was evaluated.[9] The aim of the current systematic review was 2-fold: (1) to review the published evidence regarding chiropractic care (including but not limited to spinal manipulation) for pregnancy-related LBP and (2) to assess the quality of the literature on this topic.

Methods

MEDLINE, CINAHL, AMED and the Index to Chiropractic Literature were searched for relevant literature between January 1982 and July 2007. The key words used in the search were the Medical Subject Headings of *chiropractic* or *spinal manipulation*, *pregnancy*, and *low back pain*. A second search was done using the Index to Chiropractic Literature with only the terms *pregnancy* and *low back pain*, as it was reasoned that any articles in this database were already related to chiropractic and/or spinal manipulation and that using this search string may yield more articles (which turned out to be true). The Cochrane Library was also searched for a relevant systematic review using the search terms *chiropractic*, *pregnancy*, and *low back pain*.

The authors scrutinized the electronic search results, the titles and abstracts in particular, and the full manuscripts of citations were obtained if they included outcomes of chiropractic care for pregnant women with LBP. All study designs were considered except single case reports, personal narratives, and qualitative designs. Conference abstracts and proceedings were deemed acceptable for inclusion and obtained when appropriate.

The inclusion and exclusion criteria used for this review are described in Table 1. These criteria were applied to all of the obtained full manuscripts, conference abstracts, and conference proceedings. The reference lists of all retrieved articles, conference abstracts, and proceedings from the database searches were hand-searched for further relevant articles not captured by the electronic literature search.

The table of contents of several relevant journals were hand-searched for additional relevant articles. These journals included the *Journal of Manipulative and Physiological Therapeutics*, *Clinical Chiropractic* (and its predecessor the *British Journal of Chiropractic*), the *Journal of Chiropractic Medicine*, the *Journal of the Canadian Chiropractic Association*, and *Chiropractic and Osteopathy*. We also

contacted experts in the field of prenatal chiropractic treatment to determine if they had any unpublished studies in this area or were aware of any further studies that we had not identified.

One of the authors (KS) initially extracted data (i.e., description of study, context of care, critical appraisal of study methods) from the studies meeting the inclusion criteria after a critical appraisal of the full-text articles. The second author (DS) checked and edited all entries for accuracy and consistency. The data from all included manuscripts and conference abstracts/proceedings were recorded onto a data extraction sheet by the authors as part of the review. Recorded data included details of the study design, sample, and results, including any adverse events. To avoid duplication of results from the same study (e.g., if there was a conference abstract and a full article), details were extracted from the relevant journal article only.

The methodological quality of the studies that met the selection criteria was assessed by the authors using the 27-item scoring checklist developed by Downs and Black.[11] This scoring checklist is considered valid and reliable for assessing randomized and nonrandomized studies.[11,12] It was known from the outset that there likely would be no randomized controlled trials obtained during this review, and as such, a methodological scoring system that allowed nonrandomized studies to be evaluated was deemed necessary. We revised item 27 from the original Downs and Black checklist to be worth 1 point so that the modified total score was 27. Studies that mentioned any power analysis or clinically important effects received 1 point on the revised item. The authors reviewed each included article for quality (based upon the Downs and Black checklist) using a quality scoring sheet. Quality scores above 20 were considered good; 11 to 20, moderate; and below 11, poor.[13] The 2 authors independently rated all the studies and resolved any differences by discussion.

Results

The initial electronic searches identified 55 citations (including overlapping citations between databases), 4 from MEDLINE, 11 from CINAHL, 4 from AMED, and 13 from the Index to Chiropractic Literature; a final 22 was identified using a modified search (only using the search terms *pregnancy* and *low back pain*) on the Index to Chiropractic Literature for the reasons mentioned above. The search of the Cochrane Library yielded a systematic review that evaluated different treatments for LBP during pregnancy,[4] and while chiropractic care is mentioned as a potential treatment no articles on chiropractic care were included in that review. Three additional articles were identified by hand searching the reference lists of retrieved articles, all from the review article written by Miller et al.[9] Hand-searching the table of contents of several chiropractic journals did not yield any additional articles, nor did contacting experts in the area of prenatal chiropractic care. An additional article by Mantero and Cripsini[14] was retrieved by searching one of the authors' (DS) personal collection of articles. The full text of 15 articles[14-28] was obtained after screening the titles and/or abstracts to determine if they would meet the review's inclusion criteria. Eleven articles came from electronic database searches, 3 came from reference list evaluations, and 1 came from our personal collection.

Six articles met all of the inclusion/exclusion criteria for this review. Four [15-18] were identified by the electronic database searches, whereas the fifth and sixth papers [14,19] were identified by hand-searching. The remaining 9 articles[20-28] were excluded for a variety of reasons. All 15 articles were written in English.

Of the 6 included articles, 1 was a quasi-experimental, single-group pretest-posttest design, 4 were case series designs, and 1 used a cross-sectional case series design. There were no randomized controlled trials (RCTs), controlled studies, case control studies, or cohort studies. Table 2 provides information on each of the 6 included studies with respect to the study design, sample, interventions, outcome measures, results, and conclusions in addition to the quality score of each article.

Diakow et al[16] conducted a retrospective cross-sectional survey of women attending 1 of 5 chiropractic clinics regarding back pain during pregnancy and labor. Twenty-five of the 179 subjects had seen a chiropractor for LBP during their pregnancy, and 21 (84%) reported relief of their LBP.[16] Fallon conducted a case series, reported as an abstract only, of 103 patients who received chiropractic care during their pregnancy.[19] All of the women reported greater than 50% decrease in back pain on a questionnaire.[19] Guadagnino[18] conducted a case series on 12 patients where they all received 2 particular treatment modalities (trigger point therapy and manual traction) and 1 of 3 manipulative techniques according to their presentation. The subjects had average baseline pain ratings of 7.58 of 10, and these decreased to 4.25 of 10 while they were under care.[18] Mantero and Crispini[14] conducted a case series where 120 pregnant women with LBP underwent an average of 15 chiropractic treatments, 25% had complete remission of their back pain, 50% reported feeling very well, 15% were feeling better, and 10% noted no change in condition.

Lisi[17] conducted a retrospective case series on 17 pregnant patients with LBP using a multimodal chiropractic treatment plan. He found that the average pain levels of all but one of the patients displayed clinically important improvements on an 11 point numerical pain rating scale.[17] Clinically important improvement was observed within 1.8 treatments on average occurring over an average of 4.5 days.[17] The average pain level of patients at the end of their treatment regimens were 1.5 of 10 on average, down from 5.9 of 10 on average at baseline.[17]

Skaggs et al conducted a quasi-experimental single group pretest-posttest study, reported as an abstract only, on 58

Table 2. *Features of included studies*

Study authors; quality score	Study design	Sample	Interventions	Outcome measure	Main results/ conclusions
Mantero and Crispini[14]; 6/27	Case series	120 Patients, aged 20-40 y	Chiropractic care, avg of 15 manips	Assumed to be a questionnaire	All but 10% reported improvement, 50% reported feeling very well, 25% reported remission of LBP
Skaggs et al[15]; 11/27	Single-group pretest-posttest, abstract only	58 Patients saw chiro out of 170 attending msk pain during pregnancy clinic	Education, STT, manips, mobs, stab exercises; only 1 tx	Bournemouth questionnaire at baseline and 2nd visit	BQ scores went from 45 on avg at baseline to 34 on avg at the 2nd visit
Diakow et al[16]; 10/27	Retrospective cross-sectional survey	25 Patients received chiropractic manips during pregnancy out of 179 attending 5 different chiro clinics	No details other than received chiropractic manual manipulation	Questionnaire about the improvement of LBP after manipulation	21 out of 25 reported relief of LBP
Lisi[17];14/27	Retrospective case series	17 Patients, aged 21-42, avg gestational age 23.7 wk, avg initial pain rating 5.9/10.	Included myofascial release, mobs, manips, education, and exercise instruction	11-point numerical pain rating scale, improvement ≥2 on the 11-point scale = clinically important improvement	Pain levels went to 1.5/10 on avg. Only 1 did not have clinically important improvement. For rest of the patients, clinically important improvement was seen in 4.5 days on avg or after 1.8 tx on avg.
Guadagnino[18]; 13/27	Case series	12 patients, aged 14-34	Patients were treated 2-3 times/wk until delivery. Received either diversified, SOT, or Gonstead knee-chest manips. All received manual txn and TPT.	Questionnaires mailed to patients after tx about pain (on 10-point scale) when they first went for care, immediately after care, the next day, and in general while under care.	During care the average pain rating was 4.25/10 compared with 7.58 at baseline
Fallon[19]; 5/27	Case series, abstract only	65 Patients initially, then an additional 38 with LBP were added	Chiro care, no. of tx and type of manips unknown	Questionnaire to assess LBP levels	All women reported >50% decrease in back pain

Chiro indicates chiropractic; avg, average; msk, musculoskeletal; manips, manipulation; STT, soft tissue therapy; TPT, trigger point therapy; tx, treatment; txn, traction; SOT, sacrooccipital technique.

pregnant patients with LBP who saw a chiropractor at a musculoskeletal pain pregnancy clinic.[15] These patients were all treated with a multimodal treatment regimen in 1 visit.[15] The average scores on the Bournemouth Questionnaire went from 45 at the initial visit to 34 at the second visit.[15] Since a change score of 4.5 is considered clinically significant, this study demonstrates both clinically and statistically significant improvements in pregnancy-related LBP after chiropractic care.[29]

None of the studies indicated any adverse effects or evidence of harm to either the pregnant woman or unborn child from the treatments rendered. However, only the study by Lisi[17] formally reported that there were no adverse events; the remaining studies did not comment one way or the other.

Table 3 depicts the quality scoring of each of the included articles. Our overall level of disagreement after independent ratings was 8.6% (14/162). We resolved these differences by discussion. The methodological quality of the articles was moderate to poor. The highest score on the Downs and Black[11] scoring system was 14 of 27, achieved by the Lisi[17] study, the most recent of the included articles, despite the fact that it was a retrospective case series. The studies by Skaggs et al[15] and Guadagnino[18] also achieved moderate quality ratings, scoring 11 and 13, respectively. The other 3 studies[14,16,19] all rated poorly (<11) in methodological quality.

None of the included studies featured any means of randomization to groups, blinding of subjects or caregivers, or those measuring the outcomes. There were no control groups; no attempts to adjust for confounding factors in the analyses; no analyses that adjusted for different lengths of follow-up for patients; and no mention of actual probability values, power calculations, or determination of effect sizes in any of the studies, and these are all likely functions of the study designs chosen. Finally there was very little description of the progression of the subjects through each study from invitation to participation to analysis.

The included studies yielded moderate to low quality ratings on the Downs and Black[11] checklist. These

Table 3. *Article quality scoring using a scoring method adapted from Downs and Black*[11]

No.	Brief item description	Mantero and Crispini[14]	Skaggs et al[15]	Diakow et al[16]	Lisi[17]	Guad-agnino[18]	Fallon[19]
1	Hypothesis/aim/objective described?	0	1	1	1	1	1
2	Main outcomes to be measured described?	1	1	1	1	1	1
3	Characteristics of patients described?	0	0	1	1	1	1
4	Interventions of interest clearly described?	1	1	0	1	1	0
5	Distributions of confounders described?	0	0	0	0	0	0
6	Main findings clearly described?	1	1	1	1	1	1
7	Estimates of random variability in data?	0	1	1	0	0	0
8	Important adverse events reported?	0	0	0	1	0	0
9	Describe patients lost to follow-up?	0	0	0	0	1	0
10	Actual probability values reported except where *P* value <.001?	0	0	1	0	0	0
11	Subjects asked to participate representative of population?	0	0	0	1	0	0
12	Subjects prepared to participate representative of population?	0	0	0	1	0	0
13	Staff, places, and facilities representative of treatment majority of patients receive?	1	1	1	1	1	0
14	Attempt made to blind subjects?	0	0	0	0	0	0
15	Attempt made to blind those measuring the outcomes to intervention?	0	0	0	0	0	0
16	Any of the results based on "data dredging," was this made clear?	1	1	1	1	1	1
17	Analyses adjust for different lengths of follow-up of patients, or is time period between the intervention and outcome the same for cases and controls?	0	0	0	0	1	0
18	Statistical tests appropriate?	0	1	1	1	1	0
19	Compliance with treatments reliable?	0	1	0	0	0	0
20	Outcome measures valid/reliable?	0	1	0	1	1	0
21	Patients in intervention groups or cases and controls recruited from same population?	1	1	0	1	1	0
22	Subjects in different intervention groups or cases and controls recruited over same period?	0	0	1	0	1	0
23	Subjects randomized to groups?	0	0	0	0	0	0
24	Randomized assignment concealed until recruitment was complete?	0	0	0	0	0	0
25	Adjustment for confounding in analyses?	0	0	0	0	0	0
26	Losses to follow-up accounted for?	0	0	0	0	1	0
27	Sufficient power to detect clinically important effect where *P* value for difference due to chance is < 5%?	0	0	0	1	0	0
	Total score (/27)	6	11	10	14	13	5

ratings were primarily due to problems with external validity (questions 11-13, Table 3) and internal validity (questions 14-20, Table 3), which addressed biases in the measurement of the intervention and the outcome along with bias in the selection of study subjects (questions 21-26, Table 3). Because of these flaws, along with differences in treatment regimens and numbers of treatments, it was deemed inappropriate to attempt a meta-analysis to determine treatment effect of chiropractic care for LBP during pregnancy.[30]

Discussion

To our knowledge, this is the first systematic review of the literature regarding chiropractic care for pregnancy-related LBP. Although the studies included in this review all demonstrated reduced pain and/or disability following chiropractic care, the quality of this evidence is insufficient to determine the efficacy of chiropractic care for pregnancy-related LBP. The highest level of evidence was achieved by the Skaggs et al[15] study because of its quasi-experimental design, although it scored only moderate in methodological quality. The disappointing state of the literature on this topic cannot be overstressed, as all of the studies evaluated lacked both a comparison group and randomization.

The use of chiropractic during pregnancy is relatively common but not pervasive. Stapleton et al[7] found in their survey that 11% of the women who experienced LBP during at least 1 pregnancy sought chiropractic treatment. Ranzini et al[31] reported in a survey of 463 postpartum women that 5.2% had seen a chiropractor during pregnancy. A more recent cross-sectional survey of 950 pregnant Connecticut women found that 5.9% reported using chiropractic care during their pregnancies.[32] These survey findings suggest that chiropractic could play a part in reducing the pain experienced by pregnant women with LBP, and they corroborate the mostly observational designs in this review. From a practitioner's standpoint, observational studies are important because they are more suitable to detect rare or late adverse effects of treatments and are more likely to provide an indication of what is achieved in daily practice.[33]

A recent convenience survey of 18 Canadian chiropractors[34] revealed that close to 78% (n = 14) of the respondents indicated seeing between zero and 5 pregnant

patients monthly, whereas the remaining 22 percent of the subjects (n = 4) indicated seeing between 6 and 10 pregnant patients monthly.[34] These results are comparable with those obtained in the Canadian job analysis survey of chiropractic conducted by the National Board of Chiropractic Examiners in 1993 where 587 Canadian chiropractors reported seeing pregnant patients at an average frequency of 2.37 on a 4-point scale, which corresponded to being between "sometimes" and "often".[35] These results are slightly higher than the rates of pregnant patients seen in the most recent job analysis survey of chiropractic in the United States conducted by the National Board of Chiropractic Examiners[36] in 2005 where 2167 American chiropractors indicated that pregnant patients were seen with an average frequency of 1.4 out of 4, which corresponds to being between "rarely" and "sometimes."[36]

With respect to the safety of spinal manipulative therapy for pregnancy-related LBP, Stuber found that slightly over 94% of his sample of chiropractors (n = 17) indicated that they felt that spinal manipulative therapy was appropriate for treating pregnant patients with LBP.[34] Almost all of the surveyed chiropractors (94%) indicated that they felt that spinal manipulative therapy was at least "somewhat safe" for pregnant patients, and more than half indicated that they felt that this therapy was "extremely safe" during pregnancy, whereas none of these chiropractors opined that this therapy is unsafe during pregnancy; of course, there would likely be some inherent bias towards their chosen profession.[34] That survey was limited by the small sample size, an unproven survey instrument, and the convenience sampling method.[34]

The highest level of evidence was achieved by the Skaggs et al study [15] because of its quasi-experimental design, although it scored only moderate in methodological quality. This design is relatively weak because it has no comparison group. However, this design can be defended since previous research has documented the unchanged (or worse) outcomes of pregnant LBP controls during the time course of pregnancy.[6] On that basis the Skaggs et al[15] study could be justified in using a single experimental group.[37] With this in mind, we might reasonably expect that future well-designed trials of chiropractic care could produce both clinically and statistically significant treatment effects comparable to those achieved by Skaggs et al.[15]

Many observational studies frequently lack standardized or objective outcome measures. As per the inclusion criteria for this review, one of the outcome measures of interest in each study had to be pain. However, the means by which the pain was quantified varied. Only the studies by Guadagnino[18], Skaggs et al[15], and Lisi[17] used validated and reliable methods to assess pain by way of numerical pain rating scales, and only Skaggs et al used any means to assess the impact of back pain through their use of the Bournemouth Questionnaire.[8-40]

Case series often lack adequate description of the patient populations and study settings from which the sample under study was drawn, give poor or no description of subject recruitment, lack dropout rates or reasons for dropouts, and do not account for the possibility of referral or self-selection bias. Only Lisi[17] described the gestational ages of his subjects and only Lisi[17], Guadagnino[18], and Mantero and Crispini[14] described the ages of the included patients during their pregnancies. The single cross-sectional study included in this systematic review also suffered from numerous methodological issues such as using a nonstandardized outcome measure and lacking a control group.[16] Several of the included studies used retrospective designs,[16,17] again hindering their overall quality.

Case series frequently lack detailed information about the treatments used, for the studies in this review descriptions of treatment types and frequencies were inconsistent, making it difficult to assess similarities and differences between the treatment regimens used in the different studies and the ensuing results. Common to all of the treatment plans was the use of some form of chiropractic manual manipulation; however, only the study by Guadagnino[18] actually mentions the particular techniques used (sacrooccipital technique, Gonstead knee chest table, and diversified), although it is not indicated which patients received which type of manipulation. Adjunctive therapies were used in at least 3 of the included studies[15,17,18], but without comparison groups, it is difficult to ascertain the effects of these modalities.

It could be argued that the quality of this review was influenced or reduced by excluding articles that used spinal manipulation for LBP in pregnant patients by health professionals other than chiropractors. However, in his systematic review of chiropractic manipulation for neck pain studies, Ernst[41] intimates that only including chiropractic studies could be seen as a potential strength. There are often differences between chiropractic manipulations (often called adjustments) and manipulations performed by nonchiropractors (such as physical therapists, osteopaths, orthopedic surgeons, or physiatrists). Chiropractors generally use high-velocity, low-amplitude, short-lever manipulations, whereas those other health care professionals may use different forms of manipulative techniques.[41] Thus, by only comparing articles using chiropractic manipulation in this review, one could reason that there is a better chance of comparing similar treatments.

The checklist used in this review was created by Downs and Black[11]; it has been tested and found to be valid and reliable.[11,12] However, there is still a need for the checklist to undergo further testing.[11,12] Regardless, the Downs and Black checklist was used in this review as the authors were aware that there would likely be no RCTs pertaining to the chiropractic care of pregnancy-related LBP. According to Saunders et al,[12] the checklist created by Downs and Black was perhaps the best suited to assess the methodological quality of nonrandomized intervention studies.

The power of this review was limited by the small number of studies and their moderate to poor quality. This