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Lumbar supports for prevention and treatment of low-back pain (Cochrane Review)

van Tulder MW, Jellema P, van Poppel MNM, Nachemson AL, Bouter LM

ABSTRACT

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A substantive amendment to this systematic review was last made on 23 May 2000. Cochrane reviews are regularly checked and updated if necessary.

Background: Lumbar supports are used in the treatment of low back pain patients to make the impairment and disability vanish or decrease. Lumbar supports are also used to prevent the onset of low back pain (primary prevention) or to prevent recurrences of a low back pain episode (secondary prevention).

Objectives: The objective of this systematic review was to assess the effects of lumbar supports for prevention and treatment of non-specific low back pain.

Search strategy: We searched the Medline, Cinahl and Current Contents databases and the Cochrane Controlled Trials Register up to September 1999, and the Embase database up to September 1998. We also screened references given in relevant reviews and identified controlled trials, and used Science Citation Index to identify additional controlled trials.

Selection criteria: Controlled clinical trials that reported on any type of lumbar supports as preventive or therapeutic intervention for non-specific low back pain were included.

Data collection and analysis: One reviewer extracted data from the trials considering characteristics of the study population, characteristics of the interventions and the final results for each outcome measure. The reviewer compared these findings to data regarding the same characteristics of the same studies published already in other reviews. The methodological quality was independently assessed by two reviewers. Because it was not possible to perform a quantitative analysis, a qualitative meta-analysis was performed in which the strength of evidence on the effectiveness of lumbar supports was classified as being strong, moderate, limited or conflicting, and no evidence.

Main results: Five randomized and two nonrandomized controlled preventive trials and six randomized therapeutic trials were included in our review. Overall the methodological quality of the studies included in our review was rather low. Only four of the thirteen studies scored positive on 50% or more of the the internal validity items. There was moderate evidence that for primary prevention lumbar supports are not more effective than other types of treatment or no intervention. No evidence was found on the effectiveness of lumbar supports for secondary prevention. The systematic review of therapeutic trials showed that there is limited evidence that lumbar supports are more effective than no treatment, while it is still unclear if lumbar supports are more effective than other interventions for treatment of low back pain.

Reviewers' conclusions: There is still a need for high quality randomised trials on

the effectiveness of lumbar supports. One of the most essential issues to tackle in these future trials seems to be the realisation of an adequate compliance.

Citation: van Tulder MW, Jellema P, van Poppel MNM, Nachemson AL, Bouter LM. Lumbar supports for prevention and treatment of low-back pain (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

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LUMBAR SUPPORTS FOR PREVENTION AND TREATMENT OF LOW BACK PAIN

van Tulder MW, Jellema P, van Poppel MNM, Nachemson AL, Bouter LM

* * *

Date of most recent substantive amendment: 23 May 2000

This review should be cited as: van Tulder MW, Jellema P, van Poppel MNM, Nachemson AL, Bouter LM. Lumbar supports for prevention and treatment of low back pain (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003. Oxford: Update Software.

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Background

Lumbar supports are used in the treatment of low back pain patients to make the impairment and disability vanish or decrease. Lumbar supports are also used to prevent the onset of low back pain (primary prevention) or to prevent recurrences of a low back pain episode (secondary prevention).

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The objective of this systematic review was to assess the effects of lumbar supports for prevention and treatment of non-specific low back pain.

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Because it was not possible to perform a quantitative analysis, a qualitative meta-analysis was performed in which the strength of evidence on the effectiveness of lumbar supports was classified as being strong, moderate, limited or conflicting, and no evidence.

Main Results

Five randomized and two nonrandomized controlled preventive trials and six randomized therapeutic trials were included in our review. Overall the methodological quality of the studies included in our review was rather low. Only four of the thirteen studies scored positive on 50% or more of the the internal validity items. There was moderate evidence that for primary prevention lumbar supports are not more effective than other types of treatment or no intervention. No evidence was found on the effectiveness of lumbar supports for secondary prevention. The systematic review of therapeutic trials showed that there is limited evidence that lumbar supports are more effective than no treatment, while it is still unclear if lumbar supports are more effective than other interventions for treatment of low back pain.

Reviewers' conclusions

There is still a need for high quality randomised trials on the effectiveness of lumbar supports. One of the most essential issues to tackle in these future trials seems to be the realisation of an adequate compliance.

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BACKGROUND

Low back pain (LBP) is a very common health problem in western industrialised countries. Lifetime prevalence of LBP exceeds 70%, with peak point prevalences between ages 35 and 55 (Andersson 1997). Furthermore, recurrent episodes of LBP occur very frequently and a considerable number of people suffer permanently from LBP (Andersson 1997). Chronic LBP is present in 3% to 7% of the population in western industrialised countries (Andersson 1997). The impairment and disability associated with LBP frequently leads to absence from work and associated loss of productivity. The total costs of LBP to industry in 1988 in the United States was estimated to be between US\$26.8 and US\$56 billion (Mitchell 1994). In The Netherlands, the total costs of absenteeism and disablement due to back pain - the indirect costs - were estimated at US\$3.1 billion and US\$1.5 billion, respectively, in 1991, while the total direct medical costs were estimated at US\$368 million (van Tulder 1995).

Lumbar supports are frequently used in the management of low back pain and are also a common intervention in industry to prevent back injuries (Dillingham 1998). Lumbar supports are provided as treatment to people suffering from LBP with the aim to make the impairment and disability vanish or decrease. Lumbar supports are provided as intervention for prevention with the aim to prevent the onset of LBP (primary prevention) or to prevent recurrent LBP episodes (secondary prevention). Although a large variety of preventive and therapeutic interventions are available for LBP, the efficacy of most of these interventions has not been demonstrated yet (van Tulder 1997a; van Poppel 1997).

Nachemson 1987 reported different desired functions of a lumbar support: 1) to correct deformity; 2) to limit spinal motion; 3) to stabilise part of the spine; 4) to reduce mechanical uploading; 5) miscellaneous effects: massage, heat, placebo. However, at the present time the putative mechanisms of action of a lumbar support remain a matter of debate (Barron 1994; Calmels 1996; Dillingham 1998; Minor 1996).

Potential adverse effects of wearing a lumbar support that have been reported, are skin lesions, gastro-intestinal disorders and muscle wasting (Calmels 1996), higher blood pressure and higher heart rates (McGill 1993).

The still growing popularity of lumbar supports has led to several studies investigating the preventive and therapeutic effects. These studies have already been summarised in several reviews, papers and editorials on the effectiveness of lumbar supports for prevention (Barron 1994; Karas 1996; Minor 1996; van Poppel 1997; Dillingham 1998) and for treatment (Koes 1994).

The present systematic review of the effectiveness of lumbar supports for prevention and treatment of non-specific low back pain distinguishes itself from the above mentioned reviews by 1) evaluating the literature systematically using the up-to-date methodology recommended by the Cochrane Collaboration Back Review Group; 2) by including the most recent literature up to September 1999; and 3) by reviewing lumbar supports in the context of both treatment and prevention.

OBJECTIVES

The objectives of this systematic review were to determine if lumbar supports are effective for prevention of non-specific LBP and if lumbar supports are effective for treatment of non-specific LBP.

Comparisons that were investigated are:

- 1a) Lumbar support as intervention for prevention of LBP versus no intervention.
- 1b) Lumbar support as intervention for prevention of LBP versus other types of prevention.
- 1c) Lumbar support as supplement to another type of prevention of LBP versus that other type of prevention alone.
- 2a) Lumbar support as intervention for treatment of LBP versus no intervention.
- 2b) Lumbar support as intervention for treatment of LBP versus other types of treatment.
- 2c) Various types of lumbar support.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Both randomised controlled trials (RCTs) and non-randomised controlled trials (CCTs) were included. CCTs were included because of the small number of available RCTs. There were no language restrictions.

Types of participants

For preventive trials, the study population had to consist of workers aged 18 to 65 years. For therapeutic trials, the study population had to consist of subjects with non-specific low back pain. RCTs and CCTs that included subjects with low back pain caused by specific pathological entities such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, or fractures were excluded.

Types of intervention

Any type of lumbar support, flexible and rigid, for prevention or treatment of non-specific LBP was included. Special types of lumbar supports for severe scoliosis and kyphosis were excluded as were special lumbar supports after back surgery.

Types of outcome measures

Only preventive studies that used at least one of the following outcome measures were included: incidence of low back pain, duration of low back pain, absenteeism (% of the studied population, number of days) and back pain specific functional status (Roland Disability Questionnaire (RDQ), Oswestry scale). For therapeutic studies only RCTs and CCTs that used at least one of the following outcome measures were included: pain (Visual Analogical Scale (VAS), Numerical Rating Scale (NRS)), overall improvement (% improvement, NRS), return to work (% of

the population, number of days of absenteeism) and back pain specific functional status (RDQ, Oswestry scale).

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: [Cochrane Back Group search strategy](#)

We searched the Medline, Cinahl and Current Contents databases and the Cochrane Controlled Trials Register up to September 1999. The Embase database was searched up to September 1998. The search strategy recommended by the Editorial Board of the Cochrane Back Review Group ([van Tulder 1997b](#)) was used. We also screened references given in relevant reviews and identified trials, and used Science Citation Index to identify additional trials.

METHODS OF THE REVIEW

Study selection:

Two reviewers (M van Tulder and P Jellema) ran the complete search strategy in Medline and Embase together. One reviewer (P Jellema) ran the search in Cinahl and Current Contents. Authors, title, subject-headings, publication type and abstract of the studies identified by the search strategy were downloaded. Studies that met the inclusion criteria were included in the review. A consensus method was used to resolve disagreements about the inclusion of studies and a third reviewer (M van Poppel) was consulted if disagreement persisted.

Methodological quality assessment:

The methodological quality was independently assessed by two reviewers (M van Tulder and P Jellema). The articles were not blinded for author, institution and journal, because one of the quality assessors (M van Tulder) was very familiar with the literature and would have recognized blinded studies easily. The other quality assessor (P Jellema) was a layperson in the field of intervention research on back pain and not familiar with the literature. A consensus method was used to resolve disagreements concerning the assessment of the methodological quality of the RCTs and CCTs included in the review. A third reviewer (M van Poppel) was consulted if disagreement persisted.

If the article did not contain sufficient information on one or more of the criteria, the authors were contacted for additional information. If the authors could not be contacted or if the information was no longer available, the criteria were scored as 'unclear'.

Data extraction:

Using a standardized form, one reviewer (P Jellema) extracted data considering characteristics of the study population (age, gender), type of work performed by the study population (in prevention trials), type of LBP (with or without radiation, in treatment trials), duration of LBP (acute or chronic, in treatment trials), type of study (RCT or CCT), duration of intervention period, timing of follow-up measurements, characteristics of the studied intervention (type of lumbar support, the number of hours per day the subjects were prescribed to wear the lumbar support, duration of intervention period), characteristics of the control intervention (type, intensity, duration of intervention period), adverse effects due to the interventions, compliance, and the final results for each outcome measure on the effectiveness of lumbar supports. The reviewer compared these findings to data regarding the same characteristics of the same studies published in other reviews ([Koes 1994](#); [van Poppel 1997](#)). The articles were not blinded for author, institution and journal.

Data analysis:

Many studies did not report the results in a way enabling statistical pooling (for example means with standard deviations for continuous data). Furthermore, studies were heterogeneous with regard to study populations, interventions and outcomes. Therefore, we decided not to perform a meta-analysis but to qualitatively summarise the results. A rating system was used, consisting of four levels of scientific evidence based on the design (RCT or CCT), the quality, and the outcome of the studies:

- 1) Strong evidence - provided by generally consistent findings in multiple high quality RCTs.
- 2) Moderate evidence - provided by generally consistent findings in one high quality RCT and one or more low quality RCTs or by generally consistent findings in multiple low quality RCTs.
- 3) Limited evidence - only one RCT (either high or low quality) or generally consistent findings in CCTs.
- Conflicting evidence - inconsistent findings in multiple RCTs and CCTs.
- 4) No evidence - no CCTs or RCTs.

We defined multiple high quality RCTs as more than one RCT which fulfilled 50% or more of the validity criteria, but also performed sensitivity analyses exploring the results when high quality was defined as fulfilling 40% and 60% or more of the validity criteria. Another sensitivity analysis was performed in which all 'unclear' scores on the internal validity items were assumed to be 'positive'. Findings were considered to be 'generally consistent' when at least 75% of the studies showed similar results.

Subgroup analyses for prevention were performed for: 1) primary versus secondary prevention, 2) short-term follow-up (<6 months after randomisation) versus long-term follow-up (>6 months after randomisation). Subgroup analyses for treatment were performed for: 1) acute versus chronic LBP, 2) short-term follow-up (<6 months after randomisation) versus long-term follow-up (>6 months after randomisation).

DESCRIPTION OF STUDIES

Study characteristics are summarised in the table with characteristics of included studies.

PREVENTION

Of the seven preventive studies, five were RCTs (Alexander 1995; Gaber 1999; Reddell 1992; van Poppel 1998; Walsh 1990) and two were CCTs (Anderson 1993; Thompson 1994). In three studies it was reported that workers with a past history of LBP were included, and in two studies it was reported that workers with current LBP were included. In the other studies no information was given about in- or exclusion of workers with a past history of LBP or current LBP. Walsh 1990 excluded patients who were 'currently' treated for back pain or back injury. The number and type of control interventions used in the preventive studies varied considerably. In all studies the subjects were prescribed to wear the lumbar support at work. Only three studies presented data regarding compliance (Anderson 1993; Reddell 1992; van Poppel 1998). The compliance rate varied from 43% of the subjects who wore the belt at least half of the time (van Poppel 1998) to 80% of the subjects who wore the belt most of the time (Anderson 1993).

Two studies presented results of subgroup analyses for subjects with a history of back pain. van Poppel 1998 showed that, within a subgroup of subjects with LBP at baseline, workers using a lumbar support had lesser days with LBP per month compared to workers without lumbar support. Barron 1994 suggested, using data of Walsh 1990, that workers with a history of LBP may be an appropriate population for consideration of prophylactic bracing in the workplace rather than the general workforce.

TREATMENT

All six studies on treatment were RCTs. None of the treatment studies included solely patients with acute LBP, and only one study included solely patients with chronic LBP (Million 1981). Four studies included a mix of patients with acute, subacute and chronic LBP (Coxhead 1981; Doran 1975; Hsieh 1992; Valle-Jones 1992). One study did not give any information about the duration of the LBP complaints of the patients (Penrose 1991). The lumbar supports and control interventions used in the studies varied considerably. One study reported that 'any type' of lumbar support was used (Coxhead 1981). Two studies used a lumbar support with rigid stays in the back (Million 1981; Hamonet 1993), while one study used a pneumatic lumbar support (Penrose 1991). The other two studies did not provide much information about the type of belt (Coxhead 1981; Valle-Jones 1992). In the study of Million 1981 two types of lumbar supports were compared. Only three studies did report the number of hours a day the lumbar support should be worn (Hsieh 1992; Million 1981; Penrose 1991). Compliance with wearing the belt was reported in only one study; 56% of the patients wore the belt more than 7 hours a day (Hsieh 1992).

METHODOLOGICAL QUALITY

The methodological quality of the studies was assessed using the criteria list recommended by the Cochrane Back Review Group for Spinal Disorders (van Tulder 1997b). Only the items reflecting the internal validity of the RCTs and CCTs were used to assess the methodological quality. The item regarding the blinding of care providers was not included in our quality assessment, because blinding of care providers for lumbar support use seems impossible.

The internal validity items are:

1. Was a method of randomization performed?
2. Was the treatment allocation concealed?
3. Were the groups similar at baseline regarding the most important prognostic indicators?
4. Were co-interventions avoided or comparable between groups?
5. Was the compliance rate (in each group) unlikely to cause bias?
6. Was the patient blinded?
7. Was the outcome assessor blinded?
8. Was the withdrawal/drop-out rate unlikely to cause bias?
9. Was the timing of the outcome assessment in both groups comparable?
10. Was an intention-to-treat analysis used?

Each criteria was scored as either 'positive', 'negative' or 'unclear'. A validity item was scored as 'positive' when the available information regarding that item did not reveal any bias, 'negative' when no information at all was provided regarding that item or when the available information did reveal any bias. A validity item was scored as 'unclear' when the available information regarding that item was too scarce to make a conclusion regarding potential bias.

The operationalisation of the methodological quality items was as follows:

1. In order to score 'positive', a random (unpredictable) assignment sequence has to be performed. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.
2. In order to score 'positive', the assignment has to be generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
3. Treatment: In order to score 'positive', groups have to be similar at baseline with regarding to at least three of the following important prognostic characteristics: 1) age, 2) duration of complaints, 3) percentage of patients with radiating pain and 4) value of main outcome measure(s).
Prevention: In order to score a 'yes', groups have to be similar at baseline with regarding to at least three of the following important prognostic characteristics: 1) age, 2) incidence and/or duration of a previous episode of low back pain, 3) incidence and/or duration of a present episode of low back pain, 4) type of work, 5) value of main outcome measures.

Moreover, for each group the mean and SD values of these characteristics have to be presented (for example in a table). When they aren't presented, the score is 'unclear'.

4. In order to score 'positive', co-interventions should either be avoided in the trial design or should be comparable between the index and control groups.
5. The reviewer determines when the compliance to the interventions is acceptable to score 'positive'. This determination is based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). In case of a lumbar support the reported number of hours a day and the reported total number of days the subjects actually wore the belt should be acceptable enough to answer the research question without bias caused by compliance.
6. The reviewer determines when enough information about the blinding is given in order to give a 'positive' score.
7. The reviewer determines (per outcome parameter) when enough information about blinding is given in order to give a 'positive' score.
8. In order to score 'positive', a description is needed of the participants who were included in the study but 1) did not complete the observation period or 2) were not included in the analysis. But, when the percentage of withdrawals and drop-outs during the intervention period exceeds 20%, 'negative' should be scored. (N.B. these percentages are arbitrary, not supported by literature).
9. In order to score 'positive', the timing of the outcome assessment should be identical for all intervention groups and for all important outcome assessments. Only when a statement is made about a different timing of the outcome measurements, 'negative' should be scored.
10. In order to score 'positive' all randomized patients/subjects need to be reported/analyzed for the most important moments of effect measurement in the group they were allocated to by randomization, irrespective of non-compliance and co-interventions. N.B. This does not apply to the missing values.

RESULTS

Study Selection.

The search strategy in the four databases resulted in the identification of 153 articles; 43 articles were identified in Medline, 93 articles in Embase, six articles in Cinahl and 11 articles in Current Contents. Because 17 articles were found in two databases, four articles in three databases and one article in all four databases, the total number of potentially relevant articles was 125. Based on titles, subject headings, abstracts and journal types, we concluded that seven articles met the eligibility criteria (Doran 1975; Hsieh 1992; Larsson 1980; Million 1981; Valle-Jones 1992; van Poppel 1998; Walsh 1990). The reviewers disagreed upon or were not sure about inclusion of six studies (Amudsen 1982; Garg 1992; Hamonet 1993; Jonai 1997; Marty 1998; Spratt 1993). All six articles were excluded after reading the full articles (see Table with Characteristics of excluded studies for reason of exclusion).

The papers of Hsieh et al. (1992) and Pope et al. (1994) appeared to be reports of the same study (Hsieh 1992). Both papers were used to assess the quality of this study and to extract relevant data.

Screening references of two reviews (Koes 1994; van Poppel 1997) resulted in identification of five additional studies (Alexander 1995; Anderson 1993; Coxhead 1981; Reddell 1992; Thompson 1994). In 1991, some additional data of the study of Walsh 1990 has been published in a letter to the editor (Walsh & Schwartz 1991). Screening the latest issue of the Cochrane library, resulted in identification of four RCTs, which had already been identified.

Citation tracking in the Science Citation Index of the selected RCTs and CCTs resulted in identification of 42 articles. However, none of these studies met the inclusion criteria.

Two additional studies came from our own personal files (Gaber 1999; Penrose 1991).

In summary, seven studies on prevention were included in the present review (Alexander 1995; Anderson 1993; Gaber 1999; Reddell 1992; Thompson 1994; van Poppel 1998; Walsh 1990) and six studies on treatment (Coxhead 1981; Doran 1975; Million 1981; Penrose 1991; Hsieh 1992; Valle-Jones 1992).

Methodological Quality.

The two quality assessors disagreed about 55 of the 227 validity items (24%). After one consensus meeting all disagreements, mostly due to reading errors, were resolved.

The authors of the studies have been informed about the methodological quality assessment (Alexander 1995; Anderson 1993; Coxhead 1981; Million 1981; Hsieh 1992; Reddell 1992; Thompson 1994; van Poppel 1998; Walsh 1990). The addresses of two authors could not be traced (Doran 1975; Valle-Jones 1992). We asked the authors if they agreed with the scores and if they could provide more information on the items that were scored as 'unclear'. The authors of four studies responded to this request (Coxhead 1981; Hsieh 1992; Million 1981; van Poppel 1998). Seven scores were changed by this information; four unclear scores and 3 negative scores were changed into positive.

Overall the methodological quality of the studies included in the present review was low. Only four of the thirteen studies met our preset level for high quality of more than 50% positive scores (Hsieh 1992; Million 1981; van Poppel 1998; Walsh 1990). Prevalent methodological flaws were inadequate randomisation procedure (items 1), no concealment of treatment allocation (item 2), no assessment of co-interventions (item 4) and compliance (item 5), and no blinding of patients (item 6) and outcome assessors (item 7).

EFFECTS OF LUMBAR SUPPORTS IN PREVENTION OF LOW BACK PAIN

1. Lumbar supports versus no intervention.

Four RCTs (Alexander 1995; Gaber 1999; Reddell 1992; van Poppel 1998) and one CCT (Anderson 1993) included a 'no intervention' group. One study was considered to be a high quality RCT (van Poppel 1998), while three

studies were considered to be low quality RCTs (Alexander 1995; Gaber 1999; Reddell 1992). None of these studies evaluated lumbar supports for secondary prevention and, therefore, a subgroup analysis for primary versus secondary prevention was not performed.

Four RCTs reported no differences in back pain injury or incidence of LBP after 3 months (Alexander 1995), 6 months (van Poppel 1998), 8 months (Reddell 1992), and 12 months (Gaber 1999). Three RCTs, including the high quality study, did not find any differences on sick leave (Gaber 1999; Reddell 1992; van Poppel 1998). There is moderate evidence (level 2) that lumbar supports do not prevent LBP.

2. Lumbar support versus other types of prevention.

Two studies were identified, one high quality trial (van Poppel 1998) and one low quality (Reddell 1992). Both RCTs used incidence of LBP and sick leave due to LBP as outcome measures. In both trials these outcome measures did not show significant differences between intervention and control groups. There is moderate evidence (level 2) that lumbar supports are not more effective than other types of prevention for LBP.

3. Lumbar support as supplement to another type of prevention versus that other type of prevention.

Two studies compared lumbar support plus back school with the back school program alone in the prevention of low back pain (Thompson 1994; Walsh 1990). In one trial, all subjects also got instructions on warming-up exercises (Thompson 1994). One trial was considered a high quality RCT (Walsh 1990), the other trial was a CCT (Thompson 1994). Both studies used incidence of LBP (work injury) as outcome measure, and one study also used days lost from work by back injury as outcome measure (Walsh 1990). Both trials found no significant differences between the two intervention groups regarding incidence of LBP (work injury). The high quality study found a significant effect of wearing the belts in addition to a back school program on the number of days lost from work by back injury (Walsh 1990).

With regard to the incidence of LBP, there is limited evidence (level 3) that a lumbar support added to a back school program is not more effective than a back school alone. However, there is limited evidence (level 3) that a lumbar support added to a back school program is more effective than a back school alone regarding the number of days lost from work due to back injury .

EFFECTS OF LUMBAR SUPPORTS IN TREATMENT OF LOW BACK PAIN.

4. Lumbar support versus no intervention.

One low quality RCT compared the effect of a lumbar support to no intervention (Penrose 1991). In this study the pain index showed a significant effect in favour of the lumbar support group. There is limited evidence (level 3) that lumbar supports provides some pain relief in low back pain patients.

5. Lumbar support versus other types of treatment.

Four trials compared lumbar supports with some type of treatment for LBP (Coxhead 1981; Doran 1975; Hsieh 1992; Valle-Jones 1992). Only one trial was considered a high quality RCT (Hsieh 1992). All four studies used pain as main outcome measure. Only the trial of Valle-Jones 1992 found a significant difference on pain in favour of the lumbar support group, the other three studies, including the high quality RCT, reported no differences. There is moderate evidence (level 2) that a lumbar support is not more effective in reducing pain than other types of treatment.

Overall improvement was used as main outcome measure in three low quality studies (Coxhead 1981; Doran 1975; Valle-Jones 1992). Only one study (Valle-Jones 1992) found a significantly greater overall improvement in the lumbar support group, while the other two did not find any differences. There is conflicting evidence (level 3) that patients wearing a lumbar support do or do not show significantly more overall improvement than patients receiving another type of treatment.

Return to work (or ability to work) was used as main outcome measure in two low quality studies (Coxhead 1981; Valle-Jones 1992). One study found no significant difference between the groups (Coxhead 1981), while the other found a significant difference in favour of the lumbar support group (Valle-Jones 1992). There is conflicting evidence (level 3) that patients who use a lumbar support as treatment return to their work more quickly than patients who use another type of treatment.

In the high quality study, two different back pain specific functional status tests have been used (Hsieh 1992). The Roland Disability Questionnaire showed a significant difference between the lumbar support group and the soft tissue massage group. The revised Oswestry Scale showed no significant difference between the groups. Therefore, there is conflicting evidence (level 3) on the effectiveness of lumbar supports improving the back pain specific functional status compared to other types of treatment.

6. Comparison of different types of lumbar supports.

One high quality RCT (Million 1981) compared two different types of lumbar supports; one with and one without rigid insert in the back. Patients wearing the lumbar support plus rigid insert showed significantly more global improvement (on a subjective index) than those without rigid insert. There is limited evidence (level 3) that a lumbar support with a rigid insert in the back provides more overall improvement than a lumbar support without a rigid insert in the back.

Sensitivity Analyses.

We have conducted a sensitivity analysis to evaluate the influence of different thresholds for high quality on the overall conclusions. We also conducted a sensitivity analysis in which all 'unclear' scores on internal validity items were considered 'positive'.

1. Different thresholds for high quality.

When using a threshold of 40% for studies on prevention, one additional RCT was considered high quality

(Alexander 1995) resulting in a total of three high quality RCTs (Alexander 1995; van Poppel 1998; Walsh 1990). Consequently, the conclusion on the comparison of lumbar supports versus no intervention changed from 'moderate evidence' to 'strong evidence' that lumbar supports are not more effective in preventing back injury or LBP than no intervention.

When using a threshold of 40% for studies on treatment, the studies of Penrose 1991 and Valle-Jones 1992 were also considered high quality. For the comparison of lumbar supports to other types of treatment, only the conclusion on pain intensity changed from 'moderate evidence' (level 2) that lumbar supports are not more effective than other types of treatment to 'conflicting evidence' (level 3). When compared to no intervention, 'limited evidence' that lumbar supports are more effective than no intervention changed into 'moderate evidence' (level 2).

When using a threshold of 60% for studies on prevention, the study of Walsh 1990 changed from high quality to low quality RCT, but the evidence is still limited (level 3).

Using a threshold of 60% for studies on treatment, conclusions did not change, because the studies of Hsieh 1992 and Million 1981 were still high quality studies.

2. All 'unclear' scores 'positive' .

When all 'unclear' scores were assumed to be 'positive', four studies on prevention (Alexander 1995; Gaber 1999; van Poppel 1998; Walsh 1990) and five studies on treatment (Doran 1975; Hsieh 1992; Million 1981; Penrose 1991) were considered high quality RCTs at the 50% cut-off.

The conclusion regarding the comparison 'lumbar support versus no intervention' changed from 'moderate evidence' (level 2) to 'strong evidence' (level 1) that a lumbar support is not more effective in preventing LBP than no intervention.

The conclusion regarding the comparison 'lumbar support versus another type of treatment' changed from 'moderate evidence' (level 2) that a lumbar support is not more effective in reducing pain to 'conflicting evidence' (level 3). The conclusion regarding the comparison of 'lumbar supports versus no intervention' did not change, i.e. there is limited evidence (level 3) that a lumbar support is more effective than no intervention.

DISCUSSION

Selection bias.

Despite the extensive search strategy used to identify all relevant studies on the effectiveness of lumbar supports, some studies may have been missed. The keywords may not have been in accordance with the keywords used in the search strategy of the present review, or the journals may have been indexed in other databases. To find out whether there are more trials published in non-indexed journals, we have to wait for the results of the hand-searching which is currently being done within the Cochrane Back Review Group.

Methodological quality.

The two reviewers who assessed the methodological quality were not blinded for authors, journal and institution. Potential bias caused by the non-blinded quality assessment was expected to be low. First, there was no conflict of interest among the two reviewers, i.e., the reviewers did not have any (financial or other) interest in positive or negative results. Second, one reviewer (M van Tulder) was an expert in the field of LBP and very familiar with the literature. Blinding this reviewer did not seem feasible. The other reviewer (P Jellema) was a layperson in the field of LBP. Blinding of such a reviewer did not seem necessary, because that reviewer was new to the field.

Furthermore, we presented the methodological criteria list, the operationalisation of criteria, and the final results of our assessment, so readers can determine whether they agree with the conclusions or not.

The methodological quality was defined by the internal validity criteria, which refer to characteristics of the study that might be related to bias. The methodological quality of the studies included in our review was rather low.

Only four of the thirteen studies scored positive on 50% or more of the internal validity items and were considered high quality (Hsieh 1992; Million 1981; van Poppel 1998; Walsh 1990). Methodological flaws that were identified considered the randomisation procedure, the assessment of co-interventions and compliance, and blinding of patients and outcome assessors.

Although the authors of 11 studies claimed that their study design was a randomised controlled trial, an appropriate method of randomisation and concealment of treatment allocation was described in only three papers. Most studies did not report data on co-interventions or compliance. The studies of van Poppel 1998 and Reddell 1992 reported a low compliance. Being compliant with wearing lumbar supports is very important, because it will be impossible to find evidence for the effectiveness of lumbar supports if the subjects in a trial are not compliant with wearing them.

Blinding of subjects is difficult in trials on the effectiveness of lumbar supports. Only one study succeeded in blinding the patients (Million 1981). Even more important should be blinding of the outcome assessor. However, only three of the 13 studies did use or did report the use of a blinded outcome assessor.

The validity, reliability and responsiveness of outcome measures were often not reported. Therefore, it is unclear whether the instruments actually measured what they were supposed to measure, whether they measured with consistency, and whether they were able to measure change over time. Future studies should use valid, reliable and responsive instruments to evaluate the effectiveness of preventive and therapeutic interventions.

Levels of evidence.

In this review, we refrained from statistical pooling because of the heterogeneity of study populations, control interventions and outcome measures. The conclusions on the effectiveness of lumbar supports were based on a qualitative analysis of the strength of scientific evidence. The classification of the comparisons to a level of evidence was sometimes quite arbitrary. When results of several studies regarding a comparison did not entirely agree with each other, it was difficult to decide whether these results should be entitled as 'generally consistent findings' or as 'inconsistent findings'. For example, if all trials were positive, it is obvious that the findings are

consistent, but are findings also consistent if five out of seven trials are positive or if four out of seven are positive? We arbitrarily defined consistency when 75% or more of the studies had similar results. We have presented extensive tables, so readers can determine if they agree with the classification of evidence in this review.

Effectiveness of lumbar supports.

Seven preventive studies and six therapeutic studies were included in this systematic review. The results of the systematic review showed that there is no strong evidence in favour of or against the effectiveness of lumbar supports as intervention for prevention and treatment. Even in our sensitivity analyses, when the thresholds for high quality were changed from 50% to 40% and when all 'unclear' scores were assumed to be 'positive', no strong evidence could be demonstrated in favour of lumbar supports.

The results on prevention showed that there was moderate evidence that lumbar supports are not effective in preventing LBP and that lumbar supports are not more effective than other types of prevention for LBP. The results of this review are in agreement with the point of view of the National Institute for Occupational Safety and Health (NIOSH) as presented in several reviews (Brown 1995 ; Gillen 1995; Karas 1996). According to NIOSH, the current literature lacks scientific evidence to support the use of lumbar supports as a primary preventive measure. The systematic review of van Poppel 1997 also reported a lack of conclusive evidence in favour of or against the effectiveness of lumbar supports for primary prevention.

Information regarding the possible secondary preventive effects of lumbar supports was provided by subgroup analyses in two studies (van Poppel 1998; Walsh 1990). These subgroup analyses suggested that workers with a past history of LBP might be at reduced risk for recurrent episodes of LBP. However, to investigate the effectiveness of lumbar supports for secondary prevention a randomised controlled trial focussing on this question needs to be conducted.

The results on treatment showed that there was conflicting evidence on the effectiveness of lumbar supports compared to other types of treatment. Koes 1994 concluded in their systematic review that the effectiveness of lumbar supports in the treatment of LBP remained controversial. According to the available international guidelines for the management of LBP in primary care, a lumbar support should not be prescribed for patients with acute LBP (Faas 1996).

Limited evidence was found in favour of a lumbar support with a rigid insert in the back compared to a lumbar support without rigid insert, indicating that some types of lumbar supports may be more effective in reducing LBP than others. Most studies included in the review did not provide detailed information about the type of lumbar support that was used. The scarce information revealed that probably different types of lumbar supports have been used. Some reviews commented that the type of lumbar supports that has been used in controlled studies, such as those by Walsh and Reddell, are not typically used or recommended in industry. Because there are now world-wide over 70 types of lumbar supports for prevention (Hodgson 1996), and more than 30 types for treatment of spinal disorders (Pope 1997), it would be interesting to know what the specific effects are of different types of lumbar supports.

REVIEWER'S CONCLUSIONS

Implications for practice

The systematic review did not provide evidence that lumbar supports are or are not useful in the primary prevention of low back pain in industry. The results of the systematic review showed that there is conflicting evidence on the effectiveness of lumbar supports in the treatment of low back pain. Lumbar supports are not recommended for primary prevention and treatment of low back pain.

Implications for research

Because none of the studies has evaluated the effectiveness of lumbar supports in the secondary prevention of low back pain, future studies (if any) could focus on this topic. Future trials should be of high quality and special attention should be paid to adequate compliance.

POTENTIAL CONFLICT OF INTEREST

One author (Mireille van Poppel) has published a randomised trial on prevention of back pain that was included in this review.

Two authors (Alf Nachemson and Lex Bouter) are editors of the Cochrane Back Review Group. Editors are required to conduct at least one Cochrane review. This requirement ensures that editors are aware of the processes and commitment needed to conduct reviews. None of the editors are first authors. This involvement do not seem to be a source of conflict of interest in the Back Review Group. Any editor who is a reviewer is excluded from editorial decisions on the review in which they are contributors.

TABLES

Characteristics of included studies

 Detach table

Study	Alexander 1995
Methods	RCT.
Participants	Subjects: 60 health care workers; 48 women and 12 men. Mean age 37 years. Exclusion criteria: subjects who have had back surgery, current workers' compensation claims, cardiovascular problems or were pregnant. Authors did not report whether workers with LBP or a past history of LBP were included in the study.
Interventions	Preventive intervention: 1) Back belt group (n=30). Belt use at work for 3 months. Control intervention: 2) No intervention (n=30)
Outcomes	Work related back injuries, and perception of physical pain. No significant differences.
Notes	The most common complaints: belt rode up, changed position and increased perspiration. No data available regarding compliance.
Allocation concealment	C
Study	Anderson 1993
Methods	CCT.
Participants	Subjects: 266 workers in a grocery distribution warehouse. No data available on age. Authors did not report whether workers with LBP or a past history of LBP were included in the study.
Interventions	Preventive intervention: 1) Back belt group (n=266) A spandex belt with shoulder straps. Belt use at work for 12 months. Control intervention: 2) No intervention (2 other work sites).
Outcomes	Lower incidence of injury in back belt group.
Notes	The supervisors reported that over 80% of the workers wore the belts most of the time.
Allocation concealment	C
Study	Coxhead 1981
Methods	RCT; factorial design.
Participants	Subjects: 334 patients with pain of sciatic distribution; 185 men and 149 women. Mean age 41.9, mean duration of symptoms 14.3 weeks. Exclusion-criteria: specific LBP, patients undergone trunk, lower-limb or spinal surgery within the previous three months and pregnant & postpartum women.
Interventions	Treatment intervention: 1) Fabric made lumbar support, 4 weeks (n=124). No data on number of hours / day. Control interventions: 2) No lumbar support (n=168).
Outcomes	Overall improvement, pain, return to work / normal activities. No differences after 4 weeks, 4 months ad 16 months.
Notes	334 patients entered the study, 12 were later found ineligible. Of these 322 patients, 292 were assessed at 4 weeks. At 4 months 250 patients and at 16 months 258 patients were assessed. No data available regarding compliance.
Allocation concealment	C
Study	Doran 1975
Methods	RCT.
Participants	Subjects: 456 patients with non-specific LBP; 211 women, 245 men. Age 20-50, duration of symptoms: less than a week to more than 6 months.

	Inclusion criteria: 1) age 20-50 years, 2) painful limitation of movement in the lumbar spine and 3) suitable for any treatment.
Interventions	Treatment interventions: 1) Corset (= 109), any type, 3 weeks. No data on number of hours/day. Control interventions: 2) Manipulation (n= 116), 2 treatments/ wk 3) Physiotherapy (n= 114), any treatment except manipulation, 2 treatments/wk 4) Analgesic tablets (n=113) 2 paracetamols / 4 hours.
Outcomes	Pain Overall assessment by the doctor. No significant differences after 3 and 6 weeks, and 3 and 12 months.
Notes	456 patients entered the trial. At baseline 452 patients were assessed. After 3 weeks 395 patients were assessed, after 6 weeks 340, after 3 month 335 and after 12 month 262 patients were assessed. No data available regarding compliance.
Allocation concealment	B
Study	Gaber 1999
Methods	RCT.
Participants	Subjects: 209 male workers whose jobs included manual material handling at an airport. The majority of the workers (77%) had no or only mild LBP at the start of the study.
Interventions	Preventive intervention: 1) Synthetic lumbar support (n=118), lumbar support use at work for 12 months. Control intervention: 2) No intervention (n=91)
Outcomes	Pain score, medicine intake due to LBP, sick leave due to LBP. No differences in pain and sick leave; less medication intake in lumbar support group.
Notes	Of the 267 workers included at the start of the study only 209 have finished the study. Only data of these subjects is presented in the study. No data on compliance.
Allocation concealment	B
Study	Hsieh 1992
Methods	RCT.
Participants	Subjects: 164 patients, 62 women and 102 men with non-specific LBP and no sciatica. Median age 32 and mean duration of complaints between 3 weeks and 6 months. Inclusion criteria: 1) age 18-55 years, 2) LBP between 3 weeks and 6 months duration, 3) good health.
Interventions	Treatment intervention: 1) Corset (n=29), lumbosacral canvas corset with metal stays in the back. Corset use during waking hours, 3 weeks. Control interventions: 2) Spinal manipulation (n=70), 3 times / week. 3) Soft tissue massage (n=37), 3 times / week. 4) TMS (n=28), unit should be worn for 8 hours / day.
Outcomes	Pain, functional status. Only better functional status after 4 weeks compared to massage, not to manipulation and TMS. No differences in pain.
Notes	88% of the original patients completed the assessments at baseline and at 4 weeks. Data of RDQ and revised Oswestry are reported by Hsieh (1992) for a subgroup of 83 patients from the study population of Pope. Compliance: 65% wore the belt more than 7 hours a day during the intervention period.
Allocation concealment	A

Study	Million 1981
Methods	RCT.
Participants	Subjects: 19 patients, 13 women and 6 men. No data available on mean age. Inclusion criteria: 1) over 18 years of age, 2) suffering from chronic non-specific LBP > 6 months, 3) not responding to any form of treatment.
Interventions	Treatment intervention: 1) Corset and lumbar support (n=9). Support is of rigid material. Corset use during the day, 8 weeks. Control intervention: 2) Corset (n=10), lumbosacral corset use during the day, 8 weeks.
Outcomes	Subjective and objective index. Rigid support better subjective index after 4 and 8 weeks.
Notes	The subjective index is an overall measurement of the severity of symptoms and of the interference of these symptoms with normal activities. The objective index is an overall measurement of the straight leg raising and of spinal movements. No data on compliance.
Allocation concealment	A
Study	Penrose 1991
Methods	RCT.
Participants	Subjects: 30 patients, 8 women and 22 men. Mean age 34 years (range 19 - 61 years). Patients were diagnosed as having muscular strain/sprain of the lower back by an orthopedic-neurologic examination. No information available on mean duration of complaints.
Interventions	Treatment intervention: 1) Pneumatic lumbar support (n=15). Lumbar support use during 6 hours / day, 5 days / week, 6 weeks. Control intervention: 2) No intervention.
Outcomes	Pain index; lumbar supports better after 1 hour, 3 weeks and 6 weeks.
Notes	No data on compliance.
Allocation concealment	A
Study	Reddell 1992
Methods	RCT.
Participants	Subjects: 896 fleet service clerks; 70 women, 572 men. Age range: 19-67 years. 26% of 642 subjects had suffered a previous back injury and 56% a previous back pain. No data available regarding subjects with current LBP.
Interventions	Preventive intervention: 1) Weightlifting belt (n=145), belt use at work, 8 months. 2) Belt plus training class (n=127), belt use at work and 1 hour training class on spine anatomy and body mechanics. Control intervention: 3) Training class (n=122), 1 hour training class. 4) No intervention (n=248).
Outcomes	Lumbar injuries, lost work days case lumbar injury, restricted work days, case lumbar injury, compensation cost. No significant differences after 8 months.
Notes	Of the 896 clerks selected to participate in this study 642 were located and interviewed at the end of 8 months. Only data of these subjects is presented in the article. Compliance: 58% stopped using it before the end of 8 months. Complaints: heat production around the waist, the belt rides up and pinches ribs.
Allocation concealment	C
Study	Thompson 1994

Methods	CCT.
Participants	Subjects: 60 hospital workers; both men and women. Authors did not report whether workers with LBP or a past history of LBP were included in the study. Age range 21-65 years.
Interventions	Preventive intervention: 1) Weightlifting belt plus 8 hrs back school and instructions on warm-up exercises (n=41), thick woven, deformable nylon, daily use, 3 months. Control intervention: 2) Back school and 8 hrs instructions on warm-up exercises (n=19).
Outcomes	Incidence of LBP significantly lower in lumbar support group.
Notes	The authors stated that belt use resulted in less LBP. However, it is unclear how the authors came to this conclusion. At baseline a difference in frequency of LBP already existed. No data presented. No data on compliance.
Allocation concealment	C
Study	Valle-Jones 1992
Methods	RCT.
Participants	Subjects: 216 patients with non-specific LBP; 97 women, 113 men and 6 'unknown'. Mean age 43, median duration of symptoms 11 days. Inclusion criteria: 1) first episode of non-specific LBP, 2) chronic non-specific LBP, 3) acute exacerbation of a longer-standing problem.
Interventions	Treatment intervention: 1) Back support (n=111), elasticated with an attached silicone rubber pad of special shape, 3 weeks. Control intervention: 2) Standard therapy: advice on rest and lifestyle (n=105).
Outcomes	Pain, limitation of activity, ability to work, use of analgesics, overall improvement; all significantly better in lumbar support group after 3 weeks.
Notes	No data on compliance.
Allocation concealment	C
Study	Walsh 1990
Methods	RCT.
Participants	Subjects: 90 male warehouse workers. Individuals currently being treated for back pain or back injury were excluded, although those with a prior history of back injury were not excluded. Mean age 29 years.
Interventions	Preventive intervention: 1) A lumbosacral orthosis at work plus back school: a 1-hr training session on back pain prevention and body mechanics, 6 months (n=30). Control intervention: 2) Back school (n=30), 1-hr training session. 3) No intervention (n=30).
Outcomes	Work injury incidence, productivity, use of health care services, days lost from work by back injury. Days lost from work significantly better in lumbar support group.
Notes	A total of 90 workers were randomly assigned. Follow-up was obtained at 6 months from 82 workers. Only the data of these 82 workers is presented in the article. No data on compliance.
Allocation concealment	C
Study	van Poppel 1998
Methods	RCT.
Participants	Subjects: 312 workers whose jobs included manual material handling. Workers who had a permanent partial work disability were excluded. Mean age 35.1. 172 subjects with previous LBP, 49 subjects with LBP at baseline.
Interventions	Preventive interventions:

	1) Lumbar support (n=83), 6 months. 2) Lumbar support use at work plus education (n=70), 6 months. Control intervention: 3) Education: 5 hrs lifting instructions (n=82) 4) No intervention (n=77)
Outcomes	LBP incidence, sick leave due to back pain; no differences after 6 months.
Notes	A total of 312 workers were randomised of whom 282 were available for the 6-month follow-up. Compliance with wearing the lumbar support at least half of the time was 43%.
Allocation concealment	A

Characteristics of excluded studies

Study	Reason for exclusion
Amudsen 1982	No control group.
Garg 1992	The lumbar support was used as intervention for the transfer of patients and not as intervention for prevention or treatment of LBP.
Hamonet 1993	No relevant outcome measures. The effect of a lumbar support was evaluated by measuring the activity level of the abdominal muscles.
Jonai 1997	The effect of a lumbar support was evaluated by measuring the range and velocity of torso motion.
Larsson 1980	No contrast for lumbar supports.
Marty 1998	No contrast for lumbar support.
Spratt 1993	No contrast for lumbar support.

ADDITIONAL TABLES

Table 01 Methodological quality of preventive trials

Studies	1 ; 2	3	4	5	6	7	8	9	10
Alexander	? ; -	+	-	?	-	-	+	+	+
Anderson	- ; -	-	-	+	-	-	?	+	?
Gaber	? ; ?	+	+	-	-	-	-	+	-
Reddell	? ; -	+	-	-	-	-	?	+	-
Thompson	- ; -	-	-	-	-	-	-	+	?
Van Poppel	+ ; +	+	-	-	-	-	+	+	+
Walsh	+ ; -	+	?	-	-	+	+	+	?

Table 02 Methodological quality of treatment trials

Studies	1 ; 2	3	4	5	6	7	8	9	10
Coxhead	+ ; -	?	-	-	-	-	-	+	+
Doran & Newell	? ; ?	?	?	-	-	+	-	+	-
Million	+ ; +	-	-	-	+	-	+	+	+
Penrose	? ; +	?	-	?	-	-	+	+	+
Pope	+ ; +	+	+	+	-	+	-	+	-
Valle-Jones	? ; -	?	+	-	-	-	+	+	+

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* Indicates the major publication for the study

GRAPHS

This review has no graphs.

COVER SHEET

Title	Lumbar supports for prevention and treatment of low back pain
Reviewer(s)	van Tulder MW, Jellema P, van Poppel MNM, Nachemson AL, Bouter LM
Contribution of reviewer(s)	Petra Jellema and Maurits van Tulder identified and selected studies. Petra Jellema and Maurits van Tulder assessed the methodological quality of studies. Petra Jellema performed the data extraction. Petra Jellema, Mireille van Poppel and Maurits van Tulder conducted the data analyses. All authors were involved in writing of the review protocol and writing of the final review.
Issue protocol first published	1999/4
Issue review first published	2000/3
Date of most recent amendment	Information not available
Date of most recent SUBSTANTIVE amendment	23 May 2000
Most recent changes	Information not supplied by reviewer
Date new studies sought but none found	Information not supplied by reviewer
Date new studies found but not yet included/excluded	Information not supplied by reviewer
Date new studies found and included/excluded	Information not supplied by reviewer
Date reviewers' conclusions section amended	Information not supplied by reviewer
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SOURCES OF SUPPORT

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- Dutch Health Insurance Board NETHERLANDS

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SYNOPSIS

Synopsis pending

Index Terms

Medical Subject Headings (MeSH)

Braces ; Low Back Pain [prevention & control] [therapy]; Randomized Controlled Trials

Mesh check words: Human

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