

BMJ Open Effect of spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis: protocol for a systematic review and meta-analysis

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To cite: Aboutorabi A, Arazpour M, Ahmadi Bani M, *et al.* Effect of spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis: protocol for a systematic review and meta-analysis. *BMJ Open* 2018;**8**:e015813. doi:10.1136/bmjopen-2016-015813

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2016-015813>).

Received 2 January 2017

Revised 27 May 2017

Accepted 20 June 2017



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ABSTRACT

Introduction Thoracic hyperkyphosis is one of the most common spinal disorders in older people, creating impairment, postural instability, gait disorders and a reduced quality of life. The use of spinal orthoses and/or postural taping may be feasible conservative interventions, but their efficacy is uncertain. The aim of this review is therefore to investigate the effectiveness of spinal orthoses and taping on the balance and gait of older people with hyperkyphosis.

Methods and analysis We will include randomised controlled trials and clinical trial studies which assess the efficacy of spinal orthoses and taping using the WHO International Classification of Functioning, Disability and Health (ICF) outcome measures in older people with hyperkyphosis of the thoracic spine. A search will be performed in PubMed, SCOPUS, ISI Web of Knowledge, CENTRAL, EMBASE, CINAHL, AMED, PEDro, REHAB DATA and RECAL databases with no restriction of language. Two independent reviewers will perform the study selection and data extraction. Quality assessment will be implemented using modified Down and Black checklists. Publication bias and data synthesis will be assessed by funnel plots, Begg's and Egger's tests, and plots using STATA software V.12.1 version.

Ethics and dissemination No ethical issues are predicted. These findings will be published in a peer reviewed journal and presented at national and international conferences.

PROSPERO registration number CRD42016045880.

INTRODUCTION

Progressive degeneration of the spine can lead to the development of thoracic kyphosis in older individuals.¹ Hyperkyphosis may negatively affect several aspects of an individual's health.² The adverse health consequences of thoracic hyperkyphosis are varied and include diminished pulmonary function, increased vertebral fractures, back pain and disability.³ Decreased quality of life⁴ and physical function impairment in association

Strengths and limitations of this study

- This systematic review will evaluate the efficacy of spinal orthoses and postural taping on balance in older people with hyperkyphosis using a comprehensive search of several databases without restriction to languages.
- Study screening, data extraction and risk of bias assessment of the current study will be conducted by two researchers independently.
- We expect some potential heterogeneity between studies, including orthoses types, outcome measures with different tools, and the time of follow-up and hyperkyphosis aetiology and severity.

with hyperkyphosis have also been demonstrated.^{5 6} In addition, impairment in activities of daily living and poorer satisfaction with health status has also been reported.⁷⁻⁹ Subjects with hyperkyphosis have poorer balance control, longer stance times during gait and slower walking speed. Notably, these factors have been associated with an increased risk of falls and an increase in mortality.^{2 10}

The treatment offered for hyperkyphosis in an older person may be surgical or conservative in nature. Surgery to correct this deformity is not typically recommended and may be considered for hyperkyphosis when there is obstinate pain, severe disability, significant pulmonary function impairment or progressive neurological deficits.¹¹ Initial treatment would normally involve non-surgical management, including exercise based interventions, spinal orthoses and postural taping to optimise body alignment and improve thoracic kyphosis. Exercise based treatments which focus on postural alignment, strengthening back extensor muscles and maintenance of spinal flexibility are relatively effective.^{12 13}

The use of spinal orthoses and postural taping can also be an effective conservative treatment. Orthoses help in improving balance and preventing falls¹⁴⁻¹⁶ as well as correcting posture.¹⁴⁻¹⁷ Pfeifer *et al*¹⁸ showed that the use of the Spinomed orthosis resulted in a decrease in centre of mass sway and subsequently improved balance in older women. However, current evidence surrounding the use of some spinal orthoses appears to be vague, and often contradictory.

Like spinal orthoses, postural taping aims to decrease thoracic hyperkyphosis, reduce pain and assist activity of the postural muscles in a more optimal spinal position.¹⁹ Many people with hyperkyphosis have vertebral fractures. There have been previous systematic reviews synthesising the evidence of effectiveness of spinal orthoses and taping for osteoporotic fractures in older adults.²⁰⁻²¹ However, vertebral fractures are not evident in all cases of hyperkyphosis. Approximately one-third of individuals presenting with hyperkyphosis have underlying vertebral fractures.²²⁻²³ Previous reviews that have broadly focused on this area have indicated that there appear to be unclear strategies regarding the risk of bias and inconsistent results between studies. Additionally, due to non-reporting of significant differences in these reviews,²⁰⁻²¹ quantitative synthesis (meta-analysis) was not conducted. Therefore, the aims of this review are to combine evidence about the efficacy of spinal orthoses/bracing and taping on balance in older people with hyperkyphosis and also assess and find sources of heterogeneity between studies.

OBJECTIVES

Our primary objective is the efficacy of spinal orthoses/bracing and postural taping on balance parameters.

Secondary objectives will include the following:

- ▶ Outcomes relating to WHO International Classification of Functioning, Disability and Health (ICF) domains of body structure and function, activities and participation. ICF components include body structure and function related to pain, spinal muscle strength, kyphosis angle, kinetic and kinematic of gait, as well as measures of activities, participation and environmental factors related to physical activity, function, activities of daily living and quality of life.²⁴
- ▶ Comparisons between the effect of spinal orthoses/bracing and postural taping according to gender.
- ▶ Comparisons between different hyperkyphosis aetiologies and the efficiency of orthoses/bracing and postural taping.
- ▶ Comparisons between the effect of different orthoses/bracing and postural taping on outcome measures.
- ▶ Evaluation of treatment on outcome measures.
- ▶ Evaluation of outcomes related to adverse events and treatment compliance.
- ▶ Evaluation of heterogeneity and its potential sources in primary studies.

METHODS

The protocol of this systematic review has been registered in PROSPERO (registration No: CRD42016045880). Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols 2015 (PRISMA-P 2015) will be used for the preparation and reporting of this protocol for the systematic review.²⁵ The PRISMA Flow Diagram will be used to describe the flow of information through the different phases of this systematic review.²⁶

Eligibility criteria

Types of studies

We will include randomised controlled trials (RCTs) and pilot RCTs (included; crossover or parallel RCT designs, blind or open label), and controlled clinical trials without true randomisation.

Type of participants

Studies which involve the participation of subjects with a diagnosis of thoracic hyperkyphosis, aged at least 55 years,²⁷ of either or both genders, will be included. Hyperkyphosis will be diagnosed as an angle curvature of 45° using radiographic image or devices such as the kyphometer, goniometer, inclinometer and flexi curve ruler measurements of the kyphosis index >13°²⁸). Hyperkyphosis caused by osteoporosis with or without vertebral compression fracture or disk degeneration, poor spinal muscles strength and soft tissue degeneration in acute and chronic conditions will be included. However, hyperkyphosis subjects with other aetiologies, such as traumatic vertebral fractures or neurological disease, will be excluded.

Interventions and comparisons

Studies which compare spinal orthoses (such as the Spinomed, Osteo-med, Posture Training Support (PTS), the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) or bracing or postural taping with inactive control will be included, as well as studies that involve other co-interventions (eg, exercise), provided that the co-interventions are applied in the same manner to both the control and experimental group participants. For non-controlled studies, only those where the evaluation is related to the spinal orthoses or bracing or taping will be included. We will exclude spinal orthoses that are used as part of functional electrical stimulation treatment.

Information sources

Electronic searches

A search will be made in the following electronic databases to identify potential studies:

- ▶ PubMed
- ▶ SCOPUS
- ▶ ISI Web of Knowledge
- ▶ Cochrane Library (CENTRAL)
- ▶ EMBASE
- ▶ CINAHL (EBSCO)
- ▶ AMED database (Ovid)
- ▶ ClinicalTrials.gov(<http://ClinicalTrial.gov/>)

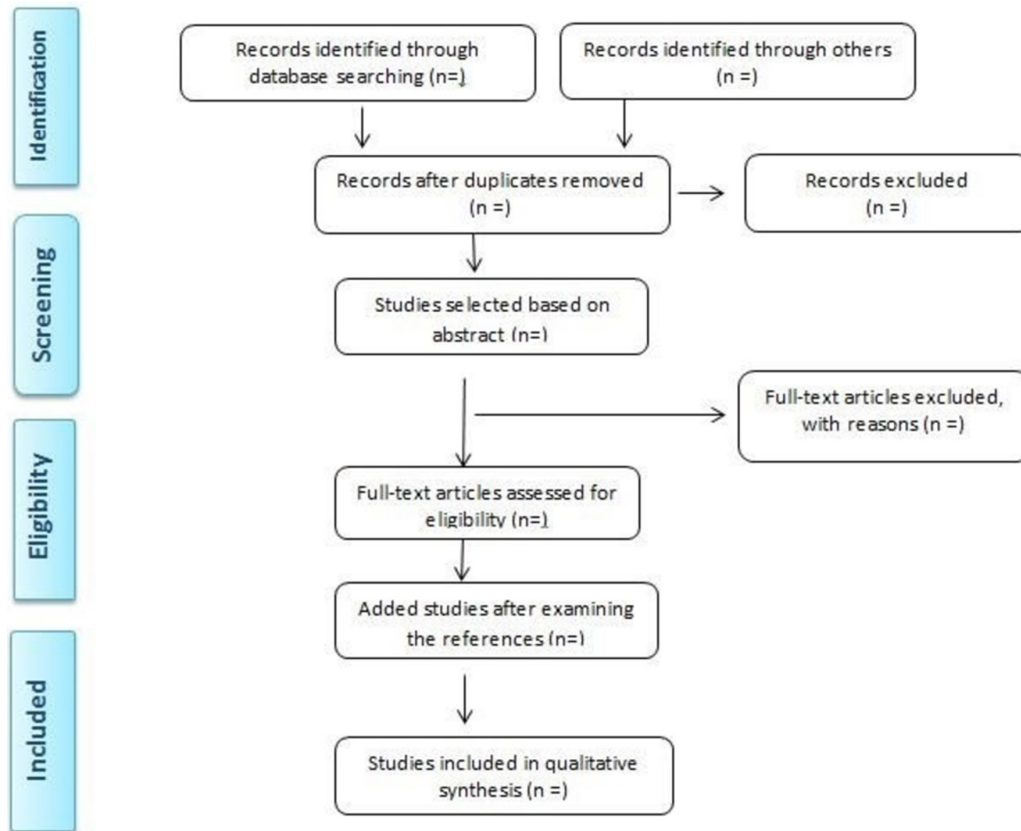


Figure 1 Flow diagram of the study selection process based on the PRISMA guideline.

- ▶ Physiotherapy Evidence Database (PEDro library) (www.pedro.org.au/)
- ▶ REHAB DATA (<http://www.naric.com/research/rehab/>)
- ▶ RECAL database (comprehensive database in the field of prosthetics, orthotics and related physical medicine and rehabilitation) (<http://cdlr.strath.ac.uk/recal/>)

Other resources

- ▶ Reference lists of all included papers and other reviews on the topic
- ▶ Grey literatures (dissertations and theses; conference papers)
- ▶ Google Scholar (<https://scholar.google.com/>)
- ▶ Hand searching of key journals on this topic

Search strategy

The PubMed search strategy will be employed, as appropriate, for each database from inception. The searches will be refined using the bloom term 'AND' between the topics of orthoses OR postural taping AND kyphosis. Language limitation will not be applied. Broad terms related to the population and interventions (P AND I) of PICOs interest will be searched. Details of the PubMed search strategy is shown in the online supplementary file.

Selection process

Two independent reviewers (AA and MAB) will be involved in study selection. The study selection process

is summarised below in the PRISMA flow diagram (figure 1).

Data management

Titles and/or abstracts of studies will be retrieved using the search strategy, and two review authors (AA and MAB) will identify studies that potentially meet the inclusion criteria outlined above and those from additional sources will be screened independently. The full text of those potentially eligible studies will be retrieved and independently assessed for eligibility by two review team members. Information not currently available within the studies will be sourced directly from the authors via email. Any discrepancies will be resolved by consensus strategy.

Data collection process

A data extraction form has been developed, and study data will be independently assessed and extracted by two reviewers (AA and MAB).

Data items

The following data will be extracted from each included study:

1. Overall study characteristics (including first author, year of publication, language)
2. Characteristics of participants (age, gender or disease type and aetiology)
3. Information on study design (type of study, number of participants)

4. Aspects of the intervention (details of the intervention and the control intervention, duration of intervention and time of follow-up)
5. Outcome measures
6. Main findings

Outcomes

Primary outcomes

The primary outcomes of interest will comprise balance parameters (centre of pressure or centre of gravity sway measurement) or clinical tests related to dynamic balance measurement (Berg Balance Test, Functional Reach Test)

Secondary outcomes

1. Gait parameters (spatial-temporal parameters, kinetics and kinematics)
2. Functional mobility tests (such as Timed Up and Go)
3. Spinal muscle strength
4. Kyphosis angle
5. Impairment such as pain
6. Activity limitations: using measures such as the Functional Independence Measure or Barthel Index
7. Participation restrictions, quality of life measures
8. Patient satisfaction following the intervention
9. Compliance with the orthosis
10. Adverse events, such as skin damage or discomfort

Risk of bias in individual studies

The methodological quality of the primary studies will be assessed according to the Modified Downs and Black checklist.²⁹ Two authors (AA and MAB) will complete these forms separately and disagreements will be resolved by consensus. A total of 15 out of 27 items in the checklist will be used for quality assessment of the studies. These will consist of 15 appropriate items that report on and assess the internal and external validity of the primary studies and power study assessment. These items are listed below.

1. Are the hypotheses/aims/objectives of the study clearly described?
2. Are the main outcomes to be measured clearly described in the introduction or methods section?
3. Are the characteristics of the patients/samples included in the study clearly described?
4. Are the interventions of interest clearly described?
5. Are the main findings of the study clearly described?
6. Does the study provide estimates of the random variability in the data for the main outcomes?
7. Have actual probability values been reported (eg, 0.035 rather than <0.05) for the main outcomes except where the probability value is <0.001?
8. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?
9. Was an attempt made to blind study subjects to the intervention they have received?
10. Was an attempt made to blind those measuring the main outcomes of the intervention?

11. Were the statistical tests used to assess the main outcomes appropriate?
12. Were the main outcome measures used accurate (valid and reliable)?
13. Were study subjects randomised to the intervention groups?
14. Was the randomised intervention assignment concealed from both patients and healthcare staff until recruitment was complete?
15. Does the study provide estimates of statistical power using either a sample size calculation or a post hoc power analysis?

Assessment of heterogeneity

We will assess the intervention effect heterogeneity based on the Q Cochrane test and the related 'P' value for analysis. Furthermore, we will use I^2 as measure of categorisation for heterogeneity between studies. If the measure proves to be 50–74.9% or >75%, we will have severe and highly severe heterogeneity, respectively. To investigate the potential sources of heterogeneity, we will use a subgroup analysis method. We will assess the intervention efficacy according to different trial designs (randomised vs non-randomised, blind vs open label/non-blind, etc), participants' characteristics (gender, age groups, hyperkyphosis aetiology, etc) and intervention related factors (types of orthoses, duration of wear, follow-up).

Assessment of reporting bias

We will assess the publication or reporting bias by funnel plot, Beg's and Egger's tests, and plots. Furthermore, if the bias cannot be ignored we will use the Fill and Trim method to correct the final result.

Statistical analysis and data synthesis

We will perform a meta-analysis for each outcome measure where possible. First, we will choose the appropriate effect size measure for evaluating the intervention efficacy based on the outcome variable type (continuous, nominal, ordinal, etc). The appropriate measure will be SMD (standardised mean difference) or relative risk (RR).

Then, the data required for calculating the effect size measure will be collated into a 2×2 table, using the outcome variable mean, SD and sample size in two intervention and comparison/control groups. The primary outcome variable data in addition to the secondary outcome variable data and the related data (eg, quality score, first author, publication year, study time/year, study location or geographical area) will be entered into STATA V.12.1.

The study level appropriate effect size measure (SMD or RR) will be combined with the 'fixed effect' or 'random effect' models according to the study characteristics. Forest plots will be used to present the combined measure and the different study level measures.

To investigate potential sources of heterogeneity we will use a subgroup analysis or meta-regression method

for assessing the relationships between the study qualities (risk of bias) measure/score and the intervention efficacy. If the intervention effect in low quality studies is greater than in high quality studies, we will use a sensitivity analysis technique to correct or adjust the bias. In cases of severe methodological heterogeneity where meta-analysis is not possible, we will use meta-synthesis or narrative synthesis.³⁰

DISCUSSION

Our systematic review and meta-analysis will determine the level of efficacy associated with the use of spinal orthoses and postural taping for older people with hyperkyphosis. We anticipate that this knowledge will help clinicians and researchers to determine the most effective orthotic treatment and rehabilitation plans, utilising the most appropriate devices, thereby increasing the quality of care for affected people.

Acknowledgements The authors would like to acknowledge the efforts of Dr Stephen Hutchins and John Head for their diligent and thoughtful editing of the manuscript.

Contributors AA and MAB developed the search strategies. AA, MAB, MA and AK were involved in the study design, implementation and analysis. AA and MAB drafted the manuscript of the protocol. MA and AAK revised the manuscript. AA and MAB will screen the potential studies, extract the data and assess quality. Any discrepancies will be resolved by consensus between the two authors.

Funding This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All recorded data from the data extraction process will be available on request to the extent that it is not included in the systematic review article.

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