BMJ Open

The 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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-015813
Article Type:	Protocol
Date Submitted by the Author:	02-Jan-2017
Complete List of Authors:	aboutorabi, atefeh; university of social welfare and rehabilitation sciences , Department of Orthotics and Prosthetics; Iranian Research Center on Aging Ahmadi Bani, Monireh; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Arazpour, Mokhtar; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Keshtkar, Abbasali; Tehran university of medical sciences, department of health sciences education development, school of public health;
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Geriatric medicine
Keywords:	elderly, hyperkyphosis, spinal orthosis, postural taping

The 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

Atefeh Aboutorabi[1, 2], Monireh Ahmadi Bani[1, 2], Mokhtar Arazpour[1, 3], Abbas Ali Keshtkar[4]

Corresponding author: Monireh Ahmadi Bani, PhD, Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Kodakyar st., Daneshjo Blvd., Evin, Tehran, 1985713834, Iran.
Telephone number: 0098 (21) 22 18 00 10
Fax number: 0098(21) 22 18 00 49
Email address: m.ahmadi_bani@yahoo.com

ABSRACT

Introduction: Thoracic hyperkyphosis is one of the most common spinal disorders in older people which create 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 balance and the gait of older subjects with hyperkyphosis.

Methods and analysis: We will include randomized controlled trials and clinical trial studies which assess the efficacy of spinal orthoses and taping using 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 version 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.

Trail registration number: This systematic review protocol is registered in the PROSPERO International Prospective Register of Systematic Reviews, registration number CRD42016045880.

Article summary:

Strengths and limitations of this study:

- This systematic review, for the first time, will evaluate the efficacy of spinal orthoses and postural taping 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 orthosis types, outcome measures with different tools, and the time of follow up and hyperkyphosis etiology and severity.

INTRODUCTION

With increasing age, progressive degeneration of the spine contributes to a tendency of developing thoracic kyphosis in older individuals[1]. Hyperkyphosis is defined as excessive curvature of the thoracic spine in flexion in the sagittal plane. The mean thoracic kyphosis angle increases with age, from 20 degrees in young adults to above 53 degrees in old adults[2]. The prevalence of hyperkyphosis in older individuals is not exactly known but has been stated to be between 20% and 40%[3]. The pathogenesis of hyperkyphosis in older subjects is multifactorial.

Hyperkyphosis may result from a variety of idiopathic, anatomic, genetic, or metabolic conditions[4]. Osteoporosis and vertebral compression fractures are widely thought to be a major contributing factor in the development of age-related hyperkyphosis. There is a strong correlation (between 0.45 to 0.78) between the likelihood of vertebral fractures and hyperkyphosis [5-7]. Additionally, as bone mineral density decreases, the severity of wedging associated with compression fractures increases[8, 9]. Intervertebral discs shrink with increasing age and degenerative disc disease play important roles in progression of thoracic hyperkyphosis in older individuals[9, 10]. In addition to structural changes in the vertebral column, general degeneration is an important contributing factor in the older population[11]. Functional and postural changes in other regions such as cervical and lumbar curvatures[12, 13], changes in muscle strength[14, 15], intervertebral ligament disorders[16] and metabolic or genetic disease (such as Scheuermann's disease or osteogenesis imperfecta)[17] are also associated with a degree of kyphosis. Sinaki *et al.* showed that thoracic hyperkyphosis is related to reduced muscle strength and plays an important role in increasing body sway, gait instability, and risk of falls in older subjects[16].

Hyperkyphosis may negatively affect several aspects of an individual's health [8]. The adverse health consequences of thoracic hyperkyphosis are varied and include diminished pulmonary function, increased vertebral fractures, back pain and disability[18]. Decreased quality of life[19] and physical function impairment in association with hyperkyphosis have also been demonstrated [20, 21]. In addition, impairment in activities of daily living (ADLs) and poorer satisfaction with health status has also been reported [22-24]. 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 [8].

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[4]. Non-surgical management of age-related hyperkyphosis includes exercise-based interventions, pharmacological therapy, spinal orthoses and postural taping to optimize bone mineral density and improvement in thoracic kyphosis; and should be considered at first. Exercise-based treatments which focus on postural alignment, strengthening back extensor muscles, and maintenance of spinal flexibility are effective.

The use of spinal orthoses and postural taping is one alternative form of conservative treatment. These orthoses help in improving balance and preventing falls[25-27] as well as correcting posture.[25, 28], Pfeifer *et al*.[29] showed that the use of the Spinomed orthosis resulted in a decrease in centre of mass (CoM) sway and subsequently improved balance in older women. However, evidence for the efficacy of other nonoperative options (spinal orthosis, postural taping) is unclear[4]and no existing systematic review was found which focuses on spinal orthotic and postural taping for older people with hyperkyphosis.

OBJECTIVES

The primary aim of this review is to investigate the efficacy of spinal orthoses and taping on balance, gait and quality of life of elderly with hyperkyphosis.

Secondary objectives will include:

- Comparisons between the effect of spinal orthoses and postural taping according to gender;
- Comparisons between different hyperkyphosis etiologies and the efficiency of orthoses and postural taping;
- Comparisons between the effect of different orthoses 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 number: 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[15].The PRISMA Flow Diagram will be employed to describe the flow of information through the different phases of this systematic review[29].

Eligibility Criteria

Types of studies

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

Type of Participants

We will include studies which involve the participation of older subjects aged at least 50 years or more (because of different definitions of older people between countries[14]) for both sexes with a diagnosis of thoracic hyperkyphosis. We will include those with hyperkyphosis because of osteoporosis with or without vertebral compression fracture, disk degeneration; poor spinal muscles strength and soft tissue degeneration. However, hyperkyphosis subjects with other etiologies such as traumatic vertebral fractures or neurological disease will be excluded.

Interventions and Comparisons

We will include studies which compare spinal orthoses (such as the Spinomed, Osteo-med, Posture Training Support (PTS), the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) and postural taping with inactive control, as well as studies that involve other co-interventions (for example exercise) provided 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 related to the spinal orthoses/tape will be included. We will exclude spinal orthoses that are 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/)
- Physiotherapy Evidence Database (PEDro library) (www.pedro.org.au/);
- REHAB DATA (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
- Gray Litratures (Dissertations and Theses - conference papers)
- Google Scholar (https://scholar.google.com/)
- Hand searching of Key journals in this topic

Search strategy

We will adapt the PubMed search strategy, as appropriate, for each database. 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.

PubMed search strategy

1. Orthoses
2. Orthosis
3. Orthotic
4. Orthotic devices
5. Brace
6. Thoracolumbosacral Orthosis
7. Thoracolumbosacral Orthoses
8. "lumbosacral Orthoses"
9."lumbosacral Orthosis"
10."Thoracolumbar Orthosis"
11."Thoracolumbar Orthosis"
12.Spinomed
13. Posture Training Support
14. Weighted Kypho-Orthosis
15. Osteo-med
16. Postural Taping
17.1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16
18. kyphosis
19. Kyphotic
20. Hyperkyphosis
21. Hyperkyphotic
22. 18 OR 19 OR 20 OR 21
23.17 AND 22

(Orthoses OR Orthosis OR Orthotic OR "Orthotic Devices" OR Braces OR "Thoracolumbosacral Orthosis" OR "Thoracolumbosacral Orthoses" OR "lumbosacral Orthoses" OR"lumbosacral Orthosis" OR "Thoracolumbar Orthosis" OR "Thoracolumbar Orthosis" OR Spinomed OR "Posture Training Support" OR "Weighted Kypho-Orthosis" OR

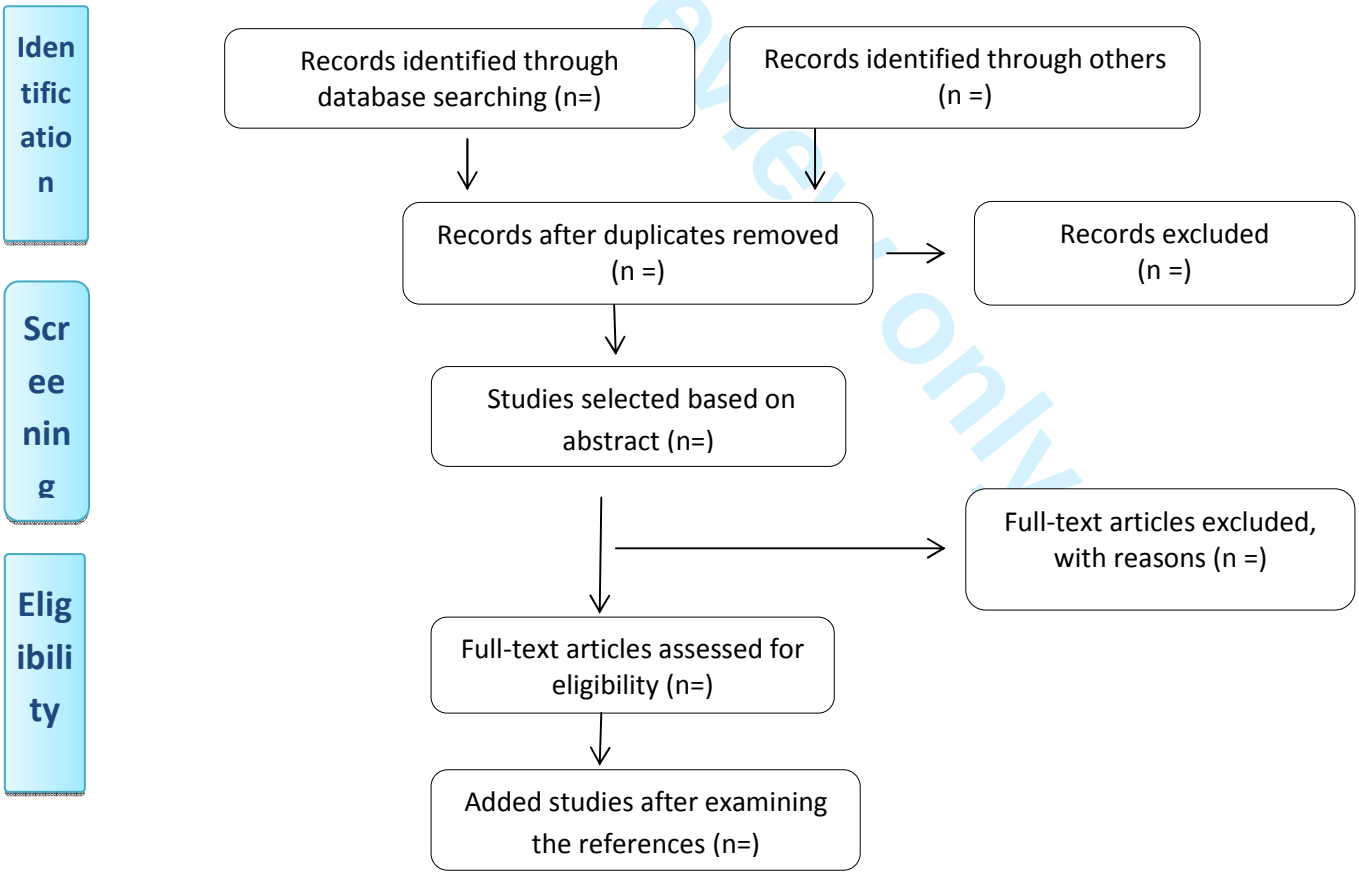
Osteo-med OR "Postural taping") AND (Kyphosis OR Kyphotic OR Hyperkyphosis OR Hyperkyphotic)

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 available in the studies, will be sought from authors by email. Any discrepancies will be resolved by consensus strategy.

Selection process

Two independent reviewers (AA and MAB) will be involved in study selection. The study selection process is summarized below in a PRISMA flow diagram (figure 1).



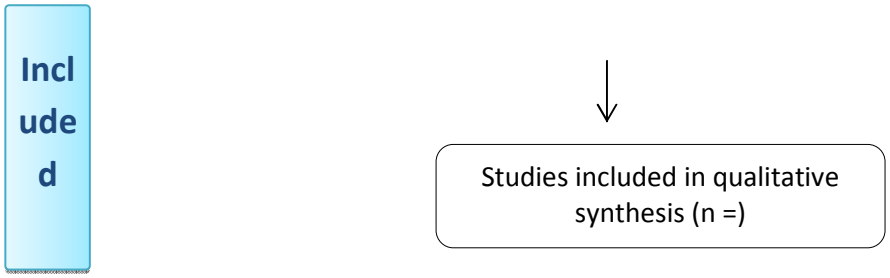


Figure 1: Flow diagram of the study selection process based on PRISMA guidelines

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 etiology)
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 of ICF components[30].

1. Balance parameters (CoP or CoG sway measurement) or clinically tests related dynamic balance measurement(Berg Balance Test, Functional Reach Test)
2. Gait parameters (spatial-temporal parameters, kinetics and kinematics),
3. Functional mobility tests (such as Timed Up and Go)
4. Spinal muscle strength
5. Kyphosis angle
6. Impairment such as pain

7. Activity limitations: using measures such as the Functional Independence Measure (FIM), or Barthel Index (BI)
8. Participation restrictions, quality of life measures (QoL)

Secondary outcomes

1. Patient satisfaction following the intervention
2. Compliance with the orthosis
3. Adverse events, such as skin damage or discomfort

Risk of bias in individual studies

Methodological quality of primary studies will be assessed according to the Modified Downs and Black checklist [30]. Two authors (AA and MAB) will complete forms separately and disagreements will be resolved by consensus. A total of 15 out of 27 items of the checklist will be used for quality assessment of studies. These items comprise reporting items, items that assess internal and external validity of primary studies and power study assessment. The 15 items are listed below:

1. Are the hypothesis /aim /objective 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 (e.g., 0.035 rather than rather than <0.05) for the main outcomes except where the probability value is less than 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 randomized to intervention groups?
14. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete?
15. Does the study provide estimate 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 Q Cochrane test and the related p value. Furthermore, we will use I^2 measure as categorization measure of heterogeneity. If the measure proves to be 50-74.9% or >75%, we will have severe and highly severe heterogeneity, respectively. To investigate potential sources of heterogeneity, we will use a sub-group analysis method. We will assess the intervention efficacy according to different trial designs (randomized versus non-randomized, blind versus open label/ non-blind etc.), participants' characteristics (gender, age groups, hyperkyphosis etiology etc.), and intervention-related factors (types of orthoses, the duration worn, different follow-up times, etc…).

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 is not ignorable, we use the Fill & Trim method for correcting the final result.

Statistical analysis and data synthesis

First, we will choose the appropriate effect-size measure for evaluating the intervention efficacy based on the outcome variable types (continuous, nominal, ordinal, etc). The appropriate measure will be SMD (Standardized Mean Difference) or Relative Risk (RR).

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

The study level appropriate effect-size measure (SMD or RR) will be combined by Fixed effect or Random effect models according to the study characteristics. Forest plots will be used for presenting the combined measure and the different study level measures.

We will use sub-group analysis or meta-regression methods for assessing relationships between the study qualities (Risk of Bias) measure/ score and the intervention efficacy. If the intervention effect in low quality studies will be greater than high quality studies, we will use Sensitivity Analysis for correcting or adjusting the bias.

DISCUSSION

Our systematic review and meta-analysis will determine efficiency of spinal orthoses and postural taping with different follow up durations for older people with hyperkyphosis and will potentially help patients, clinicians, and researchers to choose the best orthotic intervention for older people with hyperkyphosis.

Author's affiliations

[1] Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Islamic Republic of Iran

[2] Iranian Research Center on Aging, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[3] Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[4] Department of Health Sciences Education Development, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Acknowledgement:

The authors would like to acknowledge the efforts of Dr. Stephen Hutchins for his diligent and thoughtful editing of the manuscript.

Contributors

AA and MAB developed the search strategies. AA, MAB, MA and AAK was involved in study design, implementation, and analysis. AA and MAB drafted the manuscript of the protocol, MA

and AAK revised it. AA and MAB will also screen the potential studies, extract data and assess quality. Any discrepancies will be resolved by consensus between the two authors.

Declaration of interest

The review authors declare no conflict of interest.

Funding

None

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.

Referenceses

1. Novak, A.C., et al., *Age-related differences in dynamic balance control during stair descent and effect of varying step geometry.* Applied ergonomics, 2016. **52**: p. 275-284.
2. Ensrud, K.E., et al., *Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group.* J Am Geriatr Soc, 1997. **45**(6): p. 682-7.
3. Kado, D.M., et al., *Hyperkyphotic posture predicts mortality in older community-dwelling men and women: a prospective study.* J Am Geriatr Soc, 2004. **52**(10): p. 1662-7.
4. Ailon, T., et al., *Progressive Spinal Kyphosis in the Aging Population.* Neurosurgery, 2015. **77**: p. S164-S172.
5. Dionyssiotis, Y., et al., *Prospective study of spinal orthoses in women.* Prosthet Orthot Int, 2015. **39**(6): p. 487-95.
6. AZADINIA, F., et al., *THE EFFECT OF POSTURE TRAINING SUPPORT ORTHOSIS ON STATIC BALANCE IN ELDERLY PATIENTS WITH SPINAL HYPER KYPHOSIS.* 2012.
7. Fink, M., et al., *Assessment of postural effects of an osteoporosis orthosis (Osteo-med): a randomised, placebo-controlled comparison.*
8. Katzman, W.B., et al., *Physical function in older men with hyperkyphosis.* J Gerontol A Biol Sci Med Sci, 2015. **70**(5): p. 635-40.
9. Goh, S., et al., *The relative influence of vertebral body and intervertebral disc shape on thoracic kyphosis.* Clin Biomech, 1999. **14**(7): p. 439-48.
10. Kado, D.M., et al., *Factors associated with kyphosis progression in older women: 15 years' experience in the study of osteoporotic fractures.* J Bone Miner Res, 2013. **28**(1): p. 179-87.
11. Balzini, L., et al., *Clinical characteristics of flexed posture in elderly women.* J Am Geriatr Soc, 2003. **51**(10): p. 1419-26.

12. Fink, M., et al., *Efficacy of a flexible orthotic device in patients with osteoporosis on pain and activity of daily living.* Journal of rehabilitation medicine, 2007. **39**(1): p. 77-80.
13. Watanabe, H., et al., *New concept of spinal orthosis for weakened back muscles.* Prosthetics and orthotics international, 1995. **19**(1): p. 56-58.
14. WHO, *Definition of an older or elderly person*, 2011, World Health Organization Geneva.
15. Moher, D., et al., *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement.* Systematic reviews, 2015. **4**(1): p. 1.
16. Sinaki, M., et al., *Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength.* Osteoporosis international, 2005. **16**(8): p. 1004-1010.
17. Elias, F., et al., *The role of sternum in the etiopathogenesis of Scheuermann disease of the thoracic spine.* Spine, 2008. **33**(1): p. E21-E24.
18. Ettinger, B., et al., *Kyphosis in older women and its relation to back pain, disability and osteopenia: the study of osteoporotic fractures.* Osteoporos Int, 1994. **4**(1): p. 55-60.
19. Martin, A.R., et al., *The impact of osteoporosis on quality-of-life: the OFELY cohort.* Bone, 2002. **31**(1): p. 32-6.
20. Sinaki, M., et al., *Correlation of back extensor strength with thoracic kyphosis and lumbar lordosis in estrogen-deficient women.* Am J Phys Med Rehabil, 1996. **75**(5): p. 370-4.
21. Ryan, S.D. and L.P. Fried, *The impact of kyphosis on daily functioning.* J Am Geriatr Soc, 1997. **45**(12): p. 1479-86.
22. Kado, D.M., et al., *Hyperkyphotic posture and poor physical functional ability in older community-dwelling men and women: the Rancho Bernardo study.* J Gerontol A Biol Sci Med Sci, 2005. **60**(5): p. 633-7.
23. Lombardi, I., Jr., et al., *Evaluation of physical capacity and quality of life in osteoporotic women.* Osteoporos Int, 2004. **15**(1): p. 80-5.
24. Takahashi, T., et al., *Trunk deformity is associated with a reduction in outdoor activities of daily living and life satisfaction in community-dwelling older people.* Osteoporosis international, 2005. **16**(3): p. 273-279.
25. Pfeifer, M., B. Begerow, and H.W. Minne, *Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial.* American Journal of Physical Medicine & Rehabilitation, 2004. **83**(3): p. 177-186.
26. Sinaki, M., et al. *Significant reduction in risk of falls and back pain in osteoporotic-kyphotic women through a Spinal Proprioceptive Extension Exercise Dynamic (SPEED) program*. in *Mayo Clinic Proceedings*. 2005. Elsevier.
27. Sinaki, M. and S.G. Lynn, *Reducing the risk of falls through proprioceptive dynamic posture training in osteoporotic women with kyphotic posturing: a randomized pilot study.* American Journal of Physical Medicine & Rehabilitation, 2002. **81**(4): p. 241-246.
28. Kaplan, R.S. and M. SINAKI. *Posture training support: preliminary report on a series of patients with diminished symptomatic complications of osteoporosis*. in *Mayo Clinic Proceedings*. 1993. Elsevier.
29. Pfeifer, M., et al., *Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a*

randomized trial. American Journal of Physical Medicine & Rehabilitation, 2011. **90**(10): p. 805-815.

30. Üstün, T.B., et al., *The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health.* Disability and rehabilitation, 2003. **25**(11-12): p. 565-571.
31. Moher, D., et al., *CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials.* Journal of clinical epidemiology, 2010. **63**(8): p. e1-e37.
32. Slim, K., et al., *Methodological index for non-randomized studies (MINORS): development and validation of a new instrument.* ANZ journal of surgery, 2003. **73**(9): p. 712-716.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	page number in manuscript
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Page 1
Update	1b	Not applicable (n/a)
Registration	2	Page 2 in abstract and 5 in main text
Authors:		
Contact	3a	page 1 in abstract and 13 in main text
Contributions	3b	Page 12
Amendments	4	n/a
Support:		
Sources	5a	Page 12
Sponsor	5b	n/a
Role of sponsor or funder	5c	n/a
INTRODUCTION		
Rationale	6	Page 3
Objectives	7	Page 4
METHODS		
Eligibility criteria	8	Page 5
Information sources	9	Page 6
Search strategy	10	Page 6
Study records:		
Data management	11a	Page 8
Selection process	11b	Page 8
Data collection process	11c	Page 9
Data items	12	Page 9
Outcomes and prioritization	13	Page 9
Risk of bias in individual studies	14	Page 10
Data synthesis	15a	Page 11
	15b	Page 11

	15c	Page 11
	15d	n/a
Meta-bias(es)	16	Page 11
Confidence in cumulative evidence	17	n/a

.

BMJ Open

The 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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-015813.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Apr-2017
Complete List of Authors:	aboutorabi, atefeh; university of social welfare and rehabilitation sciences , Department of Orthotics and Prosthetics; Iranian Research Center on Aging Ahmadi Bani, Monireh; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Arazpour, Mokhtar; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Keshtkar, Abbasali; Tehran university of medical sciences, department of health sciences education development, school of public health;
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Geriatric medicine
Keywords:	REHABILITATION MEDICINE, STATISTICS & RESEARCH METHODS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

The 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

Atefeh Aboutorabi[1, 2], Monireh Ahmadi Bani[1, 2], Mokhtar Arazpour[1, 3], Abbas Ali Keshtkar[4]

Corresponding author: Monireh Ahmadi Bani, PhD, Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Kodakyar st., Daneshjo Blvd., Evin, Tehran, 1985713834, Iran.
Telephone number: 0098 (21) 22 18 00 10
Fax number: 0098(21) 22 18 00 49
Email address: m.ahmadi_bani@yahoo.com

ABSRACT

Introduction: Thoracic hyperkyphosis is one of the most common spinal disorders in older people which creates 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 balance and the gait of older subjects with hyperkyphosis.

Methods and analysis: We will include randomized controlled trials and clinical trial studies which assess the efficacy of spinal orthoses and taping using 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 version 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.

Trial registration number: This systematic review protocol is registered in the PROSPERO International Prospective Register of Systematic Reviews, registration number CRD42016045880.

Article summary:

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 etiology and severity.

INTRODUCTION

With increasing age, progressive degeneration of the spine contributes to a tendency of developing 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 life (4) and physical function impairment in association with hyperkyphosis have also been demonstrated (5, 6). In addition, impairment in activities of daily living (ADLs) 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). Non-surgical management of age-related hyperkyphosis includes exercise-based interventions, spinal orthoses and postural taping to optimize body alignment and improvement in thoracic kyphosis; and should be considered at first. Exercise-based treatments which focus on postural alignment, strengthening back extensor muscles, and maintenance of spinal flexibility are effective.

The use of spinal orthoses and postural taping is one alternative form of conservative treatment. Orthoses help in improving balance and preventing falls (12-14) as well as correcting posture (12, 15), Pfeifer et al. (16) showed that the use of the Spinomed orthosis resulted in a decrease in centre of mass (COM) sway and subsequently improved balance in older women. Like spinal orthoses, postural taping aims to decrease thorasic hyperkyphosis, reduce pain, and assist activity of the postural muscles in a more optimal spinal position (17). However, Current evidence surrounding spinal orthoses is inconsistent. Many people with hyperkyphosis have vertebral fractures. There have been previous systematic reviews synthesizing the evidence of effectiveness of spinal orthoses and taping for osteoporotic adults with vertebral fractures (18, 19). However, vertebral fractures do not comprise all cases of hyperkyphosis. About one third of the older persons with hyperkyphosis have underlying vertebral fractures (20, 21). Previous reviews conducted a broad search strategy in this area, indicating unclear risk of bias and inconsistent

results between studies. Additionally, due to non-reporting of significant differences in these reviews (18, 19), quantitative synthesis (meta-analysis) was not conducted. Therefore, the aim of this review is to combine evidence about the efficacy of spinal orthoses/bracing and taping on balance of elderly with hyperkyphosis and also assessing and finding of source 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:

- Outcomes relating to WHO International Classification of Functioning, Disability and Health (ICF) domains of body structure and function, activities and participation. ICF components included 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 factor related to physical activity, function, activity daily living (ADL) and quality of life (22).
- Comparisons between the effect of spinal orthoses/bracing and postural taping according to gender;
- Comparisons between different hyperkyphosis etiologies 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 number: 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 (23).The PRISMA Flow Diagram will be employed to describe the flow of information through the different phases of this systematic review (24).

Eligibility Criteria

Types of studies

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

Type of Participants

We will include studies which involve the participation of older subjects aged at least 55 years or more (25) for both sexes with a diagnosis of thoracic hyperkyphosis (greater than 45 degree whom measured with different techniques; radiography or such devices as the kyphometer, goniometer, inclinometer, and flexible ruler (26)). We will include those with hyperkyphosis because of osteoporosis with or without vertebral compression fracture, disk degeneration; poor spinal muscles strength and soft tissue degeneration in acute and chronic conditions. However, hyperkyphosis subjects with other etiologies such as traumatic vertebral fractures or neurological disease will be excluded.

Interventions and Comparisons

We will include 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, as well as studies that involve other co-interventions (for example exercise) provided 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 related to the spinal orthoses OR bracing OR taping will be included. We will exclude spinal orthoses that are 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/)
- Physiotherapy Evidence Database (PEDro library) (www.pedro.org.au/);
- REHAB DATA (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
- Gray Literatures (Dissertations and Theses - conference papers)
- Google Scholar (https://scholar.google.com/)
- Hand searching of Key journals in this topic

Search strategy

We will adapt the PubMed search strategy, 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 PubMed search strategy is shown in supplementary file.

Selection process

Two independent reviewers (AA and MAB) will be involved in study selection. The study selection process is summarized below in a PRISMA flow diagram (figure 1).

Please insert figure 1 below here

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 available in the studies, will be sought from authors by 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 etiology)
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 (COP or COG sway measurement) or clinically tests related 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 (FIM), or Barthel Index (BI)
7. Participation restrictions, quality of life measures (QOL)
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

Methodological quality of primary studies will be assessed according to the Modified Downs and Black checklist (27). Two authors (AA and MAB) will complete forms separately and disagreements will be resolved by consensus. A total of 15 out of 27 items of the checklist will be used for quality assessment of studies. These items comprise reporting items, items that assess internal and external validity of primary studies and power study assessment. The 15 items are listed below:

1. Are the hypothesis /aim /objective 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 (e.g., 0.035 rather than rather than <0.05) for the main outcomes except where the probability value is less than 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 randomized to intervention groups?
14. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete?
15. Does the study provide estimate 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 Q Cochrane test and the related p value. Furthermore, we will use I^2 measure as categorization measure of heterogeneity. If the measure proves to be 50-74.9% or >75%, we will have severe and highly severe heterogeneity, respectively. To investigate potential sources of heterogeneity, we will use a sub-group analysis method. We will assess the intervention efficacy according to different trial designs (randomized versus non-randomized, blind versus open label/ non-blind etc.), participants' characteristics (gender, age groups, hyperkyphosis etiology etc.), and intervention-related factors (types of orthoses, the duration worn, different follow-up times, etc…).

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 bias is non-ignorable, we will use the Fill & Trim method for correcting the final result.

Statistical analysis and data synthesis

We will perform meta-analysis in each outcome measure will be possible. First, we will choose the appropriate effect-size measure for evaluating the intervention efficacy based on the outcome variable types (continuous, nominal, ordinal, etc). The appropriate measure will be SMD (Standardized Mean Difference) or Relative Risk (RR).

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

The study level appropriate effect-size measure (SMD or RR) will be combined by Fixed effect or Random effect models according to the study characteristics. Forest plots will be used for presenting the combined measure and the different study level measures.

For investigating potential sources of heterogeneity we will use sub-group analysis or meta-regression methods for assessing relationships between the study qualities (Risk of Bias) measure/ score and the intervention efficacy. If the intervention effect in low quality studies will be greater than high quality studies, we will use Sensitivity Analysis for correcting or adjusting the bias. In severe methodological heterogeneity that meta-analysis is not possible; we will use meta-synthesis or narrative synthesis (28).

DISCUSSION

Our systematic review and meta-analysis will determine efficiency of spinal orthoses and postural taping with different follow up durations for older people with hyperkyphosis and will potentially help patients, clinicians, and researchers to determine the effectiveness or utility of orthotic interventions for older people with hyperkyphosis.

Author's affiliations

[1] Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Islamic Republic of Iran

[2] Iranian Research Center on Aging, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[3] Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[4] Department of Health Sciences Education Development, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Acknowledgement:

The authors would like to acknowledge the efforts of Dr. Stephen Hutchins for his diligent and thoughtful editing of the manuscript.

Contributors

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

Declaration of interest

The review authors declare no conflict of interest.

Funding

None

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.

References

1. Novak AC, Komisar V, Maki BE, Fernie GR. Age-related differences in dynamic balance control during stair descent and effect of varying step geometry. Applied ergonomics. 2016;52:275-84.
2. Katzman WB, Harrison SL, Fink HA, Marshall LM, Orwoll E, Barrett-Connor E, et al. Physical function in older men with hyperkyphosis. J Gerontol A Biol Sci Med Sci. 2015;70(5):635-40.
3. Ettinger B, Black DM, Palermo L, Nevitt MC, Melnikoff S, Cummings SR. Kyphosis in older women and its relation to back pain, disability and osteopenia: the study of osteoporotic fractures. Osteoporos Int. 1994;4(1):55-60.
4. Martin AR, Sornay-Rendu E, Chandler JM, Duboeuf F, Girman CJ, Delmas PD. The impact of osteoporosis on quality-of-life: the OFELY cohort. Bone. 2002;31(1):32-6.
5. Sinaki M, Itoi E, Rogers JW, Bergstralh EJ, Wahner HW. Correlation of back extensor strength with thoracic kyphosis and lumbar lordosis in estrogen-deficient women. Am J Phys Med Rehabil. 1996;75(5):370-4.
6. Ryan SD, Fried LP. The impact of kyphosis on daily functioning. J Am Geriatr Soc. 1997;45(12):1479-86.
7. Kado DM, Huang MH, Barrett-Connor E, Greendale GA. Hyperkyphotic posture and poor physical functional ability in older community-dwelling men and women: the Rancho Bernardo study. J Gerontol A Biol Sci Med Sci. 2005;60(5):633-7.
8. Lombardi I, Jr., Oliveira LM, Monteiro CR, Confessor YQ, Barros TL, Natour J. Evaluation of physical capacity and quality of life in osteoporotic women. Osteoporos Int. 2004;15(1):80-5.

9. Takahashi T, Ishida K, Hirose D, Nagano Y, Okumiya K, Nishinaga M, et al. Trunk deformity is associated with a reduction in outdoor activities of daily living and life satisfaction in community-dwelling older people. Osteoporosis international. 2005;16(3):273-9.
10. Ensrud KE, Black DM, Harris F, Ettinger B, Cummings SR. Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group. J Am Geriatr Soc. 1997;45(6):682-7.
11. Ailon T, Shaffrey CI, Lenke LG, Harrop JS, Smith JS. Progressive Spinal Kyphosis in the Aging Population. Neurosurgery. 2015;77:S164-S72.
12. Pfeifer M, Begerow B, Minne HW. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. American Journal of Physical Medicine & Rehabilitation. 2004;83(3):177-86.
13. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR, editors. Significant reduction in risk of falls and back pain in osteoporotic-kyphotic women through a Spinal Proprioceptive Extension Exercise Dynamic (SPEED) program. Mayo Clinic Proceedings; 2005: Elsevier.
14. Sinaki M, Lynn SG. Reducing the risk of falls through proprioceptive dynamic posture training in osteoporotic women with kyphotic posturing: a randomized pilot study. American Journal of Physical Medicine & Rehabilitation. 2002;81(4):241-6.
15. Kaplan RS, SINAKI M, editors. Posture training support: preliminary report on a series of patients with diminished symptomatic complications of osteoporosis. Mayo Clinic Proceedings; 1993: Elsevier.
16. Pfeifer M, Kohlwey L, Begerow B, Minne HW. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. American Journal of Physical Medicine & Rehabilitation. 2011;90(10):805-15.
17. Greig AM, Bennell KL, Briggs AM, Hodges PW. Postural taping decreases thoracic kyphosis but does not influence trunk muscle electromyographic activity or balance in women with osteoporosis. Manual Therapy. 2008;13(3):249-57.
18. Goodwin VA, Hall AJ, Rogers E, Bethel A. Orthotics and taping in the management of vertebral fractures in people with osteoporosis: a systematic review. BMJ open. 2016;6(5):e010657.
19. Newman M, Lowe CM, Barker K. Spinal orthoses for vertebral osteoporosis and osteoporotic vertebral fracture: a systematic review. Archives of physical medicine and rehabilitation. 2016;97(6):1013-25.
20. Kado DM, Browner WS, Palermo L, Nevitt MC, Genant HK, Cummings SR. Vertebral fractures and mortality in older women: a prospective study. Archives of internal medicine. 1999;159(11):1215-20.
21. Schneider DL, von Mühlen D, Barrett-Connor E, Sartoris DJ. Kyphosis does not equal vertebral fractures: the Rancho Bernardo study. The Journal of rheumatology. 2004;31(4):747-52.
22. Üstün TB, Chatterji S, Bickenbach J, Kostanjsek N, Schneider M. The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health. Disability and rehabilitation. 2003;25(11-12):565-71.
23. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic reviews. 2015;4(1):1.
24. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. ANN INTERN MED. 2009;151(4):W-65-W-94.
25. WHO. Definition of an older or elderly person. World Health Organization Geneva; 2011.
26. Kado DM, Prenovost K, Crandall C. Narrative review: hyperkyphosis in older persons. Annals of Internal Medicine. 2007;147(5):330-8.
27. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. Journal of epidemiology and community health. 1998;52(6):377-84.

28. reviews Cf, dissemination. Systematic reviews: CRD's guidance for undertaking reviews in health care: Centre for Reviews and Dissemination; 2009.

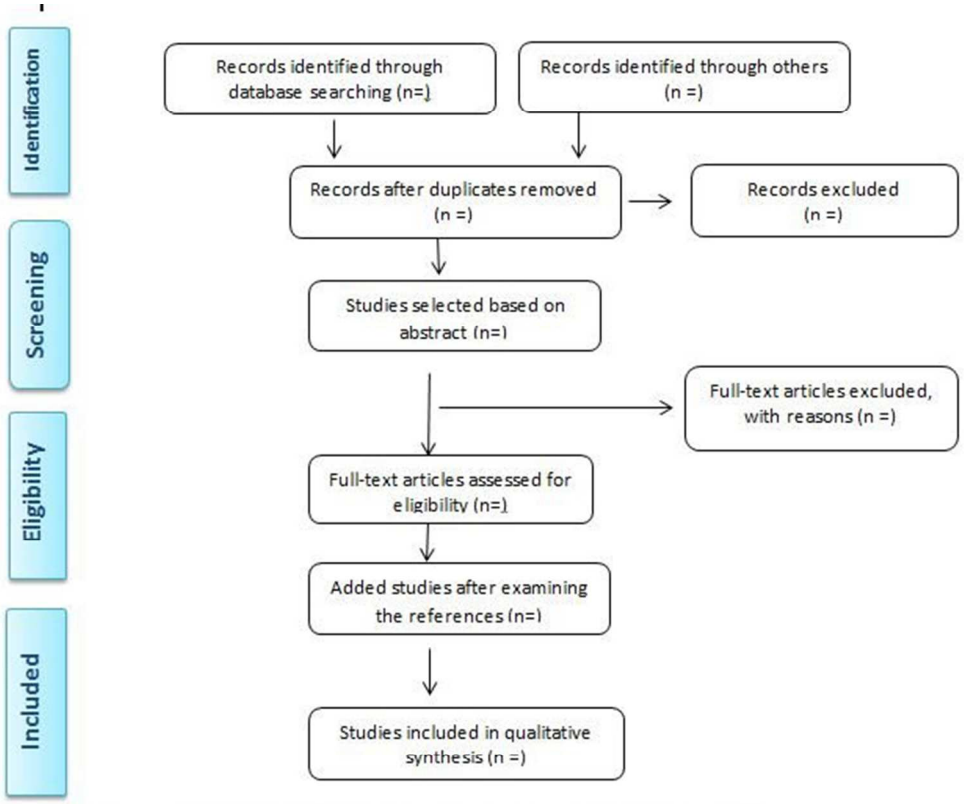


Figure 1: Flow diagram of the study selection process based on PRISMA guidelines

54x46mm (300 x 300 DPI)

Appendix1

PubMed search strategy

1. Orthoses
2. Orthosis
3. Orthotic
4. Orthotic devices
5. Brace
6. Bracing
7. Thoracolumbosacral Orthosis
8. Thoracolumbosacral Orthoses
9. “lumbosacral Orthoses”
10. “lumbosacral Orthosis”
11. “Thoracolumbar Orthosis”
12. “Thoracolumbar Orthosis”
13. Spinomed
14. Posture Training Support
15. Weighted Kypho-Orthosis
16. Osteo-med
17. Postural Taping
18. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17
19. kyphosis
20. Kyphotic
21. Hyperkyphosis
22. Hyperkyphotic
23. 18 OR 19 OR 20 OR 21 OR 22
24. 18 AND 23

(Orthoses OR Orthosis OR Orthotic OR “Orthotic Devices” OR Brace OR Bracing OR “Thoracolumbosacral Orthosis” OR “Thoracolumbosacral Orthoses” OR “lumbosacral

Orthoses" OR"lumbosacral Orthosis" OR "Thoracolumbar Orthosis" OR "Thoracolumbar Orthosis" OR Spinomed OR "Posture Training Support" OR "Weighted Kypho-Orthosis" OR Osteo-med OR "Postural taping") AND (Kyphosis OR Kyphotic OR Hyperkyphosis OR Hyperkyphotic)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	page number in manuscript
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Page 1
Update	1b	Not applicable (n/a)
Registration	2	Page 2 in abstract and 5 in main text
Authors:		
Contact	3a	page 1 in abstract and 13 in main text
Contributions	3b	Page 12
Amendments	4	n/a
Support:		
Sources	5a	Page 12
Sponsor	5b	n/a
Role of sponsor or funder	5c	n/a
INTRODUCTION		
Rationale	6	Page 3
Objectives	7	Page 4
METHODS		
Eligibility criteria	8	Page 5
Information sources	9	Page 6
Search strategy	10	Page 6
Study records:		
Data management	11a	Page 8
Selection process	11b	Page 8
Data collection process	11c	Page 9
Data items	12	Page 9
Outcomes and prioritization	13	Page 9
Risk of bias in individual studies	14	Page 10
Data synthesis	15a	Page 11
	15b	Page 11

	15c	Page 11
	15d	n/a
Meta-bias(es)	16	Page 11
Confidence in cumulative evidence	17	n/a

.

BMJ Open

The 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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-015813.R2
Article Type:	Protocol
Date Submitted by the Author:	27-May-2017
Complete List of Authors:	aboutorabi, atefeh; university of social welfare and rehabilitation sciences , Department of Orthotics and Prosthetics; Iranian Research Center on Aging Ahmadi Bani, Monireh; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Arazpour, Mokhtar; university of social welfare and rehabilitation sciences, Department of Orthotics and Prosthetics Keshtkar, Abbasali; Tehran university of medical sciences, department of health sciences education development, school of public health;
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Geriatric medicine
Keywords:	REHABILITATION MEDICINE, STATISTICS & RESEARCH METHODS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

The 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

Atefeh Aboutorabi[1, 2], Monireh Ahmadi Bani[1, 2], Mokhtar Arazpour[1, 3], Abbas Ali Keshtkar[4]

Corresponding author: Monireh Ahmadi Bani, PhD, Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Kodakyar st., Daneshjo Blvd., Evin, Tehran, 1985713834, Iran.
Telephone number: 0098 (21) 22 18 00 10
Fax number: 0098(21) 22 18 00 49
Email address: m.ahmadi_bani@yahoo.com

ABSRACT

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 randomized 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 version 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.

Trial registration number: This systematic review protocol is registered in the PROSPERO International Prospective Register of Systematic Reviews, registration number CRD42016045880.

Article summary:

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 etiology and severity.

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 life (4) and physical function impairment in association with hyperkyphosis have also been demonstrated (5, 6). In addition, impairment in activities of daily living (ADLs) 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 optimize body alignment and improvement in 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 falls (14-16) 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 (COM) 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 thorasic 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 synthesizing 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 of older with hyperkyphosis and also assessing and finding of source 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:

- Outcomes relating to WHO International Classification of Functioning, Disability and Health (ICF) domains of body structure and function, activities and participation. ICF components included 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 factor related to physical activity, function, activity daily living (ADL) and quality of life (24).
- Comparisons between the effect of spinal orthoses/bracing and postural taping according to gender;
- Comparisons between different hyperkyphosis etiologies 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 number: 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 employed to describe the flow of information through the different phases of this systematic review (26).

Eligibility Criteria

Types of studies

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

Type of Participants

Studies which involve the participation of subjects with diagnosis of thoracic hyperkyphosis aged at least 55 years or more (27) of either or both genders will be included. Hyperkyphosis will be diagnosed as an angle curvature 45 degrees using either radiographic image or such devices as the kyphometer, goniometer, inclinometer, and flexi curve ruler measurements of the kyphosis index >13 degree (28)). Hyperkyphosis caused by osteoporosis with or without vertebral compression fracture, disk degeneration; poor spinal muscles strength and soft tissue degeneration in acute and chronic conditions will be included. However, hyperkyphosis subjects with other etiologies 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 (for example 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/)
- Physiotherapy Evidence Database (PEDro library) (www.pedro.org.au/);
- REHAB DATA (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
- Gray Literatures (Dissertations and Theses - conference papers)
- Google Scholar (https://scholar.google.com/)
- Hand searching of Key journals in 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 supplementary file.

Selection process

Two independent reviewers (AA and MAB) will be involved in study selection. The study selection process is summarized below in a PRISMA flow diagram (figure 1).

Please insert figure 1 below here

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 etiology)
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 (COP or COG 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 (FIM), or Barthel Index (BI)
7. Participation restrictions, quality of life measures (QOL)
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 of the checklist will be used for the 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 hypothesis /aim /objective 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 (e.g., 0.035 rather than rather than <0.05) for the main outcomes except where the probability value is less than 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 randomized to intervention groups?
14. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete?
15. Does the study provide estimate 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 categorization 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 sub-group analysis method. We will assess the intervention efficacy according to different trial designs (randomized versus non-randomized, blind versus open label/ non-blind etc.), participants' characteristics (gender, age groups, hyperkyphosis etiology 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 bias is non-ignorable, we will use the Fill & Trim method to correct the final result.

Statistical analysis and data synthesis

We will perform a meta-analysis in each outcome measure will be possible. First, we will choose the appropriate effect-size measure for evaluating the intervention efficacy based on the outcome variable types (continuous, nominal, ordinal, etc). The appropriate measure will be SMD (Standardized Mean Difference) or Relative Risk (RR).

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

The study level appropriate effect-size measure (SMD or RR) will be combined by '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 sub-group analysis or meta-regression method for assessing 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 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, utilizing the most appropriate devices, and thereby increasing the quality of care for affected people.

Author's affiliations

[1] Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Islamic Republic of Iran

[2] Iranian Research Center on Aging, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[3] Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[4] Department of Health Sciences Education Development, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Acknowledgement:

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

Contributors

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

Declaration of interest

The review authors declare no conflict of interest.

Funding

None

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.

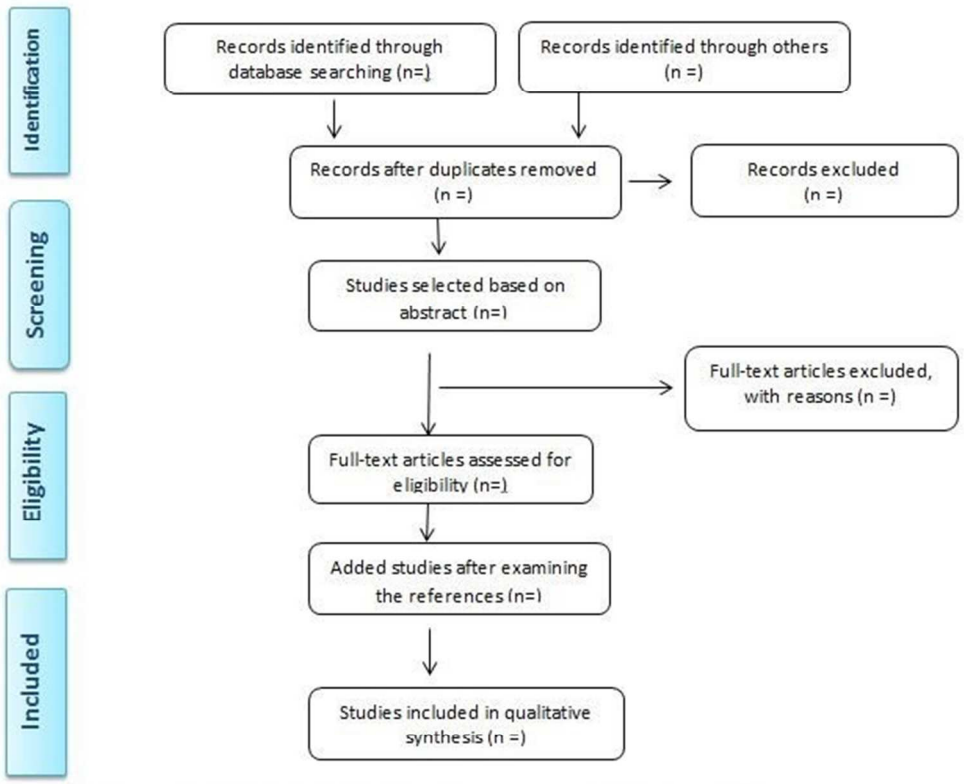
References

1. Novak AC, Komisar V, Maki BE, Fernie GR. Age-related differences in dynamic balance control during stair descent and effect of varying step geometry. Applied ergonomics. 2016;52:275-84.
2. Katzman WB, Harrison SL, Fink HA, Marshall LM, Orwoll E, Barrett-Connor E, et al. Physical function in older men with hyperkyphosis. J Gerontol A Biol Sci Med Sci. 2015;70(5):635-40.
3. Ettinger B, Black DM, Palermo L, Nevitt MC, Melnikoff S, Cummings SR. Kyphosis in older women and its relation to back pain, disability and osteopenia: the study of osteoporotic fractures. Osteoporos Int. 1994;4(1):55-60.
4. Martin AR, Sornay-Rendu E, Chandler JM, Duboeuf F, Girman CJ, Delmas PD. The impact of osteoporosis on quality-of-life: the OFELY cohort. Bone. 2002;31(1):32-6.
5. Sinaki M, Itoi E, Rogers JW, Bergstralh EJ, Wahner HW. Correlation of back extensor strength with thoracic kyphosis and lumbar lordosis in estrogen-deficient women. Am J Phys Med Rehabil. 1996;75(5):370-4.
6. Ryan SD, Fried LP. The impact of kyphosis on daily functioning. J Am Geriatr Soc. 1997;45(12):1479-86.
7. Kado DM, Huang MH, Barrett-Connor E, Greendale GA. Hyperkyphotic posture and poor physical functional ability in older community-dwelling men and women: the Rancho Bernardo study. J Gerontol A Biol Sci Med Sci. 2005;60(5):633-7.

8. Lombardi I, Jr., Oliveira LM, Monteiro CR, Confessor YQ, Barros TL, Natour J. Evaluation of physical capacity and quality of life in osteoporotic women. Osteoporos Int. 2004;15(1):80-5.
9. Takahashi T, Ishida K, Hirose D, Nagano Y, Okumiya K, Nishinaga M, et al. Trunk deformity is associated with a reduction in outdoor activities of daily living and life satisfaction in community-dwelling older people. Osteoporosis international. 2005;16(3):273-9.
10. Ensrud KE, Black DM, Harris F, Ettinger B, Cummings SR. Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group. J Am Geriatr Soc. 1997;45(6):682-7.
11. Ailon T, Shaffrey CI, Lenke LG, Harrop JS, Smith JS. Progressive Spinal Kyphosis in the Aging Population. Neurosurgery. 2015;77:S164-S72.
12. Katzman WB, Sellmeyer DE, Stewart AL, Wanek L, Hamel KA. Changes in flexed posture, musculoskeletal impairments, and physical performance after group exercise in community-dwelling older women. Archives of physical medicine and rehabilitation. 2007;88(2):192-9.
13. Ball J, Cagle P, Johnson B, Lucasey C, Lukert B. Spinal extension exercises prevent natural progression of kyphosis. Osteoporosis international. 2009;20(3):481.
14. Pfeifer M, Begerow B, Minne HW. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. American Journal of Physical Medicine & Rehabilitation. 2004;83(3):177-86.
15. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR, editors. Significant reduction in risk of falls and back pain in osteoporotic-kyphotic women through a Spinal Proprioceptive Extension Exercise Dynamic (SPEED) program. Mayo Clinic Proceedings; 2005: Elsevier.
16. Sinaki M, Lynn SG. Reducing the risk of falls through proprioceptive dynamic posture training in osteoporotic women with kyphotic posturing: a randomized pilot study. American Journal of Physical Medicine & Rehabilitation. 2002;81(4):241-6.
17. Kaplan RS, SINAKI M, editors. Posture training support: preliminary report on a series of patients with diminished symptomatic complications of osteoporosis. Mayo Clinic Proceedings; 1993: Elsevier.
18. Pfeifer M, Kohlwey L, Begerow B, Minne HW. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. American Journal of Physical Medicine & Rehabilitation. 2011;90(10):805-15.
19. Greig AM, Bennell KL, Briggs AM, Hodges PW. Postural taping decreases thoracic kyphosis but does not influence trunk muscle electromyographic activity or balance in women with osteoporosis. Manual Therapy. 2008;13(3):249-57.
20. Goodwin VA, Hall AJ, Rogers E, Bethel A. Orthotics and taping in the management of vertebral fractures in people with osteoporosis: a systematic review. BMJ open. 2016;6(5):e010657.
21. Newman M, Lowe CM, Barker K. Spinal orthoses for vertebral osteoporosis and osteoporotic vertebral fracture: a systematic review. Archives of physical medicine and rehabilitation. 2016;97(6):1013-25.
22. Kado DM, Browner WS, Palermo L, Nevitt MC, Genant HK, Cummings SR. Vertebral fractures and mortality in older women: a prospective study. Archives of internal medicine. 1999;159(11):1215-20.

23. Schneider DL, von Mühlen D, Barrett-Connor E, Sartoris DJ. Kyphosis does not equal vertebral fractures: the Rancho Bernardo study. The Journal of rheumatology. 2004;31(4):747-52.
24. Üstün TB, Chatterji S, Bickenbach J, Kostanjsek N, Schneider M. The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health. Disability and rehabilitation. 2003;25(11-12):565-71.
25. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic reviews. 2015;4(1):1.
26. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. ANN INTERN MED. 2009;151(4):W-65-W-94.
27. WHO. Definition of an older or elderly person. World Health Organization Geneva; 2011.
28. Kado DM, Prenovost K, Crandall C. Narrative review: hyperkyphosis in older persons. Annals of Internal Medicine. 2007;147(5):330-8.
29. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. Journal of epidemiology and community health. 1998;52(6):377-84.
30. reviews Cf, dissemination. Systematic reviews: CRD's guidance for undertaking reviews in health care: Centre for Reviews and Dissemination; 2009.

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



54x46mm (300 x 300 DPI)

Appendix1

PubMed search strategy

1. Orthoses
2. Orthosis
3. Orthotic
4. Orthotic devices
5. Brace
6. Bracing
7. Thoracolumbosacral Orthosis
8. Thoracolumbosacral Orthoses
9. “lumbosacral Orthoses”
10.“lumbosacral Orthosis”
11.“Thoracolumbar Orthosis”
12.“Thoracolumbar Orthosis”
13.Spinomed
14. Posture Training Support
15. Weighted Kypho-Orthosis
16. Osteo-med
17. Postural Taping
18.1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17
19. kyphosis
20. Kyphotic
21. Hyperkyphosis
22. Hyperkyphotic
23. 18 OR 19 OR 20 OR 21 OR 22
24.18 AND 23

(Orthoses OR Orthosis OR Orthotic OR “Orthotic Devices” OR Brace OR Bracing OR “Thoracolumbosacral Orthosis” OR “Thoracolumbosacral Orthoses” OR “lumbosacral Orthoses” OR“lumbosacral Orthosis” OR “Thoracolumbar Orthosis” OR “Thoracolumbar Orthosis” OR Spinomed OR “Posture Training Support” OR “Weighted Kypho-Orthosis” OR

Osteo-med OR "Postural taping") AND (Kyphosis OR Kyphotic OR Hyperkyphosis OR Hyperkyphotic)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	page number in manuscript
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Page 1
Update	1b	Not applicable (n/a)
Registration	2	Page 2 in abstract and 5 in main text
Authors:		
Contact	3a	page 1 in abstract and 10 in main text
Contributions	3b	Page 11
Amendments	4	n/a
Support:		
Sources	5a	Page 11
Sponsor	5b	n/a
Role of sponsor or funder	5c	n/a
INTRODUCTION		
Rationale	6	Page 3
Objectives	7	Page 4
METHODS		
Eligibility criteria	8	Page 5
Information sources	9	Page 5
Search strategy	10	Page 6
Study records:		
Data management	11a	Page 6
Selection process	11b	Page 6
Data collection process	11c	Page 7
Data items	12	Page 7
Outcomes and prioritization	13	Page 7
Risk of bias in individual studies	14	Page 8
Data synthesis	15a	Page 9
	15b	Page 9

	15c	Page 9
	15d	n/a
Meta-bias(es)	16	Page 9
Confidence in cumulative evidence	17	n/a

.