TITLE: Mattresses for Chronic Back or Neck Pain: A Review of the Clinical Effectiveness and Guidelines

DATE: 14 May 2014

CONTEXT AND POLICY ISSUES

Persistent back pain is a common presentation in primary care settings. It presents significant costs in relation to care, absenteeism, and early retirement.[1] Chronic back and neck pain can be moderate to severe and debilitating. Often back and neck pain of musculoskeletal origin is self-limited and resolves with little or no intervention, however it is also often recurrent.[2]

While chronic back and neck pain is often of musculoskeletal origin, the possibility of other serious etiologies must also be considered.[2]

Common approaches to nonspecific back and neck pain include physical therapy, advice to stay active and analgesia. The main treatment goals are pain reduction and improving function.[2]

It has been reported that firmness and/or construction of bedding systems may be associated with complaints of back and neck discomfort or pain.[3]

The purpose of this report is to retrieve and review the existing evidence of efficacy and evidence-based guidelines for the use of specific mattresses to reduce chronic back and neck pain of musculoskeletal origin.

RESEARCH QUESTIONS

1. What is the evidence for the effectiveness of different mattress types for adults with chronic back or neck pain?

2. What are the evidence-based guidelines for mattress attributes to reduce chronic back or neck pain?

KEY FINDINGS

Limited conclusive evidence was identified regarding the efficacy of specific mattress types for treatment of back and neck pain. One trial was identified presenting evidence that firm mattresses may be the least effective treatment for lower back pain. Four guidelines were identified that found a lack of evidence to form a basis for mattress recommendations for the treatment of chronic back and neck pain of musculoskeletal origin.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 4), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2004 and April 14, 2014.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications and evaluated the full-text publications for the final article selection, according to selection criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults with chronic back or neck pain of musculoskeletal origin
Intervention	Mattresses
Comparator	Mattresses of different firmness, thickness, composition (e.g. foam, coil, air) and padding
Outcomes	Reduction or elimination of neck or back pain
Study Designs	Health Technology Assessments (HTA)/ Systematic review (SR)/Meta-analysis (MA); Randomized controlled trials (RCTs); Non-randomized studies; and Guidelines

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria, were duplicates or included in a selected SR, MA or HTA, or were published prior to 2004. Studies were also excluded for a lack of methodological quality. More specifically, studies were excluded if they lacked appropriate controls necessary for attributing any effect to mattresses under investigation.

Critical Appraisal of Individual Studies

The quality of the included RCT was evaluated using the Down and Black checklist.[4] Strengths and limitations were described narratively.

Critical appraisal of guidelines use the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.[5] The strengths and limitations of the guidelines were described narratively instead of assigning an AGREE numerical score.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search strategy initially identified 377 articles of potential. Following screening titles and available abstracts, 13 full text articles were retrieved. In addition, four articles were identified in the grey literature. Upon review, four guidelines and one RCT met the selection criteria. The 12 excluded articles consisted of two narrative reviews, two commentaries, two studies examining irrelevant interventions, one duplicate of an excluded study, three studies that lacked sufficient methodological quality, one study examining an irrelevant population, and one survey study. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart describes the selection procedure of the included studies of this review (Appendix 1). No systematic reviews or meta-analyses studies met the inclusion criteria.

Summary of Study Characteristics

Randomized Controlled Trials

Characteristics of the included RCT are tabulated in Appendix 2, Table A2.1.

Study design

The design of RCT consists of three parallel treatment arms, and while examiners were blinded, patients could not be blinded to the type of mattress they were sleeping on.[6] A stratifying program was used for random allocation. The aim was to equalize baseline data of the three groups with respect to age, sex, duration and severity of LBP, the number of LBP-related days off work in the past 12 months, and daily physical workload.[6]

Population

The RCT inclusion criteria was for patients between the ages of 18 and 60 years with largely stable chronic low back pain (LBP) for at least six months. It was also required that the pain had to either dominate in the morning or be equal throughout the day. Additionally, any accompanying leg pain had to be at a constant ratio to the back pain. Patients with other serious illnesses that may impact sleep or patients that were already sleeping on a study mattress were also excluded.[6]

Intervention and Comparators

The interventions of the trial were described in limited detail. The firm mattress consisted of a foam core, surrounded by three layers of cotton with no springs. The water bed was built with four horizontal layers of fibers which stabilized the movement of water after one second. The foam mattress was made of a temperature-sensitive pressure relieving material that molds to the persons shape after a few seconds. One of these three interventions was used for one month.[6]

Outcomes

Interviews before and after the intervention were used to obtain integer scores for lower back pain (0-10), leg pain (0-10), and an activities of daily living (ADL) score (0-30). An increased ADL score reflects a decrease in daily function level. The number of hours slept was also obtained by the post-intervention interview.

Guidelines and Recommendations

Four guidelines were identified as meeting the inclusion criteria.[7-10] Study characteristics of the included guidelines are summarized in Appendix 2, Table A2.2.

Origin of reports

One included guideline from 2011, was a Canadian guideline and originated in Edmonton, Alberta.[8] This guideline was based upon eight previously published guidelines including previous versions of two guidelines included in this report.[7,10] Two identified guidelines originated in the United States, one from the Agency for Healthcare Research and Quality (AHRQ), in Rockville, MD, published in 2011[7] and one from the American Pain Society in Glenview, IL published in 2009.[9] The fourth guideline included in this report is from Europe from the Working Group on Guidelines for Prevention in Low Back Pain published in 2006.[10]

Interventions

All of the identified guidelines included various interventions for prevention and/or treatment of LBP and all include recommendations on mattresses.[7-10] The Canadian recommendations,[8] the European evidence-based guidelines,[10] and the American Pain Society guidelines[10] based their recommendations on the same single RCT published in 2003.[11] This RCT also contained more quantitative information on the definition of firm and medium-firm mattresses. The firmness of mattress (H_s) was rated according to the European Committee for Standardization scale. The scale starts at 1.0 (firmest) and stops at 10.0 (softest). The firm mattress used in the 2003 RCT was H_s 2.3 while the medium-firm mattress was rated H_s 5.6.[11] No identified guidelines contained interventions specific to neck pain.

Grading of recommendations and levels of evidence

The schemes used by the included guidelines for grading recommendations and levels of evidence are summarized in Appendix 3. Two included guidelines graded recommendations and assigned a level of evidence to the identified literature.[7,8] Guidelines from the AHRQ either Strongly Recommend or Strongly Not Recommend based upon an evidence level A, Moderately Recommend or Moderately Not Recommend based upon an evidence level B, Recommend or Not Recommend based upon an evidence level C and either Recommend, Not Recommend or have No Recommendation for evidence level I depending on consensus of the guideline development group (GDG).[7] The identified Canadian guidelines were based upon previously published guidelines and graded the previously published recommendations as Do, Do Not Do, or Do Not Know. Evidence levels were graded based upon the highest quality study identified either systematic review (SR), randomized controlled trial (RCT), case series (CS), guideline (G), or expert opinion (EO).[8] The American Pain Society did not have graded recommendations and rated evidence as good, fair or poor.[9] The European evidence-based guidelines, in

contrast, did not have levels of evidence but graded recommendations as Level A-D based upon the quality and quantity of the supporting literature.[10]

Summary of Critical Appraisal

Critical appraisal of the included RCT is tabulated Appendix 4.

The identified RCT[6] provided a CONSORT diagram, which documented the 40 percent dropout of participants. Patient characteristics were tabulated before and after randomization and after intervention. The dropouts did not create significant differences between groups in respect to any of the tabulated patient characteristics. Before intervention initiation 68% of the dropouts were from the patients allocated to the waterbed treatment while during the intervention 67% of the dropouts were from the patients allocated to the firm mattress. This uneven distribution of dropouts may be a source of study bias. The study clearly defined the role of blinded investigators, the allocation process, patient eligibility, outcome measures, and the statistical methods used. The interventions were described but not sufficiently for precise replication of the study. The study did not include a discussion of possible adverse events or limitations of the trial. The authors analyzed the data for two possible scenarios, one where the patients that dropped out of the study were perfectly representative of their assigned group and one where the patients that dropped out of the study were assigned the worst 90th percentile scores. The second analysis was used because patients that removed themselves from the study did so because of more pain or less sleep. An analysis that did not include dropouts was not reported. The self-reported, subjective outcome measures of back and leg pain, combined with the inability to blind study participants to the intervention, introduces the potential for bias in this study. The mattress interventions were supplied and installed in the participant's home by mattress industry sponsors.

Critical appraisal of the included guidelines is tabulated in Appendix 5.

Three of the four included guidelines detailed a literature search methodology.[7,9,10] Two of these three described a systematic literature search including selection criteria.[7,9] The remaining set of guidelines were based upon previously published guidelines and did not describe a literature search methodology or provide details for a supplementary literature search that was mentioned.[8] Two guidelines described attempts to improve stakeholder representation in their respective GDGs.[7,10] The included guidelines varied in stating explicitly the scope,[7-9] objectives[8,10] and target audience.[7,8,10] One guideline failed to include a conflict of interest statement.[8] The bibliography of the AHRQ guidelines were contained in a separate document.[7] While these guidelines do provide methods for recommendation formulation, there is no explicit link between the recommendations and the evidence used to formulate them.[7]

Summary of Findings

The statistically significant findings and author's conclusions of Bergholdt et al., 2008[6] are summarized in Appendix 6.

This RCT compared a waterbed mattress, a foam mattress, and a firm mattress for the treatment of chronic LBP. The study did not find any statistically significant differences between the water bed and foam mattress in any outcomes. When patients who discontinued intervention were assigned the worst 90th percentile scores the firm mattress produced a statistically significant increase in LBP scores, leg pain scores, an increase in ADL, and a

decrease in reported sleep hours compared to the water bed and foam mattress. When patients who discontinued the intervention were considered to have no effect, only a difference in LBP scores and sleep hours remained statistically significant. No analysis was done without including patients who discontinued the intervention. The authors conclude that the hard mattress resulted in worse outcomes but that the differences were small.

Relevant recommendations of the included guidelines are summarized in Appendix 7. The levels of evidence and grades of recommendations used below are described in Appendix 3.

Guidelines from the AHRQ included separate recommendations for acute, subacute and chronic LBP with interventions of mattresses, specific beds and use of optimal sleeping surfaces (e.g. bedding, water beds, and hammocks). All of the recommendations were based upon Evidence Level I (consensus), and were either No Recommendation or Not Recommended. The use of specific beds was Not Recommended for treatment of any category of LBP, while mattresses and the use of optimal sleeping surfaces had No Recommendation for any category of LBP.[7]

The Canadian guidelines,[8] used the European evidence-based guidelines[10] as a reference for the included mattress related recommendations. The Canadian guidelines had a Do Not Know recommendation for any specific type of mattress,[8] while the European evidence-based guidelines stated no recommendation for LBP prevention using mattress interventions [Level C] but suggested that chronic LBP may be reduced with a medium-firm rather than a hard mattress [Level C].[10] For chronic LBP the American Pain Society guidelines cited one RCT as evidence that a firm mattress is slightly inferior to a medium-firm mattress for pain-related disability and pain while in bed with no other pain related outcome differences [fair].[9] The Canadian recommendations,[8] the European evidence-based guidelines,[10] and the American Pain Society guidelines[10] based their recommendations on the same single RCT published in 2003.[11] None of these guidelines cited the RCT included in this report, Bergholdt et al. (2008),[6] in recommendation formulation.[7-10]

Limitations

There was a lack of evidence identified supporting the effectiveness of different mattress types for chronic back and neck pain. The absence of identified evidence may be a function of the limitations of the search strategy, however systematic literature searches of the included guidelines also identified a lack of evidence. The identified RCT was limited by the types of interventions, the subjective nature of the self-reported outcomes and the inability to blind study participants to the intervention. No evidence regarding mattress interventions for chronic neck pain was identified.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

There was a lack of identified evidence to inform the choice of mattress in order to positively influence chronic back and neck pain. All four identified guidelines reported a lack of evidence to support mattress recommendations. Two guidelines reported evidence from the same single trial that found a medium-firm mattress was superior to a firm mattress for chronic LBP. There is agreement with these two identified guidelines and the included RCT that the use of a firm mattress was the least effective intervention examined for LBP. No evidence was identified examining mattress interventions specifically for chronic neck pain.

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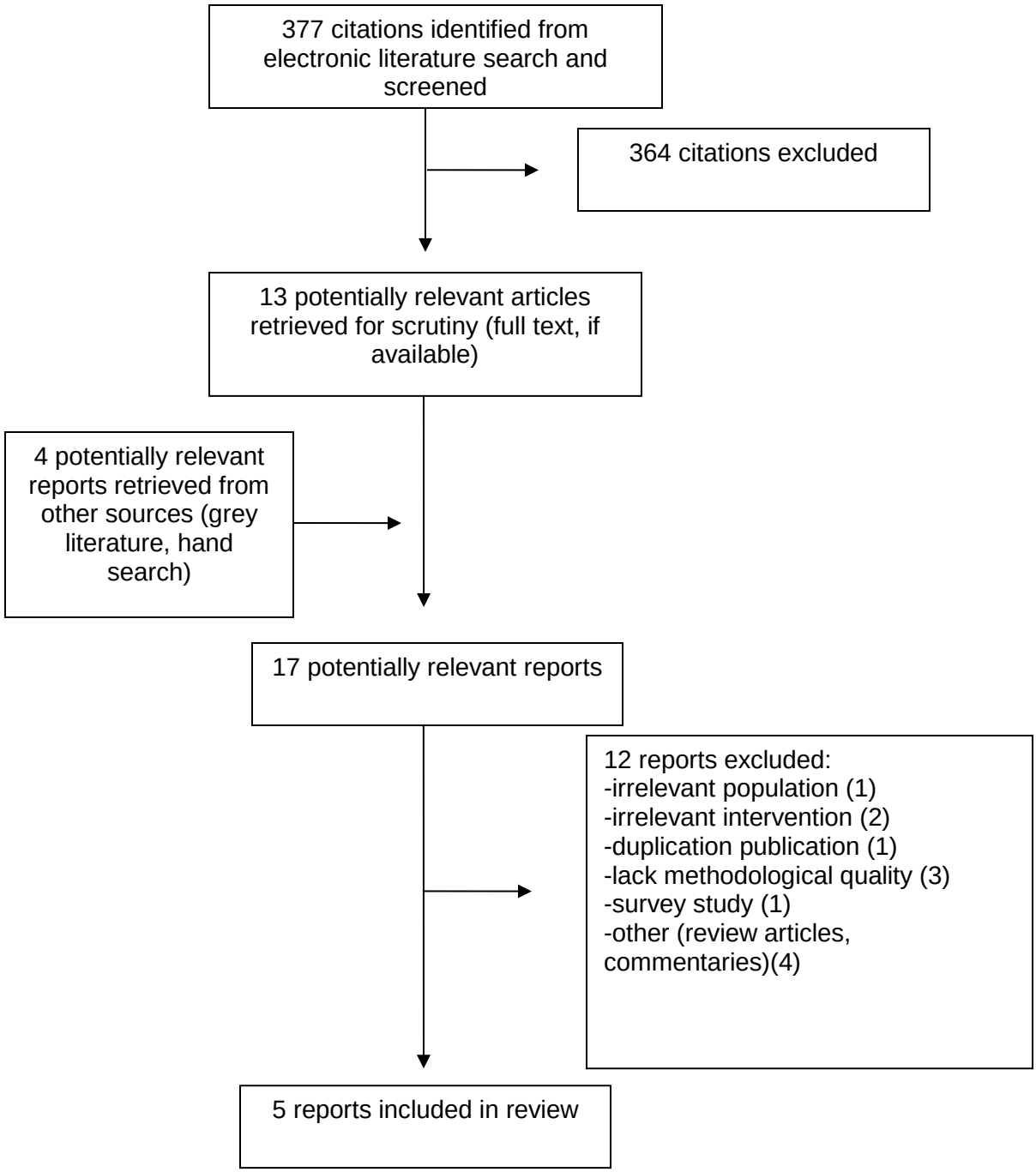
APPENDIX 1: Selection of Included Studies



APPENDIX 2: SUMMARY OF STUDY CHARACTERISTICS

Table A2.1: Summary of Study Characteristics of Included RCT

Study Design	Patient Characteristics, Sample Size	Intervention	Comparator(s)	Outcomes
Bergholdt et al., 2008[6]				
Parallel group, single-blinded RCT	Patients with largely stable chronic LBP (Th12-S1) for at least 6 months, between ages 18 to 60. Lower back pain had to be greatest in the morning or at least equivalent throughout the day. (n=160)	Firm mattress	Water bed and body-conforming foam mattress	LBP score Leg pain score Functional ADL score Reported sleep hours
ADL=activities of daily living; **LBP**= low back pain				

Table A2.2: Summary of Characteristics of Included Guidelines

Origin, Publication Year	Interventions of Interest	Grading (see Appendix 3)	Target Population
Agency for Healthcare Research and Quality (AHRQ), 2011[7]			
Rockville, MD, USA, 2011	Any specific beds or mattresses	Rating of evidence from A-C and I. Strength of Recommendations directly tied to evidence rating from Strongly Recommended to Strongly Not Recommended.	Advanced practice nurses, allied health personnel, health care providers, occupational therapists, physical therapists, physician assistants, physicians, utilization management
Towards Optimized Practice, Low Back Pain 2nd Edition, 2011[8]			
Alberta, Canada, 2009	Any specific type of mattress	Levels of Evidence Rated as abbreviation of highest quality evidence study type. Recommendations graded as Do, Do Not Do, and Do Not Know.	Primary health care providers, i.e. family physicians, osteopathic physicians, chiropractors, physical therapists, occupational therapists, nurses, pharmacists, psychologists.
American Pain Society, 2009[9]			
Glenview, IL, USA, 2009	Any specific mattresses	Rating evidence of good, fair or poor quality.	Not explicitly stated
European evidence-based guidelines, 2006[10]			
Europe, 2006	Any specific mattress	Strength of Recommendations graded Level A-D.	Other guideline development groups and indirectly the general public, people with LBP, health care providers, health promotion agencies, industry/employers, educationalists and policy makers in Europe.

LBP= low back pain; **PONV**=postoperative nausea and vomiting; **SOP**=standard operating procedure

APPENDIX 3: Guideline Grading of Recommendations and Levels of Evidence

Recommendation	Level of Evidence
Agency for Healthcare Research and Quality (AHRQ), 2011[7]	
Strongly Recommended and **Strongly Not Recommended**= Evidence A **Moderately Recommended** and **Moderately Not Recommended=** Evidence B **Recommended** and **Not Recommended=** Evidence C **Recommended**, **No Recommendation** and **Not Recommended=** Evidence I, (Consensus-based)	**A=** Strong evidence base: two or more high-quality studies **B=** Moderate evidence base: at least one high-quality study or multiple moderate-quality studies **C**= Limited evidence base: at least one study of moderate quality **I**= Insufficient evidence: evidence is insufficient or irreconcilable
Towards Optimized Practice, Low Back Pain 2nd Edition, 2011[8]	
Do=based upon original recommendations, or the GDG created a new recommendation or based upon at least one SR the action is supported. **Do Not Do=** based upon original recommendations, or the GDG created a new recommendation or based upon at least one SR the action is not supported. **Do Not Know=** based upon original recommendations, or the GDG created a new recommendation or based upon at least one SR presenting conflicting or equivocal results or lack of SRs the action is of unknown effectiveness. Original recommendations refers to recommendations of the "seed guidelines" used in the development of these guidelines.	Evidence level category based on the highest quality studies available. These categories are listed here in order of descending quality: **SR**= systematic review **RCT**= randomized controlled trial **CS**= case series **G**= guideline **EO**= expert opinion
American Pain Society, 2009[9]	
N/A	**Levels of Evidence:** **Good:** Consistent relevant results from at least two higher-quality RCTs. **Fair:** At least one higher-quality trial of sufficient sample size, two or more higher-quality trials with some inconsistency, or

Recommendation	Level of Evidence
	multiple consistent observational studies with no significant methodological flaws. **Poor:** Limited number or power of studies, large inconsistencies between higher-quality trials, flawed trials, gaps in evidence chain or lack of information on important health outcomes.
European evidence-based guidelines, 2006[10]	
Strength of Recommendations: **Level A:** Generally consistent findings of an SR of multiple RCTs **Level B:** Generally consistent findings of an SR of multiple weaker studies **Level C:** One RCT, weaker study or inconsistent findings from an SR. **Level D:** No RCTs or weaker studies. Weaker studies refers to non-RCTs	**N/A**
CS= case series; **EO**= expert opinion; **G**=guideline; **GDG**=guideline development group; **N/A**= not applicable; **RCT**=randomized controlled trial; **SR**=systematic review;	

APPENDIX 4: Summary of Critical Appraisal of RCT using the Downs and Black checklist[4]

Strengths	Limitations
Bergholdt et al., 2008[6]	
• CONSORT diagram • Patient characteristics tabulated both after randomization and after intervention (including later drop outs) • Role of blinded investigators clear • Statistical methods described • Allocation and allocation concealment methods described • Clearly defined patient eligibility and outcome measures • COI statement	• Could not blind patients to intervention • Interventions consistent but not precisely described • No statistical power calculations • No discussion of possible adverse events or study limitations • Speculative discussion on mechanism • Industry sponsored study • Although patient group characteristics remained comparable many patients dropped out after randomization and many dropped out during the intervention • All outcomes were self-assessed by patients

APPENDIX 5: Summary of Critical Appraisal of Guidelines Using AGREE[5]

Strengths	Limitations
Agency for Healthcare Research and Quality (AHRQ), 2011[7]	
• Systematic literature search methodology with predefined inclusion and exclusion criteria • Stakeholder input sought • Explicit scope and target audience • Discussion of guideline implementation • Criteria for assessment of included studies • External review procedure • Detailed COI statements for individual contributors	• Bibliography not included within guidelines • No explicit link between evidence and recommendations • No strategy for guideline implementation
Towards Optimized Practice, Low Back Pain 2nd Edition, 2011[8]	
• Explicit purpose, objectives and target audience • Table of new and revised recommendations • Flow chart for implementation	• No COI statement • Based on previous guidelines - lacks guideline development methodology • No details on supplementary literature search
American Pain Society, 2009[9]	
• Systematic literature search methodology with predefined inclusion and exclusion criteria • Explicit scope • Statement of no COIs • Tabulated study results for each research question • Comparisons to other contemporary guidelines	• Lacks guidance on implementation • No mention of stakeholder involvement
European evidence-based guidelines, 2006[10]	
• Literature search methodology outlined • Statement of no COIs • Explicitly stated objectives and target audience • Attempts to include relevant professional representation in development group	• No predefined inclusion/exclusion criteria or date limits for literature search
COI= conflict of interest; **GDG**= guideline development group;	

APPENDIX 6: Summary of Findings of the Included RCT

Main Relevant Study Findings	Author's Conclusions
Bergholdt et al., 2008[6]	
Differences from start to end of trial. Change in Lower Back Pain (mean (0-10))[IQR] †, ‡ Waterbed: -0.4[-2,0]* | Foam Mattress: 0.1[-1,1] | Firm Mattress: 0.5[0,1]** Change in Leg Pain (mean (0-10))[IQR] ‡ Waterbed: -0.5[-1,1] | Foam Mattress: -0.3[-1,1] | Firm Mattress: 0.4[0,1]** Change in ADL (mean (0-10))[IQR] ‡ Waterbed: 0[-4,2] | Foam Mattress: 1[-2,2] | Firm Mattress: 2[0,2]** Change in Sleep (hours)[IQR] †, ‡ Waterbed: 0.6[-0.5,1] | Foam Mattress: 0.3[-0.5,0.5] | Firm Mattress: -0.4[-0.5,0]** Change within mattress type over 1 month * no influence statistically significant ** worst-case statistically significant Difference between waterbed or foam mattress and firm mattress † no influence statistically significant ‡ worst-case statistically significant No significant differences were found between the water bed and foam mattress. There were a significant number of drop-outs during this study. The number of drop-outs was significantly different between the three groups. The majority of drop-outs stopped because of more pain or less sleep. Therefore the data was analyzed both as if the drop-outs had "no influence" and given baseline scores at follow-up,(*,†) or a "worst-case" scenario where drop-outs were given the worst 90th percentile scores of those fulfilling the study (**,‡).	"A waterbed and a body contour foam mattress generally influenced back symptoms, function, and sleep more positively than a hard mattress, but the differences were small." (pp. 708)
ADL= activities of daily living; **IQR**= interquartile range;	

APPENDIX 7: Summary of Recommendations by Source (for grading schemes see APPENDIX 3)

Agency for Healthcare Research and Quality (AHRQ), 2011[7]
Acute LBP Mattresses – No Recommendation [Evidence I] Specific beds – Not Recommended [Evidence I] Use of optimal sleeping surfaces (e.g. bedding, water beds, and hammocks) – No Recommendation [Evidence I] Subacute LBP Mattresses – No Recommendation [Evidence I] Specific beds – Not Recommended [Evidence I] Use of optimal sleeping surfaces (e.g. bedding, water beds, and hammocks) – No Recommendation [Evidence I] Chronic LBP Mattresses – No Recommendation [Evidence I] Specific beds – Not Recommended [Evidence I] Use of optimal sleeping surfaces (e.g. bedding, water beds, and hammocks) – No Recommendation [Evidence I]
Towards Optimized Practice, Low Back Pain 2nd Edition, 2011[8]
LBP Any specific type of mattress – Do Not Know [RCT]
American Pain Society, 2009[9]
Chronic LBP One higher-quality trial found a firm mattress slightly inferior to a medium-firm mattress for pain-related disability and pain while in bed. There were no differences in other pain outcomes. - [fair] Acute LBP There was insufficient evidence to judge the relative effectiveness of other mattress types or in patients with acute LBP. – [poor]
European evidence-based guidelines, 2006[10]
LBP There is no robust evidence for or against recommending any specific chair or mattress for prevention in LBP [Level C], though persisting symptoms may be reduced with a medium-firm rather than a hard mattress [Level C].
LBP= lower back pain; **RCT**= randomized controlled trial