Transport Accident Commission & WorkSafe Victoria

Evidence Service

Beds and Mattresses for Back Pain

Technical Report: Appendices 1-6

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INTRODUCTION

This technical report is a companion document to “Beds and Mattresses for Back Pain: Evidence Review”. It contains detailed information about the methods used in the development of the Evidence Review, summaries of the studies included in the review, and quality appraisal results for the most recent and/or most relevant included studies.

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APPENDIX 1: REVIEW PROCESS

A two-staged approach was undertaken.

STAGE 1

Identify evidence available for each intervention

• Run search in health databases, websites and on the internet, limit to EBGs, HTAs, SRs, RCTs and controlled clinical trials (CCTs)

• Apply inclusion and exclusion criteria

Critically appraise synthesised research

• Start with most recent review, apply standard appraisal criteria

• If found to be of high quality, cross check to ensure references from all other synthesised research are included and check for consistency of findings

• If not high quality, appraise next most recent and repeat process

• If there are inconsistent findings across the existing reviews, investigate the possibility of synthesis of this information or whether a new systematic review is required

Decide on actions for Stage 2

• Map available evidence (as per Table A1.1)

• Identify whether sufficient high level evidence exists to answer questions or identify what further action needs to be taken (see algorithm in Table A1.2).

STAGE 2

Address further actions identified.

Table A1.1. Map of available evidence

Synthesised Studies		Primary studies	TOTAL
EBGs	SRs & HTAs		

Table A1.2. Further action required to answer clinical questions

Is there any synthesised research available? (e.g. EBGs, HTAs, SRs)				
Yes			No	
Is this good quality research?			Are RCTs available?	
Yes		No	Yes	No
Is it current (within 2 years)?				
Yes	No			
No further action	Update existing SR	Undertake new SR	Undertake new SR	Consider looking for lower levels of evidence

APPENDIX 2: METHODS

TAC/WSV staff assisted in the development of search terms and inclusion and exclusion.

Inclusion and exclusion criteria

Inclusion and exclusion criteria were established *a priori* (Table A2.1). The two authors independently screened the search results according to the inclusion and exclusion criteria. Any discrepancies in findings were discussed and resolved.

Table A2.1 Inclusion and Exclusion criteria

Patient/ population	**Inclusion:** Adults (any gender) with spinal pain
	Exclusion: children (<18 years), geriatrics (>65 years) Peripheral, non-axial or non-spinal pain All other painful conditions, all other conditions
Intervention/ indicator	**Inclusion:** Bed and/or mattress Standard bed or therapeutic Early or acute use or later use First or second line or adjunctive use
	Exclusion: Hospital beds Electric beds with adjustable head and foot raises Water beds
Comparison/ control	**Inclusion:** therapeutic vs. standard beds therapeutic bed vs. placebo therapeutic bed beds vs. usual care (e.g. analgesics, physiotherapy, medical consults). bed vs. medication bed vs. therapy bed vs. self-help program bed vs. surgery bed vs. injections
	Exclusion: where there is no comparison e.g. case series
Outcomes	**Inclusion:** Pain measures Physical function (mobility, transfers) Psychological outcomes (anxiety, depression) Social functioning (social roles) Activities of daily living (disability) Sleep quality Quality of life Return to work Medication use Healthcare utilisation Adverse events
	Exclusion: Nil
Setting	**Inclusion:** inpatient or home
	Exclusion: long term care facility
Study Design	**Inclusion:** Evidence-based guidelines (EBG), systematic reviews (SR), health technology assessments (HTA) and controlled trials.
	Exclusion: Non-evidence-based guidelines, non-systematic reviews, cohort studies, case-control studies, case series, editorials, letters, commentaries.
Publication details	**Inclusion:** All English language studies conducted on humans
	Exclusion: Non-English language papers, or studies conducted on animals
Time period	**Inclusion:** Any time
	Exclusion: Nil

Searches undertaken

Search methods

Evidence Based Guidelines (EBGs) are generally published as electronic 'stand alone' documents on the internet rather than papers in peer reviewed journals. We searched first in standard health databases, then in websites which are known to publish high-quality research and guidelines and finally in a general search engine, as follows:

Search strategies in electronic databases

Standard systematic review strategies, as outlined below in the Medline search example, were used to identify existing reviews and trials.

Website searches to identify relevant EBGs

The reviewers were aware of websites of guideline clearinghouses, guideline developers, centres of evidence-based practice, Australian government health services and websites of specific relevance (e.g. accident compensation groups) known to contain evidence-based resources.

The 44 websites listed below were searched for relevant EBGs (see Table A2.4).

Where an internal search engine was available, websites were searched using the search strings detailed in the table below. If no search engine was available, lists of EBGs, publications or other resources identified on the site were scanned for relevant documents.

Internet searches to identify relevant references

An internet search strategy was conducted using the Google 'Advanced Search' function. The search string was limited to documents in English:

The first 100 Google search results were screened and yielded no new studies. As Google search results are presented in order of relevance, we did not screen further.

Databases accessed

A highly sensitive search was conducted in the Cochrane library, Medline, PreMedline, All EBM, CINAHL, and Embase as detailed below was undertaken for the review terms.

Table A2.2 Databases accessed

Database name	Dates covered	Date searched	Refs
Cochrane library	February 2012 Issue	27th February 2012	147
Medline (Ovid)	1946 to February Week 3 2012	27th February 2012	49
PreMedline (Ovid)	February 24, 2012	27th February 2012	3
All EBM (Ovid) *	- Week 8 2012	27th February 2012	15
CINAHL (Ovid)	- 27th February 2012	27th February 2012	56
EMBASE	1996 to 2012 Week 08	27th February 2012	57

*including The Cochrane Database of Systematic Reviews, DARE, CENTRAL, NHSEED, HTA and ACP Journal Club

The following search was conducted and adapted for use in other databases.

Table A2.3 Medline search strategy

1	effect of firmness of mattress.ti.	7	mattress*.ti,ab.
2	effect of prescribed sleep surfaces.ti.	8	6 or 7
3	better backs by better beds.ti.	9	exp Back Pain/
4	chronic back pain patients on an airbed.ti.	10	((spine* or spinal or back) adj2 pain).ti,ab.
5	or/1-4	11	or/9-10
6	exp beds/	12	8 and 11

Table A2.4 Website searches to identify relevant EBGs

Search 1: Identification of relevant guidelines for beds and/or mattresses for back pain using specific guideline-related websites		
Guideline Services	**Results**	**Search**
National Health and Medical Research Council (NHMRC)	N/A http://www.nhmrc.gov.au/guidelines/publications	Web page reviewed by: Bed OR mattress
National Institute for Health and Clinical Excellence UK (NICE)	http://www.nice.org.uk/ Metastatic spinal cord compression (CG75) http://guidance.nice.org.uk/CG75 Percutaneous intradiscal laser ablation in the lumbar spine http://publications.nice.org.uk/percutaneous-intradiscal-laser-ablation-in-the-lumbar-spine-ipg357	Web page reviewed by: mattress AND "back pain" bed AND "back pain"
New Zealand Guideline Group (NZGG)	N/A http://www.nzgg.org.nz/	Web page reviewed by: Guidelines Additional search by terms: bed OR mattress
Scottish Intercollegiate Guidelines Network (SIGN)	N/A http://www.sign.ac.uk/	Web page reviewed by: guidelines by subject Additional search by terms: bed OR mattress
Joanna Briggs Institute	N/A http://www.joannabriggs.edu.au/Best%20Practice%20Information%20Sheets	Web page reviewed by: bed OR mattress
Guidelines International Network	N/A http://www.g-i-n.net/	Web page reviewed by: pain AND bed OR mattress
Guidelines Advisory Committee	N/A http://www.g-i-n.net/	Web page reviewed by: bed OR mattress
National Guideline Clearinghouse US (NGC)	http://www.guideline.gov/ Low back disorders. 1997 (revised 2007). NGC:006456 Guideline for the evidence-informed primary care management of low back pain. 2009 Mar. NGC:007704 VA/DoD clinical practice guideline for rehabilitation of lower limb amputation. 2007 Aug. NGC:006060 Low back - lumbar & thoracic (acute & chronic). 2003 (revised 2011 Mar 14). NGC:008517 Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. 2010 Feb. NGC:007681 Metastatic spinal cord compression. Diagnosis and management of adults at risk of and with metastatic spinal cord compression. 2008 Nov. NGC:007194 Adult low back pain. 1994 Jun (revised 2010 Nov). NGC:008193 Chronic pain. 2008. NGC:007160 Osteoporosis and fracture prevention in the long-term care setting. 1998 (revised 2009).	'bed' and “back pain"(16 refs) 'mattress' and "back pain"(6 refs)

	NGC:007637 Acute low back pain. 1997 (revised 2010 Jan). NGC:008009 Neck and upper back (acute & chronic). 2003 (revised 2011 Apr 7). NGC:008518 Adapting your practice: treatment and recommendations for homeless patients with HIV/AIDS. 2003 (revised 2008). NGC:006731 Management of acute low back pain. 2008 Mar (revised 2011 Sep). NGC:008744 Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. *What's New? What's Different?* Thromboembolic disease in pregnancy and the puerperium: acute management. 2001 Apr (revised 2007 Feb). NGC:005922 Antithrombotic therapy supplement. 2001 Sep (revised 2011 Apr). NGC:008501	
TRIP Database	www.tripdatabase.com Relevant publications downloaded to Endnote library	29 references retrieved Searched by (title:bed or mattress) ("back pain")
Australian Government Websites containing Guidelines		
Australian Government Department of Health & Ageing	www.health.gov.au N/A	Mattress "back pain"; Bed "back pain"
Australian Institute of Health and Welfare	www.aihw.gov.au N/A	Mattress "back pain"; Bed "back pain"
Health Insite	www.healthinsite.gov.au N/A	Mattress "back pain"; Bed "back pain"
ACT Health	www.health.act.gov.au N/A	Mattress "back pain"; Bed "back pain"
NSW Health	www.health.nsw.gov.au Mattress prescription for Spinal Cord Injury Is it effective in pressure management and for how long? http://www.health.nsw.gov.au/resources/gmct/spinal/pdf/mattress.pdf Frequently asked questions http://www.health.nsw.gov.au/csqg/ps/chronic_pain/faqs.asp	Mattress "back pain"; Bed "back pain"
NT Department of Health and Community Services	www.nt.gov.au/health N/A	Mattress "back pain"; Bed "back pain"
Queensland Health	www.health.qld.gov.au N/A	Mattress "back pain"; Bed "back pain"
SA Department of Health and Human Services	www.health.sa.gov.au N/A	Mattress "back pain"; Bed "back pain"
Tasmanian Department of Health and Human Services	www.dhhs.tas.gov.au **Disability Services.** Bed Selection and Bed Features. Policy & Guideline http://www.dhhs.tas.gov.au/__data/assets/pdf_file/0011/61004/Bed_Selection_Bed_Features_Policy_Oct08.pdf	Mattress "back pain"; Bed "back pain"

Victorian Department of Human Services	www.dhs.vic.gov.au Residential services practice manual. Second edition 2009 http://www.dhs.vic.gov.au/__data/assets/pdf_file/0003/601077/RSPM_2ndED_2009.pdf	Mattress "back pain"; Bed "back pain"
Victorian Government Health Information	www.health.vic.gov.au N/A	Mattress "back pain"; Bed "back pain"
WA Department of Health	www.health.wa.gov.au N/A	Mattress "back pain"; Bed "back pain"
Centres of Evidence Based Practice Websites		
WA Centre for Evidence-based Nursing and Midwifery	http://wacebnm.curtin.edu.au N/A	Mattress "back pain"; Bed "back pain"
Other Accident Commissions		
Transport Accident Commission	www.tac.vic.gov.au/ N/A	Mattress "back pain"; Bed "back pain"
Australian Transport Safety Bureau	http://www.atsb.gov.au/ N/A	Mattress "back pain"; Bed "back pain"
Road Safety Victoria (TAC)	www.tacsafety.com.au/ Equipment (Rehabilitation) - Miscellaneous http://www.tacsafety.com.au/jsp/content/NavigationController.do?areaID=22&tierID=3&navID=E33792377F0000010000D08339BA3D58&pageID=1335	Mattress "back pain"; Bed "back pain"
WorkSafe Victoria	http://www.workcover.vic.gov.au/ N/A	Mattress "back pain"; Bed "back pain"
Traffic Injury Research Foundation	http://www.trafficinjuryresearch.com/index.cfm N/A	Mattress "back pain"; Bed "back pain"
Motor Accidents Authority NSW	http://www.maa.nsw.gov.au/ N/A	Mattress "back pain"; Bed "back pain"
WorkSafe British Columbia	http://www.worksafebc.com/ 1. Ergonomics - Back at Work Back Pain Basics - Sat Feb 25, 2012 http://www2.worksafebc.com/Topics/Ergonomics/BackPainBasics.asp 2. Ergonomics - Back at Work - Preventing Back Pain - Tips for preventing back pain ... http://www2.worksafebc.com/Topics/Ergonomics/PreventingBackPain.asp?... 3. Ergonomics - Back at Work - Preventing Back Pain - Sat Feb 25, 2012 http://www2.worksafebc.com/Topics/Ergonomics/PreventingBackPain.asp 4. Back Talk - An Owners Manual for Backs http://www.worksafebc.com/publications/health_and_safety/by_topic/assets/... 5. Does your back hurt? WorkSafeBC http://www.worksafebc.com/publications/health_and_safety/by_topic/assets/... 6. Back Talk - An Owners Manual for Backs http://www.worksafebc.com/publications/high_resolution_publications/assets/... 7. Back to the Future - Training Handbook	Mattress "back pain"; Bed "back pain"

http://www.worksafebc.com/about_us/library_services/reports_and_guides/wcb_...
8. Repositioning in bed: Injury prevention
http://www.worksafebc.com/about_us/library_services/reports_and_guides/wcb_...
9. WorkSafe Magazine April 2003
http://www.worksafebc.com/publications/newsletters/worksafe_magazine/...
10. Focus on Tomorrow
http://www.worksafebc.com/contact_us/research/funding_decisions/assets/pdf/...
11. Workers' Compensation Reporter 21-1, WorkSafeBC
http://www.worksafebc.com/publications/newsletters/wc_reporter/volume_21/...
12. Royal Commissions concerning the workers' compensation system in British Columbia
http://www.worksafebc.com/about_us/library_services/reports_and_guides/...
13. WorkSafe Magazine - September/October 2007
http://www.worksafebc.com/publications/newsletters/worksafe_magazine/...
14. Workers Compensation Reporter, WCB of BC
http://www.worksafebc.com/publications/newsletters/wc_reporter/volume_15/...
15. Workers' Compensation Reporter 19-2, WCB of BC
http://www.worksafebc.com/publications/newsletters/wc_reporter/volume_19/...
16. Workers Compensation Reporter 18-1, WCB of BC
http://www.worksafebc.com/publications/newsletters/wc_reporter/volume_18/...
17. Focus on Tomorrow
http://www.worksafebc.com/contact_us/research/funding_decisions/assets/pdf/...
18. Evaluation of paramedics tasks and equipment to control the risk of ...
http://www.worksafebc.com/about_us/library_services/reports_and_guides/wcb_...
19. Comprehensive Ceiling Lift Program in Continued Care - Final Report
http://www2.worksafebc.com/pdfs/healthcare/CompCeilingLiftProgram.pdf
20. WorkSafe Magazine - January / February 2012
http://www.worksafebc.com/publications/newsletters/worksafe_magazine/...
21. Preventing Injuries to Hotel and Restaurant Workers, WCB of BC
http://www.worksafebc.com/publications/reports/focus_reports/assets/pdf/...
22. WorkSafeBC - Service Sector - Most recent incidents (updated May 9, 2011) - Sat ...
http://www2.worksafebc.com/Publications/Incidents-ServiceSector.asp?...
23. WorkSafeBC - Service Sector - 2010 - Sat Feb 25, 2012
http://www2.worksafebc.com/Publications/Incidents-ServiceSector.asp?...
24. Finding Solutions

	http://www.worksafebc.com/about_us/library_services/reports_and_guides/wcb_... 25. Statistics 2000 part 2 of WCB Annual Report, WCB of BC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 26. Statistics 2005, part 2 of annual report, WorkSafeBC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 27. Statistics 2002, part 2 of WCB Annual Report, WCB of BC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 28. 1998 Annual Report of the Appeal Division, WCB of BC http://www.worksafebc.com/publications/reports/annual_reports/assets/pdf/... 29. Building Owners' Manual for SRO Buildings in Vancouver's Downtown Eastside http://www.worksafebc.com/publications/health_and_safety/by_topic/assets/... 30. Statistics 2004, part 2 of annual report, WorkSafeBC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 31. 2001 Statistics, part 2 of WCB Annual Report, WCB of BC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 32. Statistics 2008 http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 33. Focus on Tomorrow http://www.worksafebc.com/contact_us/research/funding_decisions/assets/pdf/... 34. WorkSafeBC - Item - Violence in the Workplace (Updated December 2, 2011) - Sat ... http://www2.worksafebc.com/Publications/Incidents-Item.asp?ReportID=36500 35. Transfer Assist Devices for Safer Handling of Patients http://www.worksafebc.com/publications/high_resolution_publications/assets/... 36. Transfer Assist Devices for Safer Handling of Patients http://www.worksafebc.com/publications/health_and_safety/by_topic/assets/... 37. WorkSafeBC Statistics 2009 http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 38. Statistics 2006, part 2 of annual report, WorkSafeBC http://www.worksafebc.com/publications/reports/statistics_reports/assets/... 39. Workers Compensation Reporter 17-1, WCB of BC http://www.worksafebc.com/publications/newsletters/wc_reporter/volume_17/...	
Accident Compensation Corporation	http://www.acc.co.nz/index.htm *ACC1620 Caring for your short term low back pain (acute)*	Mattress “back pain”; Bed “back pain”

Pain Treatment Topics	http://pain-topics.org/guidelines_reports/index.php N/A	Mattress "back pain"; Bed "back pain"
The George Institute	http://www.georgeinstitute.org.au/search/node N/A	Mattress "back pain"; Bed "back pain"
Injury Research and Prevention Unit	http://www.injuryresearch.bc.ca/ N/A	Mattress "back pain"; Bed "back pain"
The Brain Trauma Foundation	http://tbiguidelines.org/glHome.aspx N/A	Mattress "back pain"; Bed "back pain"
Safer Roads	http://www.saferroads.org.uk/ N/A	Mattress "back pain"; Bed "back pain"
Rail Accident Investigation Branch	http://www.raib.gov.uk/about_us/index.cfm N/A	Mattress "back pain"; Bed "back pain"
Oslo Sports Trauma Research Centre	http://www.klokeavskade.no/en/ N/A	Mattress "back pain"; Bed "back pain"
Oregon Evidence-Based Practice Centre	http://www.ohsu.edu/epc/pastProjects/index.htm N/A	Mattress "back pain"; Bed "back pain"
Injury Prevention Network of Aotearoa New Zealand	http://www.ipnanz.org.nz/ N/A	Mattress "back pain"; Bed "back pain"
Trauma Centre at Justice Resource Centre	http://www.traumacenter.org/ N/A	Mattress "back pain"; Bed "back pain"
The DANA Foundation	http://www.dana.org/ N/A	Mattress "back pain"; Bed "back pain"
European Association for Injury Prevention and Safety Promotion	http://www.eurosafe.eu.com/ N/A	Mattress "back pain"; Bed "back pain"
New Zealand Injury Prevention strategy	http://www.nzips.govt.nz/resources/publications.php N/A	Mattress "back pain"; Bed "back pain"
NHS Health at Work	http://www.nhsplus.nhs.uk/web/public/default.aspx?PageID=330 N/A	Mattress "back pain"; Bed "back pain"
The Canadian Association of Road Safety Professionals	http://www.carsp.ca/index.php?0=page_content&1=59&2=134 N/A	Mattress "back pain"; Bed "back pain"

Search 2: Identification of relevant studies for beds and/or mattresses for back pain using Google	
Find web pages that have **all these words**	evidence
Find web pages that have this **exact wording or phrase**	back pain
Find web pages that have one or more of these words	mattress
Don't show pages that have any of these unwanted words	.pdf
Site or domain	.edu; .org; .gov; .net
Language	English

Appraisal

Appraisal is generally undertaken in steps:

1. The most recent review (evidence-based guideline, systematic review or HTA) was assessed for quality using standard appraisal criteria.
2. If found to be of high quality, it was cross checked against the other available reviews to compare scope and consistency of findings.
3. If found not to be of high quality, the next most recent was appraised and the above process repeated.

However, in this case, the only available piece of synthesised evidence (an EBG) only included two out of the five primary studies identified. Because of this it was decided that the five primary studies should be synthesised, meaning that instead of appraising the quality of the EBG, we appraised the five primary studies.

Quality

The primary studies identified were appraised using standard criteria independently by two reviewers; any discrepancies were discussed and resolved. Details of quality appraisals are included in Appendix 5.

Data Extraction

Data on characteristics of the studies were extracted and summarised.

Consistency of findings

The findings of the primary studies were compared to identify any inconsistencies in the information provided.

Narrative Synthesis

As the only piece of synthesised evidence found only included two out of the five primary studies identified, the primary studies were synthesised. The variation among these studies in interventions, comparators and outcomes reported meant that statistical synthesis through meta-analysis was not possible. For this reason a narrative synthesis was conducted.

APPENDIX 3: LIST OF INCLUDED STUDIES

1. Atherton J, Clarke AK, Harrison RA, Maddison MC. Low back pain - the use of the isometric mattress. Br J Occup Ther. 1983;46:133-4.

2. Bergholdt K, Fabricius RN, Bendix T. Better backs by better beds? Spine. 2008;33(7):703-8.

3. Dubb IBM, Driver HS. Ratings of sleep and pain in patients with low back pain after sleeping on mattresses of different firmness. Physiotherapy Canada. 1993;45(1):26-8.

4. Garfin SR, Pye SA. Bed design and its effect on chronic low back pain--a limited controlled trial. Pain. 1981;10(1):87-91.

5. Kovacs FM, Abraira V, Pena A, Martin-Rodriguez JG, Sanchez-Vera M, Ferrer E, et al. Effect of firmness of mattress on chronic non-specific low-back pain: Randomised, double-blind, controlled, multicentre trial. Lancet. 2003;362(9396):1599-604.

6. Work Loss Data Institute. Low back - lumbar & thoracic (acute & chronic). The Official Disability Guidelines. Encinitas (CA): Work Loss Data Institute; 2011.

APPENDIX 4: SUMMARY OF INCLUDED STUDIES

Table A4.1 summary of included studies

1st author, year, title	Inclusion, Exclusion criteria (for P.I.C.O)	Study design	Conclusion/Recommendation	Recommendation category	Other comments
EVIDENCE-BASED GUIDELINES					
Work Loss Data Institute 2011 Low back - lumbar & thoracic (acute & chronic). The Official Disability Guidelines	**POPULATION/CLINICAL INDICATION** n/a - disability guidelines including a chapter on low back problems with a section on mattress selection N = 2 RCTs **INTERVENTION & COMPARATORS** **Study 1:** (Bergholdt 2008) (1) waterbed (Akva) vs. (2) body-conforming foam mattress (Tempur) vs. (3) a hard mattress (Innovation Futon) **Study 2:** (Kovacs 2003) firm mattress vs. medium-firm mattress **OUTCOMES:** Health benefits, side effects and risks (outcomes for the whole guideline)	EBG	Mattress selection recommendation: "Not recommended to use firmness as sole criteria...There are no high quality studies to support purchase of any type of specialized mattress or bedding as a treatment for low back pain. Mattress selection is subjective and depends on personal preference and individual factors"	*Insufficient evidence to draw conclusions*	
RANDOMISED CONTROLLED TRIALS					
Bergholdt 2008 Better backs by better beds?	**POPULATION/CLINICAL INDICATION (N=160)** **Included:** • Age between 18 and 60 years. • Daily LBP (Th12-S1) at a largely constant level for at least 6 months. • The pain had to either dominate in the morning, or be equal to that of the rest of the day. • Leg pain slightly stronger LBP was accepted if the above mentioned were fulfilled, and if the ratio back:leg pain was about constant. **Excluded:** • Other serious illness, which could influence on their sleep. • Already having 1 of the 3 mattresses involved. Other back pain treatment was not accepted for inclusion if started less than 3 month before entrance. However, treatment that had been going on for more than 3 months was accepted, but had to be kept at a steady-state level during the entire test period. **INTERVENTION & COMPARATORS** (1) waterbed (Akva) (2) body-conforming foam mattress (Tempur) (3) a hard mattress (Innovation Futon) **Excluded:** Other back pain treatment was not accepted for inclusion if started less than 3 month before entrance. However, treatment that had been going on for more than 3 months was accepted, but had to be kept at a steady-state level during the entire test period." **OUTCOMES:** Low back pain levels (0 –10), daily function (activities of daily living, 0–30),	RCT	"The Waterbed and foam mattress did influence back symptoms, function and sleep more positively as opposed to the hard mattress, but the differences were small."	*Positive for waterbed and foam mattress, but differences were small*	

1st author, year, title	Inclusion, Exclusion criteria (for P.I.C.O)	Study design	Conclusion/Recommendation	Recommendation category	Other comments
	and on the amount of sleeping hours/night. "standardized examination with both a Danish questionnaire named COBRA, and a basic physical examination including ROM and pain on specific movements, neurology, *etc.* This was used as baseline data. The COBRA questionnaire includes the LBP rating scale19 with, among other things, 2 11-point box scales (0–10) assessing respectively LBP and sciatica, and a 15-question scale that grades the daily function level, such as problems with carrying grossary bags, walking, (un)dressing, *etc.* (ADL, score 0–30). All were averaged over the past 2 weeks." **SETTING:** home				
Kovacs 2003 Effect of firmness of mattress on chronic non-specific low-back pain: Randomised, double-blind, controlled, multicentre trial	**POPULATION/CLINICAL INDICATION (N=313)** **Included:** adults who had chronic non-specific low-back pain, who complained of backache while lying in bed and on rising **Excluded:** patients with referred pain **INTERVENTION & COMPARATORS** Firm mattress Medium-firm mattress **OUTCOMES:** Primary outcomes intensity of pain while lying in bed and on rising degree of disability Secondary outcomes low-back pain low-back pain in bed or on rising more intense pain in bed when lying down for an extended time Side effects complaints of pain while lying in bed from the participants' partners **SETTING:** home	RCT	A mattress of medium firmness improves pain and disability among patients with chronic non-specific low back pain.	*Positive for medium-firm mattress*	
Atherton 1983 Low back pain - the use of the isometric mattress	**POPULATION/CLINICAL INDICATION (N=30)** Patients suffering from low back pain for at least the previous six months **INTERVENTION & COMPARATORS** Mattress A – Isometric mattress (two layers of foam with 3 moveable inserts fitted to provide support to specific areas) Mattress B – A soft interior sprung mattress (Airsprung) **OUTCOMES:** Range of movement in lumbar spine Pain-free range of passive straight leg raising Subjective pain level Comfort of the mattress Average length of time taken to get to sleep **SETTING:** Home (outcomes measured in outpatient clinic)	RCT	In conclusion, 56% of the total patients, who incidentally tended to be in the under-40 age group found that the Isometric mattress gave them a better night's sleep coupled with less objective and subjective 'stiffness' on rising and a decrease in their pain. Therefore, in young patients who suffer from low back pain and who have sleep problems the Isometric mattress is worth considering purchasing	Positive for isometric mattress for people under the age of 40	

1st author, year, title	Inclusion, Exclusion criteria (for P.I.C.O)	Study design	Conclusion/Recommendation	Recommendation category	Other comments
Garfin 1981 Bed design and its effect on chronic low back pain - a limited controlled trial	**POPULATION/CLINICAL INDICATION (N=15)** Patients with chronic low back pain of any aetiology attending a back clinic patients who: (a) had a minimum of 3 months of low back pain; (b) were not felt to be immediate surgical candidates by their attending physician; (c) were not in the midst of an acute attack or exacerbation of back pain and; (d) would be available for a minimum 1 month period **INTERVENTION & COMPARATOR** (1) hard bed - "orthopedic" or "back support" bed containing 720 individually reinforced coils, a built-in bed board, and approximately 1.5 cm of foam overlying the coils (2) soft bed - standard 500 coil bed (box spring and mattress) (3) waterbed - waterbed filled to a depth of 25 cm with a quilted top-piece over the water-filled "mattress" (4) hybrid bed - "hybrid" bed or combination water foam flotation system (a polyurethane shell surrounding 7-8 cm of water). **OUTCOMES** A daily questionnaire was filled out by the patients - asking simple questions (i.e. how did you sleep?, what awakened you?, how is your pain?)... Neurological evaluations including straight leg raising were performed periodically on each patient while in each bed" plus MMPI testing **SETTING:** Inpatients at a back clinic	RCT	This limited study indicates that hard beds should remain the first choice of patients with chronic low back pain. However, if relief is not obtained for these chronic pain patients, a trial on a waterbed may prove beneficial	Positive for hard bed, waterbed was the next most positive	
CONTROLLED TRIALS					
Dubb 1993 Ratings of sleep and pain in patients with low back pain after sleeping on mattresses of different firmness	**POPULATION/CLINICAL INDICATION (N=9)** Healthy volunteers, 18-30 years suffering from back LBP and at some stage sought professional help **INTERVENTION & COMPARATORS** Hard mattress Medium mattress Soft mattress **OUTCOMES** Subjective ratings with visual analog scales: Evening – agitation, discomfort Morning – sleep quality, morning vigilance ("bright, fresh, alert"), backache, discomfort, mood, strength of mind (decisiveness), vitality, irritability, concentration, need for sleep **SETTING:** Sleep laboratory	CCT	In our patients, low back pain on awakening was significantly reduced on the second night on the hard mattress compared to the soft mattress, irrespective of whether their symptoms were relieved by flexion or extension. Patients suffering from low back pain therefore may well benefit by sleeping on a hard firmness of mattress-base bed set. Whether the benefit is sustained following continuous sleeping on the harder mattress, and whether there are associated improvements in objective correlates of the back pain remains to be investigated	Positive for hard mattress	

APPENDIX 5: APPRAISAL TABLES

Table A5.1 Critical appraisal table *(Atherton 1983)*

Study: *Atherton J, Clarke AK, Harrison RA, Maddison MC. Low back pain - the use of the isometric mattress. Br J Occup Ther. 1983;46:133-4.*	
Description of study: randomised controlled trial	
Patient/population	Patients who had been suffering from low back pain for at least the previous six months
N	30 patients
Setting	Home-based intervention, outcomes measured in outpatient clinic
Intervention/indicator	Mattress A – Isometric mattress (two layers of foam with 3 moveable inserts fitted to provide support to specific areas)
Comparison/control	Mattress B – A soft interior sprung mattress (Airsprung)
Outcomes	Range of movement in lumbar spine Pain-free range of passive straight leg raising Subjective pain level Comfort of the mattress Average length of time taken to get to sleep
Inclusion Criteria	Patients suffering from low back pain for at least the previous six months
Exclusion Criteria	None specified

Study Validity.		
Is it clear that there are no conflicts of interest in the writing or funding of this study?	Not reported	
Does the study have a clearly focused question?	Yes	Yes, a clearly stated PICO
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion criteria?	Partial	Minimal inclusion criteria reported only (see above)
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Did the study have an adequate method of randomisation?	Not reported	
Was allocation to intervention group concealed?	Not reported	
Were patients blind to intervention group?	Not reported	

Were investigators and care providers blind to intervention group?	Not reported	
Were outcome assessors blind to intervention group?	Partial	Blinded - "The range of movement of the lumbar spine was measured 'blind' by an independent assessor who also measured the painfree range of passive straight leg raising" Not blinded – "The subjective pain level and the comfort of the mattress were recorded by the patient on visual analogue scales. The average length of time taken to get to sleep was also recorded as were the patient's preferred options"
Was this intervention suitable for a cross-over study?	Yes	
Was the washout period adequate?	Not reported	
All outcomes were measured in a standard, valid and reliable way?	Not reported	unknown
Were outcomes assessed objectively?	Partial	Objective measures: range of movement of lumbar spine and pain-free range of passive straight leg raises but Patient reported measures: pain level, comfort preference, and time taken to get to sleep
Were outcomes assessed independently?	Partial	Range of movement and painfree range of passive straight leg raising were measured independently of patient reported measures, but patient reported measures (pain level, comfort preference, and time taken to get to sleep) were recorded together and could influence each other.
Were the groups similar at baseline with regards to key prognostic variables?	Not reported	
Aside from the experimental intervention, were the groups treated the same?	Yes	"none of the patients was receiving physiotherapy or other physical treatment for the time that they were on the trial. They were asked not to start on any new drugs and if they felt the need to increase their dose of sleeping tablets or pain-killers we were to be informed. They were also asked as far as possible to refrain from any unaccustomed physical activity but should such be inevitable, they were to inform us at the next visit"
Were the outcomes measured appropriate?	Yes	
Was there sufficient duration of follow-up?	Partial	Followed up for duration of trial – two weeks
Was there ≤20% drop-out?	Yes	5 out of 30 patients dropped out (16.7%)
Was the study sufficiently powered to detect any differences between the groups?	Not reported	
If statistical analysis was undertaken, was this appropriate?	Not applicable	
Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?	Yes	All patients crossed over, so were analysed by intervention (mattress A vs. mattress B) rather than by group

Is the paper free of selective outcome reporting?	No	Study reported positive results for one age group although they did not mention looking at subgroups as part of their plan (it looked like this was the only way they could report a positive finding)
What is the overall risk of bias?	Moderate	Moderate - Some of the criteria have been fulfilled and those criteria that have not been fulfilled may affect the conclusions of the study

Results.

Measurements (Table 1)

The measurements showed that on option 'A' 37% of the patients showed increased movement, 26% had measurements which remained the same on both options and 37% had measurements showing decreased painfree movement. Mattress 'B' produced remarkably similar results, 38% showing improvement and 38% having less movement. As would be expected, a better range of movement was generally associated with sleeping on the mattress which the patient found to be most comfortable. Of the 75 measurements taken, only three were paradoxical indicating less movement after sleeping on the preferred mattress. Thus 'stiffness' in the morning after sleeping on an uncomfortable bed is not subjective but is represented by a measurable decrease in the amount of painfree movement in the lumbar spine. This was shown to persist, in some cases at least, for up to three hours after rising.

Pain and Comfort (Table 2)

Rating of pain and comfort (with the exception of two patients) followed the patients' own subsequent grading of the mattresses. The two exceptions showed marginal increase in pain (as marked on the V.A. scales) after sleeping on the mattress which they later stated to be the most comfortable.

Eight patients preferred their own mattress to either of the two trial mattresses. When asked, however, to decide only between 'A' and 'B', 14 patients (56%) preferred the Isometric^{R} mattress whilst 11 (44%) thought the spring interior mattress more comfortable.

Insert preference

There was a marked preference (some 60%) for insert 2, whilst the remainder of the patients were more or less equally divided over other two alternatives, 15 patients preferring insert no. 2, 2 patients preferring insert no. 3, 3 patients preferring insert no. 1, 1 patient preferring 2 and 3 equally and 3 patients preferring to use no insert.

TABLE 1
ISOMETRIC MATTRESS STUDY
MEASUREMENTS

	SLR			Lumbar Flex/Ext				Lumbar side flex		
OPTION	BETTER	SAME	WORSE	BETTER	SAME	WORSE		BETTER	SAME	WORSE
A	8 (1)	7 (5)	10 (7)	9 (3)	10 (6)	6 (4)		11 (4)	3 (2)	11 (7)
B	10 (7)	7 (5)	8 (1)	6 (4)	10 (6)	9 (3)		11 (7)	3 (2)	11 (4)

Numbers in brackets = patients OVER 40 years of age

TABLE 2
ISOMETRIC MATTRESS STUDY
PAIN AND COMFORT

	PAIN (V.A.S.)				COMFORT (V.A.S.)		
OPTION	LEAST	MOST	SAME		BEST	WORST	SAME
A	10 (5)	7 (4)	8 (4)		10 (4)	13 (8)	2 (0)
B	7 (4)	10 (5)	8 (4)		13 (8)	10 (4)	2 (0)

Numbers in brackets = patients OVER 40 years of age

Author's Conclusions.

"In conclusion, 56% of the total patients, who incidentally tended to be in the under-40 age group found that the Isometric mattress gave them a better night's sleep coupled with less objective and subjective 'stiffness' on rising and a decrease in their pain. Therefore, in young patients who suffer from low back pain and who have sleep problems the Isometric mattress is worth considering purchasing."

Our Comments/Summary.

This is a small study with a moderate risk of bias, therefore the results should not be generalised.

Table A5.2 Critical appraisal table *(Bergholdt 2008)*

Study: *Bergholdt K, Fabricius RN, Bendix T. Better backs by better beds? Spine. 2008;33(7):703-8.*	
Description of study: *randomised controlled trial*	
Patient/population	Patients with chronic low back pain
N	160
Setting	home
Intervention & comparators	1) waterbed (Akva) (2) body-conforming foam mattress (Tempur) (3) a hard mattress (Innovation Futon)
Outcomes	Low back pain levels (0 –10), daily function (activities of daily living, 0–30), and on the amount of sleeping hours/night. "standardized examination with both a Danish questionnaire named COBRA, and a basic physical examination including ROM and pain on specific movements, neurology, *etc.* This was used as baseline data. The COBRA questionnaire includes the LBP rating scale19 with, among other things, 2 11-point box scales (0–10) assessing respectively LBP and sciatica, and a 15-question scale that grades the daily function level, such as problems with carrying grossary bags, walking, (un)dressing, *etc.* (ADL, score 0–30). All were averaged over the past 2 weeks."
Inclusion Criteria	• "Age between 18 and 60 years. • Daily LBP (Th12-S1) at a largely constant level for at least 6 months. • The pain had to either dominate in the morning, or be equal to that of the rest of the day. • Leg pain slightly stronger LBP was accepted if the above mentioned were fulfilled, and if the ratio back:leg pain was about constant."
Exclusion Criteria	• "Other serious illness, which could influence on their sleep. • Already having 1 of the 3 mattresses involved. Other back pain treatment was not accepted for inclusion if started less than 3 month before entrance. However, treatment that had been going on for more than 3 months was accepted, but had to be kept at a steady-state level during the entire test period."

Study Validity.		
Is it clear that there are no conflicts of interest in the writing or funding of this study?	Unclear	"Corporate/Industry funds were received in support of this work. Although one or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript, benefits will be directed solely to a research fund, foundation, educational institution, or other nonprofit organization which the author(s) has/have been associated."
Does the study have a clearly focused question?	Yes	"The purpose of this study was to investigate the relative effect as regarding back pain, leg pain, activities of daily living (ADL) and hours of sleep of respectively a waterbed, a body-conforming, visco-elastisk foam mattress, and a more firm Futon mattress on patients with chronic LBP."
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion	Yes	*See above*

criteria?		
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Did the study have an adequate method of randomisation?	Yes	Randomization using minimization allocation "After the clinical examination, the patients were allocated into 1 of the 3 groups, using a stratifying program,20 aiming to equalize the following baseline data across the 3 treatment arms: ● Age ● Sex ● Duration and severity of back problem ● Number of LBP-related days off work the in last 12 months ● The daily physical workload"
Was allocation to intervention group concealed?	Yes	"To ensure that the examinators were blinded, the stratification and all further contact with the patients were made by a secretary until the end of the trial."
Were patients blind to intervention group?	Not reported	
Were investigators and care providers blind to intervention group?	Not reported	There weren't really any caregivers in this trial as the intervention was a bed installed in the home
Were outcome assessors blind to intervention group?	Yes	"To ensure that the examinators were blinded, the stratification and all further contact with the patients were made by a secretary until the end of the trial." "At baseline and after 4 weeks, a blinded observer inter- viewed the patients on LBP levels (0–10), daily function (activities of daily living, 0–30), and on the amount of sleeping hours/night."
All outcomes were measured in a standard, valid and reliable way?	Partial	Yes "standardized examination with both a Danish questionnaire named COBRA" Unsure "and a basic physical examination including ROM and pain on specific movements, neurology, etc."
Were outcomes assessed objectively?	Partial	Yes "standardized examination with both a Danish questionnaire named COBRA" Unsure "and a basic physical examination including ROM and pain on specific movements, neurology, etc."
Were outcomes assessed independently?	Not reported	
Were the groups similar at baseline with regards to key prognostic variables?	Yes	The only area that appeared different was median weight (waterbed group was generally 6-7kg lighter) However, this difference was not statistically significant. Stratifying program aimed to "equalize following baseline data – age, sex, duration and severity of back problem, number of LBP-related days off work in the last 12 months and the daily physical workload".
Aside from the experimental intervention, were the groups treated the same?	Unclear	
Were the outcomes measured appropriate?	Yes	
Was there sufficient duration of follow-up?	Not reported	
Was there ≤20% drop-out?	No	46 out of 160 patients dropped out (28.75% dropout rate)

		19 dropped out after randomisation but before starting the trial because they didn't want a waterbed 27 dropped out during the trial, mainly due to more pain or less sleep
Was the study sufficiently powered to detect any differences between the groups?	Not reported	
If statistical analysis was undertaken, was this appropriate?	Yes	
Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?	Not reported	
Is the paper free of selective outcome reporting?	Yes	Some post-hoc analyses done, but no significant findings from these
What is the overall risk of bias?	Low to Moderate	Low to Moderate - Most of the criteria have been fulfilled, but those criteria that have not been fulfilled may affect the conclusions of the study.

Results.

Results

Quite a large amount of test persons dropped out either before or during the trial, conf. Figure 1.

Dropouts Before Trial

The 19 participants, who never started testing a bed, were not used in the statistical material. The predominant reason for dropping out at this stage was related to the waterbed. Several test-persons dropped out due to the fact that they had some prejudice towards this type of mattress. In most cases they had never tried one themselves, but only heard negative things about it. A few patients had tried a waterbed once or a few times earlier and did not like it. The primary complaint was that they "got seasick" or woke up every time they or their partner turned around, and therefore had impaired sleep. Most importantly, no one of the patients that we know of dropped out before start because they already knew that the mattress would give them more back pain. Other reasons for never starting the mattress testing was due to practical reasons such as inability to store their usual beds during the 4 weeks, or if it was impossible to grant their wishes on double bed. Despite the large amount of dropouts in the waterbed group, the 3 groups were comparable at baseline, irrespective they were compared with or without the early dropouts (Table 1).

Dropouts During Trial

The majority of the dropouts stopped because they got more pain or less sleep. Three participants stopped because of practical reasons not related to LBP.

Mattress Effect

As seen in Table 2 there were statistically significant differences between the 3 groups on all variables when calculating on "worst-case" data disfavoring the hard mattress. When using the "no-influence" analysis, where the dropouts were given the baseline score at follow-up, there was still statistically significant difference in LBP and sleeping hours, almost so for leg pain (P = 0.07), but not for ADL. Regarding individual mattress differences, both the waterbed and the foam mattress were superior to the hard mattress when using "worst-case" data, the highest P-value being 0.015. If using no-influence data, the waterbed was still significantly better than the hard mattress group regarding both LBP, leg pain, and hours of sleep, but not quite so for ADL (P = 0.1). The foam mattress were only significantly superior to the hard 1 with "no-change data" regarding sleeping hours (P = 0.04), almost so for back pain (P = 0.06) but not in the other parameters. No significant differences were found between the waterbed and the foam mattress, the smallest P-value being between 0.12 and 0.43. Regarding the effect in the individual groups from before to after the trial, the differences are generally small. For the hard-mattress group, the difference was, however, somewhat systematic because a statistically significant difference in all parameters was seen when using the "worst-case" analysis, pointing towards the result that the patients generally got worse with that mattress. There were no significant differences if using the "no influence" data. In the other 2 groups there was a minor tendency that the patients in the waterbed group became better, but only with statistical significance for LBP. The number of patients getting better or worse from baseline to end of the trial is displayed in Figures 2 and 3, where the most relevant data are illustrated. It shows that the majority of the patients who slept in either the waterbed or the foam mattress became slightly better, whereas the opposite was the case in the hard-mattress group. Columns in Figures 2 and 3 illustrate only LBP and sleep (Figure 2), but the same tendencies were the case in all 4 effect parameters. A possible correlation between reduction in pain and gain in sleep

was also tested (Figure 4). It was not intended in advance, and was done only for a possible observation-based hypothesis. There was an overall trend for such a correlation, but neither waterbed nor foam mattress did obtain statistical significance at the Spearman analysis (P = 0.7 and 0.15, respectively), which did those on the hard mattress, P = 0.007. For the total sample, the correlation was present, P = 0.02. Another *post hoc* analysis tested a possible difference in influence from the respective beds on LBP impact whether they initially belonged to the best or worst half of the patients. No such trend was seen.

Table 2. Differences in Selected Parameters From Start to End of Trial

Difference in Selected Parameters From Start to End of Trial								
M/F	12	29	19	30	19	32		
	Waterbed		Foam Mattress		Firm Mattress			
	M	IQR	M	IQR	M	IQR	*P*	*P*
LBP (0–10)	−0.4	−2.0;0.0	0.1	−1.0;1.0	0.5	0.0;1.0	Drop out = "90%" <0.001	Drop out = "0%" 0.01
Drop out	90%	0%	90%	0%	90%	0%		
P	0.055	0.008	0.924	0.191	0.004	0.790		
Leg pain (0–10)	−0.5	−1.0;1.0	−0.3	−1.0;1.0	0.4	0.0;1.0	0.001	0.072
Drop out	90%	0%	90%	0%	90%	0%		
P	0.338	0.080	0.761	0.132	0.004	0.661		
ADL (0–30)	0	−4;2	1	−2;2	2	0;2	0.003	0.3
Drop out	90%	0%	90%	0%	90%	0%		
P	0.366	0.124	0.473	0.539	<0.001	0.278		
Sleep (h)	0.6	−0.5;1.0	0.3	−0.5;0.5	−0.4	−0.5;0.0	<0.001	0.02
Drop out	90%	0%	90%	0%	90%	0%		
P	0.219	0.056	0.949	0.204	<0.001	0261		

The data given as "90%" are with the drop-outs during the trial tested in a worst-case analysis, whereas "no change" ("0%") refers to data, where drop outs had their baseline values repeated at follow-up.
This is also the case for the horizontally placed *P*-values, which refers to the paired tests assessing differences from baseline to 1 mo within each type of mattress.
M (median) and IQR (inter-quartile range) refer to the lines with the effect variables only.

Table 1. Baseline Data of All Included (Left) and of Those Who Actually Started to Test a Bed (Right), Given by Medians (M) and Interquartile Ranges (IQR)

	Data at Baseline for All Included							Data of Patients Starting the Trial						
	Waterbed		Foam Mattress		Firm Mattress			Waterbed		Foam Mattress		Firm Mattress		
	M	IQR	M	IQR	M	IQR	*P*	M	IQR	M	IQR	M	IQR	*P*
M/F	20/34		19/33		20/34			12/29		19/30		19/32		
Age (yr)	41	35–47	42	35–54	43	37–50	0.34	41	36–49	43	37–54	42	35–50	0.67
Height (cm)	170	165–178	172	165–176	172	165–181	0.49	168	164–177	172	167–176	172	165–180	0.31
Weight	71.5	63–90	77.5	64–88	77.5	67–88	0.29	70.0	60–87	76.0	65–89	77.0	68–88	0.18
Duration of pain (yr)	4	3–10	4.5	2–10	3	2–7	0.35	4	2–8	4	3–9	3	2–9	0.48
LBP (0–10)	5.3	4–7	5.0	4–7	5.2	4–6	0.52	5.4	4–7	5.0	3–7	5.2	5–7	0.35
Leg pain (0–10)	3.2	1–5	2.9	1–5	3.0	0–6	0.72	3.8	1–5	3.1	1–5	3.6	0–6	0.52
ADL (0–30)	15	10–21	16	10–18	12	10–17	0.46	14	9–19	15	10–19	13	10–20	0.47
Sleep (h)	6.1	5.0–6.5	6.2	5.5–7.0	6.5	5.4–7.0	0.73	6.1	5.0–7.5	6.1	5.5–7.0	6.6	5.0–7.0	0.39

P-values refer to the Kruskal-Wallis test performed on the data comparing the 3 groups.

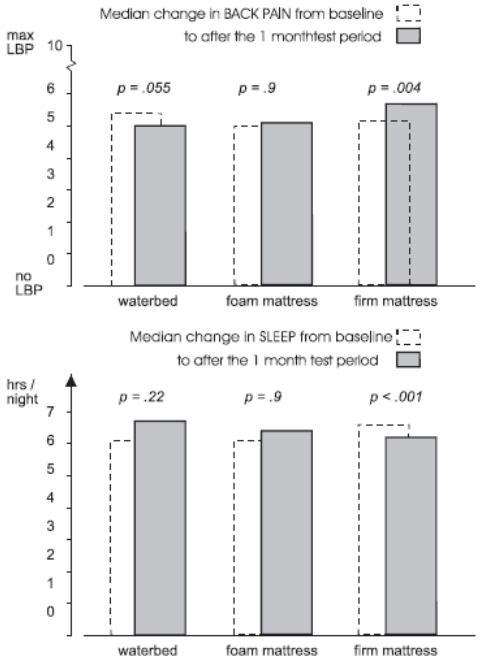


Figure 2. Effects of the three mattresses on low back pain and sleep. The *P*-values refer to before-after within each mattress, analyzed with drop-outs deemed to be as the worst 90% fractile. The differences across the beds appear from Table 2.

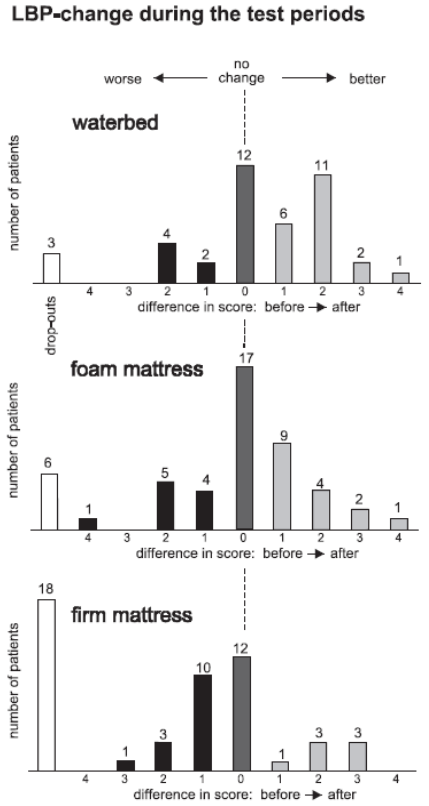
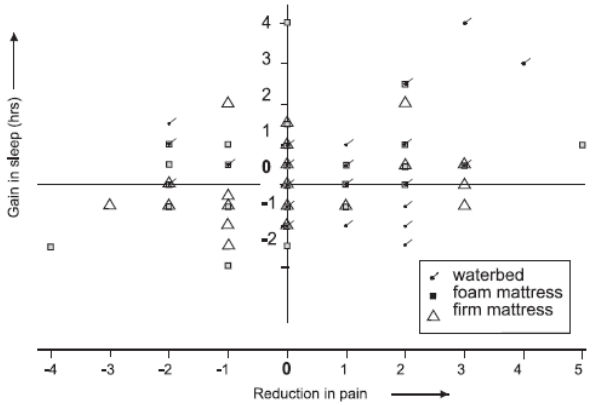


Figure 3. Number of patients that became better (right), worse (left), or remained unchanged (middle) during the 1-month test period for each mattress. Numbers of drop-outs are seen to the left.

Figure 4. Correlations between reduction of back pain during the 1-month test and gain in sleeping hours. For each bed, there was only statistical significance for the firm mattress, but an overall analysis obtained statistical significance. Please note that several points reflects more than 1 person.



Author's Conclusions.

"The Waterbed and foam mattress did influence back symptoms, function and sleep more positively as opposed to the hard mattress, but the differences were small."

Our Comments/Summary.

This was a well-conducted study with a low to moderate risk of bias

There was a high dropout rate for two of the three arms in this study: 24% of the waterbed group dropped out after randomisation but before the trial started due to preconceived negative views of waterbeds, and 35% of patients dropped out of the firm mattress group during the trial due to increased pain. This high drop-out rate and uneven distribution of dropouts between groups mean that the small differences found between groups should be interpreted with caution.

Table A5.3 Critical appraisal table *(Dubb 1993)*

Study: *Dubb IBM, Driver HS. Ratings of sleep and pain in patients with low back pain after sleeping on mattresses of different firmness. Physiotherapy Canada. 1993;45(1):26-8.*		
Description of study: *controlled clinical trial*		
Patient/population	Healthy volunteers, 18-30 years suffering from back LBP and at some stage sought professional help	
N	9	
Setting	Sleep laboratory	
Intervention & comparators	Hard mattress vs. medium mattress vs. soft mattress The subjects slept a total of six nights in a sleep laboratory, with two randomly arranged nights being spent on each of the three different mattress-base bed sets	
Outcomes	Subjective ratings with visual analog scales: Evening – agitation, discomfort Morning – sleep quality, morning vigilance ("bright, fresh, alert"), backache, discomfort, mood, strength of mind (decisiveness), vitality, irritability, concentration, need for sleep	
Inclusion Criteria	Not stated	
Exclusion Criteria	Not stated	
Study Validity.		
Is it clear that there are no conflicts of interest in the writing or funding of this study?	No	"The authors thank...Edblo Africa for financial support" Edblo Africa is a bedding manufacturer The study was carried out in Edblo Sleep Laboratory
Does the study have a clearly focused question?	Yes	"The objectives of our study were to determine whether sleeping on either a hard, medium or soft mattress and base bed set affected the quality of sleep of patients with low back pain and to assess whether pain-related factors were influenced by the hardness of the bed"
Is a CCT the appropriate method to answer this question?	Partial	RCT would be reduce the risk of bias
Does the study have specified inclusion/exclusion criteria?	No	
If there were specified inclusion/ exclusion criteria, were these appropriate?	N/A	
Was allocation to intervention group concealed?	Not reported	
Were patients blind to intervention group?	Partial	"subjects were unaware of the claimed firmness of the mattress on which they slept. The two nights on a mattress of particular firmness were non-consecutive with at least one, and no more than four, nights at home between the nights in the sleep laboratory" Three beds were in three separate, but physically similar bedrooms kept at the same environmental conditions and noise level

Were investigators and care providers blind to intervention group?	Partial	"we conducted a single-blind crossover study"
Were outcome assessors blind to intervention group?	Partial	The patients were the outcome assessors (see above)
Was this intervention suitable for a cross-over study?	Yes	May require discussion with clinician
Was the washout period adequate?	Partial	"two nights on a mattress were non-consecutive with at least one, and no more than four, nights at home between the nights in the sleep lab"
All outcomes were measured in a standard, valid and reliable way?	Not reported	Visual analogue scales used, subjective outcomes, not mention of whether these were validated.
Were outcomes assessed objectively?	No	Visual analogue scales were used to collect subjective outcomes
Were outcomes assessed independently?	Not reported	
Were the groups similar at baseline with regards to key prognostic variables?	No	all patients had differing symptoms of lower back pain
Aside from the experimental intervention, were the groups treated the same?	Yes	"The three beds were in three separate, but physically similar bedrooms kept at the same environmental conditions and noise level...The subjects were encouraged to follow their normal activity and sleeping routines"
Were the outcomes measured appropriate?	Yes	
Was there sufficient duration of follow-up?	Not reported	
Was there ≤20% drop-out?	Not reported	
Was the study sufficiently powered to detect any differences between the groups?	Not reported	Only 9 patients
If statistical analysis was undertaken, was this appropriate?	Yes	
Were all the subjects analysed in the groups to which they were allocated (ie intention to treat analysis)?	Not applicable	All were crossovers (all patients tried all levels of mattress firmness)
Is the paper free of selective outcome reporting?	Not reported	
What is the overall risk of bias?	Insufficient Information	Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias.

Results.

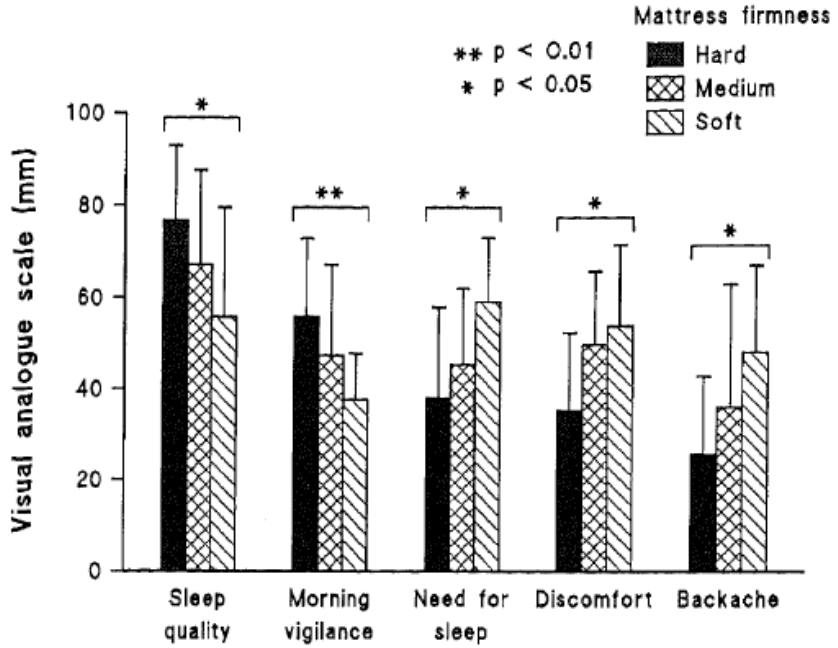


Figure 1. Mean and standard deviation of the scores on the visual analogue scales for each of the variables, measured on the second night, which showed a significant difference between the hard and soft mattress-base bed sets.

RESULTS

For the medium and soft beds, there were no significant differences between the first and second nights in any of the variables. After the second night on the hard mattress there was a significant improvement in the sleep quality ratings ($p<0.04$) and less backache ($p>0.02$) when compared to the first night.

Figure 1 shows those subjective ratings, on the hard, medium and soft mattresses, where significant differences ($p<0.05$) were found when the hard and the soft mattresses were compared. Comparison between the different mattresses in Figure 1 is shown for the second night only in an attempt to eliminate any adaptive or "first night effects" due to sleeping in a strange environment[12]. For all of these variables (Figure 1), the subjective response was more favourable when the subjects were sleeping on the hard mattress. For the following variables, not shown in Figure 1, there was no difference between hard and soft mattresses: evening agitation and discomfort; morning mood, strength of mind, vitality, irritability and concentration. No significant differences were found between the hard and the medium mattresses, for any of the variables tested. Comparing the medium and soft mattresses, a significant increase in agitation was found in the evening prior to the second night on the soft mattress ($p<0.05$).

Author's Conclusions.

"In our patients, low back pain on awakening was significantly reduced on the second night on the hard mattress compared to the soft mattress, irrespective of whether their symptoms were relieved by flexion or extension. Patients suffering from low back pain therefore may well benefit by sleeping on a hard firmness of mattress-base bed set. Whether the benefit is sustained following continuous sleeping on the harder mattress, and whether there are associated improvements in objective correlates of the back pain remains to be investigated"
Firmer mattress resulted in an improvement in the subject's perceived sleep quality and well-being; LCP was reduced on the second night of the hard mattress compared to the soft mattress

Our Comments/Summary.

Insufficient information provided on methodological quality to be able to determine risk of bias. In addition to this, the small sample size (n=9), and potential conflict of interest (funding was from a bedding company and the trial was run in a sleep lab with the same name as the bedding company) mean that the results of this study should not be generalised.

Table A5.4 Critical appraisal table *(Garfin 1981)*

Study: *Garfin SR, Pye SA. Bed design and its effect on chronic low back pain--a limited controlled trial. Pain. 1981;10(1):87-91.*	
Description of study: *randomised controlled trial*	
Patient/population	Patients with chronic low back pain of any aetiology attending a back clinic
N	15 patients
Setting	Inpatients at a Back Clinic
Intervention & comparators	(1) hard bed - "orthopedic" or "back support" bed containing 720 individually reinforced coils, a built-in bed board, and approximately 1.5 cm of foam overlying the coils (2) soft bed - standard 500 coil bed (box spring and mattress) (3) waterbed - waterbed filled to a depth of 25 cm with a quilted top-piece over the water-filled "mattress" (4) hybrid bed - "hybrid" bed or combination water foam flotation system (a polyurethane shell surrounding 7-8 cm of water).
Outcomes	"A daily questionnaire was filled out by the patients - asking simple questions (i.e. how did you sleep?, what awakened you?, how is your pain?)... Neurological evaluations including straight leg raising were performed periodically on each patient while in each bed" plus MMPI testing
Inclusion Criteria	"patients who: (a) had a minimum of 3 months of low back pain; (b) were not felt to be immediate surgical candidates by their attending physician; (c) were not in the midst of an acute attack or exacerbation of back pain and; (d) would be available for a minimum 1 month period."
Exclusion Criteria	None stated

Study Validity.		
Is it clear that there are no conflicts of interest in the writing or funding of this study?	Not reported	"supported by the Medical Research Service or the Veterans Administration"
Does the study have a clearly focused question?	Yes	"This study was designed to evaluate the effectiveness of 4 different types of beds in the treatment of chronic low back pain patients. Included in this study were two varieties of standard beds with mattresses and box springs, and two types of waterbeds."
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion criteria?	Partial	Inclusion criteria only
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Did the study have an adequate method of randomisation?	Not reported	
Was allocation to intervention group concealed?	Not reported	

Were patients blind to intervention group?	Not reported	
Were investigators and care providers blind to intervention group?	Not reported	
Were outcome assessors blind to intervention group?	Not reported	
Was this intervention suitable for a cross-over study?	Yes	
Was the washout period adequate?	Not reported	
All outcomes were measured in a standard, valid and reliable way?	Not reported	Some subjective measures used "A daily questionnaire was filled out by the patients -asking simple questions (i.e. how did you sleep?, what awakened you?, how is your pain?)." Objective neurological evaluations used – but unclear if validated tool used "Straight leg raising ability...Deep tendon reflexes, motor testing and sensation" Personality test also given, but unclear why "Minnesota Multiphasic Personality Inventories (MMPI) was given to the patients at the time of admission, if not administered previously."
Were outcomes assessed objectively?	Partial	Subjective daily questionnaire filled in by patient, plus objective neurological evaluations
Were outcomes assessed independently?	Not reported	
Were the groups similar at baseline with regards to key prognostic variables?	Not reported	
Aside from the experimental intervention, were the groups treated the same?	Yes	"The patients were essentially treated as outpatients, in that passes for routine daytime activities were given without question. Strict bed rest was not required and daytime activities were not monitored. Night time sedatives/ hypnotics were given, if desired by the patient... During the course of the study, no pain medication or physical therapeutic modality was added to the patient's regimen"
Were the outcomes measured appropriate?	Unknown	
Was there sufficient duration of follow-up?	Partial	Follow-up for duration of study (2 weeks per bed, for at least 2 beds)
Was there ≤20% drop-out?	Yes	2 out of 15 patients dropped out (13%)
Was the study sufficiently powered to detect any differences between the groups?	No	Sample size of 15
If statistical analysis was undertaken, was this appropriate?	Partial	"Statistical evaluation of the data using one-way analysis of variance was performed." – this is appropriate for continuous outcome measure (straight leg raise) and categorical predictor variable (i.e. bed A, B C, or D) No mention of planned statistical analysis in methods, and results not provided

Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?	N/A	It was planned that all patients cross over
Is the paper free of selective outcome reporting?	No	Most results were only commented on, but no clear figures provided. Straight leg raise was the only outcome with results reported following statistical analysis. Not all outcome measures are reported – MMPI, daily questionnaire detailing sleep/awake and pain regimes
What is the overall risk of bias?	Insufficient information	Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias.

Results.

"Fifteen patients completed the study requirements and were included in the evaluation (Table I). Nine patients sampled all 4 beds, while 6 left after sleeping on only two. Two patients quit the study early after sleeping on the hybrid bed. All patients except one noted increased back pain and difficulty sleeping when on the "soft" bed. Similarly, except for one individual, the hybrid bed was felt to be unsatisfactory by the group. Of the remaining patients, 6 noted decreased symptoms on the waterbed and 7 found the hard bed most comfortable. Objective criteria were more subtle. Limitations of straight leg raising parallel the pain complaints on each bed. Straight leg raising ability improved as pain was reduced on both the hard bed and waterbed. Deep tendon reflexes, motor testing and sensation were unaffected by type of beds involved.

Lateral roentgenograms were taken of at least one individual on each bed. However, X-rays could not completely penetrate the waterbeds and portions of the spine did not show up on the radiographs. Spine visualization was therefore unsatisfactory.

Statistical evaluation of the data using one-way analysis of variance was performed."

TABLE I

OBJECTIVE RESPONSES TO BEDS

	Beds			
	Hard	Soft	Water	Hybrid
SLR * improved **	3	0	4	0
SLR worse **	0	2	0	3
Total patients on each bed	9	10	11	11

* SLR = straight leg raise.
** Greater than 20° change in SLR.

Author's Conclusions.

"This limited study indicates that hard beds should remain the first choice of patients with chronic low back pain. However, if relief is not obtained for these chronic pain patients, a trial on a waterbed may prove beneficial."

Our Comments/Summary.

This paper provided insufficient information to assess methodological quality. However, due to the small sample size and selective outcome reporting, the results of this study should not be generalised.

Table A5.5 Critical appraisal table *(Kovacs 2003)*

Study: *Kovacs FM, Abraira V, Pena A, Martin-Rodriguez JG, Sanchez-Vera M, Ferrer E, et al. Effect of firmness of mattress on chronic non-specific low-back pain: Randomised, double-blind, controlled, multicentre trial. Lancet. 2003;362(9396):1599-604.*	
Description of study: *randomised controlled trial*	
Patient/population	adults who had chronic non-specific low-back pain, but no referred pain, who complained of backache while lying in bed and on rising
N	313
Setting	home
Intervention/indicator	Firm mattress
Comparison/control	Medium-firm mattress
Outcomes	"Primary outcomes were the intensity of pain while lying in bed and on rising, and the degree of disability. Secondary outcomes included low-back pain, low-back pain in bed or on rising throughout the study period, and more intense pain in bed when lying down for an extended time. We recorded complaints of pain while lying in bed from the participants' partners as a side-effect."
Inclusion Criteria	"age 18 years or older, presence of chronic low-back pain for 3 months or more without referred pain, presence of pain while lying in bed or on rising, and voluntary agreement to participate."
Exclusion Criteria	"habitual prostration, signs of possible systemic disease,[15] a diagnosis of inflammatory disease or cancer, a diagnosis or clinical suspicion of fibromyalgia (defined as pain spread throughout large muscle masses with unjustified fatigue or non-restful sleep), pregnancy, habitually sleeping in a different bed 2 or more nights per week, taking anti-inflammatory medication with a 24 h effect at any time of the day, and taking hypnotic, analgesic, anti-inflammatory, or relaxant medication for any reason from 1700 h to the time at which pain on rising was assessed."

Study Validity.		
Is it clear that there are no conflicts of interest in the writing or funding of this study?	Yes	"Conflict of interest statement: None declared. Acknowledgments: This study was done and financed by the Kovacs Foundation, a nonprofit Spanish research institution with its own funding resources that promotes evidence- based health care in clinical practice. FLEX, a Spanish bedding company, provided and installed the mattresses used in the trial without charge; nobody from that company participated in study design or in the collection, analysis, and interpretation of data."
Does the study have a clearly focused question?	Yes	"We assessed the effect of different firmnesses of mattresses on the clinical course of patients with chronic non-specific low-back pain."
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion criteria?	Yes	See above
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	

Did the study have an adequate method of randomisation?	Yes	"Randomisation was done in a central office, according to a table of random permutations[16] before interventions were assigned. One of the researchers (MG) randomly selected the starting point for reading the table of permutations. The staff of the central office, which was independent from the research staff involved in recruiting the patients, wrote correlative numbers on the front of opaque envelopes. A numeric code from the table of permutations was copied in the inside of the envelope (the number on the front corresponded to the order of that numeric code in the table). Envelopes were then sealed and interventions were assigned to numbers in the table. Once a patient had been included in the study, the research assistant informed the person responsible for randomising patients, who wrote the participant's name on the envelope showing on its front the number corresponding to the order in which the patient had been included in the study. The person in charge opened the envelope and assigned the participant to one group or the other, depending on the number shown inside the envelope."
Was allocation to intervention group concealed?	Yes	See above
Were patients blind to intervention group?	Yes	"Mattresses were distinguishable only by fictitious names that were unrelated to firmness and were similar to commercially available models. The mattresses were installed in the participants' homes under identical conditions by the same workers, who were unaware of which type of mattresses they were installing. Existing mattress support bases were substituted with a firm base if the original base supported less than 50% of the mattress surface (ie, wooden or plastic slats). Only the person who did the randomisation knew which mattress had been installed, but that person had no access to data obtained throughout the trial."
Were investigators and care providers blind to intervention group?	Yes	See above
Were outcome assessors blind to intervention group?	Yes	See above
All outcomes were measured in a standard, valid and reliable way?	Yes	"Each patient was assessed at home with validated self-assessment instruments and by a research assistant"
Were outcomes assessed objectively?	Partial	Most outcomes were measured subjectively (patient self-report), with some objective data collected by the research assistant
Were outcomes assessed independently?	Not reported	
Were the groups similar at baseline with regards to key prognostic variables?	Yes	"baseline data of patients in the two groups were similar (table 1)"
Aside from the experimental intervention, were the groups treated the same?	Yes	
Were the outcomes measured appropriate?	Yes	
Was there sufficient duration of follow-up?	Yes	Assessed at baseline and then at 90 days
Was there ≤20% drop-out?	Yes	3 patients out of 155 lost to follow-up from the medium-firm mattress arm (final n=152) 0 patients out of 158 lost to follow-up from the firm mattress arm (final n=158)

Was the study sufficiently powered to detect any differences between the groups?	Yes	"We established the size of the study population at 125 patients per group, according to Lemeshow's tables,[20] assuming a difference in the proportion of patients improving in each group of at least 20% and that the prevalence of improvement in one of the groups would be 50%. A type I error of 0·05 and a type II error of 0·10 were accepted. We increased the study population to 313 participants to compensate for an anticipated 20% loss of patients during follow-up."
If statistical analysis was undertaken, was this appropriate?	Yes	
Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?	Yes	"We did analyses by intention to treat and per protocol. To assume the most conservative approach, we decided that for the intention-to-treat analysis the poorest observed results would be assigned to losses in the group showing the best evolution, and vice versa.[22]"
Is the paper free of selective outcome reporting?	Yes	
What is the overall risk of bias?	Low	Low - All of the criteria have been fulfilled or where criteria have not been fulfilled it is very unlikely the conclusions of the study would be affected.

Results.

"At day 90, participants in both groups had experienced improvements compared with baseline in the intensity of pain while lying in bed (mean intensity improvement 70% firm and 80% medium-firm mattresses), intensity of pain on rising (each 57%), and disability (30% and 50%). Although there were differences in favour of medium-firm mattresses in all variables at day 90, only those in the degree of improvement of disability and pain on rising throughout follow-up were significant (p=0·008, table 2). Differences in the degree of improvement of pain on rising (p=0·053), having had low-back pain throughout follow-up (p=0·059), and pain while lying in bed throughout follow-up (p=0·064) were close to significance (table 2). The firmness of the new mattress was generally perceived accurately by participants; 77·2% of patients in the firm mattress group perceived their mattress to be firm or very firm, compared with 43·5% in the medium-firm mattress group who though their mattress was firm (p<0·0001, table 2). When they entered the study, 63 of the 111 individuals who shared beds with participants in the firm mattress group and 71 of the 111 who shared beds with those from the medium-firm mattress group had pain in bed (p=0·27). At the end of the study, 19 from the firm mattress group and 14 from the medium-firm mattress group had pain (p=0·35).

In most patients, the change of mattress was associated with an improvement of pain while lying in bed (firm mattress 77·8% *vs.* 82·6% medium-firm mattress, odds ratio 1·35 [95% CI 0·77–2·36], p=0·29) and on rising (80·4% *vs.* 85·8%, odds ratio 1·48 [0·81–6·68], p=0·201). Pain-related disability improved in both groups, although in a significantly higher proportion of patients in the medium-firm mattress than in the firm mattress group (81·9% *vs.* 68·3%, 2·10 [1·24–3.56], p=0·005). After installing the new mattresses, worsening was observed in some patients for pain in bed (firm mattresses 17·1%, medium-firm mattresses 9·0%), pain on rising (firm mattresses 12·7%, medium-firm mattresses 6·5%), and disability (firm mattresses 24·1%, medium-firm mattresses 9·0%). However, none of the patients requested a change of the mattress during the course, or after completion of, the study.

In the multivariate analysis, to avoid collinearity related difficulties, we eliminated the variable height-to-length bed ratio, and centred the variables fat coefficient and minutes spent in bed by subtracting their means.23 Intensity of basal pain while lying in bed, pain on rising, and perceived firmness of the new mattress were confounding variables for intensity of pain in bed. Intensity of basal pain on rising and perceived firmness of the new mattress were confounding variables for improvement of pain on rising. After adjustment for these variables, the final model showed that patients who received the medium firmness mattresses were around twice as likely to improve than were patients with firm mattresses for low-back pain while lying in bed, low-back pain on rising, and disability (table 3).

For the per-protocol analysis, we did not include data for the three patients lost to follow-up. This exclusion did not change the direction of results, although it increased the differences between the groups, and intensity of pain on rising became significant in the crude and multivariate analyses (data not shown)."

	Firmness of mattress	
	Firm (n=158)	Medium firm (n=155)
Characteristic		
Sex		
Male	42 (26·6%)	42 (27·1%)
Female	116 (73·4%)	113 (72·9%)
Median (range) age (years)	44·0 (18·0–78·0)	45·1 (19·0–82·0)
Median (range) weight (kg)	69 (45–122)	65 (45–104)
Median (range) height (cm)	164 (146–190)	164 (145–190)
Educational level		
No studies or primary education	69 (43·6%)	71 (45·8%)
Secondary education or higher	89 (56·3%)	84 (54·2%)
Smoking habit		
Never or ex-smoker	113 (71·5%)	112 (72·3%)
Current smoker	45 (28·5%)	43 (27·7%)
In employment	88 (55·7%)	91 (58·7%)
Characteristics of occupation		
Sedentary or ambulatory without strain	106 (67·1%)	105 (67·7%)
Ambulatory with strain or non-ambulatory with strain	52 (32·9%)	53 (32·2%)
Exposures at work to		
Flex-extension movements with load	42 (26·6%)	40 (25·8%)
Whole-body vibrations	8 (5·1%)	6 (3·9%)
Sport activity (>twice per week or competition level)*	86 (54·4%)	77 (49·7%)
Median (range) time in bed (min)	480 (300–771)	480 (300–626)
Most common position during sleep		
Supine knees bent	9 (5·7%)	6 (3·9%)
Supine knees straight	35 (22·2%)	41 (26·5%)
Prone	16 (10·1%)	10 (6·5%)
Fetal	86 (54·4%)	87 (56·1%)
Three-quarters	7 (4·4%)	4 (2·6%)
Other	5 (3·2%)	7 (4·5%)
Shared bed	111 (70·3%)	111 (71·6%)
Characteristics of mattress		
Median (range) age (years)	7 (2–33)	8 (2–34)
Median (range) length (cm)	190 (180–210)	182 (180–200)
Median (range) width (cm)	135 (90–180)	135 (80–190)
Median (range) thickness (cm)	16 (8–25)	16 (7–22)
Median (range) thickness of board (cm)	2 (0·3–8)	2 (1–5)
Type of base		
English mesh	16 (10·3%)	13 (8·6%)
Square-link mesh	11 (7·1%)	7 (4·6%)
Box spring	54 (34·6%)	64 (42·1%)
Board with >50% support	38 (24·4%)	30 (19·7%)
Firm base	35 (22·4%)	30 (19·7%)
Other	2 (1·3%)	8 (5·3%)
Subjective perception of the firmness of mattress		
Very soft	1 (0·6%)	5 (3·2%)
Soft	17 (10·8%)	21 (13·5%)
Neither soft nor firm	67 (42·7%)	72 (46·5%)
Firm	59 (37·6%)	51 (32·9%)
Very firm	13 (8·3%)	6 (3·9%)
Back pain of partner in bed	48 (43·2%)	40 (36·0%)
Median (range) duration of low-back pain (years)	10 (1–42)	9 (0–53)
Median (range) duration of low-back pain while lying in bed (years)	7 (1–42)	6 (0–53)
Median (range) duration of low-back pain on rising (years)	7 (1–42)	5·5 (0–53)
Median (range) pain in bed on VAS	5 (0–10)	5 (0–9)
Median (range) pain on rising on VAS	7 (0–10)	7 (0–10)
Median (range) pain-related disability on RMQ	9 (0–20)	8 (0–21)
Taking medication for low-back pain	40 (25·3%)	32 (20·6%)

RMQ=Roland Morris questionnaire. *Football, swimming, volleyball, judo, basketball, athletics, sailing, tennis, gymnastics, aerobics, indoor football, paddle-tennis, squash, and handball.

Table 1: **Baseline characteristics**

	Firmness of mattress		p
	Firm mattress (n=158)	Medium firm (n=155)	
Characteristic			
Characteristics of occupation			0·399
Sedentary or ambulatory without strain	108 (68·4%)	97 (63·8%)	
Ambulatory with strain or non-ambulatory with strain	50 (31·6%)	55 (36·2%)	
Exposures at work			
Flex-extension movements with load	38 (24·1%)	43 (28·6%)	0·396
Whole-body vibrations	4 (2·5%)	4 (2·6%)	0·956
Most common position during sleep throughout follow-up			0·379
Supine knees bent	4 (2·5%)	2 (1·3%)	
Supine	41 (25·9%)	31 (20·5%)	
Prone	12 (7·6%)	18 (5·3%)	
Fetal	93 (58·9%)	104 (68·9%)	
Three-quarters	6 (3·8%)	6 (4·0%)	
Other	2 (1·3%)	0	
Shared bed	109 (69·0%)	106 (69·7%)	0·866
Subjective perception of the firmness of mattress			<0·0001
Very soft	0	1 (0·6%)	
Soft	0	5 (3·2%)	
Neither soft nor firm	36 (22·8%)	81 (52·6%)	
Firm	102 (64·5%)	64 (41·6%)	
Very firm	20 (12·7%)	3 (1·9%)	
Collapsed categories			<0·0001
Very soft/soft/neither soft nor firm	36 (22·8%)	87 (56·4%)	
Firm/very firm	122 (77·2%)	67 (43·5%)	
Back pain of the partner in bed			0·407
No	90 (82·6%)	91 (86·7%)	
Yes	19 (17·4%)	14 (13·3%)	
Back pain of the partner in bed*			0·192
No	26 (64·4%)	28 (77·8%)	
Yes	16 (35·6%)	8 (22·2%)	
Back pain of the partner in bed†			0·386
No	57 (95·0%)	61 (91·0%)	
Yes	3 (5·0%)	6 (9·0%)	
Taking medication for low-back pain			0·983
No	135 (85·4%)	130 (85·5%)	
Yes	23 (14·6%)	22 (14·5%)	
Had low-back pain throughout follow-up			0·059
No	36 (22·8%)	48 (32·4%)	
Yes	122 (77·2%)	100 (67·6%)	
Had low-back pain in bed throughout follow-up			0·064
No	44 (27·8%)	57 (37·7%)	
Yes	114 (72·2%)	94 (62·3%)	
Had low-back pain on rising throughout follow-up			0·008
No	36 (22·8%)	55 (36·7%)	
Yes	122 (77·2%)	95 (63·3%)	
More intense pain in bed with more time in it throughout follow-up			0·087
No	73 (51·8%)	89 (61·8%)	
Yes	68 (48·2%)	55 (38·2%)	
Degree of improvement			
Median (range) pain while lying in bed on VAS	3·35 (–10 to 10)	4·0 (–5·0 to 9·20)	0·276
Median (range) pain on rising on VAS	4·0 (–7 to 9)	4·0 (–3 to 10)	0·053
Median (range) disability on RMQ	3·0 (–10 to 19)	4·0 (–14 to 19)	0·008

*Only partners who had pain while lying in bed on entering study. †Only partners free from pain while lying in bed on entering study.

Table 2: **Results of assessment at 90 days**

	Odds ratio (95% CI)	p
Variable		
Improvement of pain while lying in bed on VAS*	2·36 (1·13–4·93)	0·023
Improvement of pain on rising (VAS)†	1·93 (0·97–3·86)	0·061
Improvement of pain-related disability (RMQ)	2·10 (1·24–3·56)	0·006

RMQ=Roland Morris questionnaire. *Adjusted by perceived firmness of new mattress, pain on rising at baseline, pain while lying in bed at baseline. †Adjusted by perceived firmness of new mattress and VAS on rising at baseline.

Table 3: **Results of multiple logistic regression model for intention-to-treat analysis**

Author's Conclusions.
"A mattress of medium firmness improves pain and disability among patients with chronic non-specific lowback pain."
Our Comments/Summary.
This was a well conducted study with a low risk of bias. However, even though this is a high quality study with an adequate sample size, it is not sufficient on its own to make the results generalisable; further high quality studies with similar findings are needed before these results can be generalised.

APPENDIX 6: NARRATIVE SYNTHESIS TABLES

Table A6.1 Description of studies

Author	Year	Study design	Country	Number of patients
Bergholdt	2008	RCT	Denmark	n=160
Kovacs	2003	RCT	Spain	n=313
Dubb	1993	crossover CCT	South Africa	n=9
Atherton	1983	crossover RCT	UK	n=30
Garfin	1981	crossover RCT	USA	n=15
TOTAL				N=527

Table A6.2 Population

Study	Population
Bergholdt 2008 (n=160)	adults (<60), with daily LBP (Th12-S1) at a largely constant level for at least 6 months. Pain worse in the morning, or equal to that of the rest of the day. No other serious illness, which could influence sleep. Not receiving other back pain treatment started less than 3 month before entrance.
Kovacs 2003 (n=313)	adults with chronic non-specific LBP, who complained of backache while lying in bed and on rising Without referred pain
Dubb 1993 (n=9)	Healthy volunteers, 18-30 years with LBP that interfered with daily activities and at some stage sought professional help
Atherton 1983 (n=30)	Patients with LBP for at least the previous six months
Garfin 1981 (n=15)	Patients with chronic LBP (at least 3 months) of any aetiology attending a back clinic Not immediate surgical candidates Not in the midst of acute attack or exacerbation Available for a minimum 1 month period

Table A6.3 Interventions and comparators

Study	Interventions and comparators
Bergholdt 2008 (n=160)	(1) waterbed (Akva) (2) body-conforming foam mattress (Tempur) (3) a hard mattress (Innovation Futon) Beds were installed in patients' homes; measurements taken at baseline and at 1-month
Kovacs 2003 (n=313)	(1) Firm mattress (2) Medium-firm mattress Mattresses installed in patients' homes; measurements taken at baseline and at 90days
Dubb 1993 (n=9)	(1) Hard mattress (2) Medium mattress (3) Soft mattress Subjects slept in sleep lab for 6 nights (2 nights spent on each type of mattress). The 2 nights on a specific mattress were non-consecutive, with 1-4 nights at home between nights in the sleep lab
Atherton 1983 (n=30)	(1) Isometric mattress (two layers of foam with 3 moveable inserts fitted to provide support to specific areas) (2) Soft interior sprung mattress (Airsprung) Mattresses installed in patient's homes and trialled for 2-weeks
Garfin 1981 (n=15)	1) hard bed - "orthopedic" or "back support" bed containing 720 individually reinforced coils, a built-in bed board, and approximately 1.5 cm of foam overlying the coils (2) soft bed - standard 500 coil bed (box spring and mattress) (3) waterbed - waterbed filled to a depth of 25 cm with a quilted top-piece over the water-filled "mattress" (4) hybrid bed - "hybrid" bed or combination water foam flotation system (a polyurethane shell surrounding 7-8 cm of water). Beds located in back clinic, patients slept on each bed for 2 weeks. Patients required to try at least 2 different beds before discharge

Table A6.4 Outcomes

Study	*Outcomes*
Bergholdt 2008 (n=160)	Outcomes measured at baseline, and 1-month. - Low back pain levels (0 –10) - daily function (activities of daily living, 0–30) - sleeping hours/night. Measured using COBRA questionnaire, and physical examination (ROM, pain on specific movements, neurology, *etc).*
Kovacs 2003 (n=313)	Primary outcomes intensity of pain while lying in bed and on rising degree of disability Secondary outcomes low-back pain low-back pain in bed or on rising more intense pain in bed when lying down for an extended time Side effects complaints of pain while lying in bed from participants' partners
Dubb 1993 (n=9)	Subjective ratings with visual analog scales: Evening – agitation, discomfort Morning – sleep quality, morning vigilance ("bright, fresh, alert"), backache, discomfort, mood, strength of mind (decisiveness), vitality, irritability, concentration, need for sleep
Atherton 1983 (n=30)	Range of movement in lumbar spine Pain-free range of passive straight leg raising Subjective pain level Comfort of the mattress Average length of time taken to get to sleep
Garfin 1981 (n=15)	Subjective questionnaire filled out by patients (on sleep, pain, etc) Neurological evaluations including straight leg raising MMPI testing

Table A6.5 Results

Study	*Results*
Bergholdt 2008 (n=160)	The waterbed and foam mattress had better results for low back pain, activities of daily living and hours of sleep per night than the hard mattress, but the differences were small. There was no difference between the waterbed and the foam mattress for any outcomes.
Kovacs 2003 (n=313)	"A mattress of medium firmness improves pain and disability among patients with chronic non-specific low back pain." Statistically significant difference for the following: - Fewer patients had LBP on rising in the medium-firm bed group (n=95, 63.3% vs. n=122, 77.2%) - Greater degree of improvement in disability for the medium-firm group, as measured by the Roland Morris Questionnaire [median (range)]: 4.0 (-14 to 19) vs. 3.0 (-10 to 19) However, one finding that came close to statistical significance (p=0.053) found that there was no difference in improvement in pain between groups, as measured by visual analogue scale. All other findings were in favour of the Medium firm mattress, although not statistically significant
Dubb 1993 (n=9)	"In our patients, low back pain on awakening was significantly reduced on the second night on the hard mattress compared to the soft mattress, irrespective of whether their symptoms were relieved by flexion or extension. Patients suffering from low back pain therefore may well benefit by sleeping on a hard firmness of mattress-base bed set. Whether the benefit is sustained following continuous sleeping on the harder mattress, and whether there are associated improvements in objective correlates of the back pain remains to be investigated" Firmer mattress resulted in an improvement in the subject's perceived sleep quality and well-being; LBP was reduced on the second night of the hard mattress compared to the soft mattress
Atherton 1983 (n=30)	"In conclusion, 56% of the total patients, who incidentally tended to be in the under-40 age group found that the Isometric mattress gave them a better night's sleep coupled with less objective and subjective 'stiffness' on rising and a decrease in their pain. Therefore, in young patients who suffer from low back pain and who have sleep problems the Isometric mattress is worth considering purchasing." The reporting of results is confusing. Results reported in text do not match those in the tables and it is not clear where the figures on the conclusion came from.
Garfin 1981 (n=15)	"All patients except one noted increased back pain and difficulty sleeping when on the "soft" bed. Similarly, except for one individual, the hybrid bed was felt to be unsatisfactory by the group. Of the remaining patients, 6 noted decreased symptoms on the waterbed and 7 found the hard bed most comfortable. Objective criteria were more subtle. Straight leg raising ability improved as pain was reduced on both the hard bed and waterbed. Deep tendon reflexes, motor testing and sensation were unaffected by type of beds involved. "This limited study indicates that hard beds should remain the first choice of patients with chronic low back pain. However, if relief is not obtained for these chronic pain patients, a trial on a waterbed may prove beneficial."