National Institute for Health and Care Excellence

Final

Osteoarthritis in over 16s: diagnosis and management

[H] Evidence review for the clinical and cost effectiveness of devices for the management of osteoarthritis

NICE guideline NG226

Evidence reviews underpinning recommendations 1.3.10 and 1.3.11 and research recommendations in the NICE guideline

October 2022

Final

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1.1 Review question

What is the clinical and cost-effectiveness of devices (such as supports, splints and braces) for the management of osteoarthritis?

1.1.1 Introduction

Devices such as supports, splints, braces and walking aids are designed to help people with osteoarthritis in their daily living by improving their physical function. There is great variety in the design and type of device for different joints. While devices are frequently used, there is uncertainty about the most beneficial type of device, their acceptability to patients and associated harms.

This review aims to evaluate the clinical and cost-effectiveness of devices (including supports, splints and braces) in the management of osteoarthritis in adults.

1.1.2 Summary of the protocol

Table 1: PICO characteristics of review question

Population	Inclusion: • Adults (age ≥16 years) with osteoarthritis affecting any joint Stratify by site of osteoarthritis: • Hip • Knee • Ankle • Foot • Toe • Shoulder • Elbow • Wrist • Hand • Thumb • Finger • Temporomandibular joint (TMJ) To note that where evidence for other rare forms of osteoarthritis is identified the committee will stratify into a group they are most similar to. Exclusion: • Children (age ≤16 years) • People with conditions that may make them susceptible to osteoarthritis or often occur alongside osteoarthritis (including: crystal arthritis, inflammatory arthritis, septic arthritis, diseases of childhood that may predispose to

	osteoarthritis, medical conditions presenting with joint inflammation and malignancy). • Studies in people with meniscal injury without osteoarthritis • Studies with an unclear population (e,g, type of arthritis, proportion of participants with osteoarthritis) • Spinal osteoarthritis
Interventions	Device interventions (minimum intervention duration 1 week): • Orthotic device (insoles and shoes) • Braces • Splints • Supports (for example, tubular bandage) • Straps/tape • Walking aids Each intervention will be considered as a class and be analysed separately.
Comparisons	• Each other • Sham intervention • No device intervention (including either): ○ Device intervention versus no treatment* ○ Device intervention plus additional treatment versus additional treatment alone** **No treatment defined as either (1) doing nothing or (2) very low intensity intervention such as advice* ***Inclusion of studies where additional treatment is the same in each arm will be assessed on a case by case basis. Studies including high intensity additional treatment may not be included due to the risk that treatment could have an interaction with the intervention of interest and mask the true treatment effect.*
Outcomes	Primary outcomes: • Health-related quality of life [validated patient-reported outcomes, continuous data prioritised] at ≤3 months and >3 months • Physical function [validated patient-reported outcomes, continuous data prioritised] at ≤3 months and >3 months • Pain [validated patient-reported outcomes, continuous data prioritised] at ≤3 months and >3 months Secondary outcomes: • Psychological distress [validated patient-reported outcomes, continuous data prioritised] at ≤3 months and >3 months • Osteoarthritis flares [validated patient-reported outcomes, continuous data prioritised] at ≤3 months and >3 months • Number of adverse events [dichotomous] at ≤3 months and >3 months
Study design	RCTs and systematic reviews of RCTs

For full details see the review protocol in Appendix A.

1.1.3 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in Appendix A and the methods document.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

1.1.4 Effectiveness evidence

1.1.4.1 Included studies

Fifty seven studies[4, 6, 12, 14, 17-19, 21, 23, 27, 30, 31, 56, 59-61, 66, 67, 69, 73, 76, 79-82, 92, 94, 96, 99-101, 104, 105, 111, 115, 120, 132, 134-136, 143, 151, 152, 155-157, 161, 167, 168, 172, 187, 189, 196, 199] (reported in sixty one papers) were included in the review; these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 15). The clinical studies identified compared:

- Knee osteoarthritis:
    - Insoles compared to sham devices
    - Insoles compared to no device intervention
    - Shoes compared to sham devices
    - Braces compared to insoles
    - Braces compared to supports
    - Braces compared to sham devices
    - Braces compared to no device intervention
    - Tape compared to sham devices
    - Tape compared to no device intervention
    - Supports compared to no device intervention
    - Walking aids compared to no device intervention
- Thumb osteoarthritis:
    - Splints compared to no device intervention
- Finger osteoarthritis:
    - Tape compared to sham devices
- Foot osteoarthritis:
    - Insoles compared to sham devices
- Toe osteoarthritis
    - Shoes compared to insoles

No relevant clinical studies for the hip, ankle, toe, shoulder, elbow, wrist, hand and temporomandibular joint osteoarthritis strata were identified.

See also the study selection flow chart in Appendix C, study evidence tables in Appendix D, forest plots in Appendix E and GRADE tables in Appendix F.

1.1.4.2 Excluded studies

Four Cochrane reviews[48, 54, 74, 194] were identified during sifting. Three of these were not considered completely relevant this this review question because they did not fully match the PICO of this review[48, 74, 194]. The last study included outcomes that were not applicable to our protocol[54]. References were cross-checked for inclusion in this review as relevant.

See the excluded studies list in Appendix J.

1.1.5 Summary of studies included in the effectiveness evidence

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Akinbo 2007[6]	**Orthotic devices – Insoles** (n=25) Lateral wedge insoles with thermal therapy and soft tissue massage. **No device intervention** (n=25) Thermal therapy and soft tissue massage only. **Concomitant therapy:** Analgesia was not permitted during the study (apart from the analgesic ointment used during the massage).	**Knee osteoarthritis** Mean age (SD): 53.5 (2.8) years N = 50 Definition: Medial/varus osteoarthritis of the knee joint with femorotibial alignment >170 degrees (unclear if this included imaging). Severity: Mild/moderate Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Physical function at ≤3 months	
Arazpour 2013[12]	**Orthotic devices – Insoles** (n=12) Laterally wedge insoles and identically styled lightweight shoes **Braces** (n=12) Knee unloader brace. Custom made for each individual. **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 59.3 (2.4) years N = 24 Definition: Medial compartment knee osteoarthritis of grade 1 or 2 confirmed by radiological examination. Severity: Radiological grade 1 or 2	Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Duration of symptoms: Not stated Presence of multimorbidities: Excluded (based on extensive exclusion criteria)		
Arazpour 2017[14]	**Splint** (n=16) Custom made thumb splint. Worn for at least 5 hours a day for 4 weeks. **No device intervention** (n=9) No splint group. No further details. **Concomitant therapy:** No additional information	**Thumb osteoarthritis** Mean age (SD): 51.0 (6.1) years N = 25 Definition: Clinical and radiological diagnosis of thumb carpometacarpal joint osteoarthritis of grade 1 or 2. Severity: Radiological grade 1 or 2. Duration of symptoms: 13.1 (2.4) months Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Physical function at ≤3 months	
Aydogdu 2017[17]	**Tape** (n=28) Kinesio taping with physical therapy (ultrasound, TENS, electrical stimulation, exercise and cold packs). **No device intervention** (n=26) Physical therapy (as for the tape group) with no taping. **Concomitant therapy:** No additional information	Knee osteoarthritis Mean age (SD): 51.9 (9.3) years N = 54 Definition: Unilateral knee osteoarthritis according to the American College of Rheumatology with stage 2-3 Kellgren-Lawrence radiographic changes	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Severity: Kellgren-Lawrence grade 2-3 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Baker 2007[18]	**Orthotic devices – Insoles** (n=90) Lateral wedge insoles on the side of the affected knee for 4 weeks **Sham device** (n=90) Neutral insole wedge **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 68.0 (9.3) years N = 90 Definition: People with medial but not lateral tibiofemoral narrowing (≥1 on a 0-3 point scale) on posterior semiflexed radiographs and scores reflecting moderate pain on the WOMAC pain subscale Severity: Kellgren Lawrence grade 3-4 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Number of adverse events at ≤3 months	Crossover study – 6 week washout period
Bani 2013[19]	**Splints** (n=24) Custom made thumb splint and a prefabricated splint for 4 weeks each with a 2 week washout period between them **No device intervention** (n=11) No treatment for 10 weeks	Thumb osteoarthritis Mean age: 55.6 years N = 35 Definition: Clinical and radiological diagnosis of thumb carpometacarpal joint OA grade 1 and 2	Pain at ≤3 months Physical function at ≤3 months	Crossover study (between a prefabricated splint and a custom splint, these classes were pooled together in our analysis).

Study	Intervention and comparison	Population	Outcomes	Comments
	Concomitant therapy: No additional information	Severity: Grade 1 and 2 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Barrios 2009[21]	**Orthotic devices – Insoles** (n=35) Non-custom neutral contoured foot orthoses with individually prescribed wedging added. **Sham device** (n=31) Non-custom neutral contoured foot orthoses only. **Concomitant therapy:** Medications for pre-existing conditions, paracetamol up to 4000mg/day, and short-acting analgesics or NSAIDs were permitted.	Knee osteoarthritis Mean age (SD): 62.4 (8.5) years N = 66 Definition: Medial tibiofemoral osteoarthritis with radiological diagnosis Severity: Kellgren-Lawrence grades 2-4 Duration of symptoms: Not stated Presence of multimorbidities: Unclear/not stated	Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months Number of adverse events at ≤3 months and >3 months	
Bennell 2011[23]	**Orthotic devices – Insoles** (n=103) Lateral wedge insoles bilaterally. **Sham devices** (n=97) Neutral insoles bilaterally. **Concomitant therapy:** No additional information explicitly stated. People were allowed to use any drugs/cointerventions as long as	**Knee osteoarthritis** Mean age (SD): 64.1 (8.1) years N = 200 Definition: Medial compartment pain with osteophytes in the medial compartment or medial joint space narrowing on knee radiography	Quality of life at >3 months Pain at >3 months Physical function at >3 months Number of adverse events at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	they were recorded. There were no differences between groups.	Severity: Kellgren-Lawrence grades 1-4 Duration of symptoms: 92% had symptoms for more than 1 year Presence of multimorbidities: Not stated/unclear		
Brouwer 2006[27]	**Braces** (n=60) Commercially available knee brace available in four sizes. **No device intervention** (n=57) Conservative treatment only. **Concomitant therapy:** Conservative treatment included patient education and (if needed) physical therapy and analgesics.	**Knee osteoarthritis** Mean age (SD): 59 (50) years N = 117 Definition: Clinical diagnosis according to Ahlback score, but criteria included evidence for malalignment Severity: Not stated Duration of symptoms: 59 (76.6) months Presence of multimorbidities: Not stated/unclear	Quality of life at ≤3 months and >3 months Pain at ≤3 months and >3 months	
Callaghan 2015[30]	**Braces** (n=63) Commercially available knee brace **No device intervention** (n=63) No brace **Concomitant therapy:** Not specified	**Knee osteoarthritis** Mean age (SD): 55.5 (7.5) years N = 126 Definition: Radiographic evidence of osteoarthritis in the patellofemoral joint with clinical symptoms Severity: Kellgren-Lawrence grades 2-3	Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Duration of symptoms: Not explicitly stated (minimum 3 months) Presence of multimorbidities: Not stated/unclear		
Campos 2015[31]	**Orthotic devices – Insoles** (n=29) Lateral wedge insole(s) on the affected leg (neutral wedge on the unaffected leg if they had unilateral symptoms). **Sham device** (n=29) Neutral wedge insole **Concomitant therapy:** Analgesics (paracetamol and codeine) were permitted. It was noted that NSAIDs were not used routinely in their patients.	**Knee osteoarthritis** Mean age (SD): 64.3 (8.6) years N = 58 Definition: American Collage of Rheumatology criteria for knee osteoarthritis Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months and >3 months	
Erhart-hledik 2012[56]	**Orthotic devices – Shoes** (n=40) Variable stiffness walking shoes **Sham device** (n=39) Constant stiffness shoe **Concomitant therapy:** Not specified	**Knee osteoarthritis** Mean age (SD): 60 (10) years N = 79 Definition: Clinical diagnosis (with imaging) Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at >3 months Physical function at >3 months	
Farhadian 2019[59]	**Tape** (n=19)	**Hand osteoarthritis**	Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Kinesio-taping **No device intervention** (n=19) Concurrent care only. **Concomitant therapy:** Hand exercises including a hot pack or paraffin wax for 15 minutes, stretching exercises, grip strength training exercise, and recommendation for use of the hands in real-life tasks. The tasks consisted of opening drawers, washing and putting away dishes, carrying bags, cleaning windows, counting change and writing or typing	Mean age (SD): 69.00 (3.97) years N = 38 Definition: People previously diagnosed with hand osteoarthritis Severity: Not stated/unclear Duration of symptoms (mean [SD]): 7.16 (1.76) years Presence of multimorbidities: Not stated/unclear	Physical function at ≤3 months	
Felson 2019[60]	**Orthotic devices – Insoles** (n=62) Lateral wedge insole for 8 weeks **Sham device** (n=62) Neutral insole for 8 weeks Concomitant therapy: No additional information	**Knee osteoarthritis** Mean age (SD): 64.6 (9.4) years N = 83 Definition: Knee pain with Kellgren Lawrence grade 2-4 changes in the painful knee Severity: Kellgren Lawrence grade 2-4. Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months	Crossover study – 8 week washout period
Ferreira 2021[61]	**Orthotic devices – Insoles** (n=20)	**Knee osteoarthritis**	Quality of life at ≤3 months Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Adjusted lateral wedge insoles **Sham device** (n=18) Neutral insoles Concomitant therapy: Not specified	Mean age (SD): Intervention: 62.6 (8) and control: 60.6 (8.9) years N = 38 Definition: according to the clinical and radiographic criteria established by the American College of Rheumatology Severity: Severity K/L Grade 2: 16 and Grade 3: 22 Duration of symptoms: not stated Presence of multimorbidities: Not stated/unclear	Physical function at ≤3 months	
Gomes carreira 2010[66]	**Splints** (n=20) Thumb metacarpal-carpal joint splint **No device intervention** (n=20) No splint (except for examination purposes). **Concomitant therapy:** Not specified	**Thumb osteoarthritis** Mean age (SD): 64.0 (9.4) years N = 40 Definition: Clinical and radiological diagnosis of grade 2-3 osteoarthritic of the thumb metacarpal-carpal joint. Severity: Grade 2-3. Duration of symptoms: 7.0 (5.0) years Presence of multimorbidities:	Pain at ≤3 months Physical function at ≤3 months	
Gueugnon 2021[67]	**Braces** (n=60)	**Knee osteoarthritis**	Quality of life at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Worn for at least 6 hours a day, 5 days a week and to remove it during periods of rest and when lying down. **No device intervention** (n=61) Usual care only. **Concomitant therapy:** Usual care included pharmacological (such as NSAIDs, analgesics, steroid injections, intra-articular hyaluronic acid injections) and non-pharmacological treatments (physiotherapy, spa therapy, etc.)	Mean age (SD): 63.6 (11.5) years N = 121 Definition: Knee osteoarthritis diagnosed according to the American College of Rheumatology criteria including clinical and imaging features Severity: Radiological Kellgren-Lawrence grade II-IV, median grade III Duration of symptoms (median [IQR]): Intervention = 3.1 (1.2-9.8) years, control = 4.3 (1.0 - 6.7) years Presence of multimorbidities: Not stated/unclear	Pain at >3 months Physical function at >3 months Number of adverse events at >3 months	
Gunaydin 2020[68]	**Tape** (n=22) Kinesio-taping **No device intervention** (n=20) A third group (n=18) received extracorporeal shockwave therapy. This was not included in this analysis as it did not fulfil the protocol criteria. **Concomitant therapy:** Exercise therapy was available for all	**Knee osteoarthritis** Mean age (SD): 58.8 (6.2) years N = 60 Definition: Diagnosis made by an orthopaedic surgeon. Classified using K-L grading1-3. Severity (baseline VAS during squats): Taping group: 8.67(1.74), exercise group: 7.84 (2.14)	Pain at ≤3 months	Bilateral knee OA

Study	Intervention and comparison	Population	Outcomes	Comments
		Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Halstead 2016[69]	**Orthotic devices – Insoles** (n=19) Firm semi-rigid functional foot orthoses with additional midfoot support and heel wedging **Sham devices** (n=18) Neutral insole **Concomitant therapy:** Not specified	**Foot osteoarthritis** Mean age (SD): 58.4 (11.6) years N = 37 Definition: Radiographically confirmed. Predetermined criteria recommended in the La Trobe University Atlas of Foot Osteoarthritis. Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Physical function at ≤3 months	
Hatef 2014[73]	**Orthotic devices – Insoles** (n=75) Bilateral standardised laterally wedged insoles **Sham devices** (n=75) Bilateral neutrally wedged insoles **Concomitant therapy:** People were permitted to take NSAIDs	**Knee osteoarthritis** Mean age (SD): 48.4 (11.0) years N = 118 Definition: Medial compartment knee osteoarthritis according to the American College of Rheumatology criteria. Severity: Mild-to-moderate according to the Kellgren-Lawrence criteria	Pain at ≤3 months Physical function at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Duration of symptoms: Not stated (minimum 3 months) Presence of multimorbidities: Not stated/unclear		
Hayati 2018[75]	**Tape** (n=37) Medially directed patellar taping and NSAID (nimesulide 200mg/day) **Sham devices** (n=37) Sham taping and NSAID An additional group of tape without NSAIDs were reported – this was not included in the analysis as this would not make an adequate comparison compared to the other treatment arms. **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 52.4 (8.9) years N = 111 Definition: Previously diagnosed patellofemoral osteoarthritis with apparent osteophytes on radiography Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months	
Hinman 2003[79]	**Tape** (n=29) Therapeutic taping providing medial glide, medial tilt, and anteroposterior tilt to the patella **Sham device** (n=29) Control tape to provide sensory input only **No device intervention** (n=29) No additional information	**Knee osteoarthritis** Mean age (SD): 67.8 (8.6) years N = 87 Definition: Clinical and radiological classification criteria of the American College of Rheumatology (presence of osteophytes, age over 50 years, and pain in the knee)	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Concomitant therapy: People continued current treatment but weren't allowed to start any new ones.	Severity: Kellgren Lawrence grades 1-4 Duration of symptoms (mean [SD]): 9 (9.7) years Presence of multimorbidities: Not stated/unclear		
Hinman 2016[80]	**Shoes** (n=83) Commercially available unloading walking shoes with triple density midsoles (stiffer laterally with a mild 5-degree lateral wedge). Follow up for 6 months. **Sham devices** (n=81) Same instruction as the intervention group, but neutral walking shoe. **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean (SD): 64.3 (7.5) years N = 164 Definition: Clinical and radiographic knee osteoarthritis Severity: Radiographic severity grade 2-4, median grade 3. Duration of symptoms (mean [SD]): 9.3 (7.9) years Presence of multimorbidities: Not stated/unclear	Quality of life at >3 months Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months Number of adverse events at >3 months	
Hjartarson 2018[81]	**Braces** (n=74) Commercially available knee brace with dynamic force straps **Sham devices** (n=75) Same knee brace but without the dynamic force straps (removing functionality) **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 60.0 (7.5) years N = 150 Definition: Mild to moderate knee osteoarthritis with knee pain for more than 3 months, with arthroscopic or radiographic evidence of knee osteoarthritis	Quality of life at >3 months Pain at >3 months Physical function at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Severity: Mild-to-moderate Duration of symptoms: Not stated Presence of multimorbidities: Unclear/not stated		
Horlick 1993[82]	**Braces** (n=39) Custom-made brace designed by a brace company in Canada. This study included multiple braces (including a medial and lateral strap) and applying the brace in valgus and at neutral. These groups were pooled together for the analysis due to them falling within the same class, as specified in the protocol. **No device intervention** (n=39) No brace was provided. **Concomitant therapy:** Not reported	**Knee osteoarthritis** Mean age (range): lateral hinge group: 49 (33-65) years; medial hinge group: 46 (34-69) years. N = 39 Definition: Diagnosis of medial compartment gonarthrosis based on a history of medial joint line pain and physical examination findings of medial joint line tenderness plus clear radiographic evidence of medial joint compartment narrowing. Severity: Not stated/unclear Duration of symptoms: Not stated/unclear Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months	Double crossover trial
Jones 2012[92]	**Walking aids – Canes** (n=32) Wooden cane with a T-shaped handle **No device intervention** (n=32)	**Knee osteoarthritis** Mean age (SD): 62.1 (5.9) years N = 64	Quality of life at ≤3 months Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Waiting list control **Concomitant therapy:** No additional information	Definition: Diagnosis of knee osteoarthritis according to the American College of Rheumatology (no radiographic parameters reported). Severity: Not stated Duration of symptoms: 6.3 (3.4) years Presence of multimorbidities: Not stated/unclear		
Jones 2013[94]	**Orthotic devices – Insoles** (n=28) Laterally wedged insoles **Braces** (n=28) Off-the-shelf valgus knee brace **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 66.3 (8.2) years N = 28 Definition: Unilateral OA as diagnosed by a consultant orthopaedic surgeon with grade 2-3 Kellgren Lawrence changes Severity: Kellgren Lawrence grade 2-3 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/Unclear	Pain at ≤3 months Physical function at ≤3 months	Crossover study – Washout period of 2 weeks
Kaya mutlu 2017[96]	**Tape** (n=21) Kinesio taping **Sham device** (n=21)	**Knee osteoarthritis** Mean age (SD): 55.6 (6.3) years N = 42	Pain at ≤3 months Number of adverse events at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Placebo taping **Concomitant therapy:** No additional information	Definition: Clinically diagnosed (according to the American College of Rheumatology criteria) by an orthopaedic surgeon in the previous 3 months with grade of OA assessed by radiographic imaging Severity: Kellgren-Lawrence grades 2-4 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Kirkley 1999[99]	**Braces** (n=41) Generation II valgus-producing functional knee (unloader) brace **Supports – other supports** (n=38) Neoprene sleeve **No device intervention** (n=40) Educational pamphlet, instructions to use paracetamol for analgesia as required. **Concomitant therapy:** People taking NSAIDs at the time of presentation were asked to continue taking their medication as they had previously	**Knee osteoarthritis** Mean age: 59.2 years N = 119 Definition: Varus gonarthrosis seen by orthopaedic surgeons with clinical and radiographic evidence of the disease Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at >3 months Physical function at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
Koca 2009[100]	**Orthotic devices – Insoles** (n=19) Wedge insole **No device intervention** (n=18) No device intervention **Concomitant therapy:** Quadriceps strengthening exercises and paracetamol 1500mg/day	**Knee osteoarthritis** Mean age (SD): 55.1 (10.5) N = 37 Definition: Knee osteoarthritis according to the American College of Rheumatology criteria and classified as grade II and III according to the Kellgren Lawrence radiological grading Severity: Kellgren-Lawrence grade 2-3 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Physical function at ≤3 months	
Kocyigit 2015[101]	**Tape** (n=22) Kinesio taping **Sham device** (n=21) Sham taping with surgical hypoallergenic flexible taping in a different alignment **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 45 (15) years N = 41 Definition: Diagnosed as knee osteoarthritis according to clinical diagnostic criteria proposed by the American College of Rheumatology Severity: Mild-to-moderate Duration of symptoms: Not stated Presence of multimorbidities: Low comorbidity score (Tape group: 9 had no	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		comorbidities, 8 had 1 comorbidity, 4 had >1 comorbidities. Control group: 8 had no comorbidities, 8 had 1 comorbidity, 4 had >1 comorbidities).		
Lee 2016[102]	**Tape** (n=15) Kinesiology taping therapy **No device intervention** (n=15) Physical therapy only **Concomitant therapy:** Hot-pack treatment with surface heat for 20 minutes, as well as general physical therapy using interference wave therapy equipment at 100bps for 15 minutes	**Knee osteoarthritis** Mean age (SD): 72.6 (5.0) years N = 30 Definition: Diagnosed with degenerative knee arthritis based on clinical findings and with medical imaging such as X-rays Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months	
Leon-ballesteros 2020[104]	**Tape** (n=16) Kinesio taping with an elastic band quadriceps exercise programme **Sham device** (n=16) Sham taping with an exercise programme **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 58.1 (5.3) years N = 32 Definition: Bilateral knee osteoarthritis according to the European League Against Rheumatism (EULAR) criteria, classified as grade 2 or 3 by the radiographic scale of Kellgren and Lawrence	Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		Severity: Kellgren-Lawrence grade 2-3. Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Lewinson 2016[105]	**Orthotic devices – Insoles** (n=19) Usual footwear with laterally wedged insoles **No device intervention** (n=19) Usual footwear without any insoles **Concomitant therapy:** Allowed treatments included NSAID/paracetamol, physiotherapy/targeted exercise, compression/Tensor brace, narcotic medication and unloader braces. Corticosteroid injections were not permitted.	**Knee osteoarthritis** Mean age (SD): 59.8 (7.6) years N = 38 Definition: Confirmed diagnosis of unilateral or bilateral knee OA based on the American College of rheumatology criteria. They also were graded by the Kellgren-Lawrence severity grade. Severity: Kellgren-Lawrence grades 1-4 Duration of symptoms: Range between 0-≥10 years. Median value between 0-≤10 years. Presence of multimorbidities: Not stated/unclear	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	
Maillefert 2001[111]	**Orthotic devices – Insoles** (n=82) Bilateral laterally elevated (valgus) insoles **Sham devices** (n=74)	**Knee osteoarthritis** Mean age (SD): 64.8 (10.4) years N = 156	Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Bilateral neutrally wedged insoles **Concomitant therapy:** No additional information	Definition: Knee osteoarthritis fulfilling the American College of Rheumatology criteria with at least Kellgren and Lawrence grade 2 or more changes seen in the medial femorotibial region Severity: Kellgren-Lawrence grade 2-4 Duration of symptoms: 6 (6.5) years Presence of multimorbidities: Not stated/unclear		
Mcmanus 2021[115]	**Tape** (n=19) Rocktape applied at one week intervals for three weeks and worn during an individualised home exercise program. **Sham devices** (n=17) Hypafix sham tape applied at the same timings as the intervention group. **Concomitant therapy:** Individualised home exercise program including resistance exercises to be performed from three times per week to daily.	**Knee osteoarthritis** Mean age (SD): 69 (9) years N = 36 Definition: Diagnosis of knee osteoarthritis confirmed radiologically Severity: Kellgren Lawrence score majority grade 3/4. Duration of symptoms: Not stated/unclear. Presence of multimorbidities: Not stated/unclear	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	
Menz 2016[120]	**Orthotic devices – Shoes** (n=50) Rocker-shoe footwear	**Toe osteoarthritis** Mean age (SD): 56.8 (11.1) years N = 102	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Orthotic devices – Insoles (n=52) A pair of foot orthoses modified by adding a cut-out section beneath the first metatarsal and trimming the distal edge to the level of the second to fifth toe sulci. **Concomitant therapy:** People were permitted to use paracetamol (4 grams per day), All received an information handout discussing appropriate care and use of orthoses. No other therapy was allowed.	Definition: People with pain in the first metatarsophalangeal joint with the majority having radiological features Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Number of adverse events at ≤3 months	
Niazi 2014[132]	**Braces** (n=60) 3-point knee brace **Orthotic devices – Insoles** (n=60) Laterally wedged insoles **Concomitant therapy:** No additional information	**Knee osteoarthritis** Median age (range): 41-46 years (35-70 years) N = 120 Definition: Radiographic and clinical diagnosis of knee osteoarthritis (degenerative joint disease). Severity: Moderate to severe/Kellgren-Lawrence grades 2-4 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at >3 months Number of adverse events at >3 months	
Nigg 2006[134]	**Shoes** (n=58)	**Knee osteoarthritis**	Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Masai Barefoot Technology shoes. Gradually increased wear time up to wearing them for a full day. Follow up for 12 weeks. **Sham devices** (n=67) High-end walking shoes. **Concomitant therapy:** No additional information	Mean age (95% CI): Intervention = 57.9 (55.5-60.2) years, control = 57.4 (55.2-59.6) years N = 125 Definition: Idiopathic or secondary osteoarthritis of the knee; grades II-IV severity of osteoarthritis by radiographic evaluation using the modified Kellgren and Lawrence grading system Severity: Radiographic grade 2-4, median grade 3 Duration of symptoms: Not stated/unclear Presence of multimorbidities: Not stated/unclear	Physical function at ≤3 months	
Ogut 2018[135]	**Tape** (n=31) Kinesio taping **Sham device** (n=30) Sham taping (kinesio tape administered in incorrect positions) **Concomitant therapy:** All people were applied with a hot pack for 30 minutes, TENS for 30 minutes (100 Hz frequency and 60 milliseconds pulse duration), ultrasound	**Knee osteoarthritis** Mean age (SD): 53.5 (3.5) years N = 61 Definition: Knee osteoarthritis according to the American College of Rheumatology diagnostic criteria with Kellgren-Lawrence grade 2 or 3 severity. Severity: Kellgren-Lawrence grade 2-3	Pain at ≤3 months Physical function at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	therapy for 10 minutes (pulsed 1:1, 1 MHz frequency, and 1.5 W/cm2 intensity) and an isometric exercise program around the knee for a total of 15 sessions over a period of 3 weeks	Duration of symptoms: 26.2 (22.7) months Presence of multimorbidities: Not stated/unclear		
Oguz 2021[136]	**Tape** (n=11) Kinesio taping and usual care **No device intervention** (n=11) Usual care, consisting of exercise training which consisted of 6 weeks training with 3 days per week. **Concomitant therapy:** Both groups did 20 minute walking exercise as an acute loading before and after intervention.	**Knee osteoarthritis** Mean age (SD): Intervention : 48.18 (7.56) and control: 51.00 (3.69) years N = 22 Definition: Knee OA diagnosis according to the American College of Rheumatology, and Kellgren-Lawrence index II and III in class Severity: Kellgren Lawrence index II and III. Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Physical function at ≤3 months	
Paterson 2021[143]	**Shoes** (n=82) Commercially available flat flexible shoes worn for at least 6 hours per day. Follow up for 6 months. **Sham devices** (n=82) Commercially available stable supportive shoes worn for at	**Knee osteoarthritis** Mean (SD): 64.8 (7.3) years N = 164 Definition: Clinical and radiographic knee osteoarthritis	Quality of life at >3 months Pain at >3 months Physical function at >3 months Number of adverse events at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	least 6 hours per day. Follow up for 6 months. **Concomitant therapy:** No additional information	Severity: Radiographic Grade 3-4, median grade 4. Duration of symptoms (mean [SD]): 9.2 (7.5) years Presence of multimorbidities: Not stated/unclear		
Rannou 2009[151]	**Splints** (n=57) Rigid rest orthoses for use at night **No device intervention** (n=55) Usual care at the discretion of their physician **Concomitant therapy:** People in the study used paracetamol, paracetamol plus opioids, NSAIDs, symptomatic slow acting drugs in osteoarthritis or received no treatment.	**Thumb osteoarthritis** Mean age (SD): 63.3 (7.8) years N = 112 Definition: Pain at the base of the thumb with radiographic evidence of at least 2 of 4 radiographic items and at least 1 of 2 clinical items Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months	
Reichenbach 2020[152]	**Orthotic devices – shoes** (n=111) Biomechanical footwear device. **Sham devices** (n=109) **Concomitant therapy:** The participants were asked to discontinue their regular pain medication and advised that other interventions, such as	**Knee osteoarthritis** Mean age (SD): 65.2 (9.3) years N = 220 Definition: Symptomatic, radiologically confirmed knee osteoarthritis according to criteria from the American College of Rheumatology.	Quality of life at ≤3 months and >3 months Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months Number of adverse events at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	physical therapy, should be avoided during the trial. They were permitted daily therapy as needed with paracetamol at a maximum dose of 2 grams and the amounts taken were recorded at each visit.	Severity: Kellgren Lawrence grade 2-4, median grade 3 Duration of symptoms: Not stated/unclear Presence of multimorbidities: Not stated/unclear		
Rodrigues 2008[155]	**Orthotic devices – Insoles** (n=16) Insole and ankle brace with a raised wedge on the insole **Sham device** (n=14) Insole and ankle brace with a neutral insole **Concomitant therapy:** NSAIDs and analgesics or slow-acting drugs were allowed if prescribed at least 4 weeks and 8 weeks prior respectively	**Knee osteoarthritis** Mean age (SD): 61.7 (11.4) years N = 30 Definition: People fulfilling the American College of Rheumatology criteria for knee osteoarthritis with radiographic grading by the Kellgren and Lawrence criteria Severity: Kellgren-Lawrence grades 2-4 Duration of symptoms: 4.9 (3.9) years Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Number of adverse events at ≤3 months	
Salam 2019[156]	**Orthotic device – insoles** (n=20) Lateral wedges worn during the day as well as usual care provided to both study arms. **No device intervention** (n=20)	**Knee osteoarthritis** Age range: 40-60 years N = 40 Definition: Clinical and radiological diagnosis of OA.	Quality of life at ≤3 months Pain at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Usual care provided to both study arms **Concomitant therapy:** Conventional physical therapy ultrasound, SWD and quadriceps isomeric exercises 5 times a week up to 6 weeks. The duration of each session was 35 minutes.	Severity: Radiographic grade I/III Duration of symptoms: not reported Presence of multi-morbidities: other systemic conditions were excluded		
Sattari 2011[157]	**Braces** (n=20) Three point knee brace applied on and off every 2-3 hours for 1 week, then for as long as possible during the day subsequently. **Orthotic devices – Insoles** (n=20) Lateral wedge insoles whenever they wear shoes **No device intervention** (n=20) Conservative care only **Concomitant therapy:** Conservative management consisted of activity modification, heating agents at home, straight leg raising and isometric quadriceps home	**Knee osteoarthritis** Mean age (range): 48 (35-65) years N = 60 Definition: Moderate to severe medial compartment degenerative joint disease defined by knee pain and genu varum based on radiographic evidence Severity: Moderate to severe (Kellgren-Lawrence grades 3-4) Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	exercises, and analgesics when needed			
Silva 2020[161]	**Splints** (n=26) Worn every night for 6 months. Plus usual care provided to both study arms. **No device intervention** (n=26) Usual care provided to both study arms. **Concomitant therapy:** All participants participated in an educational programme on hand OA (three 40 minute sessions providing information about the disease, its symptoms, medical treatments, joint protection and energy conservation.)	**Hand osteoarthritis** Mean age (SD): Orthosis group: 64.1 (8.4) years, control group: 63.5 (7.8) years N = 52 Definition: ACR criteria Severity (AUSCAN pain at baseline): orthosis group: 10.6 (4.1), control group: 9.4 (3.8) Duration (years): orthosis group: 8.2 (3.8), control group: 6.1 (4.6) Presence of multi-morbidities: not reported	Pain at ≤3 months and >3 months Physical function at ≤3 months and >3 months	
Taheri 2017[167]	**Tape** (n=22) Taping in three consecutive weeks **No device intervention** (n=22) Standard care only **Concomitant therapy:** All people received exercise and drug therapy. Exercise included three consecutive sessions of stretching the hamstring and calf muscles (holding stretch for 30 seconds, repeating the stretch	**Knee osteoarthritis** Mean age (SD): 56.3 (6.4) years N = 44 Definition: Knee pain diagnosed as knee osteoarthritis with radiological grade 2 to 3 Severity: Kellgren-Lawrence grade 2-3.	Pain at ≤3 months Number of adverse events at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	throughout the session at least 5 times, three sessions per day), and strengthening quadriceps muscles (holding contraction of muscle for 10s, repeating it throughout the session at least 5 times, three sessions per day). The volume and frequency of the exercise was checked by self-reported diary. Drug therapy in both groups including celecoxib (100mg 1-3 capsules per day according to pain severity). People were prohibited from taking any other analgesics during the study	Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear		
Tan 2019[168]	**Orthotic devices – insoles** (n=13) Commercially available foot orthoses. **Sham devices** (n=13) Flat insert, similar in appearance to the foot orthoses. **Concomitant therapy:** Rescue medication was permitted (e.g. paracetamol) and co-interventions to relieve pain were documented with a daily log-book.	**Knee osteoarthritis** Mean age (SD): 60 (8) years N = 26 Definition: Clinical diagnosis without imaging Severity (usual pain VAS, 0-100mm): foot orthoses group: 31 (13), flat inserts group: 56 (29) Duration of pain (n): 3-6 months (2), 6-12 months (0), 1-2 years (2), ≥2 years (22) Presence of multi-morbidities: other systemic conditions were excluded	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	
Thoumie 2018[172]	**Braces** (n=32)	**Knee osteoarthritis**	Pain at ≤3 months	ROTOR trial

Study	Intervention and comparison	Population	Outcomes	Comments
	Unloading knee brace for at least 6 hours daily **No device intervention** (n=35) Usual care only **Concomitant therapy:** All people received analgesics (paracetamol and NSAIDs), daily exercise programs as recommended by the French Society of Rheumatology, and patient information (as per OARSI guidance)	Mean age (SD): 65.7 (9.7) years N = 67 Definition: People with symptomatic medial knee OA defined by pain according to American College of Rheumatology Criteria, and based on radiological findings within the previous 24 months. Severity: Kellgren-Lawrence grades 2-4 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Number of adverse events at ≤3 months	
Van Ginckle 2019[186]	**Walking aids** (n=40) Generic “swan neck” cane for 3 months **No device intervention** (n=39) Usual care only. **Concomitant therapy:** Both groups were allowed to continue regular medication for knee pain.	**Knee osteoarthritis** Mean age (SD): 66.1 (7.3) years N = 79 Definition: Knee pain on most days for the past month and radiographic evidence of medial tibiofemoral osteoarthritis (Kellgren Lawrence grade at least 2 and Osteoarthritis Research Society grade at least 1 medial joint space narrowing and greater than lateral), at	Quality of life at ≤3 months Pain at ≤3 months Physical function at ≤3 months Number of adverse events at ≤3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
		least one medial tibiofemoral bone marrow lesion on MRI. Severity: Kellgren-Lawrence grade 2-4 (median grade 3). Duration of symptoms: 8.4 (9.0) years Presence of multimorbidities: High multimorbidity (most people appeared to have a comorbidity)		
Van raaij 2010[187]	**Orthotic devices – Insoles** (n=45) Custom made lateral wedge insole **Braces** (n=46) Commercially available valgus knee brace **Concomitant therapy:** No additional information	**Knee osteoarthritis** Mean age (SD): 54.7 (7.0) years N = 91 Definition: Symptomatic medial compartmental knee osteoarthritis (diagnosed when there was pain and tenderness in combination with osteoarthritis signs according to the Kellgren-Lawrence system of grade 1 or higher were located over the medial tibiofemoral compartment of the knee). Severity: Kellgren-Lawrence grade 1-4 Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at >3 months Physical function at >3 months Number of adverse events at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
Wade 2018[189]	**Tape** (n=6) Tape applied to the dorsum of the symptomatic proximal interphalangeal joint **Sham device** (n=5) Tape applied in a manner that should deliver no analgesic effect **Concomitant therapy:** No additional information	**Finger osteoarthritis** Mean age (SD): 62.4 (8.4) years N = 11 Definition: Established diagnosis of chronic osteoarthritis of the proximal interphalangeal joint of any finger based on both symptoms and radiographic changes Severity: Not stated Duration of symptoms: Not stated Presence of multimorbidities: Not stated/unclear	Pain at ≤3 months Osteoarthritis flares at ≤3 months	
Wyndow 2020[196]	**Orthotic devices – insoles** (n=24) Customised foot orthoses plus standardised footwear **No device intervention** (n=22) Standardised footwear **Concomitant therapy:** All participants received an education package outlining wearing-in procedures. General information on OA and advice regarding management of the condition was provided	**Knee osteoarthritis** Mean age (SD): Orthosis + footwear group: 58 (10) years, footwear group: 56 (10) years N = 46 Definition: Radiographic evidence of PF OA, including joint space narrowing and/or presence of ostephytes (K-L≥ grade1) plus clinical examination by a registered podiatrist. Severity: K-L grade ≥1 but not ≥3	Quality of life at ≤3 months and >3 months Pain at ≤3 months and >3 months Psychological distress at ≤3 months and >3 months Number of adverse events at >3 months	

Study	Intervention and comparison	Population	Outcomes	Comments
	Participants were permitted to continue use of their normal medications	Duration: FO+footwear group: 3-6 months: 1, 6-12 months: 2, 1-2 years: 2, >2 years: 19; footwear group: 3-6 months: 2, 6-12 months: 0, 1-2 years: 1, >2 years: 19 Presence of multimorbidities: Not stated/unclear		
Yamamoto 2019[199]	**Brace** (n=30) Patellofemoral functional brace worn for up to a maximum of 12 hours/ day. **Sham devices** (n=30) Knee brace with a patellar orifice worn for up to a maximum of 12 hours/ day. **Concomitant therapy:** Pain relief as required. All patients attended a half day course on OA and its forms of treatment base on an OA disease group educational programme for patients with knee OA.	**Knee osteoarthritis** Mean age (SD): 64.2 (7.8) years N = 60 Definition: The diagnosis of patellofemoral osteoarthritis was made using the clinical criteria of the American College of Rheumatology Severity (WOMAC pain at baseline): 8.5 (4) vs. 9.1 (3.3)/ Kellgren Lawrence grades II/III excluded. Duration: participants had been receiving treatment for knee OA for >6 months. Presence of multi-morbidities: other systemic conditions were excluded	Pain at ≤3 months Physical function at ≤3 months	

See Appendix D for full evidence tables.

1.1.5.1 Summary matrices

Table 3: Matrix of comparisons for the knee osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Orthotic devices: Insoles	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	1 GRADE Outcome (2 studies) N=80 Very low	1 GRADE Outcome (1 study) N=56 Moderate	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	1 GRADE Outcome (3 studies) N=188 Low	4 GRADE Outcomes (9 studies) N=898 High-Low	2 GRADE Outcomes (6 studies) N=512 Very low	No evidence identified	No evidence identified	1 GRADE Outcome (4 studies) N=286 Very low
	No device intervention	2 GRADE Outcome (3 studies) N=104 Very low	1 GRADE Outcome (5 studies) N=199 Very low	1 GRADE Outcome (3 studies) N=120 Very low	2 GRADE Outcomes (1 study) N=35 Very low	No evidence identified	1 GRADE Outcome (1 study) N=33 Low

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Orthotic devices: Shoes	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	2 GRADE Outcomes (1 study) N=220 Moderate	2 GRADE Outcomes (3 studies) N=499 High	2 GRADE Outcomes (3 studies) N=499 High	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Braces	Orthotic devices: Insoles	No evidence identified	1 GRADE Outcome (2 studies) N=80 Very low	1 GRADE Outcome (1 study) N=56 Moderate	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	1 GRADE Outcome (1 study) N=57 Very low	1 GRADE Outcome (1 study) N=57 Very low	No evidence identified	No evidence identified	No evidence identified
	No device intervention	1 GRADE Outcome (1 study) N=117 Very low	1 GRADE Outcome (4 studies) N=388 Very low	No evidence identified	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=67 Low
Splints	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Supports	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Straps/tape	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
	Sham intervention	4 GRADE Outcomes (3 studies) N=135 Low-Very low	3 GRADE Outcomes (7 studies) N=317 Moderate-Low	1 GRADE Outcome (4 studies) N=181 Moderate	No evidence identified	No evidence identified	1 GRADE Outcome (4 studies) N=109 Low
	No device intervention	4 GRADE Outcomes (2 studies) N=112 Very low	2 GRADE Outcomes (6 studies) N=240 Low-Very low	2 GRADE Outcomes (2 studies) N=112 Low-Very low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=44 Low
Walking aids	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	9 GRADE Outcomes (2 study) N=138 Moderate-Very low	2 GRADE Outcomes (2 study) N=138 Moderate-Low	1 GRADE Outcome (1 study) N=79 Low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=79 Low

Table 4: Matrix of comparisons for the knee osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Orthotic devices: Insoles	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	1 GRADE Outcome (3 studies) N=245 Very low	1 GRADE Outcome (1 study) N=91 Low	No evidence identified	No evidence identified	1 GRADE Outcome (2 studies) N=205 Moderate
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	1 GRADE Outcome (1 study) N=179 High	2 GRADE Outcomes (4 studies) N=388 High-Very low	2 GRADE Outcomes (3 studies) N=330 Low-Very low	No evidence identified	No evidence identified	1 GRADE Outcome (2 studies) N=227 Moderate
	No device intervention	1 GRADE Outcome (1 study) N=33 Very low	1 GRADE Outcome (2 studies) N=79 Very low	No evidence identified	2 GRADE Outcomes (1 study) N=38 Very low	No evidence identified	1 GRADE Outcome (1 study) N=46 Very low

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Orthotic devices: Shoes	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	3 GRADE Outcomes (3 studies) N=541 High-Moderate	2 GRADE Outcomes (4 studies) N=596 High-Very low	2 GRADE Outcomes (4 studies) N=596 High-Low	No evidence identified	No evidence identified	1 GRADE Outcome (3 studies) N=548 Very low
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Braces	Orthotic devices: Insoles	No evidence identified	1 GRADE Outcome (3 studies) N=245 Very low	1 GRADE Outcome (1 study) N=91 Low	No evidence identified	No evidence identified	1 GRADE Outcome (2 studies) N=205 Moderate
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Supports	No evidence identified	1 GRADE Outcome (1 study) N=77 Very low	1 GRADE Outcome (1 study) N=77 Very low	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	1 GRADE Outcome (1 study) N=86 Very low	1 GRADE Outcome (1 study) N=86 Very low	1 GRADE Outcome (1 study) N=86 Very low	No evidence identified	No evidence identified	No evidence identified
	No device intervention	1 GRADE Outcome (1 study) N=117 Very low	2 GRADE Outcomes (3 studies) N=231 Very low	1 GRADE Outcome (1 study) N=74 Very low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=67 Low
Splints	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Supports	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	1 GRADE Outcome (1 study) N=77 Very low	1 GRADE Outcome (1 study) N=77 Very low	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	1 GRADE Outcome (1 study) N=69 Very low	1 GRADE Outcome (1 study) N=69 Very low	No evidence identified	No evidence identified	No evidence identified
Straps/tape	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Walking aids	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 5: Matrix of comparisons for the thumb osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Splints	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	1 GRADE Outcome (1 study) N=171 Low	1 GRADE Outcome (1 study) N=174 High	1 GRADE Outcome (1 study N=171 High	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=233 Low
	No device intervention	No evidence identified	1 GRADE Outcome (4 studies) N=201 Very low	3 GRADE Outcomes (4 studies) N=201 Moderate-Low	No evidence identified	No evidence identified	No evidence identified

Table 6: Matrix of comparisons for the thumb osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Splints	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	1 GRADE Outcome (1 study) N=97 Low	1 GRADE Outcome (1 study) N=95 Low	No evidence identified	No evidence identified	No evidence identified

Table 7: Matrix of comparisons for the hand osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Splints	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	1 GRADE Outcome (1 study)	1 GRADE Outcome (1 study)	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
			N=52 Very low	N=52 Very low			
Straps/tape	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	1 GRADE Outcome (1 study) N=38 Low	1 GRADE Outcome (1 study) N=38 Low	No evidence identified	No evidence identified	No evidence identified

Table 8: Matrix of comparisons for the hand osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Splints	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	No device intervention	No evidence identified	1 GRADE Outcome (1 study) N=52 Very low	1 GRADE Outcome (1 study) N=52 Very low	No evidence identified	No evidence identified	No evidence identified
Straps/tape	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 9: Matrix of comparisons for the finger osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Straps/tape	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
	Sham intervention	No evidence identified	1 GRADE Outcome (1 study) N=10 Very low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=10 Very low	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 10: Matrix of comparisons for the finger osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Straps/tape	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 11: Matrix of comparisons for the foot osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at ≤3 months	Pain at ≤3 months	Physical function at ≤3 months	Psychological distress at ≤3 months	Osteoarthritis flare-ups at ≤3 months	Number of adverse events at ≤3 months
Orthotic devices: Insoles	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	1 GRADE Outcome (1 study) N=36 Very low	1 GRADE Outcome (1 study) N=36 Very low	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 12: Matrix of comparisons for the foot osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Orthotic devices: Insoles	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 13: Matrix of comparisons for the toe osteoarthritis stratum at ≤3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Orthotic devices: Insoles	Orthotic devices: Shoes	2 GRADE Outcomes (1 study) N=98 Moderate-Low	1 GRADE Outcome (1 study) N=98 Moderate	1 GRADE Outcome (1 study) N=98 Low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=98 Moderate
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Orthotic devices: Shoes	Orthotic devices: Insoles	2 GRADE Outcomes (1 study) N=98 Moderate-Low	1 GRADE Outcome (1 study) N=98 Moderate	1 GRADE Outcome (1 study) N=98 Low	No evidence identified	No evidence identified	1 GRADE Outcome (1 study) N=98 Moderate
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Table 14: Matrix of comparisons for the toe osteoarthritis stratum at >3 months

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
Orthotic devices: Insoles	Orthotic devices: Shoes	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

Intervention	Control	Quality of life at >3 months	Pain at >3 months	Physical function at >3 months	Psychological distress at >3 months	Osteoarthritis flare-ups at >3 months	Number of adverse events at >3 months
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
Orthotic devices: Shoes	Orthotic devices: Insoles	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Braces	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Splints	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Supports	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Straps/tape	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Walking aids	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	Sham intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified
	No device intervention	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified	No evidence identified

1.1.6 Summary of the effectiveness evidence

Knee osteoarthritis

Table 15: Clinical evidence summary: insoles compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with insoles	
Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months	188 (3 RCTs) follow up: mean 8 weeks	⊕⊕◯◯ LOW [a]	-	-	MD **1.99 higher** (2.17 lower to 6.15 higher)	MID = 7.25 (0.5 x median baseline SD)
Quality of life (assessment of quality of life instrument, -0.04-1.00, high is good, change score) at >3 months	179 (1 RCT) follow up: 12 months	⊕⊕⊕⊕ HIGH	-	The mean quality of life was -0.01	MD **0.01 lower** (0.05 lower to 0.03 higher)	MID = 0.5 SD (SMD)
Pain (VAS, 0-100, high is poor, change score, parallel trial) at ≤3 months	118 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a]	-	The mean pain was -6.25	MD **23.05 lower** (28.31 lower to 17.79 lower)	MID = 0.5 SD (SMD)
Pain (KOOS, WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months	358 (6 RCTs) follow up: mean 8 weeks	⊕⊕◯◯ LOW [a,b]	-	-	SMD **0.04 SD higher** (0.37 lower to 0.44 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC, 0-500, high is poor, change score, crossover trial) at ≤3 months	180 (1 RCT) follow up: 6 weeks	⊕⊕⊕⊕ HIGH	-	-	MD **14.5 higher** (23.1 lower to 52.1 higher)	MID = 0.5 SD (SMD)
Pain (KOOS, 0-100, high is good, final value, crossover trial) at <3 months	124 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a]	-	The mean pain was 58.82	MD **1.84 higher** (2.83 lower to 6.51 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with insoles	
Pain (WOMAC, VAS [different scale ranges], high is poor, final values) at >3 months	209 (3 RCTs) follow up: mean 14 months	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **0.33 SD higher** (0.22 lower to 0.89 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC, 0-20, high is poor, change score) at >3 months	179 (1 RCT) follow up: 12 months	⊕⊕⊕⊕ HIGH	-	The mean pain was -1.2	MD **0.5 higher** (0.35 lower to 1.35 higher)	MID = 0.5 SD (SMD)
Physical function (KOOS, WOMAC, 0-100, high is poor, final values) at ≤3 months	335 (4 RCTs) follow up: mean 10 weeks	⊕⊕◯◯ VERY LOW [a,b]	-	-	MD **1.19 higher** (6.9 lower to 4.52 higher)	MID = 9.5 (0.5 x median baseline SD)
Physical function (WOMAC, Edinburgh Knee Function Scale [different scale ranges], high is poor, change scores) at ≤3 months	177 (2 RCTs) follow up: mean 6 weeks	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **0.36 SD lower** (2.82 lower to 2.1 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC, 0-100, high is poor, final value) at >3 months	106 (1 RCT) follow up: 2 years	⊕⊕◯◯ LOW [a]	-	The mean physical function was 50.4	MD **0.4 lower** (9.47 lower to 8.67 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC [different scale ranges], high is poor, change scores) at >3 months	224 (2 RCTs) follow up: mean 12 months	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **0.61 SD lower** (1.36 lower to 0.13 higher)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	286 (4 RCTs) follow up: mean 6 weeks	⊕◯◯◯ VERY LOW [a,b,c]	RR 1.05 (0.44 to 2.52)	177 per 1,000	**9 more per 1,000** (99 fewer to 270 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with insoles	
Number of adverse events at >3 months	227 (2 RCTs) follow up: mean 12 months	⊕⊕⊕◯ MODERATE [a]	RR 2.15 (1.40 to 3.30)	183 per 1,000	**210 more per 1,000** (73 more to 420 more)	MID (precision) = RR 0.8-1.25.

[a]. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b]. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

[c]. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 16: Clinical evidence summary: insoles compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with insoles	
Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months	73 (2 RCTs) follow up: mean 9 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 32.5	MD **24.13 higher** (11 lower to 59.26 higher)	MID = 6.94 (0.5 x median baseline SD)
Quality of life (EQ-5D VAS total score, 0-100, high is good, final values) at ≤3 months	31 (1 RCT) follow up: 8 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean quality of life was 86	MD **6 lower** (14.18 lower to 2.18 higher)	MID = 0.5 SD (SMD)
Quality of life (EQ-5D VAS total score, 0-100, high is good, final values) at >3 months	33 (1 RCT) follow up: 16 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean quality of life was 84	MD **4 lower** (18.34 lower to 10.34 higher)	MID = 0.5 SD (SMD)
Pain (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months	199 (5 RCTs)	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **1 SD lower**	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with insoles	
	follow up: mean 9 weeks				(2.02 lower to 0.02 higher)	
Pain (KOOS, VAS, 0-10, high is good, final values) at >3 months	79 (2 RCTs) follow up: mean 7 months	⊕◯◯◯ VERY LOW [a,b,c]	-	The mean pain was 62.5	MD **7.89 higher** (9.66 lower to 25.44 higher)	MID = 7.7 (0.5 x median baseline SD)
Physical function (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months	120 (3 RCTs) follow up: mean 10 weeks	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **0.79 SD lower** (1.67 lower to 0.1 higher)	MID = 0.5 SD (SMD)
Psychological distress (HADS anxiety, 0-21, high is poor, final value) at ≤3 months	35 (1 RCT) follow up: 8 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean psychological distress was 2.8	MD **2 higher** (0.22 lower to 4.22 higher)	MID = 0.5 SD (SMD)
Psychological distress (HADS depression, 0-21, high is poor, final value) at ≤3 months	35 (1 RCT) follow up: 8 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean psychological distress was 1.7	MD **0.9 higher** (0.69 lower to 2.49 higher)	MID = 0.5 SD (SMD)
Psychological distress (HADS anxiety, 0-21, high is poor, final value) at >3 months	38 (1 RCT) follow up: 16 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean psychological distress was 4	MD **0.6 higher** (1.88 lower to 3.08 higher)	MID = 0.5 SD (SMD)
Psychological distress (HADS depression, 0-21, high is poor, final value) at >3 months	38 (1 RCT) follow up: 16 weeks	⊕◯◯◯ VERY LOW [a,c]	-	The mean psychological distress was 2.4	MD 0.**2 lower** (2.27 lower to 1.87 higher)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	33 (1 RCT) follow up: 12 weeks	⊕⊕◯◯ LOW [a]	RR 2.60 (1.31 to 5.15)	333 per 1,000	**533 more per 1,000** (103 more to 1,383 more)	MID (precision) = RR 0.8-1.25.

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with insoles	
Number of adverse events at >3 months	46 (1 RCT) follow up: 16 weeks	⊕◯◯◯ VERY LOW [a,c]	RR 0.46 (0.04 to 4.71)	91 per 1,000	**49 fewer per 1,000** (87 fewer to 337 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 17: Clinical evidence summary: shoes compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with shoes	
Quality of life (SF-36 physical component, 0-100, high is good, final values) at ≤3 months	220 (1 RCT) follow-up: 12 weeks	⊕⊕⊕◯ MODERATE[a]	-	The mean quality of life was 43.8	MD **0.7 lower** (2.67 lower to 1.27 higher)	MID = 2 (established value)
Quality of life (SF-36 mental component, 0-100, high is good, final values) at ≤3 months	220 (1 RCT) follow-up: 12 weeks	⊕⊕⊕◯ MODERATE[a]	-	The mean quality of life was 44.5	MD **1.4 higher** (0.64 lower to 3.44 higher)	MID = 3 (established value)
Quality of life (AQoL-6D, -0.04-1, high is good, change scores) at >3 months	321 (2 RCTs) follow-up: mean 6 months	⊕⊕⊕⊕ HIGH	-	The mean quality of life was 0 (change score)	MD **0** (0.02 lower to 0.03 higher)	MID = 0.05 (0.5 x median baseline SD)
Quality of life (SF-36 physical component, 0-100, high is good, final values) at >3 months	220 (1 RCT)	⊕⊕⊕◯ MODERATE[a]	-	The mean quality of life was 44.5	MD **1.4 higher** (0.64 lower to 3.44 higher)	MID = 2 (established value)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with shoes	
	follow-up: 24 weeks					
Quality of life (SF-36 mental component, 0-100, high is good, final values) at >3 months	220 (1 RCT) follow-up: 24 weeks	⨁⨁⨁⨁ HIGH	-	The mean quality of life was 56	MD **0.8 higher** (1.3 lower to 2.9 higher)	MID = 3 (established value)
Pain (WOMAC [different scale ranges], high is poor, change scores) at ≤3 months	279 (2 RCTs) follow-up: mean 12 weeks	⨁⨁⨁⨁ HIGH	-	-	SMD **0.03 SD lower** (0.26 lower to 0.21 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC, 0-10, high is poor, final value) at ≤3 months	220 (1 RCT) follow-up: 12 weeks	⨁⨁⨁⨁ HIGH	-	The mean pain was 2.6	MD **0.3 lower** (0.81 lower to 0.21 higher)	MID = 0.5 SD (SMD)
Pain (KOOS, WOMAC [different scale ranges], high is poor, change scores) at >3 months	321 (2 RCTs) follow-up: mean 6 months	⨁⨁⨁⨁ HIGH	-	-	SMD **0.05 SD higher** (0.17 lower to 0.27 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC [different scale ranges], high is poor, final values) at >3 months	275 (2 RCTs) follow up: mean 38 weeks	⨁◯◯◯ VERY LOW[a,b]	-	The mean pain was 11.4	SMD **0.48 SD lower** (1.12 lower to 0.17 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC [different scale ranges], high is poor, change scores) at <3 months	279 (2 RCTs) follow-up: mean 12 weeks	⨁⨁⨁⨁ HIGH	-	-	SMD **0.01 SD higher** (0.22 lower to 0.25 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC, 0-10, high is poor, final value) at ≤3 months	220 (1 RCT) follow-up: 12 weeks	⨁⨁⨁⨁ HIGH	-	The mean physical function was 2.5	MD **0.4 lower** (0.86 lower to 0.06 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with shoes	
Physical function (WOMAC, 0-68, high is poor, change scores) at >3 months	321 (2 RCTs) follow-up: mean 6 months	⊕⊕⊕⊕ HIGH	-	The mean physical function was -7	MD **0.92 higher** (1.61 lower to 3.45 higher)	MID = 5.2 (0.5 x median baseline SD)
Physical function (WOMAC [different scale ranges], high is poor, final value) at >3 months	275 (2 RCTs) follow up: mean 38 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean physical function was 39.2	SMD **0.45 SD lower** (0.94 lower to 0.05 higher)	MID = 0.5 SD (SMD)
Number of adverse events at >3 months	548 (3 RCTs) follow-up: mean 26 weeks	⊕◯◯◯ VERY LOW[a,b]	RR 1.19 (0.62 to 2.31)	257 per 1,000	**49 more per 1,000** (98 fewer to 337 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 18: Clinical evidence summary: braces compared to insoles

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with insoles	Risk difference with braces	
Pain (WOMAC, VAS, 0-100, high is poor, final values) at ≤3 months	80 (2 RCTs) follow up: mean 4 weeks	⊕◯◯◯ VERY LOW [a,b]	-	-	MD **1.29 lower** (5.92 lower to 3.34 higher)	MID = 3.9 (0.5 x median baseline SD)
Pain (VAS, 0-10, high is poor, change score and final values) at >3 months	245 (3 RCTs) follow up: mean 8 months	⊕◯◯◯ VERY LOW [a,b]	-	The mean pain was 3.2	MD **0.64 lower** (1.06 lower to 0.22 lower)	MID = 0.8 (0.5 x median baseline SD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with insoles	Risk difference with braces	
Physical function (WOMAC, 0-100, high is poor, final values) at ≤3 months	56 (1 RCT) follow up: 8 weeks	⊕⊕⊕◯ MODERATE [b]	-	The mean physical function was 47.2	MD **0.5 lower** (7.91 lower to 6.91 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC, 0-100, high is good, change score) at >3 months	91 (1 RCT) follow up: 6 months	⊕⊕◯◯ LOW [a]	-	The mean physical function was 4.2	MD **0.2 lower** (7.56 lower to 7.16 higher)	MID = 0.5 SD (SMD)
Number of adverse events at >3 months	205 (2 RCTs) follow up: 6 months	⊕⊕⊕◯ MODERATE [a]	Peto OR 8.52 (2.97 to 24.45)	0 per 1,000	**140 fewer per 1,000** (220 fewer to 70 fewer) [c]	MID (precision) = Peto OR 0.8-1.25.

[a]. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b]. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

[c]. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

Table 19: Clinical evidence summary: braces compared to supports

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with supports	Risk difference with braces	
Pain (WOMAC, 0-500, high is poor, change score) at >3 months	77 (1 RCT) follow up: 6 months	⊕◯◯◯ VERY LOW [a,b]	-	The mean pain was -13.1	MD **30.1 lower** (47.33 lower to 12.87 lower)	MID = 0.5 SD (SMD)
Physical function (WOMAC, high is poor, change score) at >3 months	77 (1 RCT)	⊕◯◯◯ VERY LOW [a,b]	-	The mean physical function was -68.9	MD **88.3 lower** (145.2 lower to 31.4 lower)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with supports	Risk difference with braces	
	follow up: 6 months					

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 20: Clinical evidence summary: braces compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with braces	
Quality of life (KOOS, 0-100, high is good, change score) at >3 months	86 (1 RCT) follow up: 12 months	⊕◯◯◯ VERY LOW a,b	-	The mean quality of life was -2.7	MD **6.2 higher** (0.07 lower to 12.47 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC, 0-20, high is poor, final value) at ≤3 months	57 (1 RCT) follow-up: 3 months	⊕◯◯◯ VERY LOW a,b	-	The mean pain was 6.4	MD **0.1 higher** (2.13 lower to 2.33 higher)	MID = 0.5 SD (SMD)
Pain (KOOS, 0-100, high is good, change score) at >3 months	86 (1 RCT) follow up: 12 months	⊕◯◯◯ VERY LOW a,b	-	The mean pain was 2.6	MD **5.1 higher** (0.74 higher to 9.46 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC, 0-68, high is poor, final value) at ≤3 months	57 (1 RCT) follow-up: 3 months	⊕◯◯◯ VERY LOW a,b	-	The mean physical function was 26.4	MD **3.5 lower** (11.21 lower to 4.21 higher)	MID = 0.5 SD (SMD)
Physical function (KOOS, 0-100, high is good, change score) at >3 months	86 (1 RCT)	⊕◯◯◯ VERY LOW a,b	-	The mean physical function was 1.8	MD **8 higher** (2.74 higher to 13.26 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with braces	
	follow up: 12 months					

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 21: Clinical evidence summary: braces compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with braces	
Quality of life (EQ-5D, 0-1, high is good, mean difference) at ≤3 months	117 (1 RCT) follow up: 12 weeks	⊕◯◯◯ VERY LOW a,b	-	-	MD **0.03 higher** (0.05 lower to 0.11 higher)	MID = 0.03 (established value)
Quality of life (EQ-5D, 0-1, high is good, mean difference) at >3 months	117 (1 RCT) follow up: 12 months	⊕◯◯◯ VERY LOW a,b	-	-	MD **0.01 higher** (0.08 lower to 0.1 higher)	MID = 0.03 (established value)
Quality of life (KOOS, 0-100, high is good, change score) at >3 months	121 (1 RCT) follow up: 12 months	⊕◯◯◯ VERY LOW a,b	-	The mean quality of life was 8.1	MD **7.9 higher** (0.18 higher to 15.62 higher)	MID = 0.5 SD (SMD)
Pain (KOOS, VAS, 0-100, high is poor, final values and change score, parallel and crossover trials) at ≤3 months	388 (4 RCTs) follow up: mean 8 weeks	⊕◯◯◯ VERY LOW a,b,c	-	-	MD **12.74 lower** (23.47 lower to 2.01 lower)	MID = 9.2 (0.5 x median baseline SD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with braces	
Pain (KOOS, WOMAC [different scale ranges], high is poor, change scores) at >3 months	195 (2 RCTs) follow up: mean 9 months	⊕◯◯◯ VERY LOW [a,b]	-	-	SMD **0.6 SD lower** (0.89 lower to 0.31 lower)	MID = 0.5 SD (SMD)
Pain (VAS, 0-10, high is poor, final value and change score) at >3 months	157 (2 RCTs) follow up: mean 11 months	⊕◯◯◯ VERY LOW [a,b,c]	-	-	MD **1.82 lower** (3.77 lower to 0.13 higher)	MID = 0.9 (0.5 x median baseline SD)
Pain (WOMAC, 0-500, high is poor, change score) at >3 months	74 (1 RCT) follow up: 6 months	⊕◯◯◯ VERY LOW [a,b]	-	The mean pain was 13.1	MD **56.3 lower** (88.48 lower to 24.12 lower)	MID = 0.5 SD (SMD)
Physical function (KOOS, WOMAC[different scale ranges], high is poor, change score) at >3 months	195 (2 RCTs) follow up: mean 9 months	⊕◯◯◯ VERY LOW [a,b]	-	-	SMD **0.52 SD lower** (0.8 lower to 0.23 lower)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	67 (1 RCT) follow up: 6 weeks	⊕⊕◯◯ LOW [a,b]	RR 3.65 (1.10 to 12.08)	86 per 1,000	**227 more per 1,000** (9 more to 950 more)	MID (precision) = RR 0.8-1.25.
Number of adverse events at >3 months	121 (1 RCT) follow up: 12 months	⊕◯◯◯ VERY LOW [a,b]	RR 1.02 (0.07 to 15.88)	16 per 1,000	**0 fewer per 1,000** (15 fewer to 244 more)	MID (precision) = RR 0.8-1.25. MID (clinical importance): 50 per 1,000.

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 22: Clinical evidence summary: supports compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with supports	
Pain (WOMAC pain subscale, 0-500, high is poor, change score) at >3 months	69 (1 RCT) follow up: 6 months	⊕◯◯◯ VERY LOW [a,b]	-	The mean pain was 13.1	MD **26.2 lower** (41.13 lower to 11.27 lower)	MID = 0.5 SD (SMD)
Physical function (WOMAC physical function subscale, 0-1700, high is poor, change score) at >3 months	69 (1 RCT) follow up: 6 months	⊕◯◯◯ VERY LOW [a,b]	-	The mean physical function was 6.5	MD **75.4 lower** (124.95 lower to 25.85 lower)	MID = 0.5 SD (SMD)

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 23: Clinical evidence summary: tape compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with tape	
Quality of life (KOOS, Nottingham Health Profile [different scale ranges], high is poor, final values) at ≤3 months	77 (2 RCT) follow up: mean 4 weeks	⊕⊕◯◯ LOW [a,b]	-	-	SMD **0.17 SD higher** (0.28 lower to 0.62 higher)	MID = 0.5 SD (SMD)
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 70.3	MD **10.2 lower** (22.75 lower to 2.35 higher)	MID = 3 (established value)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with tape	
Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 47.8	MD **5.9 lower** (18.38 lower to 6.58 higher)	MID = 3 (established value)
Quality of life (SF-36 physical role subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 57	MD **15.6 lower** (38.6 lower to 7.4 higher)	MID = 3 (established value)
Pain (KOOS, WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months	220 (5 RCTs) follow up: mean 6 weeks	⊕⊕⊕◯ MODERATE [a]	-	-	SMD **0.04 SD lower** (0.31 lower to 0.23 higher)	MID = 0.5 SD (SMD)
Pain (WOMAC, 0-20, high is poor, final value, crossover trial) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean pain was 5.8	MD **1.5 higher** (0.42 lower to 3.42 higher)	MID = 0.5 SD (SMD)
Pain (VAS, 0-10, high is poor, change score) at ≤3 months	39 (1 RCT) follow up: 6 weeks	⊕⊕⊕◯ MODERATE [b]	-	The mean pain was 1.11	MD **0.45 lower** (2.1 lower to 1.2 higher)	MID = 0.5 SD (SMD)
Physical function (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months	181 (4 RCTs) follow up: mean 7 weeks	⊕⊕⊕◯ MODERATE [a]	-	-	SMD **0.03 SD lower** (0.27 lower to 0.32 higher)	MID = 0.5 SMD
Number of adverse events at ≤3 months	148 (4 RCTs) follow up: mean 4 weeks	⊕⊕◯◯ VERY LOW [a,b,c]	RD -0.02 (-0.09 to 0.06)	41 per 1,000	**20 fewer per 1,000** (90 fewer to 60 more) [d]	Precision calculated through Optimal Information Size (OIS) due to zero events in some studies (0.8-0.9 = serious, <0.8 = very serious).

[a.] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with tape	

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
c. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)
d. Absolute measure calculated by risk difference due to zero events in one or both study arms

Table 24: Clinical evidence summary: tape compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with tape	
Quality of life (KOOS, 0-100, high is good, final value) at ≤3 months	54 (1 RCT) follow up: 3-6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 61.3	MD **1.77 lower** (9.14 lower to 5.6 higher)	MID = 0.5 SD (SMD)
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 48.6	MD **11.5 higher** (1.45 lower to 24.45 higher)	MID = 3 (established value)
Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 38.7	MD **3.2 higher** (9.39 lower to 15.79 higher)	MID = 3 (established value)
Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 34.6	MD **6.8 higher** (16.6 lower to 30.2 higher)	MID = 3 (established value)
Pain (KOOS, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months	182 (5 RCTs) follow up: mean 7 weeks	⊕◯◯◯ VERY LOW [a,b,c]	-	-	SMD **0.34 SD lower** (1.01 lower to 0.33 higher)	MID = 0.5 SD (SMD)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with tape	
Pain (WOMAC, 0-20, high is poor, final value, crossover trial) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean pain was 9.4	MD **2.1 lower** (4.09 lower to 0.11 lower)	MID = 0.5 SD (SMD)
Physical function (KOOS, 0-100, high is good, final value, parallel trial) at ≤3 months	54 (1 RCT) follow up: 3-6 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean physical function was 78.38	MD **0.4 higher** (3.85 lower to 4.65 higher)	MID = 0.5 SD (SMD)
Physical function (WOMAC physical function subscale, 0-68, high is poor, final value, crossover trial) at ≤3 months	58 (1 RCT) follow up: 6 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean physical function was 31.5	MD **5.5 lower** (12.29 lower to 1.29 higher)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	44 (1 RCT) follow up: 6 weeks	⊕⊕◯◯ LOW [a,b]	RR 2.00 (0.20 to 20.49)	45 per 1,000	**45 more per 1,000** (36 fewer to 886 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 25: Clinical evidence summary: walking aids compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with walking aids	
Quality of life (AQoL, -0.04-1, high is good, change score) at ≤3 months	79 (1 RCT) follow-up: 12 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean quality of life was 0	MD **0** (0.04 lower to 0.04 higher)	MID = 0.5 SD (SMD)
Quality of life (SF-36 physical functioning subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean quality of life was 35.94	MD **9.06 higher** (0.31 higher to 17.81 higher)	MID = 3 (established value)
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean quality of life was 46.03	MD **14.16 higher** (4.02 higher to 24.3 higher)	MID = 3 (established value)
Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean quality of life was 26.06	MD **16.75 higher** (1.81 higher to 31.69 higher)	MID = 3 (established value)
Quality of life (SF-36 vitality subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean quality of life was 38.59	MD **15.5 higher** (1.53 higher to 29.47 higher)	MID = 2 (established value)
Quality of life (SF-36 general health subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 56.81	MD **2.06 higher** (10.11 lower to 14.23 higher)	MID = 2 (established value)
Quality of life (SF-36 mental health subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean quality of life was 51.1	MD **7.72 higher** (2.6 lower to 18.04 higher)	MID = 3 (established value)

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with walking aids	
Quality of life (SF-36 role emotional subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean quality of life was 24.9	MD **18.08 higher** (3.02 higher to 33.14 higher)	MID = 4 (established value)
Quality of life (SF-36 social functioning subscale, 0-100, high is good, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean quality of life was 49.22	MD **7.94 higher** (4.41 lower to 20.29 higher)	MID = 3 (established value)
Pain (WOMAC pain, 0-20, high is poor, change score) at ≤3 months	79 (1 RCT) follow-up: 12 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean pain was -1.8	MD **0.4 higher** (1.17 lower to 1.97 higher)	MID = 0.5 SD (SMD)
Pain (visual analogue scale, 0-10, high is poor, final value) at ≤3 months	59 (1 RCT) follow up: 8 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean pain was 5.95	MD **2.11 lower** (2.83 lower to 1.39 lower)	MID = 0.5 SD (SMD)
Physical function (WOMAC physical function, 0-68, high is poor, change score) at ≤3 months	79 (1 RCT) follow-up: 12 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean physical function was -4.3	MD **0.8 lower** (5.4 lower to 3.8 higher)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	79 (1 RCT) follow-up: 12 weeks	⊕⊕◯◯ LOW [a,b]	RR 8.78 (1.17 to 66.04)	26 per 1,000	**199 more per 1,000** (4 more to 1,668 more)	MID (precision) = RR 0.8-1.25.

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Thumb osteoarthritis

Table 26: Clinical evidence summary: splints compared to sham devices

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with splints	
Quality of life (EQ-5D, -0.11-1, high is good, final value) at ≤3 months	171 (1 RCT) follow-up: 12 weeks	⊕⊕◯◯ LOW [a]	-	The mean quality of life was 0.64	MD **0.01 lower** (0.07 lower to 0.05 higher)	MID = 0.5 SD (SMD)
Pain (AUSCAN pain, 0-20, high is poor, final value) at ≤3 months	174 (1 RCT) follow-up: 12 weeks	⊕⊕⊕⊕ HIGH	-	The mean pain was 10.3	MD **0.6 lower** (1.73 lower to 0.53 higher)	MID = 0.5 SD (SMD)
Physical function (AUSCAN function, 0-38, high is poor, final value) at ≤3 months	171 (1 RCT) follow-up: 12 weeks	⊕⊕⊕⊕ HIGH	-	The mean pain was 18	MD **0.7 lower** (2.98 lower to 1.58 higher)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	233 (1 RCT) follow-up: 12 weeks	⊕⊕◯◯ LOW [a]	RR 2.52 (0.50 to 12.74)	17 per 1,000	**26 more per 1,000** (9 fewer to 201 more)	MID (precision) = RR 0.8-1.25.

[a] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 27: Clinical evidence summary: splints compared to no device intervention

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with splints	
Pain (VAS, 0-10, high is poor, final values, parallel and crossover) at ≤3 months	201 (4 RCTs) follow up: mean 8 weeks	⊕◯◯◯ VERY LOW [a,b,c]	-	The mean pain was 0	**MD 1.66 lower** (4.28 lower to 0.96 higher)	MID = 0.6 (0.5 x median baseline SD)
Pain (VAS, 0-100, high is poor, change score) at >3 months	97 (1 RCT) follow up: 12 months	⊕⊕◯◯ LOW [a,c]	-	The mean pain was -7.9	MD **14.3 lower** (23.6 lower to 5 lower)	MID = 0.5 SD (SMD)
Physical function (MHQ subscale, DASH scale [different scale ranges], high is poor, final values, parallel trials) at ≤3 months	65 (2 RCTs) follow up: mean 9 weeks	⊕⊕◯◯ LOW [a,c]	-	-	SMD **0.34 SD lower** (0.83 lower to 0.16 higher)	MID = 0.5 SD (SMD)
Physical function (DASH scale, 0-100, high is good, final value, crossover trial) at ≤3 months	35 (1 RCT) follow up: 10 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean physical function was 53.5	MD **20.65 higher** (12.47 higher to 28.83 higher)	MID = 0.5 SD (SMD)
Physical function (Cochin hand function scale, 0-90, high is poor, change score) at ≤3 months	101 (1 RCT) follow up: 4 weeks	⊕⊕◯◯ LOW [a,c]	-	The mean physical function was -0.3	MD **1.6 higher** (2.3 lower to 5.5 higher)	MID = 0.5 SD (SMD)
Physical function (Cochin hand function scale, 0-90, high is poor, change score) at >3 months	95 (1 RCT) follow up: 12 months	⊕⊕◯◯ LOW [a,c]	-	The mean physical function was 4.3	MD **6.2 lower** (10.77 lower to 1.63 lower)	MID = 0.5 SD (SMD)

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with splints	
c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs						

Hand osteoarthritis

Table 28: Clinical evidence summary: splints compared to no device intervention

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with splints	
Pain (AUSCAN, 0-20, high is poor, final value) at ≤3 months	52 (1 RCT) follow-up: 12 weeks	⊕◯◯◯ VERY LOW a,b	-	The mean pain was 8.9	MD **0.3 lower** (2.67 lower to 2.07 higher)	MID = 0.5 SD (SMD)
Pain (AUSCAN, 0-20, high is poor, final value) at >3 months	52 (1 RCT) follow-up: 24 weeks	⊕◯◯◯ VERY LOW a,b	-	The mean pain was 9.9	MD **2.4 lower** (4.57 lower to 0.23 lower)	MID = 0.5 SD (SMD)
Physical function (AUSCAN, 0-36, high is poor, final value) at ≤3 months	52 (1 RCT) follow-up: 12 weeks	⊕◯◯◯ VERY LOW a,b	-	The mean physical function was 18.4	MD **0.2 higher** (3.66 lower to 4.06 higher)	MID = 0.5 SD (SMD)
Physical function (AUSCAN, 0-36, high is poor, final value) at >3 months	52 (1 RCT) follow-up: 24 weeks	⊕◯◯◯ VERY LOW a,b	-	The mean physical function was 18.2	MD **1.9 lower** (5.87 lower to 2.07 higher)	MID = 0.5 SD (SMD)
a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs						

Table 29: Clinical evidence summary: tape compared to no device intervention

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with no device intervention	Risk difference with tape	
Pain (VAS, 0-10, high is poor, final value) at ≤3 months	38 (1 RCT) follow-up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean pain was 6.21	MD **0.89 lower** (1.57 lower to 0.21 lower)	MID = 0.5 SD (SMD)
Physical function (DASH, 0-100, high is poor, final value) at ≤3 months	38 (1 RCT) follow-up: 8 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean physical function was 60.34	MD **7.58 lower** (14.91 lower to 0.25 lower)	MID = 0.5 SD (SMD)

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Finger osteoarthritis

Table 30: Clinical evidence summary: tape compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with tape	
Pain (VAS, 0-10, high is poor, final values) at ≤3 months	10 (1 RCT) follow up: 3 weeks	⊕◯◯◯ VERY LOW [a,b]	-	The mean pain was 4.5	MD **0.3 lower** (3.53 lower to 2.93 higher)	MID = 0.5 SD (SMD)
Osteoarthritis flares at ≤3 months	10 (1 RCT) follow up: 3 weeks	⊕◯◯◯ VERY LOW [b]	Peto OR 7.39 (0.15 to 372.38)	0 per 1,000	**200 more per 1000** (from 210 fewer to 610 more) [c]	MID (precision) = Peto OR 0.8-1.25.

[a] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with tape	
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs c. Absolute effect calculated from risk difference due to zero events in one study arm						

Foot osteoarthritis

Table 31: Clinical evidence summary: insoles compared to sham devices

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with sham devices	Risk difference with insoles	
Pain (NRS, 0-10, high is poor, change score) at ≤3 months	36 (1 RCT) follow up: 12 weeks	⨁◯◯◯ VERY LOW [a,b]	-	The mean pain was 0.3	MD **1.4 lower** (3.35 lower to 0.55 higher)	MID = 0.5 SD (SMD)
Physical function (MFPDI function subscale, range not reported, high is poor, change score) at ≤3 months	36 (1 RCT) follow up: 12 weeks	⨁◯◯◯ VERY LOW [a,b]	-	The mean physical function was -2.2	MD **1.4 lower** (3.98 lower to 1.18 higher)	MID = 0.5 SD (SMD)
a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs						

Toe osteoarthritis

Table 32: Clinical evidence summary: shoes compared to insoles

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				Risk with insoles	Risk difference with shoes	
Quality of life (SF-12 physical, 1-100, high is good, final value) at ≤3 months	98 (1 RCT) follow up: 12 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean quality of life was 47.1	MD **0.4 lower** (4.16 lower to 3.36 higher)	MID = 0.5 SD (SMD)
Quality of life (SF-12 mental, 1-100, high is good, final value) at ≤3 months	98 (1 RCT) follow up: 12 weeks	⊕⊕◯◯ LOW [a]	-	The mean quality of life was 52.3	MD **0.3 lower** (4.11 lower to 3.51 higher)	MID = 0.5 SD (SMD)
Pain (Foot health status questionnaire pain domain, 1-100, high is good, final value) at ≤3 months	98 (1 RCT) follow up: 12 weeks	⊕⊕⊕◯ MODERATE [a]	-	The mean pain was 73.6	MD **0.1 higher** (6.16 lower to 6.36 higher)	MID = 0.5 SD (SMD)
Physical function (Foot health status questionnaire function domain, 1-100, high is good, final value) at ≤3 months	98 (1 RCT) follow up: 12 weeks	⊕⊕◯◯ LOW [a,b]	-	The mean physical function was 92.7	MD **12.2 lower** (19.17 lower to 5.23 lower)	MID = 0.5 SD (SMD)
Number of adverse events at ≤3 months	98 (1 RCT) follow up: 12 weeks	⊕⊕⊕◯ MODERATE [b]	RR 1.16 (0.98 to 1.37)	788 per 1,000	**126 more per 1,000** (16 fewer to 292 more)	MID (precision) = RR 0.8-1.25.

[a]. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[b]. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

See Appendix F for full GRADE tables

1.1.7 Economic evidence

1.1.7.1 Included studies

Two health economic studies with the relevant comparison were included in this review.[4, 110] These are summarised in the health economic evidence profile below (Table 33) and the health economic evidence tables in Appendix H.

1.1.7.2 Excluded studies

One economic study relating to this review question was identified but was excluded due to methodological limitations.[103] This is listed in Appendix J, with reasons for exclusion given.

See also the health economic study selection flow chart in Appendix G.

1.1.8 Summary of included economic evidence

Table 33: Health economic evidence profile: Thumb splint

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Adams 2021[4] (UK)	Directly applicable[(a)]	Potentially serious limitations[(b)]	• Within trial analysis of a pragmatic, multi-centre single blinded randomised controlled superiority trial (same paper) • Cost-utility analysis (QALYs) • Population: People with symptomatic basal thumb joint OA • Comparators: 1. Therapist supported self-management programme (SSM)* 2. SSM plus a placebo thumb splint 3. SSM plus a verum thumb splint *Therapist-related support was delivered over 8 weeks. Therapists conducted a 60-minutes assessment at baseline, followed by check-ins at weeks 2, 4 and 8. Follow-up: 12 weeks	(2−1): £99 (3−1): £152 [(c)]	(2−1): 0.000 QALYs (3−1): 0.000 QALYs	Intervention 1 dominates both interventions 2 and 3	Probability Intervention 2 cost effective versus Intervention 1 (£20K threshold): 32% Probability Intervention 3 cost effective versus Intervention 1 (£20K threshold): 28% No further analysis of uncertainty reported.

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
MacPherson 2017[110] (UK)	Partially applicable	Potentially serious limitations[(d)]	• Probabilistic model based on three separate network meta-analyses of RCTs[(e)] • Cost-utility analysis (QALYs) • Population: Patients reporting pain resulting from OA of the knee. • Comparators:[(f)] 1. Usual care 2. Insoles 3. Braces Time horizon was 8 weeks	All trials[(g)] 2-1: £13 3-1: £40 Trials with adequate allocation concealment[(g)] 2-1: £13 3-1: NR Trials with adequate allocation concealment and endpoint at 3-13 weeks[(g)] 2-1: £14 3-1: NR	All trials 2-1: 0.001 3-1: 0.001 Trials with adequate allocation concealment 2-1: 0.002 3-1: NR Trials with adequate allocation concealment and endpoint at 3-13 weeks 2-1: 0.004 3-1: NR	All trials[(h)] 2-1: £13,000 3-1: £40,000 Trials with adequate allocation concealment[(h)] 2-1: £6,500 3-1: £NR Trials with adequate allocation concealment and endpoint at 3-13 weeks[(h)] 2-1: £3,540 3-1: £NR	This study analysed a variety of different intervention classes and so all reports of uncertainty were based on an analysis of all interventions and not any intervention(s) in isolation. For a summary of the analysis of uncertainty involving all interventions, see Appendix H.

Abbreviations: ICER= incremental cost-effectiveness ratio; NR = not reported; OA= osteoarthritis; QALY= quality-adjusted life years; RCT= randomised controlled trial; SSM= supported self-management

(a) EQ-5D-5L were mapped to EQ-5D-3L using NICE recommended van Hout algorithm
(b) The follow-up period was very short at 12 weeks and may not capture the full costs and benefits of the interventions.
(c) 2017/18 UK pounds. Cost components incorporated: Intervention costs, follow-up healthcare resource use costs
(d) Unit costs taken from 2011/12 may not reflect current UK NHS practice. The time horizon was only 8 weeks. Adverse events and their downstream consequences were not considered.
(e) Only model results from 2 of the 3 network meta analyses presented in this evidence profile. See Appendix H for all model results.
(f) The original report listed 13 interventions in total. Only those interventions that fit the protocol for devices were included here. Please note intervention numbers in this profile do not match to intervention numbers in evidence table (Appendix H).
(g) 2011/12 UK pounds. Cost components incorporated: Physiotherapist's time to conduct sessions. Changes in non-treatment-related visits to GPs and specialists arising from changes to EQ-5D score

(h) In a full incremental analysis of all interventions, TENS was the most cost-effective option in the network meta-analysis all trials with a cost per QALY of £2,690. In the other two network meta-analyses (1. only those trials with adequate allocation concealment and 2. only those trials with adequate allocation concealment and an endpoint between 3-13 weeks), acupuncture was the most cost-effective option with costs per QALYs of £13,502 and £14,275, respectively

1.1.9 Economic model

This area was not prioritised for new cost-effectiveness analysis.

1.1.10 Unit costs

Relevant unit costs are provided below to aid consideration of cost effectiveness.

Table 34: UK costs of devices

Device	Unit cost
Insole (pair)	£0.47 - £54
Brace (knee only)	£5.05 - £630
Splint	
Splint-on-a-roll (per metre)	£1.54 - £60.18
Individual splints	£1.40 - £54
Support (tubular bandage)	£0.40 - £109.32
Straps/Tape (per metre)	£0.16 - £2.10
Walking aids	£0.12 - £13.18

Source: NHS Supply Chain Catalogue 2020[34]

Table 35: UK costs of physician time

Physician	Unit cost
Hospital Nurse (Band 6)	£50 per hour
Specialty registrar	£50 per hour
Physiotherapy outpatient appointment	£62
Orthotics outpatient appointment Non consultant led Consultant led	 £140 £93

Source: PSSRU 2020[45], NHS reference cost 2019/20[131]

1.1.11 Economic evidence statements

- One cost utility analysis reported that insoles were cost effective compared with usual care in three separate analyses (ICERs: £13,000, £6,500 and £3,540). Braces were only included in one of the analyses and was not cost effective versus usual care (ICER: £40,000). A full incremental analysis of various non-pharmacological interventions (acupuncture, braces, heat treatment, insoles, interferential therapy, laser/light therapy, manual therapy, neuromuscular electrical stimulation, pulsed electromagnetic field, pulsed electrical stimulation, static magnets and transcutaneous electrical nerve stimulation) also reported that acupuncture was the most cost-effective strategy in two of the three network meta-analyses (£13,502 and 14,275), with transcutaneous electrical nerve stimulation the most cost-effective option in the other (£2,690). The analysis was assessed as directly applicable with potentially serious limitations.

1.1.12 The committee's discussion and interpretation of the evidence

1.1.12.1. The outcomes that matter most

The critical outcomes were quality of life, pain and physical function. These were considered critical due to their relevance to people with osteoarthritis. The Osteoarthritis Research Society International (OARSI) consider that pain and physical function were the most important outcomes for evaluating interventions. Quality of life gives a broader perspective on the person's wellbeing, allowing for examination of the biopsychosocial impact of interventions. Psychological distress, osteoarthritis flare and adverse events (including pain from the device, soft tissue injury, infection, falls and any additional adverse events as defined by the specific study) were included as important outcomes.

The committee considered osteoarthritis flares to be important in the lived experience and management of osteoarthritis. However, these were also considered difficult to measure with no clear consensus on their definition. The Flares in OA OMERACT working group have proposed an initial definition and domains of OA flares through a consensus exercise; “it is a transient state, different from the usual state of the condition, with a duration of a few days, characterized by onset, worsening of pain, swelling, stiffness, impact on sleep, activity, functioning, and psychological aspects that can resolve spontaneously or lead to a need to adjust therapy”. However, this has been considered to have limitations and has not been widely adopted. Therefore, the committee included the outcome accepting any reasonable definition provided by any studies.

Mortality was included as a treatment adverse event rather than as a discreet outcome and categorised as an important outcome. Osteoarthritis as a disease process is not considered to cause mortality by itself and mortality is an uncommon outcome from osteoarthritis interventions. The committee recognise that disability, limited physical activity and limited social participation caused by painful osteoarthritis increases the burden of physical and psychological health.

There was limited evidence for all outcomes, especially outside of people with knee osteoarthritis. However, there was more evidence reported for critical outcomes than important outcomes. Osteoarthritis flares was reported in one comparison for one stratum only, while psychological distress was not reported.

1.1.12.2 The quality of the evidence

No relevant clinical studies for devices in hip, ankle, shoulder, elbow, wrist, hand and temporomandibular joint osteoarthritis were identified. Fifty-four studies were included in the review investigating knee, thumb, finger, foot and toe osteoarthritis. For joint sites where evidence was present, the majority of the evidence was for knee osteoarthritis. Evidence was available for the following comparisons:

- Knee osteoarthritis
  - Insoles versus sham devices
  - Insoles versus no device intervention
  - Shoes versus sham devices
  - Braces versus insoles
  - Braces versus supports
  - Braces versus sham devices
  - Braces versus no device intervention
  - Tape versus sham devices
  - Tape versus no device intervention
  - Supports versus no device intervention
  - Walking aids versus no device intervention
- Thumb osteoarthritis
  - Splints versus no device intervention
- Finger osteoarthritis
  - Tape versus sham devices
- Foot osteoarthritis
  - Insoles versus sham devices
- Toe osteoarthritis
  - Shoe versus insoles

Evidence ranged from high to very low quality, with the majority being of low to very low quality. Evidence quality was often downgraded due to risk of bias and imprecision. Some outcomes were inconsistent with heterogeneity that could not be explained with subgroup analysis. The majority of the analyses were based on data from a small number of participants.

Insoles

Insoles were compared to braces, sham devices and no device interventions for people with knee osteoarthritis and to shoes for people with toe osteoarthritis.

- When insoles were compared to braces for people with knee osteoarthritis, 5 studies were included in the analysis with outcomes including between 56 and 245 participants. The quality of outcomes ranged from moderate to very low quality. Outcomes were commonly downgraded due to risk of bias and imprecision.
- When insoles were compared to sham devices for people with knee osteoarthritis, 9 studies were included in the analysis with outcomes including between 106 and 358 participants. The quality of outcomes ranged from high to very low quality, with the majority of outcomes being of low quality. Outcomes were commonly downgraded due to risk of bias and imprecision. 4 outcomes were downgraded due to inconsistency, with heterogeneity that could not be explained by subgroup analysis (this included an outcome for pain and physical function at ≤3 months and >3 months each).
- When insoles were compared to no device interventions for people with knee osteoarthritis, 5 studies were included in the analysis with outcomes included between 31 and 199 participants. The quality of outcomes ranged from low to very low quality, with the majority of outcomes being of very low quality. Outcomes were commonly downgraded due to risk of bias and imprecision. 2 outcomes (pain and physical function at ≤3 months) were downgraded due to inconsistency, with heterogeneity that could not be explained by subgroup analysis.
- When insoles were compared to shoes for people with toe osteoarthritis, 1 study was included in the analysis including 98 participants. The quality of outcomes ranged from moderate to low quality, with the majority being of moderate quality. Outcomes were commonly downgraded due to risk of bias and imprecision.

Shoes

Shoes were compared to sham devices for people with knee osteoarthritis and insoles for people with toe osteoarthritis.

- When shoes were compared to sham devices for people with knee osteoarthritis, 5 studies were included in the analysis including between 220 to 548 participants. The outcomes ranged from high to very low quality being downgraded for imprecision and inconsistent where heterogeneity could not be resolved by subgroup analyses.
- When shoes were compared to insoles for people with toe osteoarthritis, 1 study was included in the analysis including 98 participants. The quality of outcomes ranged from moderate to low quality, with the majority being of moderate quality. Outcomes were commonly downgraded due to risk of bias and imprecision.

Braces

Braces were compared to insoles, supports, sham devices and no device intervention for people with knee osteoarthritis. There was no data for other joints that may be affected by osteoarthritis.

- When braces were compared to insoles, 5 studies were included in the analysis with outcomes including between 56 and 245 participants. The quality of outcomes ranged from moderate to very low quality. Outcomes were commonly downgraded due to risk of bias and imprecision.

- When braces were compared to supports, 1 study was included in the analysis with the outcomes including 77 participants. The quality of the outcomes was very low due to risk of bias and imprecision.
- When braces were compared to sham devices, 2 studies were included in the analysis with the outcomes ranging between 57 to 86 participants. The quality of the outcomes was very low due to risk of bias and imprecision.
- When braces were compared to no device intervention, 7 studies were included in the analysis with outcomes including between 39 and 310 participants. The quality of outcomes ranged from low to very low, with all except 1 outcome being of very low quality. Outcomes were commonly downgraded due to risk of bias and imprecision. 2 outcomes were downgraded due to inconsistency, with heterogeneity that could not be resolved by subgroup analysis.

Splints

Splints were compared to sham devices and no device intervention for people with thumb osteoarthritis. There was no data for other joints that may be affected by osteoarthritis.

- When splints were compared to sham devices, 1 study was included which reported 4 outcomes. The number of participants included in the reported outcomes ranged from 171 to 233 people. The quality of the outcomes ranged from high to low quality. Where outcomes were downgraded, this was for imprecision.
- When splints were compared to no device intervention, 4 studies were included in the analysis with outcomes including between 35 and 201 people. The quality of outcomes ranged from moderate to very low quality, with the majority of outcomes being of low quality. Outcomes were commonly downgraded due to risk of bias and imprecision. 1 outcome was downgraded due to inconsistency, with heterogeneity that could not be explained by subgroup analysis.

Tape

Tape was compared to sham devices and no device intervention for people with knee osteoarthritis and sham devices only for people with finger osteoarthritis.

- When tape was compared to sham devices for people with knee osteoarthritis, 7 studies were included in the analysis with outcomes including between 39 and 220 participants. The quality of the outcomes ranged from moderate to very low quality with the majority being of low quality. Outcomes were commonly downgraded due to risk of bias and/or imprecision. The adverse events outcome was downgraded due to inconsistency as there was zero events in at least one arm of one study while other studies included events in both study arms.
- When tape was compared to no device intervention for people with knee osteoarthritis, 6 studies were included in the analysis with outcomes including between 44 and 182 participants. The quality of the outcomes ranged from low to very low quality with the majority being of very low quality. Outcomes were commonly downgraded due to risk of bias and imprecision. 1 outcome was downgraded for inconsistency, with heterogeneity that could not be explained with subgroup analysis.
- When tape was compared to sham devices for people with finger osteoarthritis, 1 study was included in the analysis including 10 participants. The outcomes were of very low quality, being downgraded due to risk of bias and imprecision.
- When tape was compared to no device intervention for people with finger osteoarthritis, 1 study was included in the analysis including 38 participants. The outcomes were of low quality, being downgraded for risk of bias and imprecision.

Supports

Supports were compared to braces and no device intervention for people with knee osteoarthritis. There was no data available for other joints that could be affected by osteoarthritis.

- When supports were compared to braces, 1 study was included in the analysis with the outcomes including 77 participants. The quality of the outcomes was very low due to risk of bias and imprecision.
- When supports were compared to no device intervention, 1 study was included in the analysis with the outcomes including 69 participants. The outcomes were of very low quality due to risk of bias and imprecision.

Walking aids

Walking canes were compared to no device intervention for people with knee osteoarthritis. There was no data available for other joints that could be affected by osteoarthritis. Outcomes were reported in two studies. The quality of outcomes ranged from moderate to very low quality, with the majority being of low quality. Outcomes were downgraded due to risk of bias and imprecision.

1.1.12.3 Benefits and harms

Key uncertainties

No evidence was found discussing the use of devices in hip, ankle, shoulder, elbow, wrist, hand and temporomandibular joint osteoarthritis. There was limited evidence comparing devices to sham devices, in particular for supports in knee osteoarthritis and splints in thumb osteoarthritis. There was also insufficient evidence of head-to-head comparisons (excluding braces and insoles in knee osteoarthritis). For many of the comparisons, quality of life was not reported, and outcomes were not reported at both short- and long-term time points. Psychological distress and osteoarthritis flares were only reported for one comparison.

There was very limited evidence identified using the protocol for this review for device use for non-knee joint sites of osteoarthritis. When this evidence was available, this was often for 1 comparison and for 2 osteoarthritis joint sites this only included 1 study. The committee considered this absence of evidence when examining interventions and making recommendations.

The committee discussed that generally the adverse events data for these trials was limited as this was generally found in small studies with a short follow up time and so it is unclear whether this is representative of the events expected to be seen in real life practice. Given this, the committee considered the evidence for adverse events to be unclear throughout the review reflecting this in their weighting of findings while making recommendations. The committee noted throughout the evidence that the number of adverse events was often low and where events were reported they were transient in nature (such as increased pain). Given this, while the committee acknowledged where clinically important differences were highlighted in the evidence, but also considered the nature and true number of these events.

Insoles

When compared to sham devices (neutral insoles only for the majority of studies), lateral wedge insoles did not cause any clinically important differences in quality of life, physical function and adverse events at less than 3 months. There was an unclear effect for pain at less than and more than 3 months and physical function at more than 3 months, with some evidence of clinically important benefit and some evidence of no difference. The effect on adverse events was unclear, with no clinically important difference at less than 3 months, but an evidence of a clinically important harm at more than 3 months. The results include a

relatively small number of events in a small number of participants, and so the effect may not be a reflection of the frequency of adverse events seen outside of a trial setting.

For the comparison of lateral wedge insoles and no device intervention in knee osteoarthritis, a clinically important benefit was seen with insoles in pain at less than and more than 3 months and physical function at less than 3 months. There were unclear changes seen for quality of life at less than 3 months, with one outcome showing a clinically important benefit while another showed no clinically important difference. There was no clinically important difference seen in this outcome after 3 months. There were unclear changes in psychological distress, with the anxiety subscale of the HADS questionnaire showing a clinically important harm of insoles at less than 3 months, while the depression subscale showed no clinically important difference. No clinically important difference was seen in this outcome after 3 months. A clinically important harm was seen in adverse events at less than 3 months while at more than 3 months there was a borderline effect that showed no clinically important difference while being close to a clinically important benefit. The clinically important benefit seen with pain and physical function at less than 3 months was associated with very serious inconsistency and serious imprecision.

The concomitant therapies in both intervention arms were considered to be high intensity interventions (including exercise, pharmacological and physical therapy interventions in combination with each other). This may have an effect on the magnitude of outcomes. However, due to the additional care being equivalent in both arms, the committee agreed that the comparison was still valid.

For the comparison of insoles and sham devices (an insole which did not provide midfoot support and heel wedging) in foot osteoarthritis, no clinically important difference was seen in pain and physical function at less than 3 months based on 1 study.

Adverse events seen with insoles included pain, blisters, instability/falls and musculoskeletal symptoms in lower limb joints.

Shoes

For the comparison of shoes (variable stiffness walking shoes) and sham devices (constant stiffness shoes) in knee osteoarthritis, no clinically important difference was seen in quality of life, pain and physical function at less than and more than 3 months and adverse events at more than 3 months only (although for the latter the effect was bordering on a clinically important harm). In people with toe osteoarthritis when rocker shoes were compared to insoles, no clinically important difference was seen in quality of life and pain at less than and equal to 3 months, while there were clinically important harms in physical function and adverse events at the same time period.

Based on limited information, the committee concluded that there was insufficient evidence of benefit from shoes in knee and toe osteoarthritis. On discussion the committee agreed that they had seen benefits from using and providing people with osteoarthritis with the correct footwear. They acknowledged that there was evidence of benefit from observational studies that were not included in this protocol. Furthermore, the committee discussed that the design of trials for this review may not have been compatible, as it is difficult to design sham devices for footwear (as the footwear provided as a sham comparison may be better than the footwear used by people on a normal basis) and no device comparisons would not be possible. Based on this, and the lack of randomised evidence, the committee made a research recommendation for additional research in this area.

Braces

For the comparison of braces and sham devices (an unloading knee brace with the functional component removed) in knee osteoarthritis, a clinically important benefit of braces was seen in physical function at more than 3 months in 1 study. No clinically important difference was

seen in quality of life at more than 3 months and pain at less than and more than 3 months in this study.

For the comparison of braces and no device intervention in knee osteoarthritis, a clinically important benefit of braces was seen in quality of life at less than 3 months, pain at less than and greater than 3 months and physical function at more than 3 months. Where benefits were seen in reducing pain, two outcomes were heterogenous with one study having a more positive effect than the other study or studies, while other studies indicated no clinically important difference. This made the results of the analysis unclear. No clinically important difference was seen in quality of life at more than 3 months. It was unclear as to whether there was a clinically important benefit or no clinically important difference in pain at more than 3 months and overall appeared that benefit was only consistently seen for quality of life at less than 3 months. A clinically important harm was observed in adverse events at less than 3 months, but no clinically important difference was seen at more than 3 months.

The concomitant therapies in both intervention arms ranged from low intensity (education and paracetamol as required) to high intensity (combined analgesic and exercise interventions) management.

For the comparison of braces and insoles in knee osteoarthritis, a clinically important harm of braces was seen for adverse events at more than 3 months. No clinically important different was seen in pain and physical function at less than and more than 3 months. In total 5 studies contributed to these findings.

For the comparison of braces and supports in knee osteoarthritis, a clinically important benefit of braces was seen in pain and physical function at more than 3 months in 1 study.

Adverse events included ipsilateral leg swelling, skin irritation and blisters.

Splints

For the comparison of splints and sham devices for people with thumb osteoarthritis, 1 study reported four outcomes. These outcomes showed no clinically important difference in quality of life, pain, physical function and adverse events at less than 3 months. For the comparison of splints and no device intervention for people with thumb osteoarthritis, a clinically important benefit of splints was seen in pain and physical function at more than 3 months. It was unclear whether there was a clinically important benefit or no clinically important difference in pain and physical function at less than 3 months. In total 4 studies contributed to these findings.

For the comparison of splints and no device intervention for people with hand osteoarthritis, 1 study reported four outcomes. These outcomes showed a clinically important benefit of splints at more than 3 months, but no clinically important difference in pain at less than 3 months and physical function at less than and more than 3 months.

The concomitant therapies in all intervention arms were generally poorly defined.

Tape

For the comparison of tape and sham devices (including sham taping in a different alignment aiming to provide no clinical effect or taping for sensory input only) for people with knee osteoarthritis, no clinically important difference was seen in pain, physical function and adverse events at less than 3 months. It was unclear as to whether there was a clinically important harm or no clinically important difference in quality of life at less than 3 months. In total 5 studies contributed to these findings.

For the comparison of tape and no device intervention for people with knee osteoarthritis, a clinically important benefit from tape was seen in physical function at less than 3 months. An unclear change was seen in pain at less than 3 months, with one outcome showing no

clinically important difference while another showed a clinically important benefit. No clinically important difference was seen in adverse events at less than 3 months. It was unclear as to whether there was a clinically important benefit or no clinically important difference in quality of life at less than 3 months. In total 4 studies contributed to these findings. For the same comparison for people with hand osteoarthritis, 1 study reported 2 outcomes. The outcomes showed clinically important benefits in pain and physical function at less than 3 months based on low quality evidence with 38 participants in total.

The concomitant treatment in both intervention arms was either not well defined or high intensity (including combined exercise, pharmacological and physical therapy interventions).

For the comparison of tape and sham devices (taping in an alignment meant to bring no clinical benefit) in finger osteoarthritis, a clinically important harm was seen in osteoarthritis flares (based on reports from one participant in the study) at less than 3 months based on 1 study. Additionally, no clinically important difference was seen in pain at less than 3 months based on this study.

Adverse events seen included allergic reaction (rash) and joint injury due to use of the device.

Supports

For the comparison of supports (neoprene sleeve supports) and no device intervention in knee osteoarthritis, a clinically important benefit of supports was seen in pain and physical function at more than 3 months in 1 study.

The concomitant therapies in both intervention arms were low intensity (education and paracetamol as required).

Walking aids

For the comparison of walking aids (T shaped cane) and no device intervention in knee osteoarthritis, outcomes from one study indicated a clinically important benefit of walking aids was seen in quality of life and pain at less than 3 months. Outcomes from a second study (swan neck cane) indicated no clinically important difference in quality of life, pain and physical function at less than 3 months. This study also indicated a clinically important harm of walking aids in the number of adverse events. On examining this evidence, it was shown that the adverse event stated in the paper for the control group included a fracture due to trauma, while the adverse events in the intervention group included worsening or new pain in parts of the body, and so were thought to be less severe adverse events. The reporting of adverse events in the paper was thought to be unclear as the adverse events data was not explicitly mentioned for the control group and was found by understanding discontinuations instead of an explicit mention of all adverse experiences from that group. The committee also noted the small sample size in the trial. Therefore, this evidence was thought to be unclear.

The concomitant therapies in both intervention arms were unclear (people were allowed to maintain their usual care).

On discussion, the committee concluded that it was not possible to produce a sham device to compare against a walking aid that would provide meaningful results (unlike other comparisons discussed previously). Based on the expert opinion of the committee, they acknowledged that there may be a benefit in using walking aids to support with balance Given the evidence provided and the expert opinion of the committee, they recommended considering the use of walking aids in people with lower limb osteoarthritis.

Weighing up the clinical benefits and harms

The committee agreed that the evidence for walking aids showed that they benefit quality of life and reduce pain compared to no walking aid while the evidence of harms was unclear. In

their experience, walking aids have the advantage of reducing the pressure in the leg joints, helps stability and movement to encourage physical activity and independence. This is particularly the case while waiting for joint replacement or if surgery cannot be undertaken and the stick helps aid exercise and confidence with walking. Therefore, on weighing up the potential benefits, with the difficulties in designing a trial to investigate the use of a walking aid, the committee agreed that the evidence, supported by their expert opinion, was enough to recommend walking aids for people with lower limb osteoarthritis.

On considering the evidence identified for other devices, the committee agreed that, in general, the evidence for insoles, braces, tape, splints and supports showed no clinically important benefits from their usage when compared to no device use. In some cases, potential harms from the devices were identified (such as blisters with braces). Given this, the committee agreed that based on the absence of strong evidence of benefit and some evidence of harm, that these devices should not be routinely offered unless certain criteria were met.

The committee acknowledged that devices may be useful for people with joint instability (when the joint has greater than normal movement in a direction) or abnormal biomechanical loading (when the joint has abnormal features that affect how forces act upon the joint). Different devices may have different indications based on this. For example:

- People with pes planus or valgus knees may have benefits from medial arch support insoles,
- People with varus knee and medial tibiofemoral osteoarthritis may benefit from a supported lateral wedge or mobility shoe,
- A knee brace may provide a feeling of support to an unstable joint or may offload a joint compartment most affected by osteoarthritis,
- A thumb splint may help to stabilise the joint to allow people to have more confidence to carry out specific functional tasks,
- A walking aid may be used to offload the joint, to help with walking function/tolerance and balance and to help people while having a flare.

The type of device to use in people with joint instability or abnormal biomechanical loading will vary on the indication and therefore seeking advice from professionals with an expertise in the area (including for correct fitting of the device to reduce the chance of adverse events) is important. The committee also agreed that some people with joint instability and abnormal biomechanical loading may find it difficult to exercise and providing the device may act as an adjunct to support them to participate in further attempts at exercise. Therefore, the committee recommended insoles, braces, tape, splints or supports should not be offered unless

- there is joint instability or abnormal biomechanical loading, and
- therapeutic exercise is ineffective or unsuitable without the addition of a device, and
- the addition of an aid or device is likely to improve movement and function.

The committee agreed that further research was required in this area. The committee acknowledged that the quality of the evidence for devices was limited, with studies including a small number of participants, having inadequate allocation concealment, and being faced with challenges in achieving blinding and using sham devices that may have active effects and so make the comparison difficult. When considering the evidence for shoes for people with osteoarthritis, the committee acknowledged the evidence used in the review, which providing extra information, had limitations to examination in this guideline due to the difficulties in conducting trials comparing specialist shoes to usual care. Given this, the committee recommended further research to investigate the clinical and cost effectiveness of footwear for people with lower limb osteoarthritis. The committee also considered the limited evidence for non-knee joint sites of osteoarthritis. Given this, the committee recommended

that further research should be done to establish the effect of different devices for non-knee joint sites and to identify which people benefit the most from each device, as this may help to show when devices should be considered for people with osteoarthritis. On considering the relative benefits of the treatments identified in this review, they agreed that further research into foot orthoses, ankle braces and toe braces would be most relevant and so made their research recommendation specific to this. The committee were aware of an ongoing randomised controlled trial on the uses of braces in osteoarthritis (https://www.keele.ac.uk/propoa/) and therefore they did not make a research recommendation in this area.

1.1.12.4 Cost effectiveness and resource use

Unit costs were presented to the committee for the consideration of the cost effectiveness.

Due to the lack of evidence for the majority of the devices, the committee primarily focused on the cost effectiveness of thumb splints and walking aids (canes/sticks).

Thumb splints

One economic evaluation was identified for this review, which compared a verum thumb splint plus a therapist supported self-management programme (SSM) to both placebo plus SSM and SSM alone. The perspective was that of the UK NHS with a trial follow-up period of 12 weeks. Health outcomes were captured via the EQ-5D-5L, which was mapped to EQ-5D-3L. The analysis incorporated costs associated with NHS staff resource use and intervention costs but did not include relevant non-treatment-related healthcare costs. It was graded as directly applicable with potentially serious limitations. The results of the analysis showed that health effects were identical across all three interventions, with the placebo and verum thumb splints incurring an additional cost compared to SSM alone. SSM therefore dominated both alternatives and was considered the optimal strategy from a cost effectiveness standpoint.

Walking aids

On average walking sticks cost around £5, ranging from less than £1 to £13.

As there was quality of life data available, simple back of the envelope calculations were undertaken to estimate the cost effectiveness of walking sticks. The SF-36 data reported in the paper from the clinical review was mapped to EQ-5D to estimate the QALY gain of walking sticks at 8 weeks. This reported a utility gain of 0.077 for walking sticks at 8 weeks compared to no intervention. Even if it is assumed that the utility gain is only maintained for 8 weeks, the cost per QALY gained is only £589.

Acknowledging the limitations of the clinical evidence (as described above) and that the evidence was from one paper with a small sample size and short follow up, the committee did not consider the clinical evidence to be sufficient to make an offer recommendation and so agreed to make a recommendation to consider walking aids in people with lower limb osteoarthritis.

The committee noted that the majority of people with lower limb osteoarthritis currently tend to have a walking aid, not necessarily always for their osteoarthritis, but sometimes due to other associated comorbidities, and so do not expect this recommendation to substantially affect current practice or have a substantial resource impact.

Braces and insoles

One economic evaluation was identified for inclusion in this review. This was based on three network meta-analyses of randomised controlled trials (RCTs) and took a UK perspective. QALYs were calculated by mapping various measures to the EQ-5D, which were then pooled to give an overall estimate. The study was deemed to be directly applicable to the review question.

The model time horizon was relatively short at 8 weeks. Unit costs were also taken from 2011/12 and were therefore unlikely to be representative of current NHS practice. The analysis was therefore graded as having potentially serious limitations.

There were three different meta-analyses used in the study, differentiating trials according to their level of grading and time frame within which outcomes were reported:

1. All trials
2. Subset of trials that were graded as having a low risk of bias for allocation concealment
3. Same as point 2 but further restricting trials to those that reported outcomes between 3 and 13 weeks.

The analysis compared various non-pharmacological interventions to usual care (acupuncture, braces, heat treatment, insoles, interferential therapy, laser/light therapy, manual therapy, neuromuscular electrical stimulation (NMES), pulsed electromagnetic field (PEMF), pulsed electrical stimulation (PES), static magnets and transcutaneous electrical nerve stimulation (TENS)). Insoles were cost effective compared with usual care in an analysis of all trials with a cost per QALY gained of £13,000, while braces was not (cost per QALY gained of £40,000). Insoles remained cost effective versus usual care in an analysis of trials with a low risk of bias for allocation concealment and trials with a low risk of bias for allocation concealment with outcomes between 3-13 weeks with costs per QALY gained of £6,000 and £3,540, respectively. There were no results available for braces.

Although the analysis reported that insoles were cost effective versus usual care, there was no strong clinical evidence of benefit and some evidence of harm. Therefore, the committee decided to not recommend their routine use in practice.

1.1.12.5 Other factors the committee took into account

The committee considered the previous recommendations made regarding devices in the guidance (originally recommended in 2008). This included:

- Offer advice on appropriate footwear (including shock-absorbing properties) as part of core treatments for people with lower limb osteoarthritis
- People with osteoarthritis who have biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/insoles as an adjunct to their core treatments
- Assistive devices (for example, walking sticks and tap turners) should be considered as adjuncts to core treatments for people with osteoarthritis who have specific problems with activities of daily living. If needed, seek expert advice in this context (For example, from occupational therapists or Disability Equipment Assessment Centres)

There was limited evidence on the use of footwear in lower limb osteoarthritis. On discussion with the experts, including people with osteoarthritis and clinicians, it was thought that appropriate footwear could be important in supporting people with lower limb osteoarthritis. Based on the insufficient clinical evidence, this was not recommended. However, it was suggested as an area for further clinical research (see research recommendations).

In this review, there was insufficient evidence of benefit to recommend the use of braces, supports and insoles in the management of osteoarthritis. This was in conjunction to evidence of potential harms with braces and insoles. Given this the committee agreed to change this recommendation and replace it with a new recommendation highlighting the uncertainty in the evidence.

The committee discussed the use of tap turners. These were considered beneficial, but it was agreed that these were outside of the scope of this review question and so did not make a recommendation regarding their use.

The committee noted that the research identified does not appear to represent the diverse population of people with osteoarthritis. They agreed that any further research should be representative of the population, including people from different family backgrounds, and socioeconomic backgrounds, disabled people, and people of different ages and genders. Future work should be done to consider the different experiences of people from diverse communities to ensure that the approach taken can be made equitable for everyone. With this in mind the committee subgrouped their research recommendation by these protected characteristics where appropriate while suggesting that people from each group should be included in the research to ensure that it is applicable to the entire population.

1.1.13 Recommendations supported by this evidence review

This evidence review supports recommendations 1.3.10 and 1.3.11 and the research recommendation on devices. Other evidence supporting these recommendations can be found in evidence review H.

1.1.14 References

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Appendices

Appendix A – Review protocols

Review protocol for the clinical and cost-effectiveness of devices in the management of osteoarthritis

ID	Field	Content
0.	PROSPERO registration number	N/A
1.	Review title	What is the clinical and cost-effectiveness of devices (such as supports, splints and braces) for the management of osteoarthritis?
2.	Review question	3.6 What is the clinical and cost-effectiveness of devices (such as supports, splints and braces) for the management of osteoarthritis?
3.	Objective	To evaluate the clinical and cost-effectiveness of devices (including supports, splints and braces) in the management of osteoarthritis in adults. Devices are frequently used. However, there is no specific type that has been recommended previously.
4.	Searches	The following databases will be searched (all years): • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE Searches will be restricted by: • English language • Human studies • Letters and comments are excluded

		Other searches: • Inclusion lists of relevant systematic reviews will be checked by the reviewer. The searches may be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion if relevant. The full search strategies for MEDLINE database will be published in the final review.
5.	Condition or domain being studied	Osteoarthritis in adults (defined as a clinical diagnosis of osteoarthritis with or without imaging)
6.	Population	Inclusion: • Adults (age ≥16 years) with osteoarthritis affecting any joint Stratify by site of osteoarthritis: • Hip • Knee • Ankle • Foot • Toe • Shoulder • Elbow • Wrist • Hand • Thumb • Finger

		• Temporomandibular joint (TMJ) To note that where evidence for other rare forms of osteoarthritis is identified the committee will stratify into a group they are most similar to. Exclusion: • Children (age ≤16 years) • People with conditions that may make them susceptible to osteoarthritis or often occur alongside osteoarthritis (including: crystal arthritis, inflammatory arthritis, septic arthritis, diseases of childhood that may predispose to osteoarthritis, medical conditions presenting with joint inflammation and malignancy). • Studies in people with meniscal injury without osteoarthritis • Studies with an unclear population (e,g, type of arthritis, proportion of participants with osteoarthritis) • Spinal osteoarthritis
7.	Intervention	Device interventions (minimum intervention duration 1 week): • Orthotic device (insoles and shoes) • Braces • Splints • Supports (for example, tubular bandage) • Straps/tape • Walking aids Each intervention will be considered as a class and be analysed separately.
8.	Comparator	• Each other • Sham intervention • No arthroscopic intervention (including either): ○ Arthroscopic intervention versus no treatment*

		○ Arthroscopic intervention plus additional treatment versus additional treatment alone** **No treatment defined as either (1) doing nothing or (2) very low intensity intervention such as advice* ***Inclusion of studies where additional treatment is the same in each arm will be assessed on a case by case basis. Studies including high intensity additional treatment may not be included due to the risk that treatment could have an interaction with the intervention of interest and mask the true treatment effect.*
9.	Types of study to be included	• Systematic reviews of RCTs • Parallel RCTs • Crossover RCTs will be considered if insufficient evidence is available from parallel RCTs* Non-randomised studies will be excluded. *Insufficient evidence defined as evidence that is insufficient to inform recommendations (either quality or quantity).
10.	Other exclusion criteria	• Non-English language studies • Non-randomised/observational studies Abstracts will be excluded as it is expected there will be sufficient full text published studies available.
11.	Context	N/A
12.	Primary outcomes (critical outcomes)	Stratify by ≤/>3 months (longest time-point in each): • Health-related quality of life [validated patient-reported outcomes, continuous data prioritised] • Physical function [validated patient-reported outcomes, continuous data prioritised] • Pain [validated patient-reported outcomes, continuous data prioritised]
13.	Secondary outcomes (important outcomes)	• Psychological distress [validated patient-reported outcomes, continuous data prioritised] • Osteoarthritis flare-ups [validated patient-reported outcomes, continuous data prioritised] • Number of adverse events [dichotomous]

14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. EviBASE will be used for data extraction. Study investigators may be contacted for missing data where time and resources allow.
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual For intervention reviews the following checklists will be used according to the study design being assessed: • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) 10% of all evidence reviews are quality assured by a senior research fellow. This includes checking: • papers were included /excluded appropriately • a sample of the data extractions • correct methods are used to synthesise data • a sample of the risk of bias assessments Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	• Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). • GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias is tested for when there are more than 5 studies for an outcome.

		The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/ • Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. • WinBUGS will be used for network meta-analysis, if possible given the data identified. Heterogeneity between studies in the effect measures will be assessed using the I^2 statistic and visual inspection. We will consider an I^2 value great than 50% as indicative of substantial heterogeneity. If significant heterogeneity is identified during meta-analysis then subgroup analysis, using subgroups predefined by the GC, will take place. If this does not explain the heterogeneity, the results will be presented using a random-effects model.	
17.	Analysis of sub-groups	Subgroup analysis to be conducted if heterogeneity in the meta-analysis is present: • Diagnosis with or without imaging (indicative of severity) • Multimorbidity (high versus low morbidity score; as defined by study, measured by validated instruments e.g. Charlson Comorbidity Index • Age (≤/> 75 years)	
18.	Type and method of review	☒	Intervention
		☐	Diagnostic
		☐	Prognostic
		☐	Qualitative
		☐	Epidemiologic
		☐	Service Delivery
		☐	Other (please specify)

19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	23/08/2019		
22.	Anticipated completion date	25/08/2021		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	☑	☐
		Piloting of the study selection process	☐	☐
		Formal screening of search results against eligibility criteria	☐	☐
		Data extraction	☐	☐
		Risk of bias (quality) assessment	☐	☐
		Data analysis	☐	☐
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail [Guideline email]@nice.org.uk [Developer to check with Guideline Coordinator for email address]		

		5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre
25.	Review team members	From the National Guideline Centre: Carlos Sharpin [Guideline lead] Rebecca Boffa [Senior systematic reviewer] George Wood [Systematic reviewer] Emma Cowles [Senior health economist] Joseph Runicles [Information specialist] Amber Hernaman [Project manager]
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10127
29.	Other registration details	TBC

30.	Reference/URL for published protocol	TBC	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords	Adults; Braces; Footwear; Insoles; Intervention; Mobility aids; Osteoarthritis; Splinting; Strapping; Taping	
33.	Details of existing review of same topic by same authors	None	
34.	Current review status	☒	Ongoing
		☐	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35..	Additional information	N/A	
36.	Details of final publication	www.nice.org.uk	

Table 36: Health economic review protocol

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken for all years using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2005, abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Studies published in 2005 or later, that were included in the previous guidelines, will be reassessed for inclusion and may be included or selectively excluded based on their relevance to the questions covered in this update and whether more applicable evidence is also identified. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[129] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included.

Where there is discretion

The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2005 or later (including any such studies included in the previous guidelines) but that depend on unit costs and resource data entirely or predominantly from before 2005 will be rated as 'Not applicable'.
- Studies published before 2005 (including any such studies included in the previous guidelines) will be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B – Literature search strategies

- What is the clinical and cost-effectiveness of devices (such as supports, splints and braces) for the management of osteoarthritis?

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[129]

For more information, please see the Methodology review published as part of the accompanying documents for this guideline.

B.1 Clinical search literature search strategy

Searches were constructed using an Osteoarthritis population. All results were then sifted for each question. Search filters were applied to the search where appropriate.

Table 37: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 17 November 2021	Randomised controlled trials Systematic review studies Exclusions (animals studies, letters, comments)
Embase (OVID)	1974 – 17 November 2021	Randomised controlled trials Systematic review studies Exclusions (animals studies, letters, comments)
The Cochrane Library (Wiley)	Cochrane Reviews to 2021 Issue 11 of 12 CENTRAL to 2021 Issue 11 of 12	None

Medline (Ovid) search terms

1.	exp osteoarthritis/
2.	(osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*).ti,ab.
3.	(degenerative adj2 arthritis).ti,ab.
4.	coxarthrosis.ti,ab.
5.	gonarthrosis.ti,ab.
6.	or/1-5
7.	letter/
8.	editorial/
9.	news/
10.	exp historical article/
11.	Anecdotes as Topic/
12.	comment/
13.	case report/
14.	(letter or comment*).ti.
15.	or/7-14

16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16
18.	animals/ not humans/
19.	exp Animals, Laboratory/
20.	exp Animal Experimentation/
21.	exp Models, Animal/
22.	exp Rodentia/
23.	(rat or rats or mouse or mice or rodent*).ti.
24.	or/17-23
25.	6 not 24
26.	limit 25 to English language
27.	randomized controlled trial.pt.
28.	controlled clinical trial.pt.
29.	randomi#ed.ti,ab.
30.	placebo.ab.
31.	randomly.ti,ab.
32.	Clinical Trials as topic.sh.
33.	trial.ti.
34.	or/27-33
35.	Meta-Analysis/
36.	exp Meta-Analysis as Topic/
37.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
38.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
39.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
40.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
41.	(search* adj4 literature).ab.
42.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
43.	cochrane.jw.
44.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
45.	or/35-44
46.	26 and (34 or 45)

Embase (Ovid) search terms

1.	exp osteoarthritis/
2.	(osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*).ti,ab.
3.	(degenerative adj2 arthritis).ti,ab.
4.	coxarthrosis.ti,ab.
5.	gonarthrosis.ti,ab.
6.	or/1-5
7.	letter.pt. or letter/
8.	note.pt.
9.	editorial.pt.
10.	case report/ or case study/
11.	(letter or comment*).ti.

12.	or/7-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animal/ not human/
16.	nonhuman/
17.	exp Animal Experiment/
18.	exp Experimental Animal/
19.	animal model/
20.	exp Rodent/
21.	(rat or rats or mouse or mice or rodent*).ti.
22.	or/14-21
23.	6 not 22
24.	Limit 23 not English language
25.	random*.ti,ab.
26.	factorial*.ti,ab.
27.	(crossover* or cross over*).ti,ab.
28.	((doubl* or singl*) adj blind*).ti,ab.
29.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
30.	crossover procedure/
31.	single blind procedure/
32.	randomized controlled trial/
33.	double blind procedure/
34.	or/25-33
35.	systematic review/
36.	meta-analysis/
37.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
38.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
39.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
40.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
41.	(search* adj4 literature).ab.
42.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
43.	cochrane.jw.
44.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
45.	or/35-44
46.	24 and (34 or 45)

Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Osteoarthritis] explode all trees
#2.	(osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*):ti,ab
#3.	(degenerative near/2 arthritis):ti,ab
#4.	coxarthrosis:ti,ab
#5.	gonarthrosis:ti,ab

#6.	(or #1-#5)

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to a Gout population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA – this ceased to be updates after March 2018). NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics studies and quality of life studies. Searches for quality of life studies were run for general information.

Table 38: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	1 January 2014 – 17 November 2021	Health economics studies Quality of life studies Exclusions (animals studies, letters, comments)
Embase	1 January 2014 – 17 November 2021	Health economics studies Quality of life studies Exclusions (animals studies, letters, comments)
Centre for Research and Dissemination (CRD)	HTA - Inception – 31 March 2018 NHSEED - Inception to 31 March 2015	None

Medline (Ovid) search terms

1.	exp osteoarthritis/
2.	(osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*).ti,ab.
3.	(degenerative adj2 arthritis).ti,ab.
4.	coxarthrosis.ti,ab.
5.	gonarthrosis.ti,ab.
6.	or/1-5
7.	letter/
8.	editorial/
9.	news/
10.	exp historical article/
11.	Anecdotes as Topic/
12.	comment/
13.	case report/
14.	(letter or comment*).ti.
15.	or/7-14
16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16

18.	animals/ not humans/
19.	exp Animals, Laboratory/
20.	exp Animal Experimentation/
21.	exp Models, Animal/
22.	exp Rodentia/
23.	(rat or rats or mouse or mice or rodent*).ti.
24.	or/17-23
25.	6 not 24
26.	limit 25 to English language
27.	Economics/
28.	Value of life/
29.	exp "Costs and Cost Analysis"/
30.	exp Economics, Hospital/
31.	exp Economics, Medical/
32.	Economics, Nursing/
33.	Economics, Pharmaceutical/
34.	exp "Fees and Charges"/
35.	exp Budgets/
36.	budget*.ti,ab.
37.	cost*.ti.
38.	(economic* or pharmaco?economic*).ti.
39.	(price* or pricing*).ti,ab.
40.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
41.	(financ* or fee or fees).ti,ab.
42.	(value adj2 (money or monetary)).ti,ab.
43.	or/27-42
44.	quality-adjusted life years/
45.	sickness impact profile/
46.	(quality adj2 (wellbeing or well being)).ti,ab.
47.	sickness impact profile.ti,ab.
48.	disability adjusted life.ti,ab.
49.	(qal* or qtime* or qwb* or daly*).ti,ab.
50.	(euroqol* or eq5d* or eq 5*).ti,ab.
51.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
52.	(hui or hui1 or hui2 or hui3).ti,ab.
53.	(health* year* equivalent* or hye or hyes).ti,ab.
54.	discrete choice*.ti,ab.
55.	rosser.ti,ab.
56.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.

57.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
58.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
59.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
60.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
61.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
62.	or/44-61
63.	26 and (43 or 62)

Embase (Ovid) search terms

1.	exp osteoarthritis/
2.	(osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*).ti,ab.
3.	(degenerative adj2 arthritis).ti,ab.
4.	coxarthrosis.ti,ab.
5.	gonarthrosis.ti,ab.
6.	or/1-5
7.	letter.pt. or letter/
8.	note.pt.
9.	editorial.pt.
10.	case report/ or case study/
11.	(letter or comment*).ti.
12.	or/7-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animal/ not human/
16.	nonhuman/
17.	exp Animal Experiment/
18.	exp Experimental Animal/
19.	animal model/
20.	exp Rodent/
21.	(rat or rats or mouse or mice or rodent*).ti.
22.	or/14-21
23.	6 not 22
24.	Limit 23 to English language
25.	health economics/
26.	exp economic evaluation/
27.	exp health care cost/
28.	exp fee/
29.	budget/
30.	funding/
31.	budget*.ti,ab.

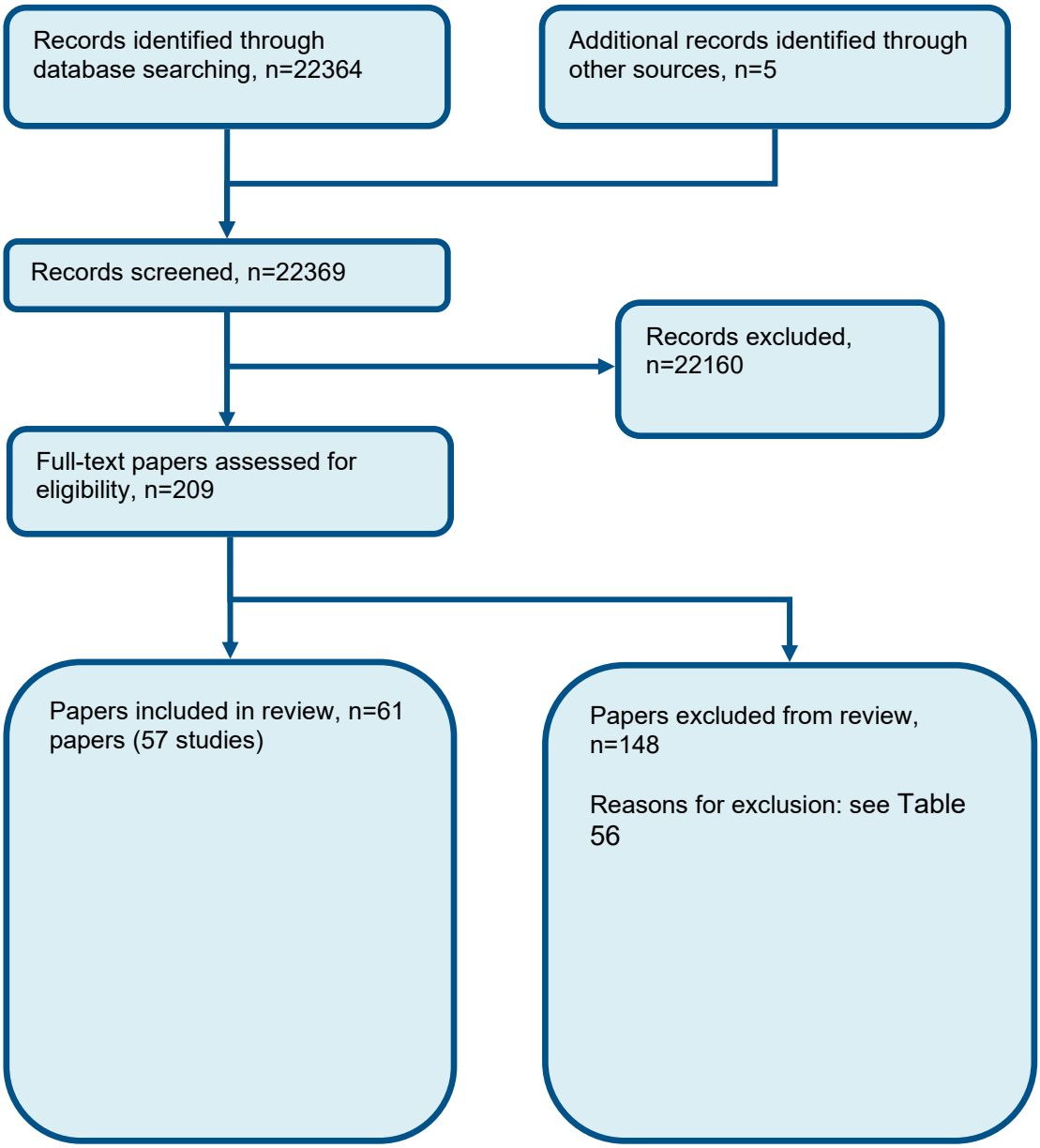
32.	cost*.ti.
33.	(economic* or pharmaco?economic*).ti.
34.	(price* or pricing*).ti,ab.
35.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
36.	(financ* or fee or fees).ti,ab.
37.	(value adj2 (money or monetary)).ti,ab.
38.	or/25-37
39.	quality adjusted life year/
40.	"quality of life index"/
41.	short form 12/ or short form 20/ or short form 36/ or short form 8/
42.	sickness impact profile/
43.	(quality adj2 (wellbeing or well being)).ti,ab.
44.	sickness impact profile.ti,ab.
45.	disability adjusted life.ti,ab.
46.	(qal* or qtime* or qwb* or daly*).ti,ab.
47.	(euroqol* or eq5d* or eq 5*).ti,ab.
48.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
49.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
50.	(hui or hui1 or hui2 or hui3).ti,ab.
51.	(health* year* equivalent* or hye or hyes).ti,ab.
52.	discrete choice*.ti,ab.
53.	rosser.ti,ab.
54.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
55.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
56.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
57.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
58.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
59.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
60.	or/39-59
61.	24 and (38 or 60)

NHS EED and HTA (CRD) search terms

#1.	MeSH DESCRIPTOR Osteoarthritis EXPLODE ALL TREES
#2.	((osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*))
#3.	((degenerative adj2 arthritis))
#4.	(coxarthrosis)
#5.	(gonarthrosis)
#6.	#1 OR #2 OR #3 OR #4 OR #5
#7.	(#6) IN NHSEED
#8.	(#6) IN HTA

Appendix C – Effectiveness evidence study selection

Figure 1: Flow chart of clinical study selection for the review of the clinical and cost-effectiveness of devices in the management of osteoarthritis



Appendix D – Effectiveness evidence

Study	Akinbo 2007[6]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Nigeria; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People referred for physiotherapy by an orthropaedic surgery with a diagnosis of medial/varus osteoarthritis of the knee joint with femorotibia alignment >170 degrees
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People who were able to walk independently without an ambulatory aid (mild/moderate varus osteoarthritis of the knee) and subjects with femorotibia alignment (angle) greater than 170 degrees.
Exclusion criteria	People with previous experience of lateral wedge insoles; a history of knee surgery; people using analgesics; people using a walking aid (e.g. walking stick, frame, and crutches); severe osteoarthritis
Recruitment/selection of patients	76 people were referred for physiotherapy rehabilitation. 10 declined to participate in the study and 16 did not meet the inclusion criteria.
Age, gender and ethnicity	Age - Mean (SD): 53.5 (2.8). Gender (M:F): 22:28. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Not stated / Unclear (?no imaging. However, only states that they had a diagnosis from an orthopaedic surgeon, so could have included imaging.). 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Mild/moderate Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Orthotic devices - Insoles. Lateral wedge insole: Made with macro rubber material. The standard insole had lateral heel elevation of 8mm, lateral sole elevation of 5mm. The insoles were constructed with standardized elevations to fit inside existing shoes of each subject and could be removed if they were not helping/worsening symptoms. The wedge could be moved to different shoes. The participants were instructed to place the insoles into footwear during weight bearing and ambulation throughout the study and wear it as much as possible for 6 weeks. Participants also had thermal therapy with soft tissue massage using the standing luminous IRR (Thera Lux model)

	three times per week for 6 weeks. The thermal irradiation was for 20 minutes per session (10 minutes for the anterior, and 10 minutes for the posterior aspects of the knee). Soft tissue massage was performed with the aid of an analgesic ointment after thermal therapy. The duration of the massage sessions was between 15 and 20 minutes.. Duration 6 weeks. Concurrent medication/care: Analgesia was not permitted during the study (apart from the ointment during the massage therapy).. Indirectness: No indirectness (n=25) Intervention 2: No device intervention. Participants had thermal therapy with soft tissue massage (no orthotic device) using the standing luminous IRR (Thera Lux model) three times per week for 6 weeks. The thermal irradiation was for 20 minutes per session (10 minutes for the anterior, and 10 minutes for the posterior aspects of the knee). Soft tissue massage was performed with the aid of an analgesic ointment after thermal therapy. The duration of the massage sessions was between 15 and 20 minutes.. Duration 6 weeks. Concurrent medication/care: Analgesia was not permitted during the study (apart from the ointment during the massage therapy).. Indirectness: No indirectness
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Knee pain intensity (WOMAC pain subscale) at 6 weeks; Group 1: mean 5.1 (SD 1.3); n=25, Group 2: mean 8.5 (SD 2.5); n=25; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Baseline insoles: 12.4 (2.2). Baseline no device intervention: 12.0 (3.0) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, height, weight and BMI.; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: Functional disability (WOMAC physical function subscale) at 6 weeks; Group 1: mean 16.1 (SD 5.2); n=25, Group 2: mean 23.3 (SD 3.8); n=25; WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Baseline insoles: 33.2 (8.6). Baseline no device intervention: 33.6 (7.0) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, height, weight and BMI.; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Arazpour 2013[12]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=24)
Countries and setting	Conducted in Iran
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Medial compartment knee osteoarthritis diagnosed clinically (by knee symptoms) and radiographically (by the Kellgren and Lawrence grading system)
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People with medial compartment knee osteoarthritis of grade 1 or 2 confirmed by radiological examination.
Exclusion criteria	Arthroscopic surgery in the past six months; knee trauma and amputation of the lower limb; neurological disease; symptomatic spine, hip, ankle, or foot disease; intra-articular steroid injection in the past three months; hyaluronic acid injection in the last nine months; previous fracture of the tibia; skin disease; peripheral vascular disease; blindness; severe cardiovascular defect; and an inability to apply a brace (e.g. because of arthritis in the hand, or difficulty in bending).
Recruitment/selection of patients	24 people were referred to the orthotics and prosthetics department of the University of Social Welfare and Rehabilitation Science by orthopaedic specialists.
Age, gender and ethnicity	Age - Mean (SD): 59.3 (2.4). Gender (M:F): 9:15. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: People with multimorbidities excluded (Not explicitly stated, but the exclusion criteria excludes people with a lot of comorbidities.).
Extra comments	Severity: Not explicitly stated. Kellgren Lawrence grades 1-2. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=12) Intervention 1: Orthotic devices - Insoles. Laterally wedged insoles prepared from a cork composite with a density of 60 durometers. Constructed with a medio-lateral elevation of 10mm along the entire length of the foot, which represented a 6 degree lateral wedge. The insoles were trimmed to fit the subjects shoes and then placed inside instead of the removal inserts of the shoes. In people with unilateral knee osteoarthritis, the lateral wedge inlay was used on the affected side. A flat 10-mm thick inlay was used on the non-affected side. All people with the inlay were provided by a pair of comfortable, identically style lightweight shoes pitches with a one-inch heel height.. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness

	(n=12) Intervention 2: Braces. Knee unloader brace, which utilized a bilateral side bar design. Custom molded from a cast of each person's lower extremity, using the application of the three point pressure principle in applying forces to correct the varus knee angulation. Comprised of thigh and calf polypropylene shells which extended in length of to 2/3 of the femoral and tibial length. The proximal and distal shells were connected via free orthotic knee joints. Adjustment of the valgus force was performed and set as needed for each volunteer subject at the initial fitting prior to the six-week period. The initial valgus angle was set at a position which did not exert excessive and unacceptable interface pressure at either the proximal and distal ends of the superstructure of the orthosis or at least the orthotic knee joint position adjacent to the lateral knee joint space while providing valgus correction tot eh knee. People subsequently attended on a weekly basis to adjust the orthosis fit.. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus BRACES Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Pain (VAS) at 6 weeks; Group 1: mean 3.91 (SD 0.79); n=12, Group 2: mean 3.83 (SD 0.83); n=12; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline insoles: 6.75 (0.86). Baseline braces: 6.08 (0.90). Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Other 2 - Low, Comments - Unclear if it is an RCT. Is reported to have random assignment, but also states that it is a 'quasi-experimental' study.; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, body mass index, indexed knee, bilateral osteoarthritis, Kellgren Lawrence grade.; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Arazpour 2017[14]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=25)
Countries and setting	Conducted in Iran; Setting:
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Thumb
Subgroup analysis within study	Not applicable
Inclusion criteria	The inclusion criteria for patients included those patients with (1) a positive clinical and radiological diagnosis of thumb CMC joint OA of grade 1 or 2, of either gender; (2) pain in the base of the thumb; and (3) a cognitive ability to respond to a questionnaire and to undergo the tests. In addition, patients who (1) had no deformities in the affected hand, or DIP joint of the thumb; (2) had not used a splint on the affected thumb during the previous 6 months; (3) had not undergone any surgery on the affected hand during the previous 6 months; (4) had no potential allergy to thesplint material; and (5) had no evidence of injection therapy in the affected hand in the previous 6 months, or the presence of additional disease affecting the ipsilateral upper limb (e.g. carpal tunnel syndrome, De Quatrains tendonitis, Dupuytren's contracture, arthritis, and fifth or sixth cervical vertebral disc herniation) were also includedas a part of this study. Ethical approval was obtained fromthe Ethics Committee of the University of Social Welfareand Rehabilitation Sciences. All patients signed the consent forms to participate in this study.
Exclusion criteria	No further exclusion criteria
Recruitment/selection of patients	Patients were referred with a diagnosis of grades 1 and 2 thumb CMC joint OA by an orthopedic surgeon at theOrthotics and Prosthetics Department of University ofSocial Welfare and Rehabilitation Sciences.
Age, gender and ethnicity	Age - Mean (SD): 50.18 ± 5.7 years; 52.33 ± 6.4 years. Gender (M:F): 3:22. Ethnicity: Not specified
Further population details	1. Age: Mixed 2. Diagnostic method: Not stated / Unclear 3. Multimorbidities: Not stated / Unclear
Extra comments	Healthy controls also selected in study but not included in analysis. The mean ± SD symptoms durations were 12 ± 1.95 months and 15 ± 1.92 months, respectively.
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Splints. Custom splint device. The first step in the production of a custom-made ortho-sis was to obtain a pattern which matched the dimensions of the patient's hand. Low-temperature moldable thermoplatic material

	with a 3.2-mm thickness (Aquafit NS Stiff:3.2 mm (1/8″), Orfit Company, Inc., Belgium) was then used to construct a custom-made device from the template by direct molding to the patient's wrist and hand (when wrist is in a neutral position and thumb and middle fingers' pulp are in touch with each other) with appropriate trim-ming to allow thumb function. After the material had cooled,a 3-mm-low-density Plastazote lining was adhered to theshell and closed by Velcro© on the patients' hand (Figure 1).The subjects were asked to wear the orthosis when performing ADLs and remove them during sleeping,bathing, and in conditions that would adversely affect the splint material (e.g. when exposed to excessive heat).Each subject was further advised to keep the splint in a clean condition. Steps to apply and remove the orthosis were also demonstrated to all the subjects. They were further instructed to contact the rehabilitation team if they felt any discomfort while wearing the orthosis. During the 4-week study period, the patients in the splint group wore the splint for at least 5 h, with mean ± SD duration of 7.5 ± 2.5 h/day.. Duration 4 weeks. Concurrent medication/care: Not specified. Indirectness: No indirectness (n=9) Intervention 2: No device intervention. No splint control group. No further details. Duration 4 weeks. Concurrent medication/care: Not specified. Indirectness: No indirectness
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SPLINTS versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Thumb: VAS pain (final values) at 4 weeks; Group 1: mean 4 (SD 1.31); n=16, Group 2: mean 3.44 (SD 0.52); n=9; VAS 0-10 Top=High is poor outcome; Comments: Baseline: 5(1.5); 3.55(1.23) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing: Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Thumb: Michigan hand questionnaire function subscale (final values) at 4 weeks; Group 1: mean 67.81 (SD 19.19); n=16, Group 2: mean 71.66 (SD 18.2); n=9; MHQ subscale 0-100 Top=High is poor outcome; Comments: Baseline 60.93 (22); 77.22(12.01) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Aydogdu 2017[17]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=54)
Countries and setting	Conducted in Turkey; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention time: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Unilateral knee osteoarthritis according to the American College of Rheumatology with stage 2-3 Kellgren-Lawrence radiographic changes
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Unilateral knee osteoarthritis according to the American College of Rheumatology and were stage 2 and 3 based on the Kellgren-Lawrence criteria
Exclusion criteria	People who underwent knee joint operation; pregnancy or "mental problems" preventing them from doing exercise; participants with infection in the areas close to the knee joint; metal implant; allergy to kinesio tape
Recruitment/selection of patients	94 people applied to the Private Meditepe and Kardelen Medical Centers for treatment. 24 were not eligible for the study.
Age, gender and ethnicity	Age - Mean (SD): 51.9 (9.3). Gender (M:F): 8:46. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear (People did not have mental health problems that interfered with their participation in the study. Otherwise, not stated.).
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grade 2-3 changes. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=28) Intervention 1: Straps/tape - Tape. Kinesio taping on quadriceps and hamstring muscles using a Y-shaped technique. All were taped according to Kinesio taping guidelines by the same physiotherapist. Before application the skin with cleaned with alcohol. It was applied while the person lay in a supine position with the hip flexed at 30 degrees and the knee flexed at 60 degrees. Taping was first applied to quadriceps femoris (from a point 10cm inferior to the anterior superior iliac spine, bisected at the junction between quadriceps femoris tendon and the patella, and circled around the patella, ending at the inferior side). The first 5cm of tape was not stretched. The portion between the first part of tape and superior patella was stretched to 50-70%. The remaining tape aroudn the patella remained un-stretched. After that, in the prone position, hamstring was taped secondly using the same method. The people were instructed to take the tape off before the subsequent applicable, with the tape being renewed daily for six weeks.

	The participants also had ultrasound, TENS, electrical stimulatio, exercise and cold packs. The hot pack was applied for 20 minutes. Ultrasound was applied for 5 minutes by using a 1.5 watt/cm² treatment dosage with a 1MHz ultrasound head, and conventional TENS was applied for 20 minutes. Supervised exercises consisted of stretching hamstring and quadriceps muscles, and isometric and isotonic exercises for quadriceps, hip adductors, gluteus medius and maximus, open chain exercises like straight leg raise and leg raise with internal and external rotation and closed chain exercises like mini squat. All exercises were repeated with 10 times and were done only one time by people. A session took about 1 hour. This treatment program started after the first assessment and took place over 3 weeks with 5 sessions a week (15 sessions in total.. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=26) Intervention 2: No device intervention. The participants had ultrasound, TENS, electrical stimulatio, exercise and cold packs. The hot pack was applied for 20 minutes. Ultrasound was applied for 5 minutes by using a 1.5 watt/cm² treatment dosage with a 1MHz ultrasound head, and conventional TENS was applied for 20 minutes. Supervised exercises consisted of stretching hamstring and quadriceps muscles, and isometric and isotonic exercises for quadriceps, hip adductors, gluteus medius and maximus, open chain exercises like straight leg raise and leg raise with internal and external rotation and closed chain exercises like mini squat. All exercises were repeated with 10 times and were done only one time by people. A session took about 1 hour. This treatment program started after the first assessment and took place over 3 weeks with 5 sessions a week (15 sessions in total.. Duration 3 weeks (15 sessions). Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (Funded by Marmara University, Scientific Research Research Projects Committee)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS QoL at 3-6 weeks; Group 1: mean 59.53 (SD 13.81); n=28, Group 2: mean 61.3 (SD 13.8); n=26; KOOS Quality of Life Subscale 0-100 Top=High is good outcome; Comments: Baseline tape: 47.96 (13.90). Baseline no device intervention: 47.96 (15.66).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, body weight, height and body mass index; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS pain at 3-6 weeks; Group 1: mean 73.21 (SD 10.43); n=28, Group 2: mean 74.57 (SD 10.89); n=26; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Baseline tape: 64.67 (11.08). Baseline no device intervention: 63.53 (8.50).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, body weight, height and body mass index; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Physical function at ≤3- or >3- months - Actual outcome for Knee: KOOS ADL at 3-6 weeks; Group 1: mean 78.78 (SD 7.5); n=28, Group 2: mean 78.38 (SD 8.36); n=26; KOOS Activities of Daily Living subscale 0-100 Top=High is good outcome; Comments: Baseline tape: 72.92 (7.22). Baseline no device intervention: 71.65 (6.77). Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: Serious indirectness, Comments: ?Indirectness - Is KOOS ADL equivalent to physical function. It also reports KOOS sports and recreation. Should these be combined to make physical function?; Baseline details: Reported age, body weight, height and body mass index; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Baker 2007[18]
Study type	RCT (Patient randomised; Crossover: 4 weeks)
Number of studies (number of participants)	1 (n=90)
Countries and setting	Conducted in USA; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention time: 6 weeks (for each intervention)
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People with medial but not lateral tibiofemoral narrowing (≥1 on a 0-3 point scale) on posterior semiflexed radiographs and scores reflecting moderate pain on the WOMAC pain subscale
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age ≥50 years, medial but not lateral tibiofemoral narrowing (≥1 on a 0-3 point scale) on posteroanterior semiflexed radiographs, and scores reflecting at least moderate pain for 2 of the 5 items of the WOMAC pain subscale
Exclusion criteria	If people were nonambulatory or wheel chair users, or usually used an ambulatory aid to walk; had limited ability to wear shoes (≤8 hours/day); had undergone amputation of or previous major trauma to a foot, raising concern that using an insert might worsen foot pain; had foot sores or ulcers; had neuropathy attributable to diabetes or other causes; were not fluent in English; experienced pain emanating more from the back or hip than from the knee; planned to moved from the area within 7 months of screening; had symptomatic comorbid disease that limited walking more than knee pain limited walking; had received a corticosteroid injection in the knee in a month before screening; had bilateral total knee replacements or plans for total knee replacement surgery during this trial period; had known inflammatory arthritis; failed to pass the run-in test; had undergone initiation of glucosamine and/or chondroitin and/or NSAID treatment 2 months prior to screening; or were unwilling to forego starting any new medication during the trial period
Recruitment/selection of patients	People were recruited from the following 3 sources: a previous natural history study, lists of individuals seeking care at a local facility who said they were interested in participating in research, and advertisements in local newspapers
Age, gender and ethnicity	Age - Mean (SD): 68.0 (9.3). Gender (M:F): 35:51. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Majority were Kellgren Lawrence grade 3-4. Duration of symptoms: not stated
Indirectness of population	No indirectness
Interventions	(n=90) Intervention 1: Orthotic devices - Insoles. A 5 degree lateral wedge insole on the side of the affected knee, made of NikelPlast material (if bilateral, was placed on the more affected side. If both sides were equally affected, the knee was selected by random). Followed by a 4 week washout period before using the neutral insole for 6 weeks.. Duration 6

	weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=90) Intervention 2: Sham device. A neutral insole wedge (1/8 inch thick shoe insert) on the side of the affected knee (if bilateral, was placed on the more affected side. If both sides were equally affected, the knee was selected by random).. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (Supported by an NIHA grant (grant P60-AR-47785))

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain score at 6 weeks; MD; 14.5 (95%CI -23.1 to 52.2) (P-value: 0.45) WOMAC pain subscale 0-500 Top=High is poor outcome, Comments: Reported to be a model predictor that is a beta coefficient. 14.5 means a lower score on WOMAC with the lateral wedge insole compared to the neutral insole. Baseline neutral to wedged group: 263 (95). Baseline wedged to neutral group: 268 (115).;
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, male sex, BMI, Kellgren-Lawrence grade, WOMAC pain score, unilateral/bilateral osteoarthritis; Group 1 Number missing: 4, Reason: Uses a model to predict outcomes. 3 people withdrew consent (2 due to travel/time commitment and 1 on the advice of their physician) and 1 had patellofemoral OA rather than tibiofemoral OA. (3 people withdrew from the neutral to wedge group, 1 person withdrew from the wedge to neutral group).; Group 2 Number missing: 4, Reason: Uses a model to predict outcomes. 3 people withdrew consent (2 due to travel/time commitment and 1 on the advice of their physician) and 1 had patellofemoral OA rather than tibiofemoral OA. (3 people withdrew from the neutral to wedge group, 1 person withdrew from the wedge to neutral group).

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Side effects at 6 weeks; Group 1: 11/86, Group 2: 18/86; Comments: Insoles: 6 musculoskeletal symptoms, 1 blister, 4 falls. Sham: 10 musculoskeletal symptoms, 5 blisters, 3 falls
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, male sex, BMI, Kellgren-Lawrence grade, WOMAC pain score, unilateral/bilateral osteoarthritis; Group 1 Number missing: 4, Reason: Uses a model to predict outcomes. 3 people withdrew consent (2 due to travel/time commitment and 1 on the advice of their physician) and 1 had patellofemoral OA rather than tibiofemoral OA. (3 people withdrew from the neutral to wedge group, 1 person withdrew from the wedge to neutral group).; Group 2 Number missing: 4, Reason: Uses a model to predict outcomes. 3 people withdrew consent (2 due to travel/time commitment and 1 on the advice of their physician) and 1 had patellofemoral OA rather than tibiofemoral OA. (3 people withdrew from the neutral to wedge group, 1 person withdrew from the wedge to neutral group).

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Bani 2013[19]
Study type	RCT (Patient randomised; Crossover: 2 weeks)
Number of studies (number of participants)	1 (n=35)
Countries and setting	Conducted in Iran; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention time: 8 week (4 weeks for each of the splints and 8 weeks for no treatment)
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiological diagnosis of thumb carpometacarpal joint OA grade 1 and 2
Stratum	Thumb
Subgroup analysis within study	Not applicable
Inclusion criteria	Clinical and radiological diagnosis of thumb carpometacarpal joint OA grade 1 and 2 in either gender, with evidence of pain in the base of the thumb
Exclusion criteria	Other deformities of the affected hand; deformities of thumb distal interphalangeal joint joint; use of a splint on the thumb during the previous 6 months; evidence of surgery on the studied hand in the previous 6 months; allergy to splint material; inability to respond to a questionnaire or to perform the function tests; evidence of injection therapy in the studied hand during the previous 6 months; existence of other diseases affecting the thumb or wrist (e.g. carpal tunnel syndrome, De Quatrains tendonitis, Dupuytren's contracture, arthritis and fifth or sixth cervical vertebral disc herniation).
Recruitment/selection of patients	People referred by an orthopaedic surgeon to the Orthotics and Prosthetics department of the University of Social Welfare and Rehabilitation Sciences
Age, gender and ethnicity	Age - Other: Mean: 55.6. Gender (M:F): 10:25. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Grade 1 and 2 Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=24) Intervention 1: Splints. Custom made thumb splint - constructed based on a pattern which matched the dimensions of the patient's hand using low temperature-moulding material (Orfit Company, Inc. Belgium) with a 1.6mm thickness. After the splint had cooled, Plastazote with a 1.6mm thickness was adhered to the inside of the splint, and the splint was then closed by Velcro on the patients' hand. People were asked to use these for their routine activities of daily living and remove them during sleeping, bathing and in dangerous conditions which could be harmful for the splint. They were advised to contact the therapist if they felt discomfort from the splint.. Duration 4 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness

	Comments: There is a second arm for splints. In the three study groups, the splint groups had four weeks with one splint and four weeks with the other (eight weeks of wearing a splint of some type). These two will be pooled together for the analysis (with values for each group reported in the comments section of each result), but shall be reported separately in the interventions section for completeness. (n=24) Intervention 2: Splints. Prefabricated splint - A manufactured splint was chosen based on the person's hand size. The neoprene prefabricated thumb splint covered the first carpometacarpal and metatarsophalangeal (?metacarpalphalangeal) joints and allowed for a full range of motion in the other fingers.. Duration 4 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness Comments: There is a second arm for splints. In the three study groups, the splint groups had four weeks with one splint and four weeks with the other (eight weeks of wearing a splint of some type). These two will be pooled together for the analysis (with values for each group reported in the comments section of each result), but shall be reported separately in the interventions section for completeness. (n=11) Intervention 3: No device intervention. No treatment. Duration 10 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (Financial support from the University of social Welfare and Rehabilitation Science)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SPLINTS versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Thumb: Pain (visual analogue scale) at 10 weeks; Group 1: mean 2.5 (SD 1.53); n=24, Group 2: mean 7.5 (SD 1.2); n=11; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Splint value calculated by pooling together the custom and prefabricated splint results. Reported custom splint: 2.9 (1.7). Reported prefabricated splint 2.1 (1.2). Baseline values: Baseline custom splint: 6.7 (2.0). Baseline prefabricated splint: 6.6 (1.9). Baseline no treatment: 6.5 (0.9).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, index hand, affected hand, splint use, and baseline values for outcomes; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Thumb: Disability of the Arm, Shoulder and Hand (DASH) questionaire at 10 weeks; Group 1: mean 74.15 (SD 9.4); n=24, Group 2: mean 53.5 (SD 12.3); n=11; Disability of the Arm, Shoulder and Hand (DASH) 0-100 Top=High is good outcome; Comments: Splint value calculated by pooling together the custom and prefabricated splint results. Reported custom splint: 75.2 (12.2). Reported prefabricated splint 73.1 (5.0). Baseline values: Baseline custom splint: 58.0 (6.5). Baseline prefabricated splint: 61.2 (4.9). Baseline no treatment: 60.1 (13.1).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, index hand, affected hand, splint use, and baseline values for outcomes; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Barrios 2009[21]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=66)
Countries and setting	Conducted in USA; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Medial tibiofemoral osteoarthritis with radiographical diagnosis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People between the ages of 40-75 years with radiographically diagnosed medial tibiofemoral osteoarthritis. Kellgren-Lawrence grades II-IV in the medial compartment. Presence of medial knee pain during walking of at least 3/10 on the visual analogue scale (VAS), and independence from assistive devices on locamotion.
Exclusion criteria	Any neurological, cardiopulmonary or musculoskeletal condition that would hinder ambulation; reduced lateral compartment joint space width on the 30 degree flexed knee radiograph; presence of lateral or patellofemoral joint symptoms; any foot condition that could potentially be aggravated by a wedged device (including hallux valgus, hallux rigidus and plantar fasciitis).
Recruitment/selection of patients	Consecutive subjects recruited from advertisements at physician, physical therapy and wellness clinics local or nearby to the University of Delaware.
Age, gender and ethnicity	Age - Mean (SD): 62.4 (8.5). Gender (M:F): 28:37. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades II-IV. Median grade: III. Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=35) Intervention 1: Orthotic devices - Insoles. A non-custom pair of neutral contoured foot orthoses. Constructed of 70 durometer crepe with a full-length micropuff covering. The amount of wedging was individually prescribed. Subjects were asked to perform a lateral step-down off of an 8 inch step while standing on their affected leg in the neutral orthosis. They were asked to grade the pain. After that a 5 degree full-length wedge of EVA material was placed under the device of the affected side. The step down test was repeated to see if there was pain relief. This was repeated with different combinations until achieving maximal pain relief with the minimal amount of wedging (between 5 and 15

	degrees). Once this was known, the wedge was adhered to the undersurface of the orthosis. Subjects were instructed to gradually increase the wear time with the orthoses and shoes over a 3-4 day period. They were instructed not to use the orthoses with any other footwear. Devices were modified after two weeks if there was any discomfort.. Duration 1 year. Concurrent medication/care: Concomitant treatments that were permitted included medications for pre-existing medical conditions, acetaminophen up to 4000mg/day, and short-acting analgesics or NSAIDs as needed for pain management. However, anaesthetic, steroid or viscosupplementation injections less than 6 months prior to study initiation were prohibited. Oral analgesia on the day of, or day before a study visit was prohibited. Concurrent physical therapy for treatment of medial femorotibial osteoarthritis was not allowed.. Indirectness: No indirectness (n=31) Intervention 2: Sham device. A non-custom pair of neutral contoured foot orthoses (same as intervention group). These were not modified with no wedge being introduced.. Duration 1 year. Concurrent medication/care: Concomitant treatments that were permitted included medications for pre-existing medical conditions, acetaminophen up to 4000mg/day, and short-acting analgesics or NSAIDs as needed for pain management. However, anaesthetic, steroid or viscosupplementation injections less than 6 months prior to study initiation were prohibited. Oral analgesia on the day of, or day before a study visit was prohibited. Concurrent physical therapy for treatment of medial femorotibial osteoarthritis was not allowed.. Indirectness: No indirectness
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 1 month; Group 1: mean 35.3 (SD 4.3); n=29, Group 2: mean 31.4 (SD 4.3); n=30; WOMAC pain subscale (100mm VAS) 0-100 Top=High is poor outcome; Comments: Reports final scores and p values for change scores - used to estimate standard deviations for change scores (converting final scores into change scores). P-value 1 month pain: ≤0.001. 1 month insole: 35.3. 1 month control: 31.4. Baseline insole: 42.9. Baseline control: 38.4.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 6, Reason: 3 withdrew for personal reasons, 2 for adverse events, 1 for intolerance; Group 2 Number missing: 1, Reason: 1 withdrew for personal reasons
- Actual outcome for Knee: WOMAC pain subscale at 1 year; Group 1: mean 32.7 (SD 2.4); n=20, Group 2: mean 30.2 (SD 2.4); n=25; WOMAC pain subscale (100mm VAS) 0-100 Top=High is poor outcome; Comments: Reports final scores and p values for change scores - used to estimate standard deviations for change scores (converting final scores into change scores). P-value 12 month pain: ≤0.001. 12 month insole: 32.7. 12 month control: 30.2. Baseline insole: 42.9. Baseline control: 38.4.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 15, Reason: 5 withdrew for personal reasons, 3 for adverse events, 2 for intolerance, 1 for inefficacy, 4 for surgery; Group 2 Number missing: 6, Reason: 4 withdrew for personal reasons, 1 for intolerance, 1 for surgery

Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function subscale at 1 month; Group 1: mean -5.2 (SD 0.55); n=29, Group 2: mean -5.7 (SD 0.55); n=30; WOMAC physical function subscale (100mm VAS) 0-100 Top=High is poor outcome; Comments: Reports final scores and p values for change scores - used to estimate standard deviations for change scores (converting final scores into change scores). P-value 1 month pain: ≤0.001. 1 month insole: 34.0. 1 month control: 31.8. Baseline insole: 39.2. Baseline control: 37.5. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 6, Reason: 3 withdrew for personal reasons, 2 for adverse events, 1 for intolerance; Group 2 Number missing: 1, Reason: 1 withdrew for personal reasons - Actual outcome for Knee: WOMAC physical function subscale at 1 year; Group 1: mean -6.2 (SD 0.28); n=20, Group 2: mean -5.9 (SD 0.28); n=25; WOMAC physical function subscale (100mm VAS) 0-100 Top=High is poor outcome; Comments: Reports final scores and p values for change scores - used to estimate standard deviations for change scores (converting final scores into change scores). P-value 1 month pain: ≤0.001. 12 months insole: 33.0. 12 months control: 31.6. Baseline insole: 39.2. Baseline control: 37.5. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 15, Reason: 5 withdrew for personal reasons, 3 for adverse events, 2 for intolerance, 1 for inefficacy, 4 for surgery; Group 2 Number missing: 6, Reason: 4 withdrew for personal reasons, 1 for intolerance, 1 for surgery Protocol outcome 3: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Withdrawal due to adverse events at 1 month; Group 1: 2/31, Group 2: 0/30; Comments: Withdrawal due to adverse events insole: 1 heel pain, 1 plantar fascia pain. Withdrawal due to adverse events control group: 0. Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 4, Reason: 3 withdrew for personal reasons, 1 for intolerance; Group 2 Number missing: 1, Reason: 1 withdrew for personal reasons - Actual outcome for Knee: Withdrawal due to adverse events at 1 year; Group 1: 3/23, Group 2: 0/25; Comments: Note this includes people who withdrew at 1 month. Withdrawals due to adverse events insole: 1 heel pain, 1 plantar fascia pain, 1 femoral pain. Withdrawal due to adverse events control: 0. Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender, age, BMI, Kellgren-Lawrence grade; Group 1 Number missing: 12, Reason: 5 withdrew for personal reasons, 2 for intolerance, 1 for inefficacy, 4 for surgery; Group 2 Number missing: 6, Reason: 4 withdrew for personal reasons, 1 for intolerance, 1 for surgery	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study (subsidiary papers)	Bennell 2011[23] (Bennell 2007[22])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=200)
Countries and setting	Conducted in Australia; Setting: Not stated
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Inclusion criteria were age 50 years or more, average knee pain on waling more than 3 on an 11 point scale (0=no pain;10=worst pain possible) at telephone screening, pain located over the medial knee compartment, evidenceof osteophytes in the medial compartment or medial joint space narrowing on an x ray film, and radio-logical knee alignment of 185 degrees or less (corre-sponding to a mechanical axis angle of ≤182 degrees and indicating neutral to varus (bow leg) knee align-ment on an x ray film of the whole leg.
Exclusion criteria	Exclusion criteria were questionable or advanced radiographic knee osteoarthritis (Kellgren and Lawr-ence grades 1 and 4),predominant patellofemoral joint symptoms on clinical examination (location of pain, pain provoking activities, tenderness on palpation, and pain during mobilisation of the patellar), knee surgery or intra-articular corticosteroid injection within six months, current or past (within four weeks) use of oral corticosteroids, systemic arthritic conditions, history of knee arthroplasty or osteotomy,other musculoskeletal or neurological condition affecting leg function, disease of the ankle or foot precluding the use of insoles, use of foot orthotics within the past six months, usual footwear unable to accommodate insoles, contraindications to magnetic resonance imaging, planning to start other treatment for knee osteoarthritis, and regular use of a gait aid.
Recruitment/selection of patients	recruited participants from the community through advertisements in local clubs and the print and radio media in metropolitan Melbourne, Australia, between May 2005 and July 2008
Age, gender and ethnicity	Age - Mean (SD): 63.3 (8.1); 65.0 (7.9) years. Gender (M:F): 82:118. Ethnicity: Not reported
Further population details	1. Age: Mixed 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	92% of participants had symptoms for more than 1 year (29% for more than 10 years)
Indirectness of population	No indirectness
Interventions	(n=103) Intervention 1: Orthotic devices - Insoles. Lateral wedge (5 degree) insoles bilaterally. Made of high density ethyl vinyl acetate wedge along the lateral border of the foot. . Duration 12 months. Concurrent medication/care: No

	additional information. Indirectness: No indirectness (n=97) Intervention 2: Sham device. Neutral insoles bilaterally. Made of low density ethyl vinyl acetate.. Duration 12 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (project grant from the National Health and Medical Research Council (No 350297)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: Health related quality of life at 12 months; Group 1: mean -0.02 (SD 0.11); n=89, Group 2: mean -0.01 (SD 0.13); n=90; Assessment of quality of life instrument -0.04-1.00 Top=High is good outcome; Comments: Baseline insoles: 0.7 (0.2). Baseline control: 0.7 (0.2).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, symptom duration, presence of unilateral symptoms, radiographic disease severity, location of osteophytes, location of joint space narrowing, mean anatomical alignment, current drug use and past treatments; Group 1 Number missing: 14, Reason: 7 refused MRI, 3 lost contact, 1 illness, 1 knee replacement, 1 could not make appointments, 1 movement overseas; Group 2 Number missing: 7, Reason: 3 refused follow up, 2 knee replacements, 1 lost contact, 1 could not make appointments

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 12 months; Group 1: mean -0.7 (SD 2.7); n=89, Group 2: mean -1.2 (SD 3.1); n=90; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Baseline insoles: 7.1 (3.0). Baseline control: 7.2 (2.9).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, symptom duration, presence of unilateral symptoms, radiographic disease severity, location of osteophytes, location of joint space narrowing, mean anatomical alignment, current drug use and past treatments; Group 1 Number missing: 14, Reason: 7 refused MRI, 3 lost contact, 1 illness, 1 knee replacement, 1 could not make appointments, 1 movement overseas; Group 2 Number missing: 7, Reason: 3 refused follow up, 2 knee replacements, 1 lost contact, 1 could not make appointments

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function subscale at 12 months; Group 1: mean -3.1 (SD 9); n=89, Group 2: mean -1.2 (SD 3.1); n=90; WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Baseline insoles: 23.7 (12.2). Baseline control: 23.6 (10.9).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, symptom duration, presence of unilateral symptoms, radiographic disease severity, location of osteophytes, location of joint space narrowing, mean anatomical alignment, current drug use and past treatments; Group 1 Number missing: 14, Reason: 7 refused MRI, 3 lost contact, 1 illness, 1 knee replacement, 1 could not make appointments, 1 movement overseas; Group 2 Number missing: 7, Reason: 3 refused follow up, 2 knee replacements, 1 lost contact, 1 could not make appointments

Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Adverse events at 12 months; Group 1: 42/89, Group 2: 21/90; Comments: Insole: 9 back pain, 32 foot pain, 15 uncomfortable or difficulty fitting in shoes, 2 increased knee pain, 0 felt unstable. Control insoles: 1 back pain, 14 foot pain, 4 uncomfortable or difficulty fitting in shoes, 5 increased knee pain, 1 felt unstable. Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, symptom duration, presence of unilateral symptoms, radiographic disease severity, location of osteophytes, location of joint space narrowing, mean anatomical alignment, current drug use and past treatments; Group 1 Number missing: 14, Reason: 7 refused MRI, 3 lost contact, 1 illness, 1 knee replacement, 1 could not make appointments, 1 movement overseas; Group 2 Number missing: 7, Reason: 3 refused follow up, 2 knee replacements, 1 lost contact, 1 could not make appointments	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Brouwer 2006[27]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=117)
Countries and setting	Conducted in Netherlands; Setting: orthopedic outpatient departments of a university medical centre and of a general hospital
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 12 months
Method of assessment of guideline condition	Partially adequate method of assessment/diagnosis: Clinical diagnosis according to Ahlback score but criteria included evidence for malalignment
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	The inclusion criteria were symptomatic unicompartmental knee OA and a malalignment in patients aged 18 years and over. We diagnosed the OA as unicompartmental when the symptoms (pain and tenderness of the joint margins)were located over the medial or the lateral tibiofemoral compartment of the knee in combination with osteoarthritic signs according to the Ahlback score (Ahlback > 0) in the same medial or lateral tibiofemoral compartment of the knee as well as in combination with varus alignment (in combination with medial compartment OA) or valgus alignment (in combination with lateral compartment OA), respectively20. The degree of malalignment and mechanical axis was measured on a whole leg radiograph in standing position and determined according to one line (mechanical axis of the femur) from the centre of the femur head using Mose circles to the middle of the distance between the tibial spines,and a second line (mechanical axis of the tibia) from the centre of the ankle to the centre of the tibial spines.
Exclusion criteria	Patients with concurrent symptomatic OA of medial and lateral compartments, symptomatic patellofemoral OA (scored on the lateral radiograph of the knee), no malalignment,rheumatoid arthritis, previous high tibial osteotomy, symptomatic hip or ankle pathology, and an insufficient command of the Dutch language were excluded.
Recruitment/selection of patients	Not specified
Age, gender and ethnicity	Age - Mean (SD): 59(50) years. Gender (M:F): 59:58. Ethnicity: Not stated
Further population details	1. Age: Not stated / Unclear 2. Diagnostic method: Diagnosed without imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Mean duration of symptoms 59(76.6) months
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Braces. In the intervention group patients were fitted with a knee brace (OAsys brace, Innovation Sports, Irvine, CA, USA);this brace is commercially available for right/left leg in four sizes. The brace is accepted and

	refunded by allDutch health insurance companies. The brace consists of a thigh shell and a calf shell (both of carbon fiber) connected by titanium hinges on the medial and lateral sides.The adjustable slide bar on the medial side of the brace provides valgisation (1e12.5 degrees) with medial unloading,or varisation (1e10 degrees) with lateral unloading. The degree of varisation or valgisation depends on the degree of malalignment and the acceptance of the patient (extensive correction will cause pressure ulcers). A specialized orthopedic technician applied the brace and gave instructions to the patients. During the follow-up this specialized orthopedic technician was present at the orthopedic outpatient department. If necessary the brace was adjusted during the follow-up visits.. Duration 12 months. Concurrent medication/care: The conservative treatment was identical in both groups and consisted of standard care: i.e., patient education (adaptation of activities and/or weight loss), and (if needed) physical therapy and analgesics.. Indirectness: No indirectness (n=57) Intervention 2: No device intervention. Conservative treatment only. conservative treatment was identical in both groups and consisted of standard care: i.e., patient education (adaptation of activities and/or weight loss), and (if needed) physical therapy and analgesics.. Duration 12 months. Concurrent medication/care: N/A. Indirectness: No indirectness
Funding	Academic or government funding (This study was supported by the Revolving Fund (RF01-12) of the Erasmus University MedicalCentre Rotterdam, The Netherlands.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: EQ-5D (mean difference) at 3 months; MD; 0.03 (95%CI -0.05 to 0.12) EQ-5D 0-1 Top=High is good outcome, Comments: Baseline values 0.53(0.28);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference for pain severity (1.1 on 0-10 scale) at baseline; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Knee: EQ-5D (mean difference) at 12 months; MD; 0.01 (95%CI -0.08 to 0.1) EQ-5D 0-1 Top=High is good outcome, Comments: Baseline values 0.53(0.28);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference for pain severity (1.1 on 0-10 scale) at baseline; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Pain severity (VAS) at 3 months; MD; -0.73 (95%CI -1.62 to 0.16) VAS 0-10 Top=High is poor outcome, Comments: Baseline values 6(2.2);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference for pain severity (1.1 on 0-10 scale) at baseline; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome for Knee: Pain severity (VAS) at 12 months; MD; -0.81 (95%CI -1.76 to 0.14) VAS 0-10 Top=High is poor outcome, Units: , Comments: Baseline values 6(2.2); Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference for pain severity (1.1 on 0-10 scale) at baseline; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Callaghan 2015[30]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=126)
Countries and setting	Conducted in United Kingdom; Setting: Not stated
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Formal diagnosis established
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Subjects were enrolled if their knee radiographs were scored by a musculoskeletal radiologist (CEH) as showing Kellgren and Lawrence grade 2 or 3 in the PF joint (based on either lateralor skyline films), and if this was greater than the grade for the tibiofemoral joint (these grades required at least probable narrowing and definite osteophytes in the PF joint). Subjects were also clinically assessed for PF joint symptoms such as pain with stair climbing, kneeling, prolonged sitting or squatting (we will call these aggravating activities), and on examination by an experienced physiotherapist (MJC) they had to have lateral or medial patellar facet tenderness or a positive patellar compression test. Pain must have been present daily for the previous 3 months and had to be sufficiently severe for a nominated aggravating activity to score 4or above on a 0–10 cm visual analogue scale (VAS). If both knees were eligible, we asked subjects to select their more symptomatic knee. Potential participants had to be on stable medication for3 months and were ineligible if they were initiating a new treatment(such as physical therapy). They were asked to remain on thebaseline treatment regimen throughout the study
Exclusion criteria	Subjects were excluded if they had undergone previous patellar surgery. We also excluded subjects with a history of known meniscal or ligament injury, rheumatoid arthritis or other forms of inflammatory arthritis, or an intra-articular steroid injection into the painful knee in the previous month. For the purposes of the MRI, patients were excluded if they had a cochlear implant, metal objects in the body including a joint prosthesis, a cardiac or neural pacemaker, a hydrocephalus shunt, an intrauterinecontraceptive device or coil, if they had kidney dysfunction,or were undergoing renal dialysis. Contrast enhanced scans were used in the study to facilitate the quantification of synovial volume. Given the use of these scans, we screened participants for renal dysfunction and excluded those with estimated glomerular filtration rate (eGFR) ≤45 mL/min. We allowed subjects to enrol even if they did not have PF BMLs at baseline with the anticipation that some would develop these lesions during the trial.
Recruitment/selection of patients	Primary and secondary care using letters from general practitioners to knee OA patients, notices in clinics, advertisements in local papers, and referrals from physiotherapists.

Age, gender and ethnicity	Age - Mean (SD): 56.4(8.1); 54.5(6.7) years. Gender (M:F): 56:70. Ethnicity: Not specified
Further population details	1. Age: Not stated / Unclear 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Mean duration of pain not stated (minimum 3 months)
Indirectness of population	No indirectness
Interventions	(n=63) Intervention 1: Braces. Active treatment consisted of a Bioskin Patellar Tracking Q Brace (Ossur UK, Manchester, England; this brace is available throughout the UK. The brace has a strap which can be pulled over the patella or it can be worn without the strap. Duration 6 weeks. Concurrent medication/care: Not specified. Indirectness: No indirectness (n=63) Intervention 2: No device intervention. No brace; no further details. Duration 6 weeks. Concurrent medication/care: Not specified. Indirectness: No indirectness
Funding	Academic or government funding (Arthritis Research UK grant #18676 and the NIHR Biomedical Research Unit at the University of Manchester.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: KOOS pain subscale at 6 weeks; Group 1: mean 57.5 (SD 16.2); n=63, Group 2: mean 51.8 (SD 12.75); n=63; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Baseline values 51.1(18.4); 48.2(18.4) Standard deviation calculated from CIs reported in the study Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7, Reason: Surgery, family comitments, unrelated hospital admissions, intolerance, unrelated hypotension, lost to follow up; Group 2 Number missing: 2, Reason: MRI not tolerated, diagnosis of unrelated illness	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Campos 2015[31]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=58)
Countries and setting	Conducted in Brazil; Setting: The study was conducted in an outpatient setting at a tertiary hospital.
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 24 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: ACR criteria for knee osteoarthritis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People that met the American College of Rheumatology criteria for knee osteoarthritis who present with varus malalignment of the knee. Needed to have been receiving stable care for osteoarthritis for at least six months and was able to understand and agree with the informed consent statement.
Exclusion criteria	Hip osteoarthritis; ankle pain; previous fracture of the index knee; previous surgery on the index knee; rheumatoid arthritis; intra-articular injection in the index knee in the past six months
Recruitment/selection of patients	No additional information
Age, gender and ethnicity	Age - Mean (SD): Mean age 64.3(8.6) years. Gender (M:F): 21:37. Ethnicity: 74.1% Black, 12.1% Mixed, 10.3% Black, 3.4% Asian.
Further population details	1. Age: Mixed 2. Diagnostic method: Not stated / Unclear 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades 1-4 Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: Orthotic devices - Insoles. All the patients used insoles on both feet. Group W patients with unilateral knee osteoarthritis used a lateral wedge insole on the affected limb and a neutral insole on the contralateral limb.Group W patients with bilateral disease used a lateral wedge insole on both limbs. Group N patients used a neutral insole on both limbs.The wedge insoles were made with a full length lateral wedge of 8 mm (equivalent to about eight degrees of inclination)attached to a figure “eight” strap around the ankle (Figure 2).The neutral insoles were exactly the same orthosis, but without a lateral wedge. All the patients were encouraged to use the insoles for 5-10 hours per day.. Duration 24 weeks. Concurrent medication/care: The usual care consists of patient education through lectures,handouts, audiovisual material and guidance given by orthopedic surgeons, nutritionists, psychologists,

	occupational therapists,physical therapists, physical educators and social workers.All patients, except those with contraindications, take analgesics(on demand), such as paracetamol and codeine. We do not routinely give non-steroidal anti-inflammatory drug (NSAIDs) to our patients.. Indirectness: No indirectness (n=29) Intervention 2: Sham device. Control wedge with neutral wedge insole and subtalar strapping. . Duration 24 weeks. Concurrent medication/care: The usual care consists of patient education through lectures,handouts, audiovisual material and guidance given by orthopedic surgeons, nutritionists, psychologists, occupational therapists,physical therapists, physical educators and social workers.All patients, except those with contraindications, take analgesics(on demand), such as paracetamol and codeine. We do not routinely give non-steroidal anti-inflammatory drug (NSAIDs) to our patients.. Indirectness: No indirectness
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 8 weeks; Group 1: mean 8 (SD 3.4); n=29, Group 2: mean 8.7 (SD 4.1); n=29; WOMAC pain subscale Not reported Top=High is poor outcome; Comments: Baseline values 9.3(4); 10.3(4.4)
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Blinding details: Participants not considered to be blinded because they could see the shape of the insole given.; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA
- Actual outcome for Knee: WOMAC pain subscale at 24 weeks; Group 1: mean 8.2 (SD 3.8); n=29, Group 2: mean 8.3 (SD 4.7); n=29; WOMAC pain subscale Not reported Top=High is poor outcome; Comments: Baseline values 9.3(4); 10.3(4.4)
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Blinding details: Participants not considered to be blinded because they could see the shape of the insole given.; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study (subsidiary papers)	Erhart-hledik 2012[56] (Erhart 2010[57])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=79)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical diagnosis (with imaging)
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	persistent medial compartment knee joint pain; age between 40 and 80 years; ambulatory without aids; ability to give informed consent; and osteoarthritic changes based on MRI/radiograph.
Exclusion criteria	nerve or muscle disease associated with walking difficulty; serious injury to foot, ankle, back, or hips; gout or recurrent pseudogout; use of shoe insert or hinged knee brace; OA in other lower extremity joint; narcotic painmedication usage, total knee replacement; intraarticularjoint injection in previous 2 months; or body mass indexgreater than 35 kg/m2.
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): 60 (10) years. Gender (M:F): 42/37. Ethnicity: Not specified
Further population details	1. Age: Mixed 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=40) Intervention 1: Orthotic devices - Shoes. Variable stiffness walking shoes. Participants were instructed to use their assigned shoes as their main walking shoes, a minimum 4 h of wear per day. Shoes were worn bilaterally by all subjects. Subjects were told that this study was evaluating the effects of control andintervention footwear on joint loading and clinical outcomes,but were blinded to their shoe type. The researcher performingthe gait analysis was not blinded to shoe type. The shoeswere a generic athletic design. The variable-stiffness interventionshoe sole was 1.3–1.5 times stiffer on the lateral side of the shoe compared to the medial side. The design forthe shoe was previously shown to reduce the adduction moment. Duration 12 months. Concurrent medication/care: Not specified. Indirectness: No indirectness (n=39) Intervention 2: Sham device. Identical treatment but constant-stiffness shoe (control; similar to normal footwear).. Duration 12 months. Concurrent medication/care: Not specified. Indirectness: No indirectness

Funding	Academic or government funding (Veterans Administration (VA A02-2577R))
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus SHAM DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: WOMAC pain at 12 months; Group 1: mean 10.3 (SD 10.9); n=32, Group 2: mean 11.4 (SD 9.2); n=23; WOMAC pain subscale Not reported Top=High is poor outcome; Comments: Data not fully reported in publication; taken instead from Cochrane review (https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004020.pub3/references#dataAndAnalyses) Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports radiographic severity, sex, age, height and mass; Group 1 Number missing: 8, Reason: Reasons for withdrawal included: non-compliance, unknown reason, too small shoe size, shoe discomfort, sciatic pain, meniscectomy (x2) and cervical spine surgery; Group 2 Number missing: 16, Reason: Reasons for withdrawal included: no initial WOMAC score, unrelated illness (x2), hip pain, foot pain (x2), shoe discomfort (x4), meniscectomy (x2), total knee replacement, time commitment conflict, back pain and total knee replacement Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function at 12 months; Group 1: mean 34.3 (SD 34.7); n=32, Group 2: mean 39.2 (SD 38); n=23; WOMAC physical function subscale Not reported Top=High is poor outcome; Comments: See above: data from Cochrane review. Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports radiographic severity, sex, age, height and mass; Group 1 Number missing: 8, Reason: Reasons for withdrawal included: non-compliance, unknown reason, too small shoe size, shoe discomfort, sciatic pain, meniscectomy (x2) and cervical spine surgery; Group 2 Number missing: 16, Reason: Reasons for withdrawal included: no initial WOMAC score, unrelated illness (x2), hip pain, foot pain (x2), shoe discomfort (x4), meniscectomy (x2), total knee replacement, time commitment conflict, back pain and total knee replacement	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**Farhadian 2019[59]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=38)

	Countries and setting	Conducted in Iran; Setting: Outpatient follow up
	Line of therapy	Unclear
	Duration of study	Intervention + follow up: 8 weeks
	Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People previously diagnosed with hand osteoarthritis
	Stratum	Hand
	Subgroup analysis within study	Not applicable
	Inclusion criteria	Being older than or equal to 60 years; having been previously diagnosed with hand osteoarthritis; being stable (i.e. no change in symptoms of the disease) at least 4 weeks before and during the period of the study based on diagnosis of specialist; considering the absence of obvious cognitive deficits
	Exclusion criteria	Receiving another specific rehabilitation intervention; suffering from neurological pathologies or severe visual or sensory deficits.
	Recruitment/selection of patients	People with hand osteoarthritis approved by Baqiyatallah University of Medical Science, Tehran, Iran.
	Age, gender and ethnicity	Age - Mean (SD): 69.00 (3.97). Gender (M:F): 24:14. Ethnicity: Not stated/unclear
	Further population details	1. Age: <75 years 2. Diagnostic method: Not stated / Unclear 3. Multimorbidities: Not stated / Unclear
	Extra comments	Severity: Not stated/unclear Duration of symptoms (mean [SD]): 7.16 (1.76) years
	Indirectness of population	No indirectness
	Interventions	(n=19) Intervention 1: Straps/tape - Tape. Kinesio tape application. The subjects were taped in accordance with Kenzo Kase's Kinesio taping Manual. Taping was applied for the subjects in a sitting position; while the shoulder was abducted, the forearm was in the neutral position, the elbow was flexed to 90 degrees, and the wrist was also in the neutral position. The I-strip was placed over the extensor muscles of the forearm from proximal to distal to cover all of the CMC joints except the trapeziometacarpal joint. The second I-strip was placed over the TMC joint up to the first thumb phalanx as a corrective strip over the snuff box and parallel to tendons. For each patient, the grip strength of the hand was assessed three times; then, their average score was considered to be the grip strength. The tape was removed and changed after 3 days or when it was necessary. There was 1-day rest after each kinesio taping session to allow the skin of the participants to rest.. Duration 8 weeks. Concurrent medication/care: Hand exercises including a hot pack or paraffin wax for 15 minutes, stretching exercises, grip strength training exercise, and recommendation for use of the hands in real-life tasks. The tasks consisted of opening drawers, washing and putting away dishes, carrying bags, cleaning windows, counting change and writing or typing.. Indirectness: No indirectness (n=19) Intervention 2: No device intervention. Exercise (hot pack or paraffin wax) only.. Duration 8 weeks. Concurrent

		medication/care: Hand exercises including a hot pack or paraffin wax for 15 minutes, stretching exercises, grip strength training exercise, and recommendation for use of the hands in real-life tasks. The tasks consisted of opening drawers, washing and putting away dishes, carrying bags, cleaning windows, counting change and writing or typing.. Indirectness: No indirectness
	Funding	Academic or government funding (Supported by the Exercise Physiology Research Center at Baqiyatallah University of Medical Sciences in Tehran, Iran.)
	RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Hand: Visual analog scale at 8 weeks; Group 1: mean 5.32 (SD 1.07); n=19, Group 2: mean 6.21 (SD 1.08); n=19; Visual analog scale 0-10 Top=High is poor outcome; Comments: Baseline taping: 6.42 (1.21). Baseline no treatment: 6.47 (1.07). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, education, hand osteoarthritis duration, pain, biophysical parameters and functional disability.; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Hand: Disabilities of the Arm, Shoulder and Hand at 8 weeks; Group 1: mean 52.76 (SD 8.6); n=19, Group 2: mean 60.34 (SD 13.85); n=19; Disabilites of the Arm, Shoulder and Hand (DASH) 0-100 Top=High is poor outcome; Comments: Baseline tape: 62.82 (14.49). Baseline no treatment: 63.37 (14.59). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, education, hand osteoarthritis duration, pain, biophysical parameters and functional disability.; Group 1 Number missing: 0; Group 2 Number missing: 0	
	Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Felson 2019[60]
Study type	RCT (Patient randomised; Crossover: 8 weeks)
Number of studies (number of participants)	1 (n=83)
Countries and setting	Conducted in United Kingdom; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 8 weeks (for each intervention)
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee pain with Kellgren Lawrence grade 2-4 changes in the painful knee
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Ages 40-85 years; severity of overall knee pain in the past week of ≥4 on a 0-10 grading scale; and Kellgren Lawrence grade of 2-4 in the painful knee (as scored by a musculoskeletal radiologist) on a posteroanterior or anteroposterior radiograph obtained within the last 2 years that showed definite medial (but no definite lateral) narrowing. Patellofemoral OA had to be less severe than medial OA and could not have a Kellgren Lawrence grade of ≥3. Additional criteria included medial joint line tenderness (with tenderness over the patella less severe than medial tenderness) upon examination by an experienced physical therapist, a stable medication regimen for 3 months, and a willingness to wear insoles in shoes for ≥4 hours daily
Exclusion criteria	A history of high tibial osteotomy; other realignment surgery; knee replacement in the painful knee; knee arthroscopy within the last 6 months; or an intraarticular injection of either steroid of viscosupplementation in the affected knee within the prior 3 months. People with the following conditions were also excluded: rheumatoid arthritis or other inflammatory arthritis, diabetic neuropathic pain or fibromyalgia, foot or ankle problems that contraindicated the use of load-modifying interventions in footwear, or severe coexisting medical morbidities. Further exclusions included inability to walk unaided without a crutch, cane or walker, BMI ≥35kg/m², and current use of or need for foot orthoses. They also excluded people who were unable to retain information regarding study procedures or were unable to walk 100 meters without stopping. People with contraindications to MRI and those who had knee surgery planned within the next 6 months.
Recruitment/selection of patients	People were recruited from general practices and by way of advertisements in Manchester, UK from January 2016 through June 2017
Age, gender and ethnicity	Age - Mean (SD): 64.6 (9.4). Gender (M:F): 51:32. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear

Extra comments	Severity: Not explicitly stated. Kellgren Lawrence grade 2-4. Duration of symptoms: Not stated.. Had an initial section where 84 people were eligible and they tested them with a lateral wedge insole. They then excluded 21 people who did not respond to the lateral wedge insole from further testing.
Indirectness of population	No indirectness
Interventions	(n=62) Intervention 1: Orthotic devices - Insoles. Lateral wedge insole (5 degrees). Duration 8 weeks. Concurrent medication/care: No additional information available. Indirectness: No indirectness; Indirectness comment: 31 people started with a lateral wedge insole then went to a neutral insole (n=62) Intervention 2: Sham device. Neutral insole. Duration 8 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness; Indirectness comment: 31 people started with a neutral insole then went to a lateral wedge insole
Funding	Academic or government funding (Supported by the NIHR Manchester Biomedical Research Centre. Dr Felson's work was supported by the NIH (grant AR-47785))

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS quality of life subscale at 8 weeks; Group 1: mean 44.18 (SD 14.3); n=62, Group 2: mean 44.09 (SD 13.2); n=62; KOOS quality of life subscale 0-100 Top=High is good outcome; Comments: Reports posttreatment adjusted means (95% CIs). Calculated SD from this. Reported insoles: 44.18 (40.62, 47.73). Reported sham: 44.09 (40.80, 47.38).
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Comments - Additional risk of bias added due to them testing eligible participants with a lateral wedge insole to see if they had a biomechanical response, and excluding any people who didn't have a positive effect from them; Indirectness of outcome: No indirectness ; Baseline details: Reports age, BMI, gender, HADS anxiety score, HADS depression score, overall knee pain, pain during nominated activity, KOOS pain subscale score, K-L grade of studied knee; Group 1 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period; Group 2 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS pain subscale at 8 weeks; Group 1: mean 60.66 (SD 13.9); n=62, Group 2: mean 58.82 (SD 12.6); n=62; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Reports posttreatment adjusted means (95% CIs). Calculated SD from this. Reported insoles: 60.66 (57.21, 64.11). Reported sham: 58.82 (55.67, 61.96).
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Comments - Additional risk of bias added due to them testing eligible participants with a lateral

	wedge insole to see if they had a biomechanical response, and excluding any people who didn't have a positive effect from them; Indirectness of outcome: No indirectness ; Baseline details: Reports age, BMI, gender, HADS anxiety score, HADS depression score, overall knee pain, pain during nominated activity, KOOS pain subscale score, K-L grade of studied knee; Group 1 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period; Group 2 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period Protocol outcome 3: Physical function at ≤3- or >3- months - Actual outcome for Knee: KOOS activities of daily living subscale at 8 weeks; Group 1: mean 66.29 (SD 12.6); n=62, Group 2: mean 65.01 (SD 12.6); n=62; KOOS activities of daily living subscale 0-100 Top=High is good outcome; Comments: Reports posttreatment adjusted means (95% CIs). Calculated SD from this. Reported insoles: 66.29 (63.15, 69.44). Reported sham: 65.01 (61.88, 68.14). Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Comments - Additional risk of bias added due to them testing eligible participants with a lateral wedge insole to see if they had a biomechanical response, and excluding any people who didn't have a positive effect from them; Indirectness of outcome: No indirectness ; Baseline details: Reports age, BMI, gender, HADS anxiety score, HADS depression score, overall knee pain, pain during nominated activity, KOOS pain subscale score, K-L grade of studied knee; Group 1 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period; Group 2 Number missing: 6, Reason: In group A (lateral wedge first) 1 withdrew for family illness. In group B (neutral wedge first) 1 withdrew for family illness, 1 developed plantar fasciitis during the washout stage and was provided with different insoles, 1 had multiple personal preexisting health issues, 1 started knee physiotherapy, 1 scheduled for a knee replacement during the trial period
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**Ferreira 2021[61]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=38)

Countries and setting	Conducted in Portugal; Setting: Porto Biomechanics Laboratory of the University of Porto
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) Diagnosis of medial knee osteoarthritis according to the clinical and radiographic criteria established by the American College of Rheumatology, namely (a) presence of medial knee pain, (b) radiographic evidence of osteophyte in the medial joint space of the knee and (c) morning stiffness last more than 30 minutes and/or crepitus during motion; (2) a Kellgren and Lawrence grade of 2 or 3 and a mechanical axis angle lower than 181 degrees in females and 183 degrees in males, indicating varus malalignment in the painful knee on a full-length anteroposterior radiograph 11; (3) age between 45 and 80 years; (4) a score on medial knee pain for the past week equal to or higher than three on the VAS.
Exclusion criteria	Symptomatic evidence of lateral compartment osteoarthritis; patellofemoral osteoarthritis; knee surgery within the previous 6 months; systemic arthritic conditions; corticosteroid injection within the previous 6 weeks; body mass index higher than 35, any other condition affecting lower limb functions. No restrictions were applied on participants' usual medications
Recruitment/selection of patients	Patients with symptomatic medial knee osteoarthritis and varus malalignment were recruited between May 2018 and October 2019 from local hospitals and clinics by study collaborators
Age, gender and ethnicity	Age - Mean (SD): Intervention: 62.6 (8) and control: 60.6 (8.9). Gender (M:F): 15/23. Ethnicity: Not reported
Further population details	1. Age: mixed 2. Diagnostic method: diagnosis with imaging 3. Multimorbidities: not reported
Extra comments	Duration of symptoms - not reported. Severity K/L Grade 2: 16 and Grade 3: 22
Indirectness of population	no indirectness
Interventions	(n=20) Intervention 1: Orthotic devices - Insoles. Adjusted lateral wedge insoles - wedge angle selected according to the biomechanical analysis of their first visit to the laboratory. Duration 12 weeks. Concurrent medication/care: Patients advised not to attend rehabilitation programs or other types of interventions but could use their usual medications. Indirectness: No indirectness (n=18) Intervention 2: Sham device. Neutral insoles. Duration 12 weeks. Concurrent medication/care: Patients were advised not to attend rehabilitation programs or other types of interventions but could use their usual medications. Indirectness: No indirectness

Funding	-- (No funding was received for this study)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE Protocol outcome 1: Quality of life at ≤3- or >3- months - Actual outcome for Knee: KOOS - quality of life at 12 weeks; Group 1: mean 44.6 (SD 21.1); n=16, Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Hours of physical activity a week; intervention: 2 and control 0.4; Group 1 Number missing: 4, Reason: Refused 2, knee replacement 2; Group 2 Number missing: 3, Reason: Refused 1, could not make appointment 1, knee replacement 1 Protocol outcome 2: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: KOOS - pain at 12 weeks; Group 1: mean 59.1 (SD 21.1); n=16, Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Hours of physical activity a week; intervention: 2 and control 0.4; Group 1 Number missing: 4, Reason: Refused 2, knee replacement 2; Group 2 Number missing: 3, Reason: Refused 1, could not make appointment 1, knee replacement 1 Protocol outcome 3: Physical function at ≤3- or >3- months - Actual outcome for Knee: KOOS - activities of daily life at 12 weeks; Group 1: mean 56.9 (SD 19.4); n=16, Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Intervention: 51 (20.1) and control: 60.6 (18.3). Hours of physical activity a week; intervention: 2 and control 0.4; Group 1 Number missing: 4, Reason: Refused 2, knee replacement 2; Group 2 Number missing: 3, Reason: Refused 1, could not make appointment 1, knee replacement 1	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Gomes carreira 2010[66]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=40)
Countries and setting	Conducted in Brazil; Setting: Not specified
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiological diagnosis
Stratum	Thumb
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligibility criteria were: a clinical and radiological diagnosis of idiopathic Grade II and III OA of the TMC joint of the dominant hand; (26) either gender; over 40 years of age; and pain in the base of the thumb of the dominant hand of between 3 and 7 on the 0–10 cm visual analogue scale (VAS) for pain.
Exclusion criteria	Exclusion criteria were patients with severe deformities of the domi- nant hand that did not allow gripping between the first, second and third fingers; deformities of the distal interphalangeal joint; the use of a splint on the thumb in the previous 6 months; surgery on the hand under study in the previous 6 months or scheduled in the upcoming 6 months; allergy to the splint material; incapacity to respond to the questionnaire and perform the tests; geographical inaccessibility; injections in the hand under study in the previous 6 months; other associated diseases such as carpal tunnel syndrome, fractures in the carpus, tendonitis, chronic inflammatory arthropathy and alterations in the use of anti-inflammatory medication and analgesics in the previous 3 months.
Recruitment/selection of patients	Not specified
Age, gender and ethnicity	Age - Mean (SD): 62.8(8.5); 65.1(10.1) years. Gender (M:F): 2:38. Ethnicity: Not specified
Further population details	1. Age: Mixed 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Mean duration of symptoms 6.3(3.4); 7.7(6.1) years
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Splints. Patients in the SG received the splint on the day of the first evaluation and took it with them for use during activities of daily living, including paid or unpaid work. They were instructed to remove it during rest (sleeping), bathing and activities in which they had contact with heat. They were also instructed as to how to put the splint on and cleaning procedures. In cases of discomfort regarding the use of the splint, patients were instructed to communicate with the therapist in order to perform the necessary adjustments. The aim of which was to stabilize the

	TMC joint, maintaining the pulp of the distal phalange of the index finger free for gripping with the other fingers and leaving the thumb in a functional. Duration 3 months. Concurrent medication/care: Not specified (n=20) Intervention 2: No device intervention. Control; no intervention. Control group wore splint for evaluation purposes only (this data not used in this review).Data after T90 not used as both groups wore splints from this date.. Duration 3 months. Concurrent medication/care: Not specified
Funding	Academic or government funding (supported by the Fundacao de Amparo a Pesquisa do Estado de Sao Paulo (FAPESP).)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SPLINTS versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Thumb: VAS pain reduction at 3 months; Group 1: mean 2.9 (SD 2.2); n=20, Group 2: mean 5.2 (SD 2); n=20; VAS 0-10 Top=High is poor outcome; Comments: Baseline :5.1(1.4); 5.1(1.1) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing: Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Thumb: DASH: Disabilities of the Arm, Shoulder and Hand questionnaire at 3 months; Group 1: mean 28.6 (SD 18); n=20, Group 2: mean 35.3 (SD 13.2); n=20; DASH scale 0-96 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**Gueugnon 2021[67]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=121)

Countries and setting	Conducted in France; Setting: Outpatient follow up - conducted at seven French sites (private and public hospitals)
Line of therapy	Unclear
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee osteoarthritis diagnosed according to the American College of Rheumatology criteria including clinical and imaging features
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age > 40 years; diagnosed with medial compartment knee OA defined according to ACR criteria (VAS pain at rest ≥40/100 in the medial compartment, with more severe pain in the medial compartment than in the lateral compartment), radiological stae II, III or IV according to K-L grading established from x-ras taken in the previous 6 monthsl; and no change in pharmacological treatment for at least 3 months. Patients had to be able to understand and complete the self-report questionnaires.
Exclusion criteria	Severe venous insufficiency or prior depep vein thrombosis in the lower limbs; acute inflammation of the knee; knee valgus; other significant rheumatic disease; or indication for total knee replacement according to the medical specialist consulted.
Recruitment/selection of patients	No additional information
Age, gender and ethnicity	Age - Mean (SD): 63.6 (11.5). Gender (M:F): Define. Ethnicity: Not stated/unclear
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Radiological Kellgren-Lawrence grade II-IV, median grade III Duration of symptoms (median [IQR]): Intervention = 3.1 (1.2-9.8) years, control = 4.3 (1.0 - 6.7) years.. NCT02765685.
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Braces. People were fitted with an ODRA brace. All orthotic adjustments were performed by a certified orthotist. People were told to wear the brace for at least 6 hours a day, 5 days a week and to remove it during periods of rest and when lying down. ODRA is a custom-made valgus-inducing knee brace designed with an innovative system of dynamic distraction and dynamic external rotation of the leg that shifts the center of the load towards the natural intercondyle position, thus limiting overload of the medial compartment.. Duration 1 year. Concurrent medication/care: Usual care included pharmacological (such as NSAIDs, analgesics, steroid injections, intra-articular hyaluronic acid injections) and non-pharmacological treatments (physiotherapy, spa therapy, etc.).. Indirectness: No indirectness (n=61) Intervention 2: No device intervention. Usual care only.. Duration 1 year. Concurrent medication/care: Usual care

	included pharmacological (such as NSAIDs, analgesics, steroid injections, intra-articular hyaluronic acid injections) and non-pharmacological treatments (physiotherapy, spa therapy, etc.).. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (Center d'Investigation Clinique INSERM 1432 and Plateforme d'Investigation Technologiques (PIT) of the Dijon CHU, as well as the PROTEOR group (France) for providing the ODRA braces to Dijon CHU for this study, and covering the costs of the orthotic specialist who molded and corrected the braces.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS quality of life at 1 year; Group 1: mean 16 (SD 22.5); n=60, Group 2: mean 8.1 (SD 20.8); n=61; KOOS quality of life 0-100 Top=High is good outcome; Comments: Baseline values not reported.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, BMI, education level, type of occupation before retirement, social deprivation, VAS pain, disease duration, radiological Kellgren-Lawrence grade, history of surgery on the target knee, other osteoarticular disease affecting the target knee and osteoarthritis treatment received.; Group 1 Number missing: 9, Reason: 6 discontinued, 2 lost to follow up, 1 withdrawal for medical reasons; Group 2 Number missing: 6, Reason: 4 discontinued, 1 consent withdrawn, 1 death

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS pain at 1 year; Group 1: mean 14.4 (SD 14.7); n=60, Group 2: mean 6.5 (SD 17.6); n=61; KOOS pain 0-100 Top=High is good outcome; Comments: Baseline values not reported.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, BMI, education level, type of occupation before retirement, social deprivation, VAS pain, disease duration, radiological Kellgren-Lawrence grade, history of surgery on the target knee, other osteoarticular disease affecting the target knee and osteoarthritis treatment received.; Group 1 Number missing: 9, Reason: 6 discontinued, 2 lost to follow up, 1 withdrawal for medical reasons; Group 2 Number missing: 6, Reason: 4 discontinued, 1 consent withdrawn, 1 death

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: KOOS function in activities of daily living at 1 year; Group 1: mean 12.6 (SD 17); n=60, Group 2: mean 5.1 (SD 18.9); n=61; KOOS function in activities of daily living 0-100 Top=High is poor outcome; Comments: Baseline values not reported.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, BMI, education level, type of occupation before retirement, social deprivation, VAS pain, disease duration, radiological Kellgren-Lawrence grade, history of surgery on the target knee, other osteoarticular disease affecting the target knee and osteoarthritis treatment received.; Group 1 Number missing: 9, Reason: 6 discontinued, 2 lost to follow up, 1 withdrawal for medical reasons; Group 2 Number missing: 6, Reason: 4 discontinued, 1 consent withdrawn, 1 death

Protocol outcome 4: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Serious adverse events at 1 year; Group 1: 1/60, Group 2: 1/61; Comments: Deep vein thrombosis (1 in each arm). Other adverse events were reported in the study. However, only the data for the braces arm was reported, making the comparison less valid. Therefore, only

serious events will be included but the outcome will be downgraded for indirectness. Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: Serious indirectness, Comments: Only serious adverse events could be extracted as there did not appear to be a reasonable comparison to the control group reported for the total adverse events outcome; Baseline details: Reported age, gender, BMI, education level, type of occupation before retirement, social deprivation, VAS pain, disease duration, radiological Kellgren-Lawrence grade, history of surgery on the target knee, other osteoarticular disease affecting the target knee and osteoarthritis treatment received.; Group 1 Number missing: 9, Reason: 6 discontinued, 2 lost to follow up, 1 withdrawal for medical reasons; Group 2 Number missing: 6, Reason: 4 discontinued, 1 consent withdrawn, 1 death	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	**Gunaydin 2020[68]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=(n=60 (including ESWT group which is not included))
Countries and setting	Conducted in Turkey; Setting: Hacettepe University School of Physiotherapy and Rehabilitation.
Line of therapy	Unclear
Duration of study	Intervention + follow up: Intervention + follow up: exercise intervention- 12 weeks, Taping intervention- 6 weeks. Follow-up at 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosis made by an orthopaedic surgeon. Classified using K-L grading1-3.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Unilateral or bilateral knee OA diagnosis (grade 1-3 according to K-L criteria); presence of pain for > 1 month; presence of bone densitometry test with the last 6 months; and willingness to participate.
Exclusion criteria	Previous knee operation; receiving medication; being over K-L stage 3; presence of osteoporosis; having perception and coordination disorders; or any systemic disease.
Recruitment/selection of patients	Patients who had been referred to the clinic following diagnosis.
Age, gender and ethnicity	Age - Mean (SD): 58.8 (6.2) years. Gender (M:F): All female. Ethnicity: Not reported

Further population details	1. Age: <75 years ((Age range 49-72).). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity (baseline VAS during squats): Taping group: 8.67(1.74), exercise group: 7.84 (2.14) Duration: not reported
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Straps/tape - Tape. Kinesio taping. Participants selected one of the tape colours without any mechanical or structural differences. For the application, subjects lay in supine position with the hip flexed at 30 degree and the knee flexed at 60 degrees. The application started approximately 10cm inferior to the anterior superior iliac spine, divided into two tails at the junction between quadriceps femoris tendon and the patella, and ended rounding the patella with no stretch. Another 'Y' cut tape starting from the patellar tendon and ending at the proximal edge of the patella was done secondly. Afterwards, 2 'I' bands were cut and applied with medial and lateral mechanical correction of the patella with 75% streyching. the taping procedure was repeated for 6 weeks and twice a week. Home exercise, prescribed by a physiotherapist for 12 weeks (no further details).. Duration 12 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=20) Intervention 2: No device intervention. Exercise. Home exercise, prescribed by a physiotherapist for 12 weeks (no further details).. Duration 12 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: KINESIO TAPING+ EXERCISE versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: VAS pain doing squats at 12 weeks.; Group 1: mean 3.05 (SD 2.36); n=20, Group 2: mean 2.74 (SD 2.16); n=20; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: Taping group: 8.67 (1.74), exercise group: 7.84 (2.14)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: unclear; Group 2 Number missing: 0, Reason: N/A

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Halstead 2016[69]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=37)
Countries and setting	Conducted in United Kingdom; Setting: Not specified
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Radiographically confirmed only. predetermined criteria recommended in the La Trobe University Atlas of Foot Osteoarthritis
Stratum	Foot
Subgroup analysis within study	Not applicable
Inclusion criteria	Participants were included if they were ≥18 years of age, reported foot pain for ≥3 months, located the foot pain within the midfoot region by drawing the location on a foot pain manikin in predetermined dorsal and medial regions of the foot and reported midfoot pain occurring with or worsening immediately following weight-bearing activities. All participants had radiographic midfoot OA verified on weight-bearing radiographs by a musculoskeletal radiologist (AG) using predetermined criteria recommended in the La Trobe University Atlas of Foot Osteoarthritis. Osteoarthritis-related foot pain was defined by a score >2/10 on an 11-point numerical rating scale (NRS) for average foot pain the last week and at least one criteria of the foot function impairment reported on most days (Manchester Foot Pain and Disability Index [MFPDI]
Exclusion criteria	Exclusion criteria were contraindications to radiographs or gait analysis; history of suspected or confirmed inflammatory joint disease, neuropathy or stress fractures; history of lower limb bone and joint surgery in the last 12 months; or existing use of over-the- counter or prescribed foot orthoses.
Recruitment/selection of patients	Participants were recruited from a community musculoskeletal service.
Age, gender and ethnicity	Age - Mean (SD): 58.4(11.6) years. Gender (M:F): 11:26. Ethnicity: Not reported
Further population details	1. Age: Mixed 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	If participants reported midfoot pain in both feet, the most painful foot was used as the study limb. If midfoot pain was equal in both feet, the dominant foot was included (defined by first step initiation).
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Orthotic devices - Insoles. In the FFO group, participants received a pair of firm semi- rigid FFOs (VectOrthotic® Healthy Step [Sensograph] Ltd), which contoured into the arch and supported the midfoot with the aim of controlling joint motion. Functional foot orthoses were prescribed as per standard clinical practice and customised to

	each participant by an experienced clinical podiatrist. . Duration 12 weeks. Concurrent medication/care: Not specified (n=18) Intervention 2: Sham device. The sham group received orthoses that mimicked the appearance of the active intervention but without firm midfoot support and heel wedging. It was hypothesised that the sham intervention had some cushioning properties but none of the significant mechanical characteristics of the active FFO and could be deemed a sham. A footwear advice leaflet was provided to all participants providing fitting and contact information.v. Duration 12 weeks. Concurrent medication/care: Not specified
Funding	Academic or government funding (This study was supported by Arthritis Research UK (grant no. 19996). The Leeds Experimental Osteoarthritis Treatment Centre is supported by Arthritis Research UK (grant no. 20083). This report includes independent research also supported by the National In- stitute for Health Research through the Comprehensive Clinical Research Network and the Biomedical Research Unit Funding Scheme. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the De- partment of Health. The funding source had no role in the study design, collection, analysis and interpretation of the data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.v)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Foot: NRS (pain in the last 24h) at 12 weeks; Group 1: mean -1.1 (SD 2.5); n=18, Group 2: mean 0.3 (SD 3.4); n=18; NRS 0-10 Top=High is poor outcome; Comments: Baseline 5.6(2); 4.7(2.4)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, BMI and foot affected; Blinding details: While they state participants were blinded, they also provided a patient information sheet giving information about both interventions. A person could use this to find out about which is likely the active intervention.; Group 1 Number missing: 1, Reason: 1 discontinued intervention due to pain related to the foot orthoses; Group 2 Number missing: 0, Reason: 2 discontinued due to pain related to the foot orthoses, 1 was lost to follow up. They included two of these people in the final analysis.

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Foot: MFPDI function (Manchester foot pain and disability index—functional subscale) at 12 weeks; Group 1: mean -3.6 (SD 3.8); n=18, Group 2: mean -2.2 (SD 4.1); n=18; MFPDI function Manchester foot pain and disability index—functional subscale Not reported Top=High is poor outcome; Comments: Baseline: 10.5(4.1); 9.8(5.3)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, BMI and foot affected; Blinding details: While they state participants were blinded, they also provided a patient information sheet giving information about both interventions. A person could use this to find out about which is likely the active intervention.; Group 1 Number missing: 1, Reason: 1 discontinued intervention due to pain related to the foot orthoses; Group 2 Number missing: 0, Reason: 2 discontinued due to pain related to the foot orthoses, 1 was lost to follow up. They included two of these people in the final analysis.

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Hatef 2014[73]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=118)
Countries and setting	Conducted in Iran; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 2 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Medial compartment knee osteoarthritis according to the American College of Rheumatology criteria for diagnosis of knee OA and mild-to-moderate knee OA according to the Kellgren and Lawrence scale.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Symptomatic medial femoro-tibial OA, pain on a daily basis for at least 1 month during the previous 3 months. Radiographic inclusion criterion was evidence for medial femorotibial OA on plain anteroposterior X-rays (Kellgren and Lawrence grade >2).
Exclusion criteria	People with secondary knee or hip OA; foot deformity; greater or similar reduction in lateral than medial femorotibial joint space width of plain anteroposterior X-rays; knee joint lavage within the previous 3 months; intraarticular corticosteroid injection within the previous month; tibial osteotomy within the previous 5 years; changes in drug treatment for osteoarthritis within the previous week.
Recruitment/selection of patients	150 people were recruited. No additional information.
Age, gender and ethnicity	Age - Mean (SD): 48.4 (11.0). Gender (M:F): 17:101. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Mild-to-moderate Duration of symptoms: At least 3 months. Not explicitly stated.
Indirectness of population	No indirectness
Interventions	(n=75) Intervention 1: Orthotic devices - Insoles. Two pairs of bilaterally standardized laterally wedged (5 degree) insoles made of ethyl vinyl acetate mounted on a leather strip, wedged along the entire lateral border of the foot. The thickness of the insoles was 10mm in the lateral side and 4mm in the medial side.. Duration 2 months. Concurrent medication/care: People were allowed to take NSAIDs. Otherwise not stated.. Indirectness: No indirectness (n=75) Intervention 2: Sham device. Two pairs of bilaterally standardized neutrally wedged insoles, made of the same

	material. Uniformly 4mm in thickness.. Duration 2 months. Concurrent medication/care: People were allowed to take NSAIDs. Otherwise not stated.. Indirectness: No indirectness
Funding	Academic or government funding (Funded by Mashhad University of Medical Sciences)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Severity of knee pain (VAS) at 2 months; Group 1: mean -29.3 (SD 16.2); n=57, Group 2: mean -6.25 (SD 12.6); n=61; Visual analogue scale 0-100 Top=High is poor outcome; Comments: Reports 95% CIs. Reported insoles: 29.3 (25.12, 33.55). Reported sham: 6.25 (3.09, 9.4). Does not report baseline values adequately (reports the number of people in categories based on severity using ranges of values). Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age. States there was no significant different in severity of knee pain, Edinburgh Knee function scale and numbers of NSAIDs prescribed.; Group 1 Number missing: 18, Reason: No reason given; Group 2 Number missing: 14, Reason: No reason given Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: Edinburgh Knee Function Scale at 2 months; Group 1: mean 7.54 (SD 4.8); n=57, Group 2: mean 0.54 (SD 3.8); n=61; Edinburgh Knee Function Scale 0-36 Top=High is good outcome; Comments: Reports 95% CIs. Reported insoles: 7.54 (6.3, 8.8). Reported sham: 0.54 (-0.41, 1.5). Does not report baseline values adequately (reports the number of people in categories based on severity using ranges of values). Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age. States there was no significant different in severity of knee pain, Edinburgh Knee function scale and numbers of NSAIDs prescribed.; Group 1 Number missing: 18, Reason: No reason given; Group 2 Number missing: 14, Reason: No reason given	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Hayati 2018[75]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=111)
Countries and setting	Conducted in Iran; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Previously diagnosed patellofemoral osteoarthritis with apparent osteophytes on radiography
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Patellofemoral osteoarthritis; age ≥50 years; apparent osteophytes on radiography; reported knee pain in the previous months and pain and discomfort when standing up from a chair and climbing stairs.
Exclusion criteria	Performed physical therapy and surgery in the past 12 months; arthroplasty; intra-articular injection in the past 6 months; systematic arthritis; skin disorders; documented skin sensitivity to previous taping technique; body mass index >36.
Recruitment/selection of patients	140 people were referred from a diagnostic medical center supervised by Qazvin University of Medical Science. 29 were excluded as they did not meet the inclusion criteria.
Age, gender and ethnicity	Age - Mean (SD): 52.4 (8.9). Gender (M:F): 37:47. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated
Indirectness of population	No indirectness
Interventions	(n=37) Intervention 1: Straps/tape - Tape. Medial directed patellar taping and NSAID therapy (nimesulide, 200mg/day, COX-2 inhibitor). A trained physical therapist applied kinesio taping to the knee joint in a physical therapy center. Tape with a width of 5cm and thickness of 0.5mm was used in all groups. A Y-strip of tape was applied in the medial direction around the patella by a physical therapist. First, the participants were requested to flex their knees about 30 degrees. The tape was applied to the lateral side of the knee aligned with the articular line of the knee found via palpation by the physical therapist. The physical therapist applied 25% tension to impose a medially directed force on the patella. During the tape application toward the medial side of the knee, the participants were asked to move their knee slowly from flexion to extension. The tape was applied three times a week at 1 day intervals after the previous tape was removed in each session. Overall, nine taping sessions were used in all three groups. . Duration 3 weeks. Concurrent medication/care: No additional information given. Indirectness: No indirectness

	(n=37) Intervention 2: Straps/tape - Tape. Medial directed patellar taping without NSAID therapy. A trained physical therapist applied kinesio taping to the knee joint in a physical therapy center. Tape with a width of 5cm and thickness of 0.5mm was used in all groups. A Y-strip of tape was applied in the medial direction around the patella by a physical therapist. First, the participants were requested to flex their knees about 30 degrees. The tape was applied to the lateral side of the knee aligned with the articular line of the knee found via palpation by the physical therapist. The physical therapist applied 25% tension to impose a medially directed force on the patella. During the tape application toward the medial side of the knee, the participants were asked to move their knee slowly from flexion to extension. The tape was applied three times a week at 1 day intervals after the previous tape was removed in each session. Overall, nine taping sessions were used in all three groups. . Duration 3 weeks. Concurrent medication/care: No additional information given. Indirectness: No indirectness (n=37) Intervention 3: Sham device. Sham taping and NSAID (nimesulide, 200mg/day, COX-2 inhibitor). Sham taping was applied in a similar way without tension in the taping technique. Nine taping sessions over three weeks.. Duration 3 weeks. Concurrent medication/care: No additional information given. Indirectness: No indirectness
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE AND NSAIDS versus SHAM DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Pain (visual analogue scale, 10cm) at 3 weeks; Group 1: mean 2.62 (SD 1.4); n=37, Group 2: mean 3.11 (SD 1.74); n=19; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline tape and NSAIDs: 5.83 (1.8). Baseline sham device: 5.00 (1.64). Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, height, weight and BMI.; Group 1 Number missing: 0; Group 2 Number missing: 18, Reason: All reported at lost to follow up.	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Hinman 2003[79]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=87)
Countries and setting	Conducted in Australia; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks intervention. 3 weeks of follow up.
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiological classification criteria of the American College of Rheumatology (presence of osteophytes, age over 50 years, and pain in the knee)
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Presence of osteophytes, age over 50 years and pain in the knee (based on American College of Rheumatology criteria)
Exclusion criteria	Allergy to tape or history of joint replacement; symptoms or signs suggestive of another cause of knee pain; physiotherapy for knee (previous six months); body mass index >38 (owing to difficulties of taping the knee effectively); rheumatoid arthritis; steroid injection or knee surgery (previous six months); history of knee taping; fragile skin around knee
Recruitment/selection of patients	Volunteers from the community responded to advertisements in local papers
Age, gender and ethnicity	Age - Mean (SD): 68.7 (8.6). Gender (M:F): 30:62. Ethnicity: Not stated
Further population details	1. Age: Mixed (Based on SD). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades 1-4. Duration of symptoms: 9 (9.7) years.
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: Straps/tape - Tape. Therapeutic tape provided medial glide, medial tilt, and anteroposterior tilt to the patella. Tape was also applied to unload either the infrapatellar fat pad or the pes anserinus. Hypoallergenic undertape was applied beneath the rigid tape to prevent irritation of the skin as the therapeutic tape.. Duration 3 weeks. Concurrent medication/care: People continued current treatment but weren't allowed to start any new ones. Indirectness: No indirectness (n=29) Intervention 2: Sham device. Control tape was applied to provide sensory input only. Hypoallergenic tape alone was laid over the same areas of skin as therapeutic tape. Duration 3 weeks. Concurrent medication/care: People continued current treatment but weren't allowed to start any new ones. Indirectness: No indirectness

	(n=29) Intervention 3: No device intervention. No additional intervention. Duration 3 weeks. Concurrent medication/care: People continued current treatment but weren't allowed to start any new ones. Indirectness: No indirectness
Funding	Other author(s) funded by industry (Funded by National Health and Medical Research Council (Grant number 114277) and the Australia New Zealand Charitable Trusts. Jenny McConnel received a royalty from sales on Endura Tape, which was not used in this study.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: SF-36 Bodily pain subscale at 6 weeks; Group 1: mean 60.1 (SD 25.6); n=29, Group 2: mean 70.3 (SD 23.1); n=29; SF-36 bodily pain subscale 0-100 Top=High is good outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 60.1 (50.8 to 69.4). Reported sham: 70.3 (61.9 to 78.7). Baseline tape: 52.2 (43.0 to 61.4). Baseline sham: 53.8 (44.2 to 63.5).
Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome for Knee: SF-36 Physical function subscale at 6 weeks; Group 1: mean 41.9 (SD 23.8); n=29, Group 2: mean 47.8 (SD 24.7); n=29; SF-36 Physical function subscale 0-100 Top=High is good outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 41.9 (33.2 to 50.5). Reported sham: 47.8 (38.8 to 56.8). Baseline tape: 39.8 (31.8 to 47.8). Baseline sham: 43.4 (34.2 to 52.6).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in outcome at baseline. Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome for Knee: SF-36 Physical role subscale at 6 weeks; Group 1: mean 41.4 (SD 46.4); n=29, Group 2: mean 57 (SD 42.9); n=29; SF-36 physical role subscale 0-100 Top=High is poor outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 41.4 (24.5 to 58.3). Reported sham: 57.0 (41.4 to 72.6). Baseline tape: 38.8 (22.2 to 55.4). Baseline sham: 44.0 (26.8 to 61.2).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in outcome at baseline. Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 6 weeks; Group 1: mean 7.3 (SD 4.1); n=29, Group 2: mean 5.8 (SD 3.3); n=29; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 7.3 (5.8 to 8.8). Reported sham: 5.8 (4.6 to 7.0). Baseline tape: 9.0 (7.7 to 10.3). Baseline sham: 7.8 (6.6 to 8.9).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in outcome at baseline.

Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function subscale at 6 weeks; Group 1: mean 26 (SD 13.1); n=29, Group 2: mean 21.8 (SD 12.1); n=29; WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 26.0 (21.2 to 30.8). Reported sham: 21.8 (17.4 to 26.2). Baseline tape: 29.4 (25.6 to 33.3). Baseline sham: 27.8 (23.5 to 32.1).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 0

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: SF-36 Bodily pain subscale at 6 weeks; Group 1: mean 60.1 (SD 25.6); n=29, Group 2: mean 48.6 (SD 24.7); n=29; SF-36 bodily pain subscale 0-100 Top=High is good outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 60.1 (50.8 to 69.4). Reported no device: 48.6 (39.6 to 57.6). Baseline tape: 52.2 (43.0 to 61.4). Baseline no device: 50.6 (41.7 to 59.4).
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: 1 withdrew to seek treatment
- Actual outcome for Knee: SF-36 Physical function subscale at 6 weeks; Group 1: mean 41.9 (SD 23.8); n=29, Group 2: mean 38.7 (SD 25.1); n=29; SF-36 Physical function subscale 0-100 Top=High is good outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 41.9 (33.2 to 50.5). Reported no device: 38.7 (29.5 to 47.8). Baseline tape: 39.8 (31.8 to 47.8). Baseline no device: 40.0 (30.6 to 49.4).
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: 1 withdrew to seek treatment
- Actual outcome for Knee: SF-36 Physical role subscale at 6 weeks; Group 1: mean 41.4 (SD 46.4); n=29, Group 2: mean 34.6 (SD 44.5); n=29; SF-36 physical role subscale 0-100 Top=High is good outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 41.4 (24.5 to 58.3). Reported no device: 34.6 (18.4 to 50.8). Baseline tape: 38.8 (22.2 to 55.4). Baseline no device: 35.6 (21.0 to 50.2).
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: 1 withdrew to seek treatment

Protocol outcome 2: Pain reduction at ≤3- or >3- months

- Actual outcome for Knee: WOMAC pain subscale at 6 weeks; Group 1: mean 7.3 (SD 4.1); n=29, Group 2: mean 9.4 (SD 3.6); n=29; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 7.3 (5.8 to 8.8). Reported no device: 9.4 (8.1 to 10.7). Baseline tape: 9.0 (7.7 to 10.3). Baseline no device: 9.0 (7.8 to 10.1). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: 1 withdrew to seek treatment Protocol outcome 3: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function subscale at 6 weeks; Group 1: mean 26 (SD 13.2); n=29, Group 2: mean 31.5 (SD 13.2); n=29; WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Reports mean score (95% confidence intervals). Converted to SD. Reported tape: 26.0 (21.2 to 30.8). Reported no device: 31.5 (26.7 to 36.3). Baseline tape: 29.4 (25.6 to 33.3). Baseline no device: 29.6 (25.3 to 33.9). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, height, weight, BMI, duration of symptoms, sex, radiographic grade, presence of osteophytes in the patellofemoral joint, and narrowing of the patellofemoral joint; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: 1 withdrew to seek treatment	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Hinman 2016[80]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=164)
Countries and setting	Conducted in Australia; Setting: Outpatient follow up. Community dwelling participants from Melbourne, Australia.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiographic knee osteoarthritis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 50 years or older; had knee pain on most days in the previous month; reported average pain of at least 4 on an 11-point numerical rating scale (NRS) in the previous week; had radiographic evidence of osteoarthritis (Kellgren Lawrence grade at least 2) and had definite medial tibiofemoral osteoarthritis on radiography (grade at least 1 medial osteophytes and grade at least 1 medial joint space narrowing that was greater than lateral)
Exclusion criteria	Presence of lateral tibiofemoral osteophytes that were worse than medial; intra-articular corticosteroid injection or knee surgery in the prior 3 months; presence of a systemic arthritic condition; prior knee arthroplasty or osteotomy or planned knee surgery in the subsequent 6 months; presence of another condition affecting lower limb function; current or previous (prior 6 months) use of shoe inserts, braces, or customized shoes from a health professional; inability to walk unaided; body mass index of 36 kg/m2 or greater; self-reported pathology or pain in the ankle or foot.
Recruitment/selection of patients	People were recruited between August 2013 and May 2015 via print, radio, television and social media advertisements and their research database.
Age, gender and ethnicity	Age - Mean (SD): 64.3 (7.5). Gender (M:F): 80:84. Ethnicity: Not stated/unclear
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Radiographic severity grade 2-4, median grade 3. Duration of symptoms (mean [SD]): 9.3 (7.9) years
Indirectness of population	No indirectness
Interventions	(n=83) Intervention 1: Orthotic devices - Shoes. Black, commercially available unloading walking shoes with triple density midsoles (stiffer laterally than medially) and mild (5-degree) lateral-wedge insoles attached to the underside of the sock liners. People were asked to wear their shoes as much as possible every day (At least 4 hours per day) for 6 months and to avoid changing shoes.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness

	(n=81) Intervention 2: Sham device. Same instruction as the intervention group but provided with a visually indistinguishable neutral walking shoe that did not contain the specific design features of the unloading shoes.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (The trial was funded by the National Health and Medical Research Council (project #1044396). Dr. Hinman is supported by an Australian Research Council Future Fellowship (FT130100175). Dr. Hunter is supported by a National Health and Medical Research Council Practitioner Fellowship (#1079777). Dr. Bennell is supported by a National Health and Medical Research Council Fellowship (#1058440).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: AQoL-6D at 6 months; Group 1: mean 0 (SD 0.1); n=80, Group 2: mean 0 (SD 0.1); n=80; AQoL -0.04-1 Top=High is good outcome; Comments: Baseline shoes: 0.8 (0.1). Baseline sham: 0.8 (0.1).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: 83 allocated - 80 completing 3 month assessment. 1 lost to follow-up, 1 declined.; Group 2 Number missing: 1, Reason: 81 allocated - 80 completed 6 month assessment.

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 3 months; Group 1: mean -2.3 (SD 3.3); n=78, Group 2: mean -2 (SD 3.6); n=78; WOMAC pain 0-20 Top=High is poor outcome; Comments: Baseline shoes: 8.7 (2.6). Baseline sham: 8.3 (3.0).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 83 allocated - 78 completing 3 month assessment. 5 lost to follow-up, 3 unable to contact, 1 family death, 1 too busy; Group 2 Number missing: 3, Reason: 81 allocated - 78 completing 3 month assessment. 3 lost to follow-up, 2 unable to contact, 1 family illness
- Actual outcome for Knee: WOMAC pain at 6 months; Group 1: mean -2.5 (SD 4.1); n=80, Group 2: mean -2.2 (SD 3.9); n=80; WOMAC pain 0-20 Top=High is poor outcome; Comments: Baseline shoes: 8.7 (2.6). Baseline sham: 8.3 (3.0).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: 83 allocated - 80 completing 3 month assessment. 1 lost to follow-up, 1 declined.; Group 2 Number missing: 1, Reason: 81 allocated - 80 completed 6 month assessment.

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 3 months; Group 1: mean -6.9 (SD 10.5); n=78, Group 2: mean -6.7 (SD 11.5); n=78; WOMAC function 0-68 Top=High is poor outcome; Comments: Baseline shoes: 29.5 (9.5). Baseline sham: 27.9 (10.7).

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 83 allocated - 78 completing 3 month assessment. 5 lost to follow-up, 3 unable to contact, 1 family death, 1 too busy; Group 2 Number missing: 3, Reason: 81 allocated - 78 completing 3 month assessment. 3 lost to follow-up, 2 unable to contact, 1 family illness - Actual outcome for Knee: WOMAC physical function at 6 months; Group 1: mean -7.8 (SD 12.8); n=80, Group 2: mean -7.3 (SD 12); n=80; WOMAC function 0-68 Top=High is poor outcome; Comments: Baseline shoes: 29.5 (9.5). Baseline sham: 27.9 (10.7). Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: 83 allocated - 80 completing 3 month assessment. 1 lost to follow-up, 1 declined.; Group 2 Number missing: 1, Reason: 81 allocated - 80 completed 6 month assessment. Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Adverse events at 6 months; Group 1: 26/83, Group 2: 20/81; Comments: Shoes: 16 ankle/foot pain, 4 back pain, 2 blisters, 3 hip pain, 13 knee pain, 2 knee stiffness/swelling, 0 shin/calf pain (26 overall). Sham: 7 ankle/foot pain, 2 back pain, 0 blisters, 4 hip pain, 13 knee pain, 2 knee stiffness/swelling, 3 shin/calf pain (20 overall). Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: 83 allocated - 80 completing 3 month assessment. 1 lost to follow-up, 1 declined.; Group 2 Number missing: 1, Reason: 81 allocated - 80 completed 6 month assessment.	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Hjartarson 2018[81]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=150)
Countries and setting	Conducted in Sweden; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Mild to moderate knee osteoarthritis with knee pain for more than three months, with arthroscopy or radiographic evidence of knee OA (Allbäck or Kellgren Lawrence grade 1-2).
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People between 30-70 years of age, with knee pain for more than three months, with arthroscopic or radiographic evidence of knee OA (Allbäck or Kellgren Lawrence grade 1-2) with BMI ≤35.
Exclusion criteria	People with prior major surgery in the same knee; a history of stroke, neurological or psychiatric problems; people using opioids or steroids; people with rheumatoid arthritis, immunological depression or other severe medical problems.
Recruitment/selection of patients	People were initially recruited from primary care or by advertisements in local newspapers and on social media.
Age, gender and ethnicity	Age - Mean (SD): 60.0 (7.5). Gender (M:F): 90:60. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: People with multimorbidities excluded
Extra comments	Severity: Mild-to-moderate Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=74) Intervention 1: Braces. Unloader One knee brace (Ossur, Iceland). Uses two dynamic force straps to impart a force against the lateral side of the knee as the knee extends.. Duration 1 year. Concurrent medication/care: No information available. Indirectness: No indirectness (n=75) Intervention 2: Sham device. Unloader One device without the dynamic force straps - making it look like the brace but be without the functionality.. Duration 1 year. Concurrent medication/care: No information available. Indirectness: No indirectness
Funding	Study funded by industry (Braces and departmental research funding was provided by Össur, Iceland)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS QoL at 1 year; Group 1: mean 3.5 (SD 15.1); n=52, Group 2: mean -2.7 (SD 14.1); n=34; KOOS Quality of Life Subscale 0-100 Top=High is good outcome; Comments: Reports 95% CIs. Reported braces: 3.5 (-0.6, 7.6). Reported sham: -2.7 (-7.5, 2.0). Baseline braces: 52.2 (49.4, 55.0). Baseline sham: 52.3 (49.5, 55.1).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, and baseline values for outcomes; Group 1 Number missing: 22, Reason: Mechanical issues with the device in 8 people, knee replacement surgery in 5, logistics in 5, no effect in 3, drop out in 1, missing data in 1, better in knee 1. Total drop out 35. By reports 52 people had 12 months results for KOOS.; Group 2 Number missing: 41, Reason: Mechanical issues in 25 people, surgery in 4, no effect in 8, medical reasons in 1, better in knee 2. Total drop out 40. However, reports that KOOS data was available for 34 people.

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS Pain at 1 year; Group 1: mean 7.7 (SD 12.9); n=52, Group 2: mean 2.6 (SD 7.7); n=34; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Reports 95% CIs. Reported braces: 7.7 (4.2, 11.2). Reported sham: 2.6 (1.4, 6.6). Baseline braces: 61.2 (58.7, 63.7). Baseline sham: 61.1 (58.7, 63.6).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, and baseline values for outcomes; Group 1 Number missing: 22, Reason: Mechanical issues with the device in 8 people, knee replacement surgery in 5, logistics in 5, no effect in 3, drop out in 1, missing data in 1, better in knee 1. Total drop out 35. By reports 52 people had 12 months results for KOOS.; Group 2 Number missing: 41, Reason: Mechanical issues in 25 people, surgery in 4, no effect in 8, medical reasons in 1, better in knee 2. Total drop out 40. However, reports that KOOS data was available for 34 people.

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: KOOS Activities of Daily Living at 1 year; Group 1: mean 9.8 (SD 12.7); n=52, Group 2: mean 1.8 (SD 11.8); n=34; KOOS Activities of Daily Living subscale 0-100 Top=High is good outcome; Comments: Reports 95% CIs. Reported braces: 9.8 (6.4, 13.3). Reported sham: 1.8 (-2.1, 5.8). Baseline braces: 65.3 (62.9, 67.7). Baseline sham: 65.1 (62.7, 67.5).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness, Comments: ?Indirect. Is activities of daily living equivalent to physical function? Also reported KOOS Sport/Rec. Should this be combined?; Baseline details: Reports age, gender, BMI, and baseline values for outcomes; Group 1 Number missing: 22, Reason: Mechanical issues with the device in 8 people, knee replacement surgery in 5, logistics in 5, no effect in 3, drop out in 1, missing data in 1, better in knee 1. Total drop out 35. By reports 52 people had 12 months results for KOOS.; Group 2 Number missing: 41, Reason: Mechanical issues in 25 people, surgery in 4, no effect in 8, medical reasons in 1, better in knee 2. Total drop out 40. However, reports that KOOS data was available for 34 people.

Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Horlick 1993[82]
Study type	RCT (Patient randomised; double-crossover trial)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in Canada; Setting: patients referred to brace company for treatment of medial compartment gonarthrosis.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: based on a history of medial joint line pain and physical examination findings of medial joint line tenderness plus clear radiographic evidence of medial joint compartment narrowing.
Stratum	Knee; One group received lateral hinge; the other group received medial hinge and the two groups were reported separately
Subgroup analysis within study	None
Inclusion criteria	Diagnosis of medial compartment gonarthrosis; age 30-70 years; manual dexterity adequate for self-application of the brace.
Exclusion criteria	Arthritides other than OA; previous fracture of ipsilateral femur or tibia; previous surgery to the affected knee other than arthroscopy, debridement, or partial meniscectomy; fixed flexion deformity >15 degrees; flexion <115 degrees; leg length discrepancy >2cm; and skin disease or peripheral vascular disease preventing brace application.
Recruitment/selection of patients	Unclear – patients were referred to the brace company but no further details.
Age, gender and ethnicity	Age - Mean (range): lateral hinge group: 49 (33-65 years); medial hinge group: 46 (34-69 years). Gender (M:F): lateral hinge group: 17:3; medial hinge group: 15:4. Ethnicity: Not stated
Further population details	1.Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated
Extra comments	Severity: Not stated Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=39) Intervention 1: Orthotic devices – Valgus brace. For the valgus phase the patients returned the brace to the manufacturer and both arms of the hinge were bent into 5 degrees of valgus for a total valgus angulation of 10 degrees in excess of the patient's normal sagittal orientation. Duration 6 weeks. Concurrent medication/care: Not reported. Patients filled out a daily diary recording pain and function. Indirectness: indirect as the two types of brace were reported separately. Results also separated by medial and lateral hinges.

	(n=39) Intervention 2: Orthotic devices – Neutral brace. The brace was not bent into an angle. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: indirect as the two types of brace were reported separately. Results also separated by medial and lateral hinges. (n=39) Intervention 3: Orthotic devices – No brace. No brace was given. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: indirect as the two types of brace were reported separately. Results also separated by medial and lateral hinges. The patients were randomised into treatment sequences of brace in neutral, brace in valgus, no brace; brace in neutral, no brace, brace in valgus; brace in valgus, no brace, brace in neutral; and brace in valgus, brace in neutral, no brace. The investigators chose not to include no brace first as this was thought to not differ from the pre-treatment status. The brace was worn during prolonged standing and/or sports activity.
Funding	Generation II Orthotics, Inc. of Vancouver, British Columbia.
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Pain level (VAS) at 6 weeks; Group 1 (Valgus brace, lateral hinge): mean 2.30 (SD 2.04); n=20, Group 2 (Valgus brace, medial hinge): mean 2.55 (SD 1.26); n=19; Group 3 (Neutral brace, lateral hinge): 2.82 (SD 2.07); N=20; Group 4 (Neutral brace, medial hinge): 2.98 (SD 1.08); n=19; Group 5 (No brace, lateral hinge): 2.98 (2.11); n=20; Group 6 (No brace, medial hinge):3.81 (SD 2.08); n=19. Visual analogue scale 0-10. Top=High is poor outcome; Comments: Baseline values: Pre-brace Lateral: 3.53 (SD 1.92); Pre-brace Medial): 2.55 (SD 1.26). Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - High, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness; Baseline details: No details of severity; very little details of Group 1 Number missing: 1; Reason: brace intolerance. Group 2 Number missing: 1; Reason: brace intolerance; Group 3 Number missing: 1; Reason: brace intolerance; Group 4 Number missing: 1; Reason: brace intolerance; Group 5 Number missing: 0; Group 6 Number missing: 0.	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months. Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Jones 2012[92]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=64)
Countries and setting	Conducted in Brazil; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 60 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosis of knee osteoarthritis according to the criteria of the American College of Rheumatology. No radiographic parameters reported.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Diagnosis of knee osteoarthritis according to the criteria of the American College of Rheumatology; visual analogue scale (VAS) for knee pain score ranging from 3 to 7 (maximum 10); stable doses of antiinflammatory drugs; no regular phyiscal exercise in the month before the study
Exclusion criteria	Symptomatic heart disease; symptomatic disease of the lower limbs (other than knee osteoarthritis) or upper limb that would secure the cane; symptomatic lung disease; severe systemic disease; severe psychological illness; regular physical exercise (three or more times per week for at least 3 months); drug injection in the knee in the previous 3 months; physiotherapy on the lower limbs in the previous 6 months; cane use in the previous 3 months; inability to walk and geographical inaccessibility.
Recruitment/selection of patients	64 people selected from the rheumatology outpatient clinic.
Age, gender and ethnicity	Age - Mean (SD): 62.1 (5.9). Gender (M:F): 7:57. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed without imaging 3. Multimorbidities: People with multimorbidities excluded
Extra comments	Severity: Not stated. Duration of symptoms (mean [SD]): 6.3 (3.4) years
Indirectness of population	No indirectness
Interventions	(n=32) Intervention 1: Walking aids - Canes. Wooden canes with a T-shaped handle. All people were positioned standing comfortably erect, with arms relaxed alongside the body and wearing shoes with low heels. The cane was placed with the tip on the floor, 10cm from the lateral margin of the ankle (towards the metatarsus) and a mark was made at the height of the distal fold of the wrist. after cutting the cane to the proper height, the elbow flexion angle was measured which be between 20 degrees and 30 degrees. If this angle was not achieved, the cane was adjusted until it reached the proper elbow flexion angle. The experimental group took the canes home and used them day-to-day for 2

	months. On the first evaluation, a physiotherapist offered a 5-minute training period to each person for instructions on using the cane on the contralateral side and setting the tip of the cane on the group alongside the more symptomatic knee during the stance phase. During the training session, the patient walked along the same path determined for the subsequent walk test.. Duration 2 months. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=32) Intervention 2: No device intervention. Similar to the experimental group - the cane was made as explained. However, they were told to maintain standard care for 2 months (waiting list control). On the first evaluation, a physiotherapist offered a 5-minute training period to each person for instructions on using the cane on the contralateral side and setting the tip of the cane on the group alongside the more symptomatic knee during the stance phase. During the training session, the patient walked along the same path determined for the subsequent walk test. They received the cane at the end of the study.. Duration 2 months. Concurrent medication/care: Standard care was maintained over 2 months. Indirectness: No indirectness
Funding	Academic or government funding (Grants from Fundacao Amparo a Pesquisa do Estado de Sao Paulo)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CANES versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: SF-36 Physical Functioning Subscale at 2 months; Group 1: mean 45 (SD 15.08); n=30, Group 2: mean 35.94 (SD 18.94); n=29; SF-36 physical functioning subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 35.9 (17.5). Baseline control: 28.9 (13.0).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Role Physical Subscale at 2 months; Group 1: mean 42.81 (SD 30.21); n=30, Group 2: mean 26.06 (SD 28.33); n=29; SF-36 role physical subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 23.4 (31.7). Baseline control: 22.7 (24.07).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Bodily Pain Subscale at 2 months; Group 1: mean 60.19 (SD 19.38); n=30, Group 2: mean 46.03 (SD 20.34); n=29; SF-36 bodily pain subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 48.7 (15.1). Baseline control: 46.1 (15.3).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew

due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 General Health Subscale at 2 months; Group 1: mean 58.87 (SD 24.13); n=30, Group 2: mean 56.81 (SD 23.55); n=29; SF-36 general health subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 49.0 (21.7). Baseline control: 57.3 (21.0).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Vitality Subscale at 2 months; Group 1: mean 54.09 (SD 26.28); n=30, Group 2: mean 38.59 (SD 28.4); n=29; SF-36 vitality subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 40.5 (25.2). Baseline control: 38.8 (22.1).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Social Functioning Subscale at 2 months; Group 1: mean 57.16 (SD 17.29); n=30, Group 2: mean 49.22 (SD 29.37); n=29; SF-36 social functioning subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 51.7 (22.57). Baseline control: 48.8 (20.0).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Role Emotional Subscale at 2 months; Group 1: mean 42.98 (SD 29.63); n=30, Group 2: mean 24.9 (SD 29.37); n=29; SF-36 role emotional subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 25.5 (31.9). Baseline control: 24.1 (30.6).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture
- Actual outcome for Knee: SF-36 Mental Health Subscale at 2 months; Group 1: mean 58.82 (SD 19.62); n=30, Group 2: mean 51.1 (SD 20.79); n=29; SF-36 mental health subscale 0-100 Top=High is good outcome; Comments: Baseline stick: 46.4 (24.7). Baseline control: 44.6 (22.6).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture

Protocol outcome 2: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Visual analogue scale (pain) at 2 months; Group 1: mean 3.84 (SD 1.44); n=30, Group 2: mean 5.95 (SD 1.4); n=29; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline stick: 5.63 (1.02). Baseline control: 5.48 (1.23). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, disease duration, heigh, weight, BMI, VAS for pain, Lequesne, WOMAC, SF-36; Group 1 Number missing: 2, Reason: 1 withdrew due to death of husband followed by depression, 1 withdrew due to breast cancer surgery; Group 2 Number missing: 3, Reason: 1 withdrew due to health problems in the family, 1 withdrew due to appendectomy, 1 withdrew due to foot fracture	
Protocol outcomes not reported by the study	Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Jones 2013[94]
Study type	RCT (Patient randomised; Crossover: 2 weeks)
Number of studies (number of participants)	1 (n=28)
Countries and setting	Conducted in United Kingdom; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention time: 2 weeks per intervention
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Unilateral OA as diagnosed by a consultant orthopaedic surgeon with grade 2-3 Kellgren Lawrence changes
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Unilateral osteoarthritis with grade 2 or 3 Kellgren Lawrence scores with medial joint space narrowing
Exclusion criteria	Symptomatic evidence of lateral compartment or patellofemoral osteoarthritis; rheumatoid arthritis; surgery within the past six months; previous stroke, hip or ankle symptoms, or a body mass index above 35
Recruitment/selection of patients	No additional information
Age, gender and ethnicity	Age - Mean (SD): 66.3 (8.2). Gender (M:F): 16:12. Ethnicity: Not stated
Further population details	1. Age: Mixed (Based on SD). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren Lawrence grade 2-3. Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=28) Intervention 1: Orthotic devices - Insoles. Laterally wedged insoles with a heel inclined at 5 degrees with the inclination gradually reduced to 0 degrees at the 5th metatarsal head with a contoured arch profile to reduce reported foot and ankle associated pain. Duration 2 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=28) Intervention 2: Braces. Off-the-shelf valgus knee brace (Conjoy OAdjuster, DJO, Vista, USA). The brace was set into 6 degrees of valgus alignment once contract was made with the lateral condyle. Duration 2 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (Braces provided by DJO)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus INSOLES

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 2 weeks; Group 1: mean 36.8 (SD 11.7); n=28, Group 2: mean 38.6 (SD 13.5); n=28; WOMAC pain subscale 0-100 Top=High is poor outcome; Comments: Baseline 1: 50 (15.7). Baseline 2: 48.6 (14.7).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, Kellgren Lawrence grade, height and mass; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC function subscale at 2 weeks; Group 1: mean 46.7 (SD 14.5); n=28, Group 2: mean 47.2 (SD 13.8); n=28; WOMAC function subscale 0-100 Top=High is poor outcome; Comments: Baseline 1: 54.2 (13.9). Baseline 2: 53.9 (13.9).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, Kellgren Lawrence grade, height and mass; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Kaya mutlu 2017[96]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=42)
Countries and setting	Conducted in Turkey; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 1 month, 2 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinically diagnosed (according to the American College of Rheumatology criteria) by an orthopaedic surgeon in the previous 3 months with grade of OA assessed by radiographic imaging
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Radiographic imaging in the previous 3 months; Kellgren Lawrence grades 2-4; clinical criteria for diagnosis of OA of the knee according to the American College of Rheumatology criteria.
Exclusion criteria	Rheumatoid arthritis; previous knee or hip joint replacement surgery of the affected joint; any other surgical procedure on the lower limbs within the previous year; a planned surgical procedure on the lower limbs within the next 6 months; any physical therapy intervention on the lower limbs in the previous 6 months; opioid analgesia or corticosteroid or analgesic injection interventions for knee pain within the previous 6 months; uncontrolled hypertension or a moderate to high risk of cardiac complications during exercise.
Recruitment/selection of patients	Outpatients at the clinical laboratory of the PHysiotherapy Department of the University of Instanbul. 45 were assessed for eligibility with 3 excluded (1 declined to participate, 2 not meeting inclusion criteria).
Age, gender and ethnicity	Age - Mean (SD): 55.6 (6.3). Gender (M:F): 6:33. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear (At least low risk of cardiovascular morbidity).
Extra comments	Severity: Kellgren Lawrence grades 2-4. Not explicitly stated. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: Straps/tape - Tape. Therapeutic Kinesio taping (Kinesio Text Tape) with a width of 5cm and a thickness of 0.5mm. 3 applications over a 12-16 day period. This was applied on their quadriceps femoris and hamstring muscle. First, people were taped using a Y-shaped Kinesio tape at the quadriceps femoris. The tap was applied a point 5cm inferior to the anterior superior iliac spine to the knee cap (origin to insertion), with the patient in a supine position with 25% tension. Then, each person flexed his or her knee, and the Y-shaped tape (the tails of the tape) was circled around the patella, ending at its inferior side with no tension.

	Next, people were taped with a Y-shaped Kinesio tape at the hamstring muscle. The tape was applied from the ischial tuberosity to the back of the knee, with the people in a standing position with their trunk bent. Then the Y-shaped tape (the tails of the tape) was applied around the lateral side of the knee and medial side of the knee.. Duration 12-16 days. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=21) Intervention 2: Sham device. Therapeutic Kinesio taping (Kinesio Text Tape) with a width of 5cm and a thickness of 0.5mm. 3 applications over a 12-16 day period. Placebo Kinesio taping was applied transverse to the muscle groups of the quadriceps and hamstring in 2 levels when the person was in a supine position with their hips flexed at 30 degrees and their knees flexed at 60 degrees.. Duration 12-16 days. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Pain: VAS rest at 1 month, 2 weeks; Group 1: mean 0.66 (SD 3.1); n=20, Group 2: mean 1.11 (SD 2.1); n=19; Visual analogue scale 0-10 Top=High is poor outcome; Comments: Using within-group score change as baselines were different. Reported as 95% CIs. Reported tape: 0.66 (-0.68, 2.02). Reported sham: 1.11 (0.17, 2.06). Final tape: 1.25 (2.02). Final sham: 2.48 (2.75). Baseline tape: 1.92 (2.66). Baseline sham device: 3.60 (2.33).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, radiological stage, affected side, people with bilateral OA and educational level.; Group 1 Number missing: 1, Reason: 1 lost to follow up (without reason); Group 2 Number missing: 2, Reason: 1 lost to follow up (without reason), 1 discontinued intervention (without reason)

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 1 month, 2 weeks; Group 1: 0/20, Group 2: 0/19
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, sex, BMI, radiological stage, affected side, people with bilateral OA and educational level.; Group 1 Number missing: 1, Reason: 1 lost to follow up (without reason); Group 2 Number missing: 2, Reason: 1 lost to follow up (without reason), 1 discontinued intervention (without reason)

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study (subsidiary papers)	Kirkley 1999[99] (Kirkley 1999[98])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=119)
Countries and setting	Conducted in Canada; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Varus gonarthrosis seen by orthopaedic surgeons with clinical and radiographic evidence of the disease
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Skeletally mature patients of either gender who lived within a two-hour drive of the treatment center and had osteoarthritis of the knee, pain localised primarilly to the medial compartment, and mechanical alignment in more than 0 degrees of varus. Age >50 years with morning stiffness of more than thiry minutes duration, or crepitus in association with active motion of the knee, such as weight-bearing or squatting.
Exclusion criteria	Arthritides other than osteoarthritis; an operation on the knee within the previous six months; symptomatic disease of the hip, ankle or foot; a previous fracture of the tibia or femur; morbid obesity (a body-mass index of more than thirty five kilograms per square meter); skin disease; peripheral vascular disease or varicose veins that would preclude use of a brace; a severe cardiovascular deficit; blindness; poor English language skills; and an inability to apply a brace because of physical limitations such as arthritis in the hand or an ability to bend over.
Recruitment/selection of patients	People from an orthopaedic outpatient clinic or people who had answered advertisements in the local newspaper.
Age, gender and ethnicity	Age - Other: Mean: 59.2. Gender (M:F): 79:31. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not stated. Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=41) Intervention 1: Braces. The same medical treatment as the control group, but were also fitted with a generation II valgus-producing functional knee (unloader) brace. The brace was custom-made and consisted of a polyethylene thigh shell connected to a polyethylene calf shell through a polyaxial hinge on the medial side. The hinge was altered with use of a calibrated apparatus to allow application of a 4-degree increase in valgus in the anteroposterior plane. The people were instructed to wear the brace while they were awake for activities that had been troublesome to them in the past.. Duration 6 months. Concurrent medication/care: Standard therapy as described in the control group: An educational

	pamphlet on osteoarthritis, which described the pathological characteristics of the disease, how the diagnosis is determined, methods of coping, and the medical treatments available; instructions to use plain paracetamol on an as neede dbasis for the relief of pain, and instructions on a home program to maintain flexiblity. This did not include formal physiotherapy. People taking NSAIDs at the time of presentation were asked to continue taking these medications as they had previously.. Indirectness: No indirectness (n=38) Intervention 2: Supports - Other supports. Same medical treatment as the control group, but also fitted with a neoprene sleeve. Instructed on the appropriate application and maintenance of the sleeve and directed to wear it while they were awake for activities that had been troublesome to them in the past.. Duration 6 months. Concurrent medication/care: Standard therapy as described in the control group: An educational pamphlet on osteoarthritis, which described the pathological characteristics of the disease, how the diagnosis is determined, methods of coping, and the medical treatments available; instructions to use plain paracetamol on an as neede dbasis for the relief of pain, and instructions on a home program to maintain flexiblity. This did not include formal physiotherapy. People taking NSAIDs at the time of presentation were asked to continue taking these medications as they had previously.. Indirectness: No indirectness (n=40) Intervention 3: No device intervention. An educational pamphlet on osteoarthritis, which described the pathological characteristics of the disease, how the diagnosis is determined, methods of coping, and the medical treatments available; instructions to use plain paracetamol on an as neede dbasis for the relief of pain, and instructions on a home program to maintain flexiblity. This did not include formal physiotherapy. People taking NSAIDs at the time of presentation were asked to continue taking these medications as they had previously.. Duration 6 months. Concurrent medication/care: No additional treatment. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus OTHER SUPPORTS

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 6 months; Group 1: mean -43.2 (SD 38.5); n=41, Group 2: mean -13.1 (SD 38.5); n=36; WOMAC pain subscale (mm) 0-500 Top=High is poor outcome; Comments: Reports p value for change scores: 0.001. SD estimated from this.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 0; Group 2 Number missing: 2, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 6 months; Group 1: mean -157.2 (SD 127.1); n=41, Group 2: mean -68.9 (SD 127.1); n=36;

WOMAC physical function subscale 0-1700 Top=High is poor outcome; Comments: Reports p value for change scores: 0.004. SD estimated from this.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 0; Group 2 Number missing: 2, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 6 months; Group 1: mean -43.2 (SD 70.2); n=41, Group 2: mean 13.1 (SD 70.2); n=33; WOMAC pain subscale (mm) 0-500 Top=High is poor outcome; Comments: Reports p value for change scores: 0.001. SD estimated from this.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 0; Group 2 Number missing: 5, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 6 months; Group 1: mean -157.2 (SD 235.4); n=41, Group 2: mean 6.5 (SD 235.4); n=33; WOMAC physical function subscale 0-1700 Top=High is poor outcome; Comments: Reports p value for change scores: 0.004. SD estimated from this.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 0; Group 2 Number missing: 5, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: OTHER SUPPORTS versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 6 months; Group 1: mean -13.1 (SD 31.6); n=36, Group 2: mean 13.1 (SD 31.6); n=33; WOMAC pain subscale 0-500 Top=High is poor outcome; Comments: Reports p value for change scores: 0.001. SD estimated from this.
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 2, Reason: Unclear. 9 patients withdrew (5 from 7 from

	control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.; Group 2 Number missing: 5, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to. Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function at 6 months; Group 1: mean -68.9 (SD 104.9); n=36, Group 2: mean 6.5 (SD 104.9); n=33; WOMAC physical function subscale 0-1700 Top=High is poor outcome; Comments: Reports p value for change scores: 0.004. SD estimated from this. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, mean varus alignment of mechanical axis, status of anterior cruciate ligament; Group 1 Number missing: 2, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.; Group 2 Number missing: 5, Reason: Unclear. 9 patients withdrew (5 from 7 from control group, 2 from support group) due to dissatisfaction with group they had been randomized to (5 people), inability to attend appointments (2 people), ill health (1 person) and a change in a scheduled date for an operation (1 person). Does not state which group these patients belonged to.
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Koca 2009[100]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=37)
Countries and setting	Conducted in Turkey; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee osteoarthritis according to the American College of Rheumatology criteria and classified as grade II and III according to the Kellgren Lawrence radiological grading
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Women with knee osteoarthritis according to the American College of Rheumatology criteria and classified as grade II and III according to the Kellgren Lawrence radiological grading
Exclusion criteria	Presence of knee flexion contracture, instability, hip and ankle pathology, involvement of the lateral compartment of the knee, history of knee surgery, signs of meniscopathy at physical examination, infective or inflammatory pathologies of the knee, presence of trauma, intraarticular injection within 6 months and physical therapy within 1 year.
Recruitment/selection of patients	People who attended the physical medicine and rehabilitation clinic
Age, gender and ethnicity	Age - Mean (SD): 55.1 (10.5). Gender (M:F): 0:37. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grade II-III. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Orthotic devices - Insoles. A 6mm wedge insole used all day in addition to the therapy prescribed for the no insole group. The outside height of the insole was 6mm, so the sagittal axis of the posteriro part of the calcaneus was tilted laterally at 5 degrees to the floor.. Duration 3 months. Concurrent medication/care: Control group treatment: Paracetamol 1500mg/day and quadriceps strenghtening exercises for 3 months. Indirectness: No indirectness (n=18) Intervention 2: No device intervention. Paracetamol 1500mg/day and quadriceps strenghtening exercises for 3 months. Duration 3 months. Concurrent medication/care: No additional treatment. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 3 months; Group 1: mean 13.31 (SD 4.44); n=19, Group 2: mean 17.33 (SD 4.15); n=18; WOMAC pain subscale 0-24 Top=High is poor outcome; Comments: Baseline insole: 16.36 (3.91). Baseline control: 17.50 (4.21).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, affected side, Kellgren-Lawrence grade, heigh, weight, BMI, mean Rich index score, pain at rest, pain at standing, pain at walking, WOMAC pain, WOMAC function, WOMAC stiffness, total WOMAC. WOMAC score baselines are different (favouring the intervention group); Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 3 months; Group 1: mean 46.16 (SD 15.18); n=19, Group 2: mean 57.94 (SD 13.98); n=18; WOMAC physical function 0-68 Top=High is poor outcome; Comments: Baseline insole: 52.68 (14.56). Baseline control: 60.27 (13.52).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, affected side, Kellgren-Lawrence grade, heigh, weight, BMI, mean Rich index score, pain at rest, pain at standing, pain at walking, WOMAC pain, WOMAC function, WOMAC stiffness, total WOMAC. WOMAC score baselines are different (favouring the intervention group); Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Kocyigit 2015[101]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=41)
Countries and setting	Conducted in Turkey; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosed as knee osteoarthritis according to clinical diagnostic criteria proposed by the American College of Rheumatology
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Knee pain diagnosed as knee osteoarthritis according to clinical diagnostic criteria proposed by ACR; mild-moderate knee pain (VAS between 20 and 70mm); Age between 30 and 70 years; no previous application of Kinesio taping; approval of inclusion in the study
Exclusion criteria	History of previous knee fracture/surgery in the last 6 months; previous or concurrent diagnosis of cruciate and collateral ligament tear; presence of acute inflammation findings in the involved knee (swelling, erythema, redness); inflammatory joint disease; history of electrotherapy or injection for the knee in the last 3 months
Recruitment/selection of patients	50 people presented to the institutional outpatient clinic with a primary complaint of knee pain. Two were diagnosed with other conditions. Three had other treatments. Two refused to participate.
Age, gender and ethnicity	Age - Mean (SD): 45 (15). Gender (M:F): 5:36. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed without imaging 3. Multimorbidities: Low comorbidity score (Tape group: 9 had no comorbidities, 8 had 1 comorbidity, 4 had >1 comorbidities. Control group: 8 had no comorbidities, 8 had 1 comorbidity, 4 had >1 comorbidities).
Extra comments	Severity: Mild-to-moderate Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Straps/tape - Tape. Kinesio Taping. 'Y-strip' representative of the quadriceps, applied while the person was lying in the supine position, knee in maximal flexion. Tails of the quadriceps strip were applied to the patella, wrapping patella medially and laterally with 25% tension. The base of the strip was applied with paper off tension towards the anterior superior iliac spine. The second strip, a Y-stip was applied between the tibial tuberosity and inferior pole of the patella when the knee is flexed 90 degres. The tails of the second strip are again applied wrapping patella medially and laterally. The tails are directed towards vastus medialis and vastus lateralis. The third strip was an I-strip

	applied when the knee was flexed 30 degrees. The strip was applied to patella mediolaterally with 75% tension in the middle and paper-off tension at the ends.. Duration 12 days. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=21) Intervention 2: Sham device. Sham taping with 5cm beta fix surgical hypoallergenic flexible tape. Identical strips were used for sham taping that did not attempt to correct misalignment by reducing muscle spasm and enhance local circulation as expected for Kinesio Taping.. Duration 12 days. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: Nottingham Health Profile total score at 12 days; Group 1: mean 173.62 (SD 138.03); n=21, Group 2: mean 121.03 (SD 114.82); n=20; Nottingham Health Profile total score 0-600 Top=High is poor outcome; Comments: Baseline tape: 199.81 (124.51). Baseline sham device: 159.54 (104.48).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, employment status, presence of comorbidities, knee involvement; Group 1 Number missing: 1, Reason: 1 discontinued intervention (difficulty in transportation); Group 2 Number missing: 1, Reason: 1 discontinued intervention (development of mild rash after taping)

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Visual analogue scale nocturnal pain at 12 days; Group 1: mean 26 (SD 22); n=21, Group 2: mean 26 (SD 8); n=20; Visual analogue scale nocturnal pain 0-100 Top=High is poor outcome; Comments: Baseline tape: 40 (27). Baseline sham: 42 (27).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness, Comments: ?indirectness. Only reports nocturnal pain. However, this is likely pain at rest. Therefore, not downgraded.; Baseline details: Reports age, gender, employment status, presence of comorbidities, knee involvement; Group 1 Number missing: 1, Reason: 1 discontinued intervention (difficulty in transportation); Group 2 Number missing: 1, Reason: 1 discontinued intervention (development of mild rash after taping)

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: Lequesne index score at 12 days; Group 1: mean 7.7 (SD 3.1); n=21, Group 2: mean 5.5 (SD 4.4); n=20; Comments: Baseline tape: 9.9 (2.6). Baseline sham: 10.6 (4.1).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, employment status, presence of comorbidities, knee involvement; Group 1 Number missing: 1, Reason: 1 discontinued intervention (difficulty in transportation); Group 2 Number missing: 1, Reason: 1 discontinued intervention (development of mild rash after taping)

Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Withdrawal due to allergic reaction (pruritic rash) to tape at 12 days; Group 1: 0/21, Group 2: 1/21 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, employment status, presence of comorbidities, knee involvement; Group 1 Number missing: 1, Reason: 1 discontinued intervention (difficulty in transportation); Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Lee 2016[102]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=30)
Countries and setting	Conducted in South Korea; Setting: Inpatient, secondary care
Line of therapy	Unclear
Duration of study	Intervention + follow up: 4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosed with degenerative knee arthritis based on clinical findings and with medical imaging such as X-rays
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People who were diagnosed with degenerative knee arthritis based on clinical findings and with medical imaging such as X-rays and had been prescribed physical therapy.
Exclusion criteria	Fractures in the knee joints or damage to ligaments or other soft titssues
Recruitment/selection of patients	Recruited from the orthopaedic hospital in Daegu, who were inpatients at the hospital
Age, gender and ethnicity	Age - Mean (SD): 72.6 (5.0). Gender (M:F): Not stated. Ethnicity: Not stated
Further population details	1. Age: Mixed (Based on SD). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not stated Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Straps/tape - Tape. Kinesiology taping therapy - 5cm wide elastic tapes applied on the hamstring and the anterior tibialis in cases where the person felt pain when the knee joint was bent or on the quadriceps femoris and gastrocnemius in cases where the patient felt pain when the knee joint was extended. The tapes were replaced with new ones at each treatment session. In the case of the hamstring, the person was instructed to extend their leg to below the bed in a lateral decubitus position, and a Y-shaped tape was prepared. The beginning tips were fixed at the back of the knee and attached at a point 3cm downward from the centerline of the back of the kneecap while being spread laterally. In the case of the anterior tibialis, the person was instructed to take a supine position, and one end of an I-shaped tape was fixed to the lateral surface of the tibial tuberosity. The tape was attached along a line that passed the medial condyle of the ankle and the medial sole and went to the centerline of the instep with the ankle in a state of plantar flexion. In the case of the quadriceps femoris, the subject was instructed to extend the leg to below the bed in a supine position, and the beginning end of a Y-shaped tape was fixed to the center of the thigh 5cm downward from the

	line of the inguinal region. The tape was attached along a line going to a point above the knee cap, with the knee joint in a state of 90 degree flexion, and the two tips of the split end were attached to the kneecap and wrapped around it. In the case of gastrocnemius, the subject was instructed to take a prone position, and a Y-shaped tape was fixed to the heel after bending the knee joint to 90 degrees. The tape was attached around the Achilles tendon after extending the knee straight and maintaining the ankle in an anatomical posture at 90 degrees, and the two tips of the split end were attached on both sides, along the gastrocnemius up to the centerline of the back of the knee.. Duration 4 weeks (3 sessions per week). Concurrent medication/care: Both groups received hot-pack treatment with surface heat for 20 minutes, as well as general physical therapy using interference wave therapy equipment at 100bps for 15 minutes.. Indirectness: No indirectness (n=15) Intervention 2: No device intervention. Physical therapy only (as explained in the background/concomitant treatment section). Duration 4 weeks (3 sessions per week). Concurrent medication/care: Both groups received hot-pack treatment with surface heat for 20 minutes, as well as general physical therapy using interference wave therapy equipment at 100bps for 15 minutes.. Indirectness: No indirectness
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Visual analogue scale (pain) at 4 weeks; Group 1: mean 4.3 (SD 1.2); n=15, Group 2: mean 5.7 (SD 0.9); n=15; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline tape: 7.5 (1.0). Baseline no device: 7.1 (1.1). Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Other 2 - Low, Comments - Unclear if randomised - explains that people were divided into groups but never uses the word random; Indirectness of outcome: No indirectness ; Baseline details: Reports age, height and weight; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Leon-ballesteros 2020[104]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=32)
Countries and setting	Conducted in Mexico; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Bilateral knee osteoarthritis according to the European League Against Rheumatism (EULAR) criteria, classified as grade 2 or 3 by the radiographic scale of Kellgren and Lawrence
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Women aged between 50 and 70 years, with BMI between 25 and 34.9, and diagnosed with bilateral knee OA according to EULAR criteria, classified as grade 2 or 3 by the radiographic scale of Kellgren and Lawrence. Only the most affected knee was evaluated.
Exclusion criteria	Knee joint replacement; pain associated with other knee injuries; strengthening therapy at the time of intervention; ≤90 degree knee flexion; known sensitivity to tape materials; contraindication for exercise
Recruitment/selection of patients	39 people were recruited. 7 were excluded by diverse conditions (3 BMI >34.9, 1 meniscopathy, 2 knee OA grade 4, 1 did not return).
Age, gender and ethnicity	Age - Mean (SD): 58.1 (5.3). Gender (M:F): 0:32. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren Lawrence grade 2-3. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Straps/tape - Tape. Kinesio taping with an elastic band quadriceps exercise program. Kinesio taping done during each follow-up visit during the study. With the knee flexed at 90 degrees, the base of the black I strip was adhered on the leg midline about 15cm above the interarticular line. No tension was applied at the strip was spread over the same midline to about 5-7.5cm below the interarticular line. The Y-strip was then applied, also without tension, and each tail extended to the sides of the midline. After applying the Kinesio tape to each participant, generation of the "convolution" effect of the skin was confirmed, requesting the participants' complete extension of both knees. The exercise program consisted of a dynamic-type strengthening exercise (6-8 per Omni Perceived Exertion Scale-Resistance Exercise Scale) in their home, with a volume of 3 sets of 15 unilateral repetitions, with extension and flexion movement for both knees (2s duration per movement), with a frequency of twice a day. At least 10 repetitions of

	extension. The band was tied to a belt worn by the participant, which would aid in stabilising the exercise. The participant leaned against a wall, sitting on the floor with both knees in extension. They were asked to flex and adjust the elastic band to generate tension against the extension of the knee. The band was adjusted to the level of effort requested according to the OMNI-RES scale. With this elastic band, the participants performed in their homes, 3 sets of 15 repetitions of extension, and 3 sets of 15 repetitions of knee flexion unilaterally. Rest intervals between each series were 30s. Frequency of execution was 3 days per week. The person was also asked to perform stretching exercises for quadriceps and hamstring muscles, lasting 15s per muscle group, twice a day and 6 days which lasted a week.. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=16) Intervention 2: Sham device. Placebo taping with an exercise program. The same material was used, but without the specifications of Kinesio tape. A single black I strip with high tension (>50%) was provided. While the knee was flexed at 90 degrees with a bearing surface, the application took place, otherwise similarly to the Kinesio tape. The exercise program consisted of a dynamic-type strengthening exercise (6-8 per Omni Perceived Exertion Scale-Resistance Exercise Scale) in their home, with a volume of 3 sets of 15 unilateral repetitions, with extension and flexion movement for both knees (2s duration per movement), with a frequency of twice a day. At least 10 repetitions of extension. The band was tied to a belt worn by the participant, which would aid in stabilising the exercise. The participant leaned against a wall, sitting on the floor with both knees in extension. They were asked to flex and adjust the elastic band to generate tension against the extension of the knee. The band was adjusted to the level of effort requested according to the OMNI-RES scale. With this elastic band, the participants performed in their homes, 3 sets of 15 repetitions of extension, and 3 sets of 15 repetitions of knee flexion unilaterally. Rest intervals between each series were 30s. Frequency of execution was 3 days per week. The person was also asked to perform stretching exercises for quadriceps and hamstring muscles, lasting 15s per muscle group, twice a day and 6 days which lasted a week.. Duration 6 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 6 weeks; Group 1: mean 5.5 (SD 1.2); n=14, Group 2: mean 5.4 (SD 2.6); n=12; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Baseline tape: 7.6 (2.9). Baseline control: 9.1 (2.6).
Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, more affected knee, OA grade 2, overweight, BMI, VAS and WOMAC subscales; Group 1 Number missing: 2, Reason: 2 voluntary withdrawals from the study; Group 2 Number missing: 4, Reason: 2 reactions associated with the use of tape, but not the materials, 1 voluntary withdrawal from the study, 1 lumbar injury imposed to continue within the study

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function subscale at 6 weeks; Group 1: mean 19.6 (SD 5); n=14, Group 2: mean 19 (SD 8.6); n=12;

WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Baseline tape: 23.0 (8.2). Baseline control: 25.7 (10.2). Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, more affected knee, OA grade 2, overweight, BMI, VAS and WOMAC subscales; Group 1 Number missing: 2, Reason: 2 voluntary withdrawals from the study; Group 2 Number missing: 4, Reason: 2 reactions associated with the use of tape, but not the materials, 1 voluntary withdrawal from the study, 1 lumbar injury imposed to continue within the study Protocol outcome 3: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Reactions to Kinesio tape but not with the materials - use of an external fixative substance and adhesive tape at 6 weeks; Group 1: 0/14, Group 2: 2/14 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, more affected knee, OA grade 2, overweight, BMI, VAS and WOMAC subscales; Group 1 Number missing: 2, Reason: 2 voluntary withdrawals from the study; Group 2 Number missing: 2, Reason: 1 voluntary withdrawal from the study, 1 lumbar injury imposed to continue within the study	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Lewinson 2016[105]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=38)
Countries and setting	Conducted in Canada; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Confirmed diagnosis of unilateral or bilateral knee OA based on the American College of rheumatology criteria. They also were graded by the Kellgren-Lawrence severity grade.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age between 40-85 years, KOOS of 75 or lower on the pain subscale on initial contact, confirmed diagnosis of unilateral or bilateral knee OA based on the American College of Rheumatology criteria, and confirmation that medial compartment disease was the primary location of symptoms based on clinical exam by a physician. Kellgren-Lawrence grades 1-4.
Exclusion criteria	X-ray older than 2 years; viscosupplementation within past 6 months; cortisone injection in past 3 months; narcotic pain medication within past 3 months; use of knee unloaded brace interventions in past 2 months; recent (past 6 months) knee or neuromuscular injury that could bias pain assessments or gait analysis results; no KAM reduction with either lateral or medial wedge insole (taken from clinicaltrials.gov)
Recruitment/selection of patients	People from the greater Calgary, Alberta area. Conducted at the University of Calgary.
Age, gender and ethnicity	Age - Mean (SD): 59.8 (7.6). Gender (M:F): 14:24. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades 1-4. Duration of symptoms: Range between 0-≥10 years. Median value between 0-≤10 years.
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Orthotic devices - Insoles. Usual footwear (footwear the person has used most regularly over the past two month) with wedged insoles. 6mm laterally wedged insoles, and 6mm medially wedged insoles. Wedges ran the length of the foot. The material used was stiff in compression, but flexible along the anterior-posterior and medial-lateral axes of the insole, similar to ethylene vinyl acetate. If no sock liner was present in the shoe, a sock liner was added. If usual footwear including an orthotic/insole, this was removed when the experimental insoles were applied.. Duration 3 months. Concurrent medication/care: Allowed treatments included NSAID/paracetamol,

	physiotherapy/targeted exercise, compression/Tensor brace, narcotic medication and unloader braces. Corticosteroid injections were not permitted.. Indirectness: No indirectness (n=19) Intervention 2: No device intervention. Usual footwear (footwear the person has used most regularly over the past two month, this could include previous orthotic/insole use) without any insoles. Duration 3 months. Concurrent medication/care: Allowed treatments included NSAID/paracetamol, physiotherapy/targeted exercise, compression/Tensor brace, narcotic medication and unloader braces. Corticosteroid injections were not permitted.. Indirectness: No indirectness
Funding	Principal author funded by industry (Principle author funded by a Vanier Canada Graduate Scholarship from the Canadian Institutes of Health Research, a MD/PhD studentship from Alberta Innovates Health Solutions, a Doctoral Scholarship from the Killam Trusts and a Footwear Research Award from New Balance Athletic Shoe Inc.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS Quality of Life at 3 months; Group 1: mean 42.1 (SD 14.3); n=15, Group 2: mean 36.1 (SD 17.1); n=18; KOOS Quality of Life 0-100 Top=High is good outcome; Comments: Baseline insoles: 37.2 (18.1). Baseline control: 36.5 (15.2).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, height, body mass, BMI, body fat, bone density, bilateral OA, OA compartments, radiographic severity, symptom duration and history of knee surgery; Group 1 Number missing: 4, Reason: 4 did not complete follow up - 3 due to pain from insole, 1 changed mind within 48 hours; Group 2 Number missing: 1, Reason: 1 received corticosteroid injections and declined to continue

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS Pain at 3 months; Group 1: mean 56.6 (SD 13.1); n=15, Group 2: mean 55.6 (SD 16.7); n=18; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Baseline insoles: 51.5 (17.1). Baseline control: 55.4 (13.5).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, height, body mass, BMI, body fat, bone density, bilateral OA, OA compartments, radiographic severity, symptom duration and history of knee surgery; Group 1 Number missing: 4, Reason: 4 did not complete follow up - 3 due to pain from insole, 1 changed mind within 48 hours; Group 2 Number missing: 1, Reason: 1 received corticosteroid injections and declined to continue

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: KOOS Activities of Daily Living at 3 months; Group 1: mean 64 (SD 15.2); n=15, Group 2: mean 64 (SD 17.8); n=18; KOOS activities of daily living subscale 0-100 Top=High is good outcome; Comments: Baseline insole: 60.1 (16.2). Baseline control: 70.2 (14.5).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness, Comments: ?Indirect - Does this count as physical function. Also reported Sport/Rec. Should this be combined?; Baseline details: Reported sex, age, height, body mass, BMI, body fat, bone density,

bilateral OA, OA compartments, radiographic severity, symptom duration and history of knee surgery; Group 1 Number missing: 4, Reason: 4 did not complete follow up - 3 due to pain from insole, 1 changed mind within 48 hours; Group 2 Number missing: 1, Reason: 1 received corticosteroid injections and declined to continue Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: New injuries during the study at 3 months; Group 1: 13/15, Group 2: 6/18 Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness; Baseline details: Reported sex, age, height, body mass, BMI, body fat, bone density, bilateral OA, OA compartments, radiographic severity, symptom duration and history of knee surgery; Group 1 Number missing: 4, Reason: 4 did not complete follow up - 3 due to pain from insole, 1 changed mind within 48 hours; Group 2 Number missing: 1, Reason: 1 received corticosteroid injections and declined to continue	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study (subsidiary papers)	Maillefert 2001[111] (Pham 2004[146])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=156)
Countries and setting	Conducted in France; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 2 years (see Pham study)
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee osteoarthritis fulfilling the American College of Rheumatology criteria with at least Kellgren and Lawrence grade 2 or more changes seen in the medial femorotibial region
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Outpatients visiting a rheumatologist and fulfilling the American College of Rheumatology criteria for knee OA. Age 18 or older, pain on a daily basis for at least 1 month during the last 3 months, pain of at least 30 (100 visual analogue scale) after physical activities during the previous 2 days, predominance of pain in the medial part of the knee, evidence of medial femorotibial OA on plain anteroposterior X-rays (Kellgren and Lawrence stage 2 or more)
Exclusion criteria	Functional class of IV (Steinbrocker); greater or similar reduction in lateral than medial femorotibial joint space width on plain anteroposterior x-rays; secondary knee OA; hip OA; hallux rigidus; valgus deformitiy of the midfoot; other symptomatic deformity of the foot; advanced arthropathy of the hindfoot; any disease treated with insoles within the past 6 months; previous ankle arthrodesis; tibial osteotomy within the previous 5 years; knee joint lavage within the previous 3 months; intraarticular corticosteroid injection within the previous month; changes in drug treatment for OA within the previous week
Recruitment/selection of patients	Outpatient visiting a rheumatologist
Age, gender and ethnicity	Age - Mean (SD): 64.8 (10.4). Gender (M:F): 41:115. Ethnicity: Not stated
Further population details	1. Age: Mixed (Based on SD). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grade II-IV. Duration of symptoms (Mean [SD]): 6 (6.5) years
Indirectness of population	No indirectness
Interventions	(n=82) Intervention 1: Orthotic devices - Insoles. Bilateral laterally elevated (valgus) insoles. Made with Ledos material (pure rubber with cork powder) mounted on a leather strip. The laterally elevated insoles were individually modeled, with elevation depending on static pedometer evaluation, but without any biomechanical evaluation during walking.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness

	(n=74) Intervention 2: Sham device. Bilateral neutrally wedged insoles. Made with Ledos material (pure rubber with cork powder) mounted on a leather strip.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (Supported in part by a 'Programme Hospitalier de Recherche Clinique' from the French Health Ministry)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain subscale at 3 months; Group 1: mean 53.4 (SD 21); n=78, Group 2: mean 48.2 (SD 17); n=69; WOMAC pain subscale 0-100 Top=High is poor outcome; Comments: Baseline insole: 53.5 (17). Baseline control: 52 (17).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, BMI, disease duration, functional severity, pain, Kellgren and Lawrence grade, proportion of subtype of knee OA; Group 1 Number missing: 4, Reason: 1 arthroplasty of the evaluated knee, 1 sudden death, 1 loss to follow up, 1 inefficacy; Group 2 Number missing: 5, Reason: 1 sudden death, 1 lost to follow up, 1 intolerance, 1 inefficacy, 1 personal reasons
- Actual outcome for Knee: WOMAC pain subscale at 2 years; Group 1: mean 51 (SD 26.7); n=55, Group 2: mean 48.2 (SD 19.9); n=51; WOMAC pain subscale 0-100 Top=High is poor outcome; Comments: Baseline insole: 53.5 (17). Baseline control: 52 (17).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, BMI, disease duration, functional severity, pain, Kellgren and Lawrence grade, proportion of subtype of knee OA; Group 1 Number missing: 27, Reason: 1 sudden death, 5 surgery, 8 personal reasons, 9 lost to follow up, 4 others; Group 2 Number missing: 23, Reason: 1 sudden death, 1 surgery, 5 personal reasons, 10 lost to follow up, 6 others

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function subscale at 3 months; Group 1: mean 52.4 (SD 20); n=78, Group 2: mean 47.2 (SD 18); n=69; WOMAC physical function 0-100 Top=High is poor outcome; Comments: Baseline insole: 48.8 (19). Baseline control: 50 (19).
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, BMI, disease duration, functional severity, pain, Kellgren and Lawrence grade, proportion of subtype of knee OA; Group 1 Number missing: 4, Reason: 1 arthroplasty of the evaluated knee, 1 sudden death, 1 loss to follow up, 1 inefficacy; Group 2 Number missing: 5, Reason: 1 sudden death, 1 lost to follow up, 1 intolerance, 1 inefficacy, 1 personal reasons
- Actual outcome for Knee: WOMAC physical function subscale at 2 years; Group 1: mean 50 (SD 26.4); n=55, Group 2: mean 50.4 (SD 21.1); n=51; WOMAC physical function subscale 0-100 Top=High is poor outcome; Comments: Baseline insole: 48.8 (19). Baseline control: 50 (19).
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, gender, BMI, disease duration, functional severity, pain, Kellgren and Lawrence grade, proportion of subtype of knee OA; Group 1 Number missing: 27, Reason: 1 sudden death, 5 surgery, 8 personal reasons, 9 lost to follow up, 4 others; Group 2 Number missing: 23, Reason: 1 sudden death, 1 surgery, 5 personal

reasons, 10 lost to follow up, 6 others	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Menz 2016[120]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=102)
Countries and setting	Conducted in Australia; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People with pain in the first metatarsophalageal joint with the majority having radiological features
Stratum	Toes
Subgroup analysis within study	Not applicable
Inclusion criteria	People had to: be age ≥18 years; report having pain in the first MTP joint on most days for at least 12 weeks; report having pain rated at least 20 mm on a 100mm visual analogue scale (VAS); have pain upon palpation of the dorsal aspect of the first MTP joint; be able to walk household distances (>50 meters) without the aid of a walker, crutches, or cane; be willing to attend the Health Sciences Clinic at La Trobe University (Melbourne, Victoria, Australia) on 2 occasions and have their foot radiographed; be willing to not receive additional interventions (such as physical therapy, foot orthoses, shoe modifications, intraarticular injections, or surgery) for the first metatarsophalageal joint pain during the course of the study; be willing to discontinue taking all medications to relieve pain at their first metatarsophalageal joint (analgesics and nonsteroidal antiinflammatory medications, except paracetamol up to 4 grams/day) for at least 14 days prior to the baseline assessment and during the study period
Exclusion criteria	Pregnancy; previous surgery on the first metatarsophalageanl joint; significant deformity of the first metatarsophalageal joint including hallux valgus (grade of 3 or 4 scored using the Manchester Scale); presence of 1 or more conditions within the foot or ankle that, in the opinion of the investigators, could confound pain and functional assessments of the first metatarsophalageal joint, such as metatarsalgia, plantar fasciitis, predislocation syndrome, Achilles tendinopathy, or degenerative joint disease (other than the first metatarsophalageal joint) determined by a podiatrist; presence of any systemic inflammatory condition, such as inflammatory arthritis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, reactive arthritis, septic arthritis, acute pseduogout, gout or any other connective tissue disease; any medical condition that, in the oppinion of the investigators, made the participant unsuitable for inclusion (e.g. severe progressive chronic disease, malignancy, clinically important pain in a part of the musculoskeletal system other than the first metatarsophalageal joint, or fibromyalgia); cognitive impairment (defined as a score of ≤7 on the Short Portable Mental Status Questionnaire; intraarticular injections into the first MTP joint in the previous 6 months; currently wearing contoured foot orthoses (although flat insoles were permitted); currently wearing specialised footwear (footwear that has been custom-made or "prescribed" by a health care practitioner); currently wearing shoes that would not be able to

	accommodate a foot orthosis; older adults with a history of recurrent falls (defined as 2 or more falls in the previous 12 months), as there is some evidence that rocker-sole shoes may have short-term detrimental effects on balance
Recruitment/selection of patients	People were recruited from radio advertisements; advertisements placed in local newspapers, magazines and social media; posters placed at health care facilities, gymnasiums, senior citizens' centers, fun runs, and markers; mail-out advertisements to people attending the La Trobe University Health Sciences clinic and to local podiatry clinics
Age, gender and ethnicity	Age - Mean (SD): 56.8 (11.1). Gender (M:F): 45:57. Ethnicity: Not stated
Further population details	1. Age: ≤75 years (Excludes older adults with a history of recurrent falls). 2. Diagnostic method: Diagnosed with imaging (Reports that around 75% of people had radiographic first metatarsophalangeal joint osteoarthritis). 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not stated Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Orthotic devices - Shoes. Rocker-sole footwear group - provided with a pair of rocker sole shoes (Mahuta or Matwa models). These shoes are characterised by a rounded sole in the anteroposterior direction and a soft cushioned heel. Across the full size range the radius of curvature of the shoe is on average 33cm overall, 18cm at the forefoot, 43cm at the midfoot, and 11cm at the heel. Fitting of the shoes was undertaken by trained assessors.. Duration 12 weeks. Concurrent medication/care: All received an information handout that outlined the appropriate use and care of their orthoses or footwear. People were permitted to use paracetamol (up to 4 grams per day). They were not permitted to have any additional treatment for their toe osteoarthritis.. Indirectness: No indirectness (n=52) Intervention 2: Orthotic devices - Insoles. A pair of foot orthoses (Vasyli Customs Medium Density, Vasyli Medical). All orthoses were full length, but were modified by adding a cut-out section beneath the first metatarsal and trimming the distal edge to the level of the second to fifth toe sulci. In participants with pronated feet (defined as an FPI score of >7), full length, 4 degree medial (varus) wedges were applied to the underside of the foot orthoses until there was a reduction in the FPI score of at least 2 points. The wedge was gradually bevelled so that it extended to the proximal margin of the cut-out section beneath the first metatarsal. Duration 12 weeks. Concurrent medication/care: All received an information handout that outlined the appropriate use and care of their orthoses or footwear. People were permitted to use paracetamol (up to 4 grams per day). They were not permitted to have any additional treatment for their toe osteoarthritis.. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (Supported by the National Health and Medical Research Council (1049085), Yodgee Footwear (provided footwear at reduced cost), Vasyli medical (provided prefabricated foot orthoses at reduced cost), and South Cost Medical Imaging (provided imaging at reduced cost). Dr Menz's work was supported by the National Health and Medical Research Council, and he is a National Health and Medical Research Council Senior Research Fellow.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus INSOLES	

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Toes: SF-12 physical at 12 weeks; Group 1: mean 46.7 (SD 9.7); n=46, Group 2: mean 47.1 (SD 9.2); n=52; SF-12 physical 1-100 Top=High is good outcome; Comments: Baseline shoes: 45.0 (9.7). Baseline insoles: 44.1 (10.7).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, height, weight, body mass index, baseline values for outcomes and baseline levels of clinical features/radiographic features; Group 1 Number missing: 9, Reason: Included data from all but 4 people who withdrew consent after randomisation but before receiving the intervention. Following this 1 was lost to follow up, 2 withdrew (could not tolerate footwear) and 2 more were lost to follow up between 4 weeks and 8 weeks; Group 2 Number missing: 5, Reason: 1 withdrew (could not tolerate orthoses), 3 were lost to follow up between 0 and 4 weeks, 1 additional person was lost to follow up between 8 and 12 weeks
- Actual outcome for Toes: SF-12 mental at 12 weeks; Group 1: mean 52 (SD 9.6); n=46, Group 2: mean 52.3 (SD 9.6); n=52; SF-12 mental 1-100 Top=High is good outcome; Comments: Baseline shoes: 51.9 (9.0). Baseline insoles: 55.8 (8.1).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, height, weight, body mass index, baseline values for outcomes and baseline levels of clinical features/radiographic features. Baseline value for SF-12 mental was different between the groups.; Group 1 Number missing: 9, Reason: Included data from all but 4 people who withdrew consent after randomisation but before receiving the intervention. Following this 1 was lost to follow up, 2 withdrew (could not tolerate footwear) and 2 more were lost to follow up between 4 weeks and 8 weeks; Group 2 Number missing: 5, Reason: 1 withdrew (could not tolerate orthoses), 3 were lost to follow up between 0 and 4 weeks, 1 additional person was lost to follow up between 8 and 12 weeks

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Toes: Foot Health Status Questionnaire (FHSQ) pain domain at 12 weeks; Group 1: mean 73.7 (SD 14.8); n=46, Group 2: mean 73.6 (SD 16.8); n=52; Foot Health Status Questionnaire pain domain 1-100 Top=High is good outcome; Comments: Baseline shoes: 51.5 (20.3). Baseline insoles: 56.7 (19.2).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, height, weight, body mass index, baseline values for outcomes and baseline levels of clinical features/radiographic features; Group 1 Number missing: 9, Reason: Included data from all but 4 people who withdrew consent after randomisation but before receiving the intervention. Following this 1 was lost to follow up, 2 withdrew (could not tolerate footwear) and 2 more were lost to follow up between 4 weeks and 8 weeks; Group 2 Number missing: 5, Reason: 1 withdrew (could not tolerate orthoses), 3 were lost to follow up between 0 and 4 weeks, 1 additional person was lost to follow up between 8 and 12 weeks

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Toes: Foot Health Status Questionnaire (FHSQ) function domain at 12 weeks; Group 1: mean 80.5 (SD 16.6); n=46, Group 2: mean 92.7 (SD 18.6); n=52; Foot Health Status Questionnaire function domain 1-100 Top=High is good outcome; Comments: Baseline shoes: 67.4 (25.5). Baseline insoles: 70.8 (22.0).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, height, weight, body mass index, baseline values for outcomes and baseline levels of clinical features/radiographic features; Group 1 Number missing: 9, Reason: Included data from all but 4 people who withdrew consent after randomisation but before receiving the intervention. Following this 1 was lost to follow up, 2 withdrew (could not tolerate footwear) and 2 more were lost to follow up between 4 weeks and 8 weeks; Group 2 Number missing: 5, Reason: 1 withdrew (could not tolerate orthoses), 3 were lost to follow up between 0 and 4 weeks, 1 additional person was lost to follow up between 8 and 12 weeks Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Toes: Adverse events at 12 weeks; Group 1: 42/46, Group 2: 41/52; Comments: The adverse events include blisters (shoes: 3, insoles: 2), discomfort (shoes: 3, insoles: 2), impaired balance (shoes: 4, insoles: 1), experienced fall during the trial (shoes: 4, insoles: 5), new back/lower extremity pain during trial (shoes: 28, insoles: 31). Events may have occurred in the same person (the trial reports number of people with at least 1 adverse event [shoes: 15, insoles: 7] but this did not seem to add up with the number of events). Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, height, weight, body mass index, baseline values for outcomes and baseline levels of clinical features/radiographic features; Group 1 Number missing: 9, Reason: Included data from all but 4 people who withdrew consent after randomisation but before receiving the intervention. Following this 1 was lost to follow up, 2 withdrew (could not tolerate footwear) and 2 more were lost to follow up between 4 weeks and 8 weeks; Group 2 Number missing: 5, Reason: 1 withdrew (could not tolerate orthoses), 3 were lost to follow up between 0 and 4 weeks, 1 additional person was lost to follow up between 8 and 12 weeks	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Niazi 2014[132]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=120)
Countries and setting	Conducted in Pakistan; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Radiographic and clinical diagnosis of knee osteoarthritis (degenerative joint disease)
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People between the age of 35-65 years with a history of knee pain and genu varum deformity based on radiographic evidence and moderate to severe medial compartment degenerative joint disease (grades II-IV of Kellgren and Lawrence grading system).
Exclusion criteria	History of any orthopaedic lower limb surgery; both compartments degenerative joint disease (based on radiological findings); symptomatic patella femoral pain syndrome (radiographically confirmed); rheumatoid arthritis; any superimposed hip or ankle problems; body mass index greater than 30.
Recruitment/selection of patients	People who attended the Orthotics Departments of HOPE Rehabilitation Center in Lahore, Pakistan
Age, gender and ethnicity	Age - Median (range): 41-46 years (35-70 years). Gender (M:F): 56:64. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Moderate to severe (Kellgren-Lawrence grades II-IV). Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Braces. 3 point knee brace adjusted and fitted by a doctor. It was further adjusted at follow up visits as required.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=60) Intervention 2: Orthotic devices - Insoles. Laterally wedged insoles - no additional information. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus INSOLES

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Visual analogue scale (pain) at 6 months; Group 1: mean 3.97 (SD 1.67); n=58, Group 2: mean 4.53 (SD 1.41); n=56; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline brace: 6.233 (1.57). Baseline insole: 6.05 (1.50).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports gender, height, weight, BMI, age, Kellgren-Lawrence grade, pain and walking distance; Group 1 Number missing: 2, Reason: Unclear. 2 lost to follow up. Potentially 2 switching, but not clearly explained.; Group 2 Number missing: 4, Reason: Unclear. 4 lost to follow up. Potentially 3 switching, but not clearly explained.

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 6 months; Group 1: 5/58, Group 2: 0/56; Comments: 5 episodes of ipsilateral leg swelling
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: reports gender, height, weight, BMI, age, Kellgren-Lawrence grade, pain and walking distance; Group 1 Number missing: 2, Reason: Unclear. 2 lost to follow up. Potentially 2 switching, but not clearly explained.; Group 2 Number missing: 4, Reason: Unclear. 4 lost to follow up. Potentially 3 switching, but not clearly explained.

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Nigg 2006[134]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=123)
Countries and setting	Conducted in Canada; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Idiopathic or secondary osteoarthritis of the knee diagnosed by the Altman and coworkers classification tree; grades II-IV severity of osteoarthritis by radiographic evaluation using the modified Kellgren and Lawrence grading system
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Idiopathic or secondary osteoarthritis of the knee diagnosed by the Altman and coworkers classification tree; grades II-IV severity of osteoarthritis by radiographic evaluation using the modified Kellgren and Lawrence grading system; symptomatic knee osteoarthritis with at least the following criteria fulfilled for at least 6 months: morning stiffness <30 minutes, crepitus, bony tenderness and bony enlargement with no palpable warmth; age >40 years; a verbal score of 3-10 out of 10 for pain while walking; ability to walk independently without the use of assistive devices (community ambulatory); on one's feet for a total of 2-3 hours/day.
Exclusion criteria	Acute knee injury or surgery within the last 6 months; total knee arthroplasty; change in NSAID, dietary supplementation use, or corticosteroid injection within the last 3 months; hyaluronic acid injection within 6 months; inflammatory or postinfection osteoarthritis of the knee; not currently seeking physiotherapy treatment; isolated medial compartment osteoarthritis grade III-IV with >10 degrees mechanical varus; isolated lateral compartment osteoarthritis grade III-IV with >10 degrees mechanical varus; other medical condition within 1 year that would affect ability to participate in this study (i.e. cancer); major neurological deficit or disorder; unable to speak or read English; psychiatric illness that would limit informed consent; unwilling to be followed for the study for 3 months
Recruitment/selection of patients	Recruited from three sources: sport medicine physicians and surgeons in the Calgary Health Region (using the patient files from 2003/2004), the Sport Medicine Centre of the Faculty of Kinesiology, recruitment bulletins through the Canadian Arthritis Society and a Calgary Rotary Club.
Age, gender and ethnicity	Age - Other: Mean (95% CI). Intervention: 57.9 (55.5-60.2) years. Control: 57.4 (55.2-59.6) years.. Gender (M:F): 56:67. Ethnicity: Not stated/unclear
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear

Extra comments	Severity: Radiographic grade 2-4, median grade 3 Duration of symptoms: Not stated/unclear
Indirectness of population	No indirectness
Interventions	(n=58) Intervention 1: Orthotic devices - Shoes. Masai Barefoot Technology (MBT) shoes. They received initial instruction training of 15 minutes to walk according to MBT instructions. People were instructed to gradually increase the wear time of the MBT shoe over a 3- to 4-day period and to use subject comfort as the major guidance in this adjustment period. Anyone who experienced discomfort with the shoes were asked to return to the clinic so that the study investigators could determine and problems (i.e. fit, wear, comfort). Once they were able to wear the shoes comfortably for a full day, subjects were instructed to wear the shoes as much as possible.. Duration 12 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=67) Intervention 2: Sham device. High-end walking shoes (New Balance 756 WB model). The wear schedule was identical to that prescribed for the MBT shoe intervention group.. Duration 12 weeks. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Study funded by industry (The study was funded by Masai Barefoot Technology (Switzerland))

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain total at 12 weeks; Group 1: mean -42 (SD 86.3); n=57, Group 2: mean -46.2 (SD 98.4); n=66; WOMAC pain 0-500 Top=High is poor outcome; Comments: Reported mean and 95% confidence intervals. Reported shoes: -42.0 (-64.4, -19.6). Reported sham: -46.2 (-69.9, -22.4). Baseline MBT: 164.8 (99.6). Baseline sham: 170.0 (unclear SD, only report one value for 95% CI)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, osteoarthritis grade and side, height, mass, BMI, biomechanical parameters and baseline values of outcomes; Group 1 Number missing: 1, Reason: 1 shoes too cumbersome; Group 2 Number missing: 1, Reason: 1 shoes increased knee pain

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 12 weeks; Group 1: mean -124.4 (SD 294.9); n=57, Group 2: mean -143.1 (SD 359.8); n=66; WOMAC physical function 0-1700 Top=High is poor outcome; Comments: Reported mean and 95% confidence intervals. Reported shoes: -124.4 (-200.9, -47.8). Reported sham: -143.1 (-230.4, -56.8). Baseline MBT: 556.3 (312.4). Baseline sham: 592.8 (350.2)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, osteoarthritis grade and side, height, mass, BMI, biomechanical parameters and baseline values of outcomes; Group 1 Number missing: 1, Reason: 1 shoes too cumbersome; Group 2 Number missing: 1, Reason: 1 shoes increased knee pain

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Ogut 2018[135]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=61)
Countries and setting	Conducted in Turkey; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Other: Intervention time: 3 weeks. Follow up in total: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee osteoarthritis according to the American College of Rheumatology diagnostic criteria with Kellgren-Lawrence grade 2 or 3 severity.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Women of age 50-60 years diagnosed with knee osteoarthritis according to the American College of Rheumatology diagnostic criteria and with Kellgren-Lawrence grade 2 or 3 changes.
Exclusion criteria	History of lower extremity surgery, K-L grade 1 or 4, received intraarticular knee joint injections within the last six months, any diagnosis of musculoskeletal disease other than osteoarthritis, evident sensory or strength loss in the lower extremity, any cognitive impairement that would prevent participation in treatment, open wound or skin lesions in the area where kinesio tape was to be applied, or any known skin allergies.
Recruitment/selection of patients	People admitted to the Physical Medicine and Rehabilitation Clinic of Hatay Mustafa Kemal University, Tayfur Ata Sökmen Faculty of Medicine between January 2016 and September 2016
Age, gender and ethnicity	Age - Mean (SD): 53.5 (3.5). Gender (M:F): 0:61. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades 2 or 3. Duration of symptoms (mean [SD]): 26.2 (22.7) months
Indirectness of population	No indirectness
Interventions	(n=31) Intervention 1: Straps/tape - Tape. Kinesio tape to the quadriceps muscle once a week for three weeks. Duration 3 weeks. Concurrent medication/care: All people were applied with a hot pack for 30 minutes, TENS for 30 minutes (100 Hz frequency and 60 milliseconds pulse duration), ultrasound therapy for 10 minutes (pulsed 1:1, 1 MHz frequency, and 1.5 W/cm2 intensity) and an isometric exercise program around the knee for a total of 15 sessions over a period of 3 weeks.. Indirectness: No indirectness (n=30) Intervention 2: Sham device. Sham kinesio tape applied without tension with 10 centimeters of kinesio tape administered transversely over the quadriceps muscle.. Duration 3 weeks. Concurrent medication/care: All people were applied with a hot pack for 30 minutes, TENS for 30 minutes (100 Hz frequency and 60 milliseconds pulse duration),

	ultrasound therapy for 10 minutes (pulsed 1:1, 1 MHz frequency, and 1.5 W/cm2 intensity) and an isometric exercise program around the knee for a total of 15 sessions over a period of 3 weeks.. Indirectness: No indirectness
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: WOMAC pain subscale at 3 months; Group 1: mean 4 (SD 0.9); n=31, Group 2: mean 4 (SD 0.7); n=30; WOMAC pain subscale 0-24 Top=High is poor outcome; Comments: Baseline tape: 10.4 (1.5). Baseline sham: 10.4 (1.4). Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, weight, height, BMI, symptom duration, affected side, K-L grade, baseline values for all tests; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function subscale at 3 months; Group 1: mean 15.4 (SD 4); n=31, Group 2: mean 15.9 (SD 3.9); n=30; WOMAC physical function subscale 0-68 Top=High is poor outcome; Comments: Baseline tape: 31.5 (4.5). Baseline sham: 31.8 (4.2). Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: reports age, weight, height, BMI, symptom duration, affected side, K-L grade, baseline values for all tests; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**Oguz 2021[136]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=22)
Countries and setting	Conducted in Turkey; Setting: Selcuk University Faculty of Medicine Division of Sports Physiology Laboratory

Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee OA diagnosis according to the American College of Rheumatology, andKellgren-Lawrence index II and III in class
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients between 38 and 60 years, having a knee OA diagnosis according to the American College of Rheumatology and Kellgren-Lawrence index II and II in class
Exclusion criteria	Rheumatoid arthritis, severe organ failure, previous joint replacement, osteoporosis and diagnosis of any disease that could limit performance
Recruitment/selection of patients	Participants selected from patients that applied to Konya Numune Hospital Physical Medicine and Rehabilitation Department outpatient clinic between June 2016 and November 2016
Age, gender and ethnicity	Age - Mean (SD): Intervention : 48.18 (7.56) and control: 51.00 (3.69) . Gender (M:F): All female. Ethnicity: Not reported
Further population details	1. Age: < 70 years 2. Diagnostic method: diagnosis with imaging 3. Multimorbidities: not stated/ unclear
Extra comments	Duration of symptoms not reported. Kellgren Lawrence index II and III.
Indirectness of population	No indirectness
Interventions	(n=11) Intervention 1: Straps/tape - Tape. Kinesio and exercise group. Kinesio taping was applied 3 times per week over study period of 6 weeks by the same experience physiotherapist. After 48 hours, the kinesio tape was removed from the skin and each subject examined for any skin sensitivity. Exercise training which consisted of 6 weeks training with 3 days per week. Programme designed based on the recommendations of the American Geriatric Society. Each exercise session consisted of a total of 50 minute sessions of 10 minutes of warm up, 20 minutes resistance, 10 minutes of balance and stabilsation, 5 minutes of lower limb stretching and 5 minutes cool down. . Duration 6 weeks. Concurrent medication/care: Both groups did 20 minute walking exercise as an acute loading before and after intervention. Indirectness: No indirectness (n=11) Intervention 2: No device intervention. Exercise training which consisted of 6 weeks training with 3 days per week. Programme designed based on the recommendations of the American Geriatric Society. Each exercise session consisted of a total of 50 minute sessions of 10 minutes of warm up, 20 minutes resistance, 10 minutes of balance and stabilsation, 5 minutes of lower limb stretching and 5 minutes cool down. . Duration 6 weeks. Concurrent medication/care: Both groups did 20 minute walking exercise as an acute loading before and after intervention. Indirectness: No indirectness
Funding	-- (Supported by the Selcuk University Scientific Research and Project Committee)

	RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Visual analogue scale (VAS) - perceived pain at rest, during activity, and during the night at 6 weeks; Group 1: mean 3.55 Not reported (SD 1.69); n=11, Group 2: mean 2.82 Not reported (SD 1.54); n=11; Comments: Baseline: Intervention 5.27 (1.35) and control 5.73 (0.79) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Only provided baseline information for age, weight, height and body mass ; Group 1 Number missing: 0; Group 2 Number missing: 0 Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: Physical function - WOMAC at 6 weeks; Group 1: mean 28.82 24 items and is assigned into 3 subunits: pain, stiffness and physical function and used a Likert-type scale to score each item (SD 13.05); n=11, Group 2: mean 21.36 24 items and is assigned into 3 subunits: pain, stiffness and physical function and used a Likert-type scale to score each item (SD 13.11); n=11; WOMAC Unclear Top=High is poor outcome; Comments: Baseline: Intervention 41.18 (17.49) and Control 47.27 (9.75) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Only provided baseline information for age, weight, height and body mass ; Group 1 Number missing: 0; Group 2 Number missing: 0	
	Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Paterson 2021[143]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=164)
Countries and setting	Conducted in Australia; Setting: Outpatient follow up, community participants from Melbourne, Australia
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiographic knee osteoarthritis
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 50 years and older; knee pain on most days of the past month; reported knee pain of an average of 4 or greater on an 11-point numeric rating scale during walking in the past week; tibiofemoral osteophytes and moderate to severe tibiofemoral osteoarthritis (Kellgren Lawrence grade 3 or 4).
Exclusion criteria	Lateral joint space narrowing greater than or equal to medial joint space narrowing on x-ray; suffered knee pain for <3 months; recent knee surgery (past 6 months) or planned surgery in next 6 months; current use of shoe orthoses, customized shoes or ankle braces; current primary use of high heels, thongs or work boots that would restrict ability to wear study shoes 6 hours/day; had a hip or knee replacement on either side; had a high tibial osteotomy on either leg; had any knee injections in the past 3 months or planned injections in next 6 months; self-report any other muscular, joint or neurological condition affecting lower limb function; self-report any systemic or inflammatory joint disease (eg rheumatoid arthritis); current or planned use of a gait aid in the next 6 months; inability to understand written/spoken English; unable to commit to study requirements (eg wearing shoes, attending appointments, completing outcomes, do not have foot size in the range of 8 to 13 US for men, and 7 to 12 US for women).
Recruitment/selection of patients	Participants were recruited by advertising in print and social media as well as through their research volunteer database.
Age, gender and ethnicity	Age - Mean (SD): 64.8 (7.3). Gender (M:F): 63:101. Ethnicity: Not stated/unclear
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Radiographic Grade 3-4, median grade 4. Duration of symptoms (mean [SD]): 9.2 (7.5) years
Indirectness of population	No indirectness
Interventions	(n=82) Intervention 1: Orthotic devices - Shoes. Commercially available flat flexible shoes (Merrell Bare Access, Vivobarefoot Primus Lite, Vivobarefoot Mata Canvas, Converse Dainty Low, Lacoste Marice). People were instructed to

	increase their shoe wear by 1 hour per day until they were wearing the shoes as much as possible (at least 6 hours per day) for 6 months.. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=82) Intervention 2: Sham device. Stable supportive shoes (ASICS Kayano, Merrell Jungle Moc, Nike Air Max 90 Ultra, Rockport Edge Hill and New Balance). People were instructed to increase their shoe wear by 1 hour per day until they were wearing the shoes as much as possible (at least 6 hours per day) for 6 months. . Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Academic or government funding (National Health and Medical Research Council funding)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: AQoL-6D at 6 months; Group 1: mean 0.01 (SD 0.12); n=81, Group 2: mean 0 (SD 0.11); n=80; AQoL-6D -0.04-1 Top=High is good outcome; Comments: Baseline shoes: 0.7 (0.1). Baseline sham: 0.7 (0.1).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: 1 family death; Group 2 Number missing: 2, Reason: 1 unwell, 1 lost contact

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS pain at 6 months; Group 1: mean 6.9 (SD 15.4); n=81, Group 2: mean 9.7 (SD 15.4); n=80; KOOS pain 0-100 Top=High is good outcome; Comments: Baseline shoes: 47.7 (13.3). Baseline sham: 50.4 (12.0).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: 1 family death; Group 2 Number missing: 2, Reason: 1 unwell, 1 lost contact

Protocol outcome 3: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC physical function at 6 months; Group 1: mean -4.7 (SD 10.7); n=81, Group 2: mean -6.7 (SD 11); n=80; WOMAC physical function 0-68 Top=High is poor outcome; Comments: Baseline shoes: 29.9 (10.1). Baseline sham: 28.9 (10.5).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: 1 family death; Group 2 Number missing: 2, Reason: 1 unwell, 1 lost contact

Protocol outcome 4: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 6 months; Group 1: 26/82, Group 2: 12/82; Comments: Shoes: Overall 26. Knee pain = 13, ankle/foot pain = 15, shin/calf pain = 1, knee swelling = 1, pain in other areas = 3. Sham: Knee pain = 2, ankle/foot pain = 9, feel over in laboratory and hurt back = 1.

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: 1 family death; Group 2 Number missing: 2, Reason: 1 unwell, 1 lost contact	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Rannou 2009[151]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=112)
Countries and setting	Conducted in France; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Pain at the base of the thumb with radiographic evidence of at least 2 of 4 radiographic items and at least 1 of 2 clinical items
Stratum	Thumb
Subgroup analysis within study	Not applicable
Inclusion criteria	Pain at the base of the thumb 30mm or greater on a visual analogue scale (VAS) (range 0 to 100mm), age 45 to 75 years, radiographic evidence of at least 2 of 4 radiographic items (osteophytes, joint space narrowing, subchondral bone sclerosis, or subchondral cysts), and at least 1 of 2 clinical items (trapeziometacarpal joint enlargement or closure of the first web) at the trapeziometacarpal joint. Other hand joints could be affected.
Exclusion criteria	Posttraumatic osteoarthritis; crystal arthritis; inflammatory arthritis; neurologic disorder involving the upper limb; hand or wrist trauma within the past 2 months; previous hand surgery; collagen disease (Dupuytren syndrome, Marfan syndrome, Ehlers-Danlos syndrome); hand or wrist infiltration within 2 months; skin disease interfering with wearing the splnt; having already worn a split for base of thumb osteoarthritis (that is, splinting had been previously proposed); having bilateral base of thumb osteoarthritis with no predominant symptomatic side; psychiatric disorder needing treatment adaptation in the past 3 months; inability to speak or write French; pregnancy.
Recruitment/selection of patients	People who consulted with a physician (mainly rheumatologists) for disabling base of thumb osteoarthritis during outpatient visits at tertiary care hospitals or at private practices
Age, gender and ethnicity	Age - Mean (SD): 63.3 (7.8). Gender (M:F): 11:101. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not stated. Duration of symptoms: Not stated.
Indirectness of population	No indirectness
Interventions	(n=57) Intervention 1: Splints. A rigid rest orthosis recommended for use only at night. It covered the base of thumb and the thenar eminence but not the wrist. Splints were made by 3 trained occupational therapists, who adjusted the splint for each person so that the first web could be opened and the thumb placed in opposition with the first long finger. People were encouraged to contact the occupational therapist if they felt the splint needed adjustment, pain increased while wearing the splint, or they had adverse effects.. Duration 1 year. Concurrent medication/care: Usual care at the

	discretion of their physician (general practitioner or rheumatologist). 19 using paracetamol. 5 using paracetamol plus opioids. 19 using NSAIDs. 23 using symptomatic slow acting drugs in osteoarthritis. 12 receiving no treatment.. Indirectness: No indirectness (n=55) Intervention 2: No device intervention. Usual care at the discretion of their physician (general practitioner or rheumatologist). Duration 1 year. Concurrent medication/care: 16 using paracetamol. 7 using paracetamol plus opioids. 15 using NSAIDs. 21 using symptomatic slow acting drugs in osteoarthritis. 12 receiving no treatment.. Indirectness: No indirectness
Funding	Academic or government funding (Funded by the Programme Hospitalier de Recherche Clinique National)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SPLINTS versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Thumb: Pain (visual analogue scale score) at 1 month; Group 1: mean -10.1 (SD 22.2); n=55, Group 2: mean -10.7 (SD 22.4); n=46; Visual analogue scale (pain) 0-100 Top=High is poor outcome; Comments: Reports standard error, converted into standard deviation. Reported splints: -10.1 (3). Reported no devices: -10.7 (3.3). Baseline splint: 45.5 (19.9). Baseline control: 47.7 (19.8).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, occupation degree of manual work, dominant side effected, family history, current treatment, and baseline values for outcomes; Group 1 Number missing: 3, Reason: Overall: 54 people made the first month follow up, 52 people made the twelve month follow up. 1 difficult to attend appointment. 1 did not give a reason. 1 could not sleep with the splint. 1 diagnosis of psoriatic arthritis. 1 could not be reached.; Group 2 Number missing: 8, Reason: Overall: 47 people made the first month follow up, 46 people made the twelve month follow up. 5 difficult to attend appointments, 3 did not give a reason, 1 had foot surgery
- Actual outcome for Thumb: Pain (visual analogue scale score) at 12 months; Group 1: mean -22.2 (SD 23.1); n=52, Group 2: mean -7.9 (SD 23.5); n=45; Visual analogue scale (pain) 0-100 Top=High is poor outcome; Comments: Reports standard errors. Converted to standard deviation. Reported splints: -22.2 (3.2). Reported no devices: -7.9 (3.5). Baseline splint: 45.5 (19.9). Baseline control: 47.7 (19.8).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, occupation degree of manual work, dominant side effected, family history, current treatment, and baseline values for outcomes; Group 1 Number missing: 5, Reason: Overall: 54 people made the first month follow up, 52 people made the twelve month follow up. 1 difficult to attend appointment. 1 did not give a reason. 1 could not sleep with the splint. 1 diagnosis of psoriatic arthritis. 1 could not be reached.; Group 2 Number missing: 9, Reason: Overall: 47 people made the first month follow up, 46 people made the twelve month follow up. 5 difficult to attend appointments, 3 did not give a reason, 1 had foot surgery

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Thumb: Cochin Hand Function Scale at 1 month; Group 1: mean 1.3 (SD 9.6); n=54, Group 2: mean -0.3 (SD 10.3); n=47; Cochin Hand Function Scale 0-90 Top=High is poor outcome; Comments: Reports standard errors. Converted to standard deviation. Reported splints: 1.3 (1.4). Reported no devices: -0.3 (1.5). Baseline splint: 19.4 (12.2). Baseline control: 17.7 (12.9).

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, occupation degree of manual work, dominant side effected, family history, current treatment, and baseline values for outcomes; Group 1 Number missing: 3, Reason: Overall: 54 people made the first month follow up, 52 people made the twelve month follow up. 1 difficult to attend appointment. 1 did not give a reason. 1 could not sleep with the splint. 1 diagnosis of psoriatic arthritis. 1 could not be reached.; Group 2 Number missing: 8, Reason: Overall: 47 people made the first month follow up, 46 people made the twelve month follow up. 5 difficult to attend appointments, 3 did not give a reason, 1 had foot surgery - Actual outcome for Thumb: Cochin Hand Function Scale at 12 months; Group 1: mean -1.9 (SD 11.2); n=49, Group 2: mean 4.3 (SD 11.5); n=46; Cochin Hand Function Scale 0-90 Top=High is poor outcome; Comments: Reports standard errors. Converted to standard deviation. Reported splints: -1.9 (1.6). Reported no devices: 4.3 (1.7). Baseline splint: 19.4 (12.2). Baseline control: 17.7 (12.9). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported age, gender, occupation degree of manual work, dominant side effected, family history, current treatment, and baseline values for outcomes; Group 1 Number missing: 5, Reason: Overall: 54 people made the first month follow up, 52 people made the twelve month follow up. 1 difficult to attend appointment. 1 did not give a reason. 1 could not sleep with the splint. 1 diagnosis of psoriatic arthritis. 1 could not be reached.; Group 2 Number missing: 9, Reason: Overall: 47 people made the first month follow up, 46 people made the twelve month follow up. 5 difficult to attend appointments, 3 did not give a reason, 1 had foot surgery	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**Reichenbach 2020[152]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=220)
Countries and setting	Conducted in Switzerland; Setting: Outpatient follow up

Line of therapy	Unclear
Duration of study	Intervention + follow up: 16 weeks intervention, 24 weeks in total of follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Symptomatic, radiologically confirmed knee osteoarthritis according to criteria from the American College of Rheumatology
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Men or non-pregnant women; aged at least 40 years; outpatient setting; American College of Rheumatology clinical criteria for osteoarthritis of the knee; radiologically confirmed symptomatic uni- or bilateral osteoarthritis of the knee for at least 6 months; at least moderate pain on the WOMAC pain subscale (at least 3 on a standardised scale range of 0-10); must understand German; informed consent documented by participant signature
Exclusion criteria	Women who are pregnant or breast-feeding; intention to become pregnant during the course of the study; lack of safe contraception, defined as: female participants of childbearing potential, not using and not willing to continue using a medically reliable method of contraception for the entire study duration, such as oral, injectable or implantable contraceptives, or intrauterine contraceptive devices, or who are not using any other method considered sufficiently reliable by the investigator in individual cases; known or suspected non-compliance, drug or alcohol abuse; inability to follow the procedures of the study (e.g. due to language problems, psychological disorders, dementia, inability to attend treatment centre); participation in another study of an investigational drug within the 30 days preceding and during the present study; previous enrolment into the current study; enrolment of the investigator, their family members, employees and other dependent persons; age <40 years; inpatient; history of an inflammatory rheumatic disease; non-knee musculoskeletal pain as or more severe than the knee pain (e.g. fibromyalgia); knee surgery in the previous six months or planned hip or knee surgery within 24 weeks of baseline assessment; glucocorticoid injections in the knees in the previous three months; previous knee osteotomy; unilateral knee hemiprosthesis; unilateral total knee joint replacement; being treated for cancer; high risk of falls based on a Stopping Elderly Accidents, Deaths and Injuries (STEADI) score at the screening visit of 4 or greater.
Recruitment/selection of patients	People were referred by general practitioners or responded to newspaper advertisements in Switzerland.
Age, gender and ethnicity	Age - Mean (SD): 65.2 (9.3). Gender (M:F): 116:104. Ethnicity: Not stated/unclear
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Kellgren Lawrence grade 2-4, median grade 3 Duration of symptoms: Not stated/unclear
Indirectness of population	No indirectness
Interventions	(n=111) Intervention 1: Orthotic devices - Shoes. Biomechanical footwear device consisting of 2 shoes with 2 convex adjustable rubber pods screwed to the outsole at the heel and forefoot. People were instructed to use the footwear

	during indoor activities for a half hour each day during the first week of the intervention, with subsequent increases of 10 minutes per week on average but were not given explicit instructions to perform specific home-based exercises. After 6 weeks of follow-up, the participants were advised to use the footwear to walk outdoors.. Duration 16 weeks. Concurrent medication/care: The participants were asked to discontinue their regular pain medication and advised that other interventions, such as physical therapy, should be avoided during the trial. They were permitted daily therapy as needed with paracetamol at a maximum dose of 2 grams and the amounts taken were recorded at each visit.. Indirectness: No indirectness (n=109) Intervention 2: Sham device. Sham footwear. Supposedly with a clinical effect. People were instructed to use the footwear during indoor activities for a half hour each day during the first week of the intervention, with subsequent increases of 10 minutes per week on average but were not given explicit instructions to perform specific home-based exercises. After 6 weeks of follow-up, the participants were advised to use the footwear to walk outdoors.. Duration 16 weeks. Concurrent medication/care: The participants were asked to discontinue their regular pain medication and advised that other interventions, such as physical therapy, should be avoided during the trial. They were permitted daily therapy as needed with paracetamol at a maximum dose of 2 grams and the amounts taken were recorded at each visit.. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (The trial was sponsored by Bern University Hospital and coordinated by CTU Bern, the University of Bern's clinical trials unit. The trial was funded by the Mäxi Foundation. Dr Jüni is a tier 1 Canadian research chair in clinical epidemiology of chronic diseases; this research was completed, in part, with funding from the Canada Research Chairs Programme. Apos Medical Assets provided the biomechanical footwear system and the control footwear, and provided the technicians trained to install and calibrate the external pods on the biomechanical footwear without charge.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHOES versus SHAM DEVICE

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: SF-36 physical component at 12 weeks; Group 1: mean 43.1 (SD 7.6); n=111, Group 2: mean 43.8 (SD 7.3); n=109; SF-36 physical component 0-100 Top=High is good outcome; Comments: Baseline shoes: 40.4 (7.1). Baseline sham: 40.3 (6.2).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)
- Actual outcome for Knee: SF-36 mental component at 12 weeks; Group 1: mean 45.9 (SD 7.4); n=111, Group 2: mean 44.5 (SD 8); n=109; SF-36 mental component 0-100 Top=High is good outcome; Comments: Baseline shoes: 57.0 (7.4). Baseline sham: 56.4 (8.8).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)
- Actual outcome for Knee: SF-36 physical component at 24 weeks; Group 1: mean 45.9 (SD 7.4); n=111, Group 2: mean 44.5 (SD 8); n=109; SF-36 physical component 0-100 Top=High is good outcome; Comments: Baseline shoes: 40.4 (7.1). Baseline sham: 40.3 (6.2).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)
- Actual outcome for Knee: SF-36 mental component at 24 weeks; Group 1: mean 56.8 (SD 6.7); n=111, Group 2: mean 56 (SD 9); n=109; SF-36 mental component 0-100 Top=High is good outcome; Comments: Baseline shoes: 57.0 (7.4). Baseline sham: 56.4 (8.8).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 12 weeks; Group 1: mean 2.3 (SD 1.7); n=111, Group 2: mean 2.6 (SD 2.1); n=109; WOMAC pain 0-10 Top=High is poor outcome; Comments: Baseline shoes: 4.3 (1.8). Baseline sham: 4.0 (2.0).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)
- Actual outcome for Knee: WOMAC pain at 24 weeks; Group 1: mean 1.3 (SD 1.3); n=111, Group 2: mean 2.6 (SD 2); n=109; WOMAC pain 0-10 Top=High is poor outcome; Comments: Baseline shoes: 4.3 (1.8). Baseline sham: 4.0 (2.0).
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason

(unwilling) Protocol outcome 3: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC physical function at 12 weeks; Group 1: mean 2.1 (SD 1.4); n=111, Group 2: mean 2.5 (SD 2); n=109; WOMAC physical function 0-10 Top=High is poor outcome; Comments: Baseline shoes: 3.5 (1.8). Baseline sham: 3.4 (1.8). Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling) - Actual outcome for Knee: WOMAC physical function at 24 weeks; Group 1: mean 1.4 (SD 1.2); n=111, Group 2: mean 2.4 (SD 1.8); n=109; WOMAC physical function 0-10 Top=High is poor outcome; Comments: Baseline shoes: 3.5 (1.8). Baseline sham: 3.4 (1.8). Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling) Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Any adverse events at 24 weeks; Group 1: 26/111, Group 2: 38/109; Comments: Events reported in the study included knee pain or swelling, low back pain, hip pain, foot pain, ankle sprain, fall, genitourinary, circulatory, nervous system, eye, respiratory system and digestive system adverse events. Serious adverse events: Intervention = 1 coronary heart disease, 1 genitourinary, 1 digestive symptom. Control: 3 total hip or knee replacement surgery, 1 low back pain, 2 coronary heart disease, 1 other circulatory, 1 eye, 1 digestive system. Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported sex, age, weight, height, body mass index, knee related symptoms and radiological grade and baseline values of outcomes; Group 1 Number missing: 8, Reason: 2 no symptom improvement, 2 symptoms worsened, 1 adverse events, 2 other reason (unwilling).; Group 2 Number missing: 13, Reason: 5 no symptom improvement, 3 symptoms worsened, 2 underwent total knee replacement, 1 underwent total hip replacement, 1 lost to follow-up, 1 other reason (unwilling)	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Rodrigues 2008[155]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=30)
Countries and setting	Conducted in Brazil; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 8 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People fulfilling the American College of Rheumatology criteria for knee osteoarthritis with radiographic grading by the Kellgren and Lawrence criteria.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People fulfilling the American College of Rheumatology criteria for knee osteoarthritis with bilateral valgus deformity ≥8 degrees. Knee osteoarthritis with lateral compartment involvement detected on radiograph (K/L class II or higher), absence or minimal involvement (K/L class 0 or I) in the medial compartment and pain on movement ≥2 as measured by a visual analogue scale.
Exclusion criteria	Body mass index ≥40kg/m²; scoliosis; difference in lower limb length >1cm; knee surgery; hallux rigidus; history of rheumatologic disease (rheumatoid arthritis, connective tissue disease, microcrystalline arthropathy, and seronegative arthropathy); soft tissue involvement (anserine, patellar and calcanael tendinopathy); foot/lower leg lymptoms; corticosteroid and hyaluronic acid infiltrations 3 and 6 months prior to entry respectively; NSAID and analgesic or slow action drugs prescribed at less than 4 and 8 weeks respectively.
Recruitment/selection of patients	Consecutive selection from the rheumatology outpatient clinic of the University of São Paulo
Age, gender and ethnicity	Age - Mean (SD): 61.7 (11.4). Gender (M:F): 0:30. Ethnicity: 15 white. No statement about the remaining 15 people.
Further population details	1. Age: ≤75 years (Majority less than 75 years, but does include people up to the age of 86). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades II to IV. Duration of symptoms (mean [SD]): 4.9 (3.9) years
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Orthotic devices - Insoles. Insole and ankle brace. Insole made of ethylene-vinyl-acetate provided by the AACD institute with a raised wedge. A commercial neoprene with elastic banding was used for ankle support. Each person was instructed to use the splints (shoes and elastic banding) for 3-6 hours daily. Correct use of the splints was checked every 2 weeks.. Duration 8 weeks. Concurrent medication/care: NSAIDs and analgesics or slow-action drugs were allowed if prescribed at least 4 weeks and 8 weeks respectively. Indirectness: No indirectness

	(n=14) Intervention 2: Sham device. Insole and ankle brace. A neutral insole made of ethylene-vinyl-acetate provided by the AACD institute. A commercial neoprene with elastic banding was used for ankle support. Each person was instructed to use the splints (shoes and elastic banding) for 3-6 hours daily. Correct use of the splints was checked every 2 weeks.. Duration 8 weeks. Concurrent medication/care: NSAIDs and analgesics or slow-action drugs were allowed if prescribed at least 4 weeks and 8 weeks respectively. Indirectness: No indirectness
Funding	Academic or government funding (Supported by Fundo de Auxı´lio a` Pesquisa e Ensino em Reumatologia da Sociedade Brasileira de Reumatologia. Dr. Bonfa''s work was supported by the CNPq.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: VAS rest at 8 weeks; Group 1: mean 2.7 (SD 2.4); n=16, Group 2: mean 3.1 (SD 2.5); n=14; Visual analogue scale (pain at rest) 0-10 Top=High is poor outcome; Comments: Baseline insole: 5.1 (2.3). Baseline sham: 3.3 (2.2).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Different baseline levels of pain, BMI and severity (less severe, but higher BMI in the control group). Reports age, race, BMI, sedentary lifestyle, disease duration, radiographic severity.; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 8 weeks; Group 1: 0/16, Group 2: 1/14; Comments: 1 person in the neutral insole group reported mild discomfort while using the insole
Risk of bias: All domain - Very high, Selection - Very high, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Different baseline levels of pain, BMI and severity (less severe, but higher BMI in the control group). Reports age, race, BMI, sedentary lifestyle, disease duration, radiographic severity.; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	ROTOR trial: Thoumie 2018[172]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=67)
Countries and setting	Conducted in France; Setting: Outpatient follow up (mixture of primary and secondary care)
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People with symptomatic medial knee OA defined by pain according to American College of Rheumatology Criteria, and based on radiological findings within the previous 24 months.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People with a body mass index ≤35kg/m², presenting with symptomatic medial knee OA defined as pain while walking for 30 days over the last 2 months prior to inclusion, and global knee pain over the last 24 hours ≥40mm (using a 100-mm visual analogue scale) on the day of inclusion. Diagnosis of medial knee compartment osteoarthritis was performed according to the American College of Rheumatology criteria, and based on radiological findings within the previous 24 months (Kellgren-Lawrence grade II-IV for the medial compartment, and Kellgren-Lawrence grade I for the lateral compartment). If bilateral, the study knee was defined as the most affected one.
Exclusion criteria	People with symptomatic OA of the patellofemoral knee compartment (radiologically diagnosed); septic arthritis; metabolic arthropathies; inflammatory rheumatic diseases; synovitis needing aspiration; contralateral knee OA needing intra-articular corticosteroids; varicous veins or venous reflux disease; lower limbs sensory disorders; lower limbs arteritis; history of intra-articular injection of hyaluronic acid in the evaluated knee or intra-articular corticosteroids administration in either knee within the last month; or history of taking opioids, corticosteroids, NSAIDs or analgesics within the last 48 hours were excluded.
Recruitment/selection of patients	Carried out by nine private practice physicians managing osteoarthritis in either primary or secondary care (including general practitioners, rheumatologists, orthopaedic surgeons, and specialists in physical medicine and rehabilitation) and one hospital-based physician
Age, gender and ethnicity	Age - Mean (SD): 65.7 (9.7). Gender (M:F): 23:44. Ethnicity: Not stated
Further population details	1. Age: Mixed (Based on SD). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grades II-IV..
Indirectness of population	No indirectness
Interventions	(n=32) Intervention 1: Braces. REBEL RELIEVER unloading knee brace (Thuasne) for at least 6 hours daily for 6 weeks. Initial fitting of the brace was performed by an orthopedist-orthotist, who made any necessary adjustments to create a

	base level of corrective force and gave instructions to the patients.. Duration 6 weeks. Concurrent medication/care: All people received usual care, consisting of analgesics (paracetamol and NSAIDs), daily exercise program as recommended by the French Society of Rheumatology, and patient information, as per OARSI's guidelines. (n=35) Intervention 2: No device intervention. Usual care only. Duration 6 weeks. Concurrent medication/care: All people received usual care, consisting of analgesics (paracetamol and NSAIDs), daily exercise program as recommended by the French Society of Rheumatology, and patient information, as per OARSI's guidelines.
Funding	Study funded by industry (Sponsored by THUASNE. Authors work for or receive fees from THUASNE or EURAXI PHARMA)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Pain on movement (100 mm VAS) at 6 weeks; Group 1: mean 26.7 (SD 21.5); n=32, Group 2: mean 59.7 (SD 22.4); n=35; Visual analogue scale (pain on movement) 0-100 Top=High is poor outcome; Comments: Baseline brace: 73.4 (12.7). Baseline control: 71.9 (13.8).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness, Comments: ?Indirectness. Pain on movement rather than at rest.; Baseline details: Reports age, gender, body mass index, BMI, Kellgren-Lawrence grade, contralateral knee osteoarthritis prevalence and outcome baselines; Group 1 Number missing: 4, Reason: 3 discontinued for patient's decision. 1 for another reason.; Group 2 Number missing: 3, Reason: 2 discontinued for patient's decision. 1 was lost to follow up.

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 6 weeks; Group 1: 10/32, Group 2: 3/35; Comments: Not clearly reported. Reports that 13 people reported an adverse event, mainly in the brace group (10 people). No serious adverse events or severe adverse events were reported. Six people reported an adverse event related to the brace, mainly skin irritation or discomfort at brace contact points. No brace-related AE leading to permanent treatment discontinuation was reported.
Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness; Baseline details: Reports age, gender, body mass index, BMI, Kellgren-Lawrence grade, contralateral knee osteoarthritis prevalence and outcome baselines; Group 1 Number missing: 4, Reason: 3 discontinued for patient's decision. 1 for another reason.; Group 2 Number missing: 3, Reason: 2 discontinued for patient's decision. 1 was lost to follow up.

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	**Salam 2019[156]**
Study type	RCT (Patient randomised; Parallel)

Number of studies (number of participants)	(n=40)
Countries and setting	Conducted in Pakistan; Setting: Madina Physiotherapy Clinic, University of Faisalabad.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical and radiological diagnosis of OA.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 40-60 years, grade II/III medial compartment knee OA
Exclusion criteria	RA, fracture, tumour, trauma or with any other systemic co-morbidity, age less than 40 and more than 60.
Recruitment/selection of patients	Not reported.
Age, gender and ethnicity	Age - Mean (SD): 4.18 (5.9). Gender (M:F): 33M/ 7F. Ethnicity: Not reported
Further population details	1. Age: <75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: People with multimorbidities excluded (Exclusion criteria: any other systemic co-morbidity).
Extra comments	Severity: grade II/III Duration: not reported.
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Orthotic devices - Insoles. Throughout the week, during the day, a lateral wedge (thickness 7mm) was applied. Participants also received conventional physical therapy ultrasound, SWD and quadriceps isomeric exercises 5 times a week up to 6 weeks. The duration of each session was 35 minutes. Ultrasound therapy as per the patient's requirement with an intensity of 1.5 watts/cm2 for 5 minutes in continuous mode at the tender point around the knee joint. SWD was used for 15 minutes to help relieve pain and swelling. The most appropriate and easy to perform isometric exercise by patients and could be easily and safely performed was carried out for a period of 15 minutes.. Duration 6 weeks. Concurrent medication/care: Not reported.. Indirectness: No indirectness (n=20) Intervention 2: No device intervention. Participants also received conventional physical therapy ultrasound, SWD and quadriceps isomeric exercises 5 times a week up to 6 weeks. The duration of each session was 35 minutes. Ultrasound therapy as per the patient's requirement with an intensity of 1.5 watts/cm2 for 5 minutes in continuous mode at the tender point around the knee joint. SWD was used for 15 minutes to help relieve pain and swelling. The most

	appropriate and easy to perform isometric exercise by patients and could be easily and safely performed was carried out for a period of 15 minutes.. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: LATERAL WEDGE INSOLES versus USUAL CARE Protocol outcome 1: Quality of life at ≤3- or >3- months - Actual outcome for Knee: KOOS Quality of life at 6 weeks; Group 1: mean 70.7 (SD 14.5823); n=20, Group 2: mean 28.85 (SD 9.59317); n=20; KOOS Quality of life 0-100 Top=High is good outcome; Comments: Baseline values: insoles group: 10.95 (12.57), usual care group: 2.5 (7.69) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Baseline KOOS quality of life scores: lateral wedge group: 10.95 (12.57), usual care group: 2.5 (7.69); Group 1 Number missing: 0, Reason: N/A; Group 2 Number missing: 0, Reason: N/A Protocol outcome 2: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: KOOS Pain at 6 weeks; Group 1: mean 91.45 (SD 4.2112); n=20, Group 2: mean 81.75 (SD 2.22131); n=20; KOOS Pain 0-100 Top=High is good outcome; Comments: Baseline values: lateral wedge group: 79.95 (2.63), usual care group: 79.25 (2.22) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Baseline KOOS quality of life scores: lateral wedge group: 10.95 (12.57), usual care group: 2.5 (7.69); Group 1 Number missing: 0, Reason: N/A; Group 2 Number missing: 0, Reason: N/A	
Protocol outcomes not reported by the study	Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Sattari 2011[157]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=60)
Countries and setting	Conducted in Iran; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 9 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Moderate to severe medial compartment degenerative joint disease defined by knee pain and genu varum based on radiographic evidence
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People with complaints of knee pain and genu varum based on radiographic evidences and moderate to severe medial compartment degenerative joint disease (grades III or IV of Kellgren and Lawrence grading system).
Exclusion criteria	History of any orthopaedic lower limb surgery; whole knee degenerative joint disease (based on radiological findings); symptomatic patellofemoral pain syndrome (radiographically confirmed); rheumatoid arthritis; any superimposed hip or ankle problems; BMI index greater than 30.
Recruitment/selection of patients	Took place in 3 outpatient departments of physical medicine and rehabilitation of Isfahan University of Medical Sciences
Age, gender and ethnicity	Age - Mean (range): 48 (35-65). Gender (M:F): 22:38. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Moderate-to-severe. Kellgren and Lawrence grades III-IV. Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Braces. Three point knee brace applied on and off every 2-3 hours for the first week, and then as long as possible during the day (taking it off at night).. Duration 9 months. Concurrent medication/care: Conservative management consisted of activity modification, heating agents at home, straight leg raising and isometric quadriceps home exercises, and analgesics when needed.. Indirectness: No indirectness (n=20) Intervention 2: Orthotic devices - Insoles. Conservative treatment with 1/4 inches lateral wedge insoles. They were instructed to apply the wedge all the time they wear shoes.. Duration 9 months. Concurrent medication/care: Conservative management consisted of activity modification, heating agents at home, straight leg raising and isometric quadriceps home exercises, and analgesics when needed.. Indirectness: No indirectness

	(n=20) Intervention 3: No device intervention. Conservative care only. Duration 9 months. Concurrent medication/care: Conservative management consisted of activity modification, heating agents at home, straight leg raising and isometric quadriceps home exercises, and analgesics when needed.. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus INSOLES

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Severity of pain (VAS) at 9 months; Group 1: mean 3.1 (SD 1.4); n=20, Group 2: mean 4.3 (SD 1.2); n=20; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline braces: 7.5 (1.5). Baseline insoles: 8 (1.4).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.; Group 2 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Severity of pain (VAS) at 9 months; Group 1: mean 3.1 (SD 1.4); n=20, Group 2: mean 5.9 (SD 1.1); n=20; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline braces: 7.5 (1.5). Baseline no device: 6.5 (1.2).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.; Group 2 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Severity of pain (VAS) at 9 months; Group 1: mean 4.3 (SD 1.2); n=20, Group 2: mean 5.9 (SD 1.1); n=20; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline insoles: 8 (1.4). Baseline no device intervention: 6.5 (1.2).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.; Group 2 Number missing: 0, Reason: Reports that 5 people were excluded as they did not come back for reevaluation. But also reports that only sixty were randomised and that sixty remained at the end of the study.

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	**NCT02789852 trial: Silva 2020[161]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=52)
Countries and setting	Conducted in Brazil; Setting: Outpatient clinic of Universidade Federal de Sa Paolo
Line of therapy	Unclear
Duration of study	Intervention + follow up: 180 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: ACR criteria
Stratum	Hand
Subgroup analysis within study	Not applicable
Inclusion criteria	Women ages 40 years and older with a diagnosis of hand OA according to ACR criteria with symptoms in the second or third finger, or both, of the dominant hand (these fingers were the most symptomatic), with pain rated between 3 and 8cm on a 10cm NRS, who had been undergoing stable pharmacological treatment for the preceding 3 weeks.
Exclusion criteria	Secondary hand OA, neurological and skeletal muscle disease that could compromise the upper limb, and cognitive deficit that could obstruct the comprehension of assessment instruments.
Recruitment/selection of patients	recruited from outpatient clinic.
Age, gender and ethnicity	Age - Mean (SD): Orthosis group: 64.1 (8.4), control group: 63.5 (7.8) years. Gender (M:F): All female. Ethnicity: Not reported
Further population details	1. Age: Not stated / Unclear 2. Diagnostic method: Not stated / Unclear 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity (AUSCAN pain at baseline): orthosis group: 10.6 (4.1), control group: 9.4 (3.8) Duration (years): orthosis group: 8.2 (3.8), control group: 6.1 (4.6)
Indirectness of population	No indirectness
Interventions	(n=26) Intervention 1: Orthotic devices - Other. A custom finger gutter thermoplastic orthosis was fabricated by a senior hand therapist by moulding the volar side of the finger and aligning the DIP and PIP joints with neutral positioning.

	Adjustments were made tot he splint's dorsal side for each client's intervention joint at the baseline visit and following assessments. Clients were shown how to fit the orthosis and were asked to wear it every night for 6 months. They were also asked not to alter their pain relief medication and other hand therapies during the study, if possible, and any changes were documented at each visit. . Duration 180 days. Concurrent medication/care: All participants participated in an educational programme on hand OA that was held in the days after the evaluations. The client education involved three 40 minute sessions that included a lecture by the trial researcher that provided information about the disease, its symptoms, medical treatments, joint protection and energy conservation.. Indirectness: No indirectness (n=26) Intervention 2: No device intervention. No orthosis was used. Participants were also asked not to alter their pain relief medication and other hand therapies during the study, if possible, and any changes were documented at each visit. . Duration 180 days. Concurrent medication/care: All participants participated in an educational programme on hand OA that was held in the days after the evaluations. The client education involved three 40 minute sessions that included a lecture by the trial researcher that provided information about the disease, its symptoms, medical treatments, joint protection and energy conservation.. Indirectness: No indirectness
Funding	Academic or government funding (Financial support was provided by grants 13/14460-3 and 13/221591 from the Sao Paolo Research Foundation (FAPESP).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HAND ORTHOSIS PLUS EDUCATION versus EDUCATION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Hand: AUSCAN pain subscale at 90 days; Group 1: mean 8.6 (SD 4.7); n=26, Group 2: mean 8.9 (SD 4.01); n=26; AUSCAN pain subscale 0-20 Top=High is poor outcome; Comments: Baseline values: orthosis group: 10.6 (4.1), control group: 9.4 (3.8)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Outcome assessor was said to be blinded, but patient was not.; Group 1 Number missing: 0, Reason: N/A; Group 2 Number missing: 0, Reason: N/A
- Actual outcome for Hand: AUSCAN pain subscale at 180 days; Group 1: mean 7.5 (SD 4.5); n=26, Group 2: mean 9.9 (SD 3.4); n=26; AUSCAN pain subscale 0-20 Top=High is poor outcome; Comments: Baseline values: orthosis group: 10.6 (4.1), control group: 9.4 (3.8)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Outcome assessor was said to be blinded, but patient was not.; Group 1 Number missing: 1, Reason: Did not attend follow-up appointment; Group 2 Number missing: 0, Reason: N/A

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Hand: AUSCAN function subscale at 90 days; Group 1: mean 18.6 (SD 7); n=26, Group 2: mean 18.4 (SD 7.2); n=26; AUSCAN function subscale 0-36 Top=High is poor outcome; Comments: Baseline values: orthosis group: 21.2 (6.7), control group: 18.6 (7.0)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Outcome assessor was said to be blinded, but patient was not.; Group 1 Number missing: 0, Reason: N/A; Group 2 Number missing: 0, Reason: N/A
- Actual outcome for Hand: AUSCAN function subscale at 180 days; Group 1: mean 16.3 (SD 8.4); n=26, Group 2: mean 18.2 (SD 6); n=26; AUSCAN

function subscale 0-36 Top=High is poor outcome; Comments: Baseline values: orthosis group: 21.2 (6.7), control group: 18.6 (7.0) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Outcome assessor was said to be blinded, but patient was not.; Group 1 Number missing: 1, Reason: Did not attend follow-up appointment; Group 2 Number missing: 0, Reason: N/A	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	Taheri 2017[167]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=44)
Countries and setting	Conducted in Iran; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee pain diagnosed as knee osteoarthritis with radiological grade II to III
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People with knee pain and diagnosed as knee OA with radiological grade II to III (based on Kellgren-Lawrence grading scale). All people were diagnosed according to the American College of Rheumatology for diagnosis of knee OA.
Exclusion criteria	People with allergic reactions to tape or any skin problems that prevents the tape being applied; presence of any inflammatory arthritis; history of any injection at knee or any surgical intervention in the past within the last 6 months; suspicion to other pathologies in the knee; severe obesity; OA grade IV; instability of the knee joint; cardiovascular disorders; trauma to the knee during the study; not following the treatment allocated to them; performing physiotherapy within the treatment schedule.
Recruitment/selection of patients	People seen at Al-Zahra Hospital, a tertiary health center affiliated with Isfahan University of Medical Sciences
Age, gender and ethnicity	Age - Mean (SD): 56.3 (6.4). Gender (M:F): 4:32. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grade II-III. Duration of symptoms not stated.
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Straps/tape - Tape. Taping - Taping in three consecutive weeks. Tapes were replaced at each session and remained retained during the week. In case of separation of the tape, the person was referred to renew it.. Duration 6 weeks. Concurrent medication/care: All people received exercise and drug therapy. Exercise included three consecutive sessions of stretching the hamstring and calf muscles (holding stretch for 30 seconds, repeating the stretch throughout the session at least 5 times, three sessions per day), and strengthening quadriceps muscles (holding contraction of muscle for 10s, repeating it throughout the session at least 5 times, three sessions per day). The volume and frequency of the exercise was checked by self-reported diary. Drug therapy in both groups including celecoxib (100mg 1-3 capsules per day according to pain severity). People were prohibited from taking any other analgesics

	during the study.. Indirectness: No indirectness (n=22) Intervention 2: No device intervention. Standard care only (see below). Duration 6 weeks. Concurrent medication/care: All people received exercise and drug therapy. Exercise included three consecutive sessions of stretching the hamstring and calf muscles (holding stretch for 30 seconds, repeating the stretch throughout the session at least 5 times, three sessions per day), and strengthening quadriceps muscles (holding contraction of muscle for 10s, repeating it throughout the session at least 5 times, three sessions per day). The volume and frequency of the exercise was checked by self-reported diary. Drug therapy in both groups including celecoxib (100mg 1-3 capsules per day according to pain severity). People were prohibited from taking any other analgesics during the study.. Indirectness: No indirectness
Funding	Academic or government funding (Support from Isfahan University of Medical Sciences)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus NO DEVICE INTERVENTION

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: Visual analogue scale (pain) at 6 weeks; Group 1: mean 2 (SD 1.13); n=20, Group 2: mean 4.13 (SD 2.3); n=16; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline taping: 7.70 (2.22). Baseline control: 7.04 (1.52).
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, radiographic grade, and outcome baseline values; Group 1 Number missing: 2, Reason: 1 due to allergic reaction to tape, 1 due to trauma to knee; Group 2 Number missing: 6, Reason: 1 due to physiotherapy during the scheduled period, 1 due to knee effusion, 4 wanted to seek treatment

Protocol outcome 2: Adverse events at ≤3- or >3- months
- Actual outcome for Knee: Adverse events at 6 weeks; Group 1: 2/22, Group 2: 1/22; Comments: Tape: 1 allergic reaction. 1 trauma to knee. No device: 1 effusion.
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, radiographic grade, and outcome baseline values; Group 1 Number missing: 0, Reason: 1 due to allergic reaction to tape, 1 due to trauma to knee. However, reports reason (including adverse events) for leaving so counted as no missing data.; Group 2 Number missing: 0, Reason: 1 due to physiotherapy during the scheduled period, 1 due to knee effusion, 4 wanted to seek treatment. However, reports reason (including adverse events) for leaving so counted as no missing data.

Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Tan 2019[168]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=26)
Countries and setting	Conducted in Australia; Setting: La Trobe University.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical diagnosis without imaging
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	1) age 50 to 70 years, (2) anterior or retropatellar knee pain aggravated by ≥2 PFJ loading activities (stair ambulation, squatting, rising from sitting), (3) pain during these activities on most days in the past month, and (4) pain severity ≥30mm on a 100mm VAS during aggravating activities.
Exclusion criteria	(1) concomitant pain from other knee structures, hip or lumbar spine, (2) recent treatment for knee pain, (3) any foot condition precluding the use of foot orthoses, (4) knee or hip arthroplasty/ osteotomy, (5) neurological or systemic arthritis conditions, (6) physical inability, or too frail or ill to undertake testing procedures (ascertained via questioning, and clinical examination if needed, or (7) inability to understand written and spoken English.
Recruitment/selection of patients	Recruited via paid (e.g. local newspapers, Facebook) and free advertisements (e.g. community newsletters, noticeboards), with a small number of referrals from physiotherapists and podiatrists. Recruited through print media: 19, recruited through social media: 3, referrals through AHPs: 4
Age, gender and ethnicity	Age - Mean (SD): 60 (8). Gender (M:F): 10M/ 16F. Ethnicity: Not reported
Further population details	1. Age: <75 years (Age 50-70 years). 2. Diagnostic method: Diagnosed without imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity (usual pain VAS, 0-100mm): foot orthoses group: 31 (13), flat inserts group: 56 (29) Duration of pain (n): 3-6 months (2), 6-12 months (0), 1-2 years (2), ≥2 years (22)
Indirectness of population	No indirectness
Interventions	(n=13) Intervention 1: Orthotic devices - Insoles. Interventions were administered by the primary study investigator, a registered podiatrist with 5 years of musculoskeletal clinical experience. Participants received one pair of commercially available prefabricated full-length foot orthoses (Vasyli Medical Labrador, Australia) and, if required, one pair of prefabricated three quarter length foot orthoses that could be accommodated into dress shoes. The foot orthoses were manufactured from ethylene-vinylacetate (EVA). had inbuilt arch support, and a 6 degree varus wedge. The high density red (Shore A 75 degree) EVA product was used, which is available in the commercial range. The foot orthoses were covered with a synthetic fabric

	(Cambrelle, Camtex Fabrics, Cumbria, CA, USA) to ensure no differentiation could be made to the flat insert. If required, devices were moulded to increase comfort. . Duration 6 weeks. Concurrent medication/care: Rescue medication was permitted (e.g. paracetamol) and co-interventions to relieve pain were documented with a daily log-book. One participant in this group underwent self massage as a co-intervention. (n=13) Intervention 2: Sham device. Participants allocated to the flat insert group received a single pair of flat inserts, similar in appearance to the foot orthoses. They were made from the same high density red (Shore A 75 degrees) EVA with identical black Cambrelle covering fabric. However the device was uniform in thickness along its full length (3mm) and had no inbuilt arch support or varus wedging. It was assumed that the flat insert had some minor cushioning properties, but limited arch support compared to the foot orthoses, and thus could be considered a sham device.. Duration 6 weeks. Concurrent medication/care: Rescue medication was permitted (e.g. paracetamol) and co-interventions to relieve pain were documented with a daily log-book. One participant in this group underwent concomitant osteopathy, and two did knee exercises/ stretches.. Indirectness: No indirectness
Funding	Academic or government funding (National Health and Medical Research Council (NHMRC ID number: 1106852) and the Discipline of Podiatry at La Trobe University, Melbourne campus (Bundoora).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus SHAM ORTHOSIS

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: KOOS Quality of life. at 6 weeks; Mean; 11.3 (95%CI -1.4 to 24) KOOS Quality of life 0-100 Top=High is good outcome, Comments: Adjusted for baseline scores.
Baseline values: orthosis group: 50.5 (12.9), sham: 34.2 (16.1);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Photos of insoles provided. It is possible some participants could have deduced which insoles were active/ control.; Group 1 Number missing: 1, Reason: Lost to follow-up; Group 2 Number missing: 2, Reason: Incomplete dataset.

Protocol outcome 2: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: KOOS Pain at 6 weeks; Mean; 8.1 (95%CI -6.9 to 23.1) KOOS Pain 0-100 Top=High is good outcome, Comments: Adjusted for baseline scores.
Baseline values: orthosis group: 67.8 (10.8), sham: 54.2 (12.5);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Photos of insoles provided. It is possible some participants could have deduced which insoles were active/ control.; Group 1 Number missing: 1, Reason: Lost to follow-up; Group 2 Number missing: 2, Reason: Incomplete dataset.

Protocol outcome 3: Physical function at ≤3- or >3- months

- Actual outcome for Knee: KOOS ADL at 6 weeks; Mean; 13.7 (95%CI 0.2 to 27.2, Comments: Adjusted for baseline scores. Baseline values: orthosis group: 80.7 (10.6), sham: 59.6 (19.8)); Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Photos of insoles provided. It is possible some participants could have deduced which insoles were active/ control.; Group 1 Number missing: 1, Reason: Lost to follow-up; Group 2 Number missing: 2, Reason: Incomplete dataset. Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Adverse events at 6 weeks; Group 1: 11/12, Group 2: 6/11; Comments: Insole group: Arch irritation/ pain: 8, back pain: 3, hip pain: 3, knee pain: 4, tightness in footwear/ shoe fit issues: 5, general foot discomfort/ ache:7, rubbing: 0, too firm: 2, tired feet: 0, discomfort/ rubbing around MTPJ/ toe joint region: 6, other (e.g. heel pain, shin pain): 0 Sham group: Arch irritation/ pain: 1, back pain: 2, hip pain: 1, knee pain: 2, tightness in footwear/ shoe fit issues: 4, general foot discomfort/ ache:1, rubbing: 1, too firm: 1, tired feet: 1, discomfort/ rubbing around MTPJ/ toe joint region: 2, other (e.g. heel pain, shin pain): 2 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Photos of insoles provided. It is possible some participants could have deduced which insoles were active/ control.; Group 1 Number missing: 1, Reason: Lost to follow-up; Group 2 Number missing: 2, Reason: Incomplete dataset.	
Protocol outcomes not reported by the study	Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Van Ginckel 2019[186]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=79)
Countries and setting	Conducted in Australia; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Knee pain on most days for the past month and radiographic evidence of medial tibiofemoral osteoarthritis (Kellgren Lawrence grade at least 2 and Osteoarthritis Research Society grade at least 1 medial joint space narrowing and greater than lateral), at least one medial tibiofemoral bone marrow lesion on MRI.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age at least 50 years; knee pain on most days for the past month and radiographic evidence of medial tibiofemoral osteoarthritis (Kellgren Lawrence grade at least 2 and Osteoarthritis Research Society grade at least 1 medial joint space narrowing and greater than lateral); at least one medial tibiofemoral bone marrow lesion on MRI; willing to use a cane daily for 3 months if allocated to cane group; sufficient English language.
Exclusion criteria	Imaging contra-indications; history of knee replacement of osteotomy on either knee; knee arthroscopy or intra-articular (corticosteroid or hyaluronan) injections in the prior 6 months; planned hip or knee surgery in subsequent 3 months; current use of potential disease-modifying and/or anti-bone resorption drugs; current and previous (past 3 months to match intervention duration) use of shoe inserts, knee/ankle braces or customized shoes prescribed by a health professional and inability/unwillingness to cease for trial; current and previous (past 3 months) cane use; other conditions affecting lower limb function or ability to use a cane.
Recruitment/selection of patients	People from two sites in Australia. Recruitment occurred from October 2014 to December 2017, with follow-up completed by March 2018.
Age, gender and ethnicity	Age - Mean (SD): 66.1 (7.3). Gender (M:F): 34:45. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Presence of multimorbidity (a range of comorbidities referenced, likely all people had some comorbidity).
Extra comments	Severity: Kellgren-Lawrence grade 2-4 (median grade 3). Duration of symptoms: 8.4 (9.0) years
Indirectness of population	No indirectness
Interventions	(n=40) Intervention 1: Walking aids. A single individual training session from a physiotherapy with >10 years of experience in musculoskeletal physiotherapy. This 30-45 minute session aimed to teach the correct cane gait technique

	to achieve optimal amount and timing of knee off-loading. A force-feedback cane with on-off vibration biofeedback through the handle during the training session, with vibration triggered when a target force window of 10% of body weight support through the cane was reached when walking. People were taught to consistently achieve at least 10% body weight support. Additionally, the session included education about benefits and barriers to cane use to facilitate adherence. People were then provided with a generic “swan neck” cane fitted to their height and instructed to use it daily whenever walking for 3 months. The cane group was contacted fortnightly via telephone to remind them to complete/return logbooks and facilitate adherence to cane use by discussing any issues including barriers. Duration 3 months. Concurrent medication/care: Both groups were allowed to continue regular medication for knee pain. Indirectness: No indirectness (n=39) Intervention 2: No device intervention. Instructed to maintain their regular lifestyle and to not use any gait aids during the study. Duration 6 months. Concurrent medication/care: Both groups were allowed to continue regular medication for knee pain. Indirectness: No indirectness
Funding	Authors supported by FWO (Pegasus) EU Marie-Sklodowska Curie Fellowship (EU Horizon 2020, #66501); National Health and Medical Research Council Principal Research Fellowship (#1058440); Australian Research Council Future Fellowship (FT130100175); NHMRC Practitioner Fellowship (#1079777); NHMRC program grants (#631717, 61887); Early Career Researcher grant (#602640). The sponsor of the trial is the University of Melbourne.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: WALKING AIDS versus NO DEVICE INTERVENTION

Protocol outcome 1: Quality of life at ≤3- or >3- months

- Actual outcome for Knee: Quality of life (AQoL-6D) at 3 months; Group 1: mean 0.0 (SD 0.1); n=40, Group 2: mean 0.0 (SD 0.1); n=39; AQoL -0.04-1 Top=High is good outcome; Comments: Baseline walking aids: 0.8 (0.1). Baseline no device intervention: 0.8 (0.1).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports a variety of characteristics, all appear matched, baseline values of outcomes appear matched; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: Lost to follow-up due to patellar bone fracture following trauma.

Protocol outcome 2: Pain reduction at ≤3- or >3- months

- Actual outcome for Knee: Pain (WOMAC) at 3 months; Group 1: mean -1.4 (SD 3.9); n=40, Group 2: mean -1.8 (SD 3.2); n=39; WOMAC pain 0-20 Top=High is poor outcome; Comments: Baseline walking aids: 7.8 (3.0). Baseline no device intervention: 7.7 (3.4).
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports a variety of characteristics, all appear matched, baseline values of outcomes appear matched; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: Lost to follow-up due to patellar bone fracture following trauma.

Protocol outcome 3: Physical function at ≤3- or >3- months

- Actual outcome for Knee: Physical function (WOMAC) at 3 months; Group 1: mean -5.1 (SD 11.3); n=40, Group 2: mean -4.3 (SD 9.5); n=39; WOMAC function 0-68 Top=High is poor outcome; Comments: Baseline walking aids: 24.6 (9.7). Baseline no device intervention: 25.3 (12.3). Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports a variety of characteristics, all appear matched, baseline values of outcomes appear matched; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: Lost to follow-up due to patellar bone fracture following trauma. Protocol outcome 3: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Adverse events at 3 months; Group 1: 9/40, Group 2: 1/39; Comments: Walking aids: 2 contralateral non-study knee pain, 1 contralateral non-study hip pain, 4 worse pain/swelling in study knee or lower limb, 2 shoulder/neck pain, 2 back and/or referred pain, 1 complaint in the elbow or wrist opposite to the cane due to additional load carrying on this side. No device intervention: 1 patellar bone fracture following trauma (leading to discontinuation). Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports a variety of characteristics, all appear matched, baseline values of outcomes appear matched; Group 1 Number missing: 0; Group 2 Number missing: 1, Reason: Lost to follow-up due to patellar bone fracture following trauma.	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Van raaij 2010[187]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=91)
Countries and setting	Conducted in Netherlands; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Symptomatic medial compartmental knee osteoarthritis (diagnosed when there was pain and tenderness in combination with osteoarthritis signs according to the Kellgren-Lawrence system of grade 1 or higher were located over the medial tibiofemoral compartment of the knee).
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	People with symptomatic medial compartmental knee osteoarthritis
Exclusion criteria	People with symptoms not related to medial compartmental osteoarthritis; younger than 35 years; an insufficient command of the Dutch language; no varus malalignment
Recruitment/selection of patients	No additional information
Age, gender and ethnicity	Age - Mean (SD): 54.7 (7.0). Gender (M:F): 45:46. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not explicitly stated. Kellgren-Lawrence grade 1-4). Duration of symptoms: Not stated
Indirectness of population	No indirectness
Interventions	(n=45) Intervention 1: Orthotic devices - Insoles. A shoe-inserted leather sole with a lateral wedge cork elevation of 10mm along the entire length of the foot. Custom made and fitted by a specialised orthopaedic shoe technician. . Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness (n=46) Intervention 2: Braces. A valgus knee brace that was commercially available for the right/left leg in four sizes and consisted of a thigh shell and a calf shell connected by coated aluminium hinges on the medial and lateral sides. Duration 6 months. Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INSOLES versus BRACES	

Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: Pain severity (VAS) at 6 months; Group 1: mean -0.9 (SD 2.4); n=45, Group 2: mean -1 (SD 2.2); n=46; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline insole: 46.5 (18.9). Baseline brace: 5.6 (2.2). Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, osteoarthritis radiological grade and outcome measures; Group 1 Number missing: 8, Reason: High tibial osteotomy in 3, usual nonoperative care in 1, lost to follow up in 4; Group 2 Number missing: 10, Reason: Uniknee prosthesis in 1, insole in 1, usual nonoperative care in 4, lost to follow up in 4 Protocol outcome 2: Physical function at ≤3- or >3- months - Actual outcome for Knee: WOMAC function at 6 months; Group 1: mean 4.2 (SD 16.9); n=45, Group 2: mean 4 (SD 18.9); n=46; WOMAC physical function subscale 0-100 Top=High is good outcome; Comments: Baseline insole: 46.5 (18.9). Baseline brace: 46.8 (18.2). NOTE: High is good in this case (different to almost every other paper reporting WOMAC). Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, osteoarthritis radiological grade and outcome measures; Group 1 Number missing: 8, Reason: High tibial osteotomy in 3, usual nonoperative care in 1, lost to follow up in 4; Group 2 Number missing: 10, Reason: Uniknee prosthesis in 1, insole in 1, usual nonoperative care in 4, lost to follow up in 4 Protocol outcome 3: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Adverse events at 6 months; Group 1: 0/45, Group 2: 10/46; Comments: Braces: 10 skin irritation (2 had small blisters) Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports age, gender, BMI, osteoarthritis radiological grade and outcome measures; Group 1 Number missing: 8, Reason: High tibial osteotomy in 3, usual nonoperative care in 1, lost to follow up in 4; Group 2 Number missing: 10, Reason: Uniknee prosthesis in 1, insole in 1, usual nonoperative care in 4, lost to follow up in 4	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	Wade 2018[189]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=11)
Countries and setting	Conducted in United Kingdom; Setting: Outpatient follow up
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Established diagnosis of chronic osteoarthritis of the proximal interphalangeal joint of any finger based on both symptoms and radiographic changes
Stratum	Finger
Subgroup analysis within study	Not applicable
Inclusion criteria	Established diagnosis of chronic osteoarthritis of the proximal interphalangeal joint of any finger based on both symptoms and radiographic changes
Exclusion criteria	Non-English speakers; those unable to consent or lacking capacity for any reason; those who lacked the dexterity to cut and apply the tape to the painful finger; those with an active infection or an unhealed wound on the same hand; dermatological conditions involving the proposed trial finger; vulnerable or thin dorsal skin on the proposed trial finger.
Recruitment/selection of patients	People attending the plastic surgery outpatient department or hand therapy unit in the host institution
Age, gender and ethnicity	Age - Mean (SD): 62.4 (8.4). Gender (M:F): 3:7. Ethnicity: Not stated
Further population details	1. Age: ≤75 years 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: Not stated. Symptom duration: Not stated.
Indirectness of population	No indirectness
Interventions	(n=6) Intervention 1: Straps/tape - Tape. Application of a 1/4 inch Suture Strip® plus tape to the dorsum of the symptomatic proximal interphalangeal joint. In the intervention group they were taught to apply it in the manner that was thought to be supportive and carry the analgesic potential for the joint (mid point of the metacarpophalangeal joint-proximal interphalangeal joint to the midpoint of the proximal interphalangeal point to distalinterphalageal joint) over the symptomatic joint, in an elliptical configuration with the extremities of the tape overlapping.. Duration 1 week on (1 week off, 1 week washout). Concurrent medication/care: No additional information. Indirectness: No indirectness (n=5) Intervention 2: Sham device. Application of a 1/4 inch Suture Strip® plus tape to the dorsum of the symptomatic proximal interphalangeal joint. In the control group they were taught to apply it in a way that should deliver no analgesic effect. They placed it over the dorsum of the proximal interphalangeal joint (parallel to the articular surfaces of the joint,

	with one strip proximal and one distal).. Duration 1 week on (1 week off, 1 week washout). Concurrent medication/care: No additional information. Indirectness: No indirectness
Funding	Study funded by industry (Funding from Kinesio and Neo-G)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: TAPE versus SHAM DEVICE Protocol outcome 1: Pain reduction at ≤3- or >3- months - Actual outcome for Finger: Mean reported pain on VAS at 3 weeks; Group 1: mean 4.2 (SD 3.1); n=5, Group 2: mean 4.5 (SD 2); n=5; Visual analogue scale (pain) 0-10 Top=High is poor outcome; Comments: Baseline tape: 5.5 (2.6). Baseline sham: 4.6 (2.9). Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender and age; Group 1 Number missing: 1, Reason: 1 discontinued as taping interfered with their occupation; Group 2 Number missing: 0 Protocol outcome 2: Osteoarthritis flare-ups at ≤3- or >3- months - Actual outcome for Finger: Flare of osteoarthritis at 3 weeks; Group 1: 1/5, Group 2: 0/5; Comments: Self defined by the patient who reported it Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Reports gender and age; Group 1 Number missing: 1, Reason: 1 discontinued as taping interfered with their occupation; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Physical function at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Study	ACT12615000002583 trial: Wyndow 2021[196]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=46)
Countries and setting	Conducted in Australia; Setting: [Queensland]: University research laboratories, [Tasmania]: private podiatric practice.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 4 months
Method of assessment of guideline condition	Partially adequate method of assessment/diagnosis: Radiographic evidence of patellofemoral (PF) OA, including joint space narrowing and/or presence of osteophytes (K-L≥ grade1) plus clinical examination by a registered podiatrist.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Age ≥40 years, anterior knee pain aggravated by two PF loading activities (e.g. squatting, stair ambulation), pain present during these activities on most days in the past month, >30mm on a 100mm VAS, and radiographic or MRI evidence of PFOA. Radiographic criteria included doubtful joint space narrowing and/ or possible osteophytic lipping (K-L grade ≥1), while MRI criteria were definite PF osteophyes and partial or full thickness cartilage loss.
Exclusion criteria	Concomitant pain from other knee structures, hip or lumbar spine, treatment for PF pain in the last 3 months, or foot orthoses (FO) or physiotherapy within the previous 12 months, any condition precluding the use of FO, knee or hip arthroplasty or osteotomy, planned lower limb surgery in the following four months, moderate to severe radiographic TFOA (K-L grade ≥3), or any neurological or systemic arthritis conditions, physical inability to undertake testing, contraindications to x-ray or inability to understand written and spoken English.
Recruitment/selection of patients	[Queensland] social media advertisements: 6, university press releases: 7, [Tasmania] local flyers: 9, sandwich boards: 6
Age, gender and ethnicity	Age - Mean (SD): Orthosis + footwear group: 58 (10),footwear group: 56 (10). Gender (M:F): Orthosis + footwear group: 58% female, footwear group: 77% female. Ethnicity: Not reported
Further population details	1. Age: Not stated / Unclear 2. Diagnostic method: Diagnosed with imaging (All participants had a x-ray, and some also had MRI.). 3. Multimorbidities: Not stated / Unclear
Extra comments	Severity: K-L grade ≥1 but not ≥3 Duration: FO+footwear group: 3-6 months: 1, 6-12 months: 2, 1-2 years: 2, >2 years: 19; footwear group: 3-6 months: 2, 6-12 months: 0, 1-2 years: 1, >2 years: 19

Study	ACT12615000002583 trial: Wyndow 2021[196]
Indirectness of population	No indirectness
Interventions	(n=24) Intervention 1: Orthotic devices - Insoles. Customised foot orthoses were manufactured by Orthema (Brisbane, Australia) from single medium to high density EVA bases (Shore A 45 degrees) and covered in 1.5mm medical grade neoprene (OrthoNeo, Orthema). Additions were according to a standardised procedure. All participants received one pair of standardised shoes (New Balance 857 cross-trainer, Boston, Massachusetts), sized by an independent retailer (The Athlete's Foot, Brisbane, Queensland; The Running Edge, Hobart, Tasmania). This shoe has equivalent lateral to medial support to minimise risk of excessive medial support or exaggeration of varus alignment in those with mild co-existing TFOA. FO modifications were performed to optimise comfort and foot alignment when worn in the prescribed footwear. Footwear could only be modified by superficial adjustments. Modifications were kept to a minimum and documented. All participants were informed that both interventions were 'active' treatments, i.e. neither was a control intervention, to improve adherence. Participants kept a written daily log of hours of use of their prescribed intervention; hours of use of alternate footwear; knee pain severity; medication use; and a description of general activities undertaken during the study. All participants were contacted via phone of email at three weeks for follow-up regarding their allocated intervention. they were invited for review the following week (week 4) in person if they had any concerns. If participants reported no problems with their allocated intervention, they were not contacted again until two month patients reported outcomes were collected, and then at the four month end point of the study. Duration 4 months. Concurrent medication/care: All participants received an education package outlining wearing-in procedures. General information on PFOA and advice regarding management of the condition was provided. Participants were encouraged to continue with all regular activities, but to avoid using new pain medications, topical preparations, knee braces , or additional physical therapies for their knee during the study. Participants were permitted to continue use of their normal medications, including anti-inflammatory medications they had been taking on a regular basis prior to commencing the study. They were discouraged from increasing the dose of any usual pain medication without informing the investigators. Indirectness: No indirectness (n=22) Intervention 2: No device intervention. All participants received one pair of standardised shoes (New Balance 857 cross-trainer, Boston, Massachusetts), sized by an independent retailer (The Athlete's Foot, Brisbane, Queensland; The Running Edge, Hobart, Tasmania). This shoe has equivalent lateral to medial support to minimise risk of excessive medial support or exaggeration of varus alignment in those with mild co-existing TFOA. FO modifications were performed to optimise comfort and foot alignment when worn in the prescribed footwear. Footwear could only be modified by superficial adjustments. Modifications were kept to a minimum and documented. All participants were informed that both interventions were 'active' treatments, i.e. neither was a control intervention, to improve adherence. Participants kept a written daily log of hours of use of their prescribed intervention; hours of use of alternate footwear; knee pain severity; medication use; and a description of general activities undertaken during the study. All participants were contacted via phone of email at three weeks for follow-up regarding their allocated intervention. they were invited for review the following week (week 4) in person if they had any concerns. If participants reported no problems with their allocated intervention, they were not contacted again until two month patients reported outcomes were collected, and

Study	ACT12615000002583 trial: Wyndow 2021[196]
	then at the four month end point of the study.. Duration 4 months. Concurrent medication/care: All participants received an education package outlining wearing-in procedures. General information on PFOA and advice regarding management of the condition was provided. Participants were encouraged to continue with all regular activities, but to avoid using new pain medications, topical preparations, knee braces , or additional physical therapies for their knee during the study. Participants were permitted to continue use of their normal medications, including anti-inflammatory medications they had been taking on a regular basis prior to commencing the study. They were discouraged from increasing the dose of any usual pain medication without informing the investigators.. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (The footwear utilised in the study was provided by New Balance, and the foot orthoses by Orthema Australasia and Orthema Switzerland. The Australian Podiatry Education and Research Foundation provided funding of $9930 for radiographs and consumables.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ORTHOSIS + FOOTWEAR versus FOOTWEAR

Protocol outcome 1: Quality of life at ≤3- or >3- months
- Actual outcome for Knee: EQ-5D- Total health. at 4 months; Group 1: mean 80 (SD 25); n=14, Group 2: mean 84 (SD 13); n=19; EQ-5D Total score 0-100 Top=High is good outcome; Comments: Baseline values:
Orthosis+ footwear group: 73 (19)
Footwear group: 79 (10)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 73 (19), footwear group: 79 (10); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 10, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure.
- Actual outcome for Knee: EQ-5D- Total health. at 2 months; Group 1: mean 80 (SD 11); n=17, Group 2: mean 86 (SD 12); n=14; EQ-5D Total score 0-100 Top=High is good outcome; Comments: Baseline values:
Orthosis+ footwear group: 73 (19)
Footwear group: 79 (10)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 73 (19), footwear group: 79 (10); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 7, Reason: Did not complete outcome measure.; Group 2 Number missing: 6, Reason: Did not complete outcome measure.
- Actual outcome for Knee: EQ-5D- Best imaginable health. at 2 months; Group 1: mean 77.5 (SD 12.2); n=19,
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 71.8 (20.6), footwear group: 75.4 (16.4); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 5, Reason: Did not complete outcome measure.; Group 2 Number missing: 4, Reason: Did not complete outcome measure.
- Actual outcome for Knee: EQ-5D- Best imaginable health. at 4 months; Group 1: mean 79.5 (SD 12); n=20, Group 2: mean 75.2 (SD 18.8); n=19; EQ-5D

Study	ACT12615000002583 trial: Wyndow 2021[196]
Best imaginable health VAS 0-100 Top=High is good outcome; Comments: Baseline values: Orthosis+ footwear group: 71.8 (20.6) Footwear group: 75.4 (16.4) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 71.8 (20.6), footwear group: 75.4 (16.4); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 4, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. Protocol outcome 2: Pain reduction at ≤3- or >3- months - Actual outcome for Knee: KOOS pain subscale at 2 months; Group 1: mean 58.3 (SD 20.3); n=20, Group 2: mean 63.3 (SD 21.9); n=19; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Baseline values: Orthosis+ footwear group: 49.3 (16.8) Footwear group: 51.9 (21.5) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 4, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. - Actual outcome for Knee: KOOS pain subscale at 4 months; Group 1: mean 64 (SD 18.8); n=20, Group 2: mean 66 (SD 22.9); n=19; KOOS pain subscale 0-100 Top=High is good outcome; Comments: Baseline values: Orthosis+ footwear group: 49.3 (16.8) Footwear group: 51.9 (21.5) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 4, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. Protocol outcome 3: Psychological distress at ≤3- or >3- months - Actual outcome for Knee: HADS anxiety at 2 months; Group 1: mean 4.8 (SD 3.6); n=18, Group 2: mean 2.8 (SD 3.1); n=17; HADS anxiety 0-21 Top=High is poor outcome; Comments: Baseline values: Orthosis+ footwear group: 6.5 (4.1) Footwear group: 4.1 (3.3) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 6.5 (4.1), footwear group: 4.1 (3.4); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 6, Reason: Did not complete outcome measure.; Group 2 Number missing: 5, Reason: Did not complete outcome measure. - Actual outcome for Knee: HADS anxiety at 4 months; Group 1: mean 4.6 (SD 4); n=19, Group 2: mean 4 (SD 3.8); n=19; HADS anxiety 0-21 Top=High is poor outcome; Comments: Baseline values: Orthosis+ footwear group: 6.5 (4.1) Footwear group: 4.1 (3.3)	

Study	ACT12615000002583 trial: Wyndow 2021[196]
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 6.5 (4.1), footwear group: 4.1 (3.4); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 5, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. - Actual outcome for Knee: HADS depression at 2 months; Group 1: mean 2.6 (SD 2.4); n=18, Group 2: mean 1.7 (SD 2.4); n=17; HADS depression 0-21 Top=High is poor outcome; Comments: Baseline values: Orthosis+ footwear group: 3 (2.7) Footwear group: 2.8 (2.7) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 6, Reason: Did not complete outcome measure.; Group 2 Number missing: 5, Reason: Did not complete outcome measure. - Actual outcome for Knee: HADS depression at 4 months; Group 1: mean 2.2 (SD 3.1); n=19, Group 2: mean 2.4 (SD 3.4); n=19; HADS depression 0-21 Top=High is poor outcome; Comments: Baseline values: Orthosis+ footwear group: 3 (2.7) Footwear group: 2.8 (2.7) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 5, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. Protocol outcome 4: Adverse events at ≤3- or >3- months - Actual outcome for Knee: Serious adverse events at 2 months; Group 1: 0/24, Group 2: 0/22 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Orthosis+ footwear group: 73 (19), footwear group: 79 (10); Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 10, Reason: Did not complete outcome measure.; Group 2 Number missing: 3, Reason: Did not complete outcome measure. - Actual outcome for Knee: Serious adverse events at 4 months; Group 1: 0/24, Group 2: 0/22 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 2, Reason: 1 withdrew due to a motor vehicle accident, 1 did not respond; Group 2 Number missing: 1, Reason: 1 withdrew due to a (non-serious) adverse event - Actual outcome for Knee: Mild/ moderate adverse events at 4 months; Group 1: 1/24, Group 2: 2/22; Comments: One participant withdrew in the footwear group due to low back pain, and another experienced mild unilateral arch pain in the first month of wearing the footwear, however it did not require additional interventions and resolved completely with no reoccurrence after 4 weeks. One participant in the foot orthosis plus footwear group experienced low back pain from sitting for prolonged periods at a conference. The pain resolved after not per-protocol health care and was considered unlikely to be related to the intervention. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,	

Study	ACT12615000002583 trial: Wyndow 2021[196]
Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Assessor was patient who was not blinded.; Group 1 Number missing: 2, Reason: 1 withdrew due to a motor vehicle accident, 1 did not respond; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Physical function at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months

Study	NCT02984254 trial: Yamamoto 2019[199]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=60)
Countries and setting	Conducted in Brazil; Setting: Department of Orthopedics and Traumatology, Faculdade de Medicina, Universidade de Sa Paolo.
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: The diagnosis of PFOA OA was made using the clinical criteria of the ACR, i.e. presence of symptoms (pain and sensitivity) in the patellofemoral compartment of the knee, associated with signs of OA according to K-L classification, and showing no misalignment.
Stratum	Knee
Subgroup analysis within study	Not applicable
Inclusion criteria	Symptomatic PFOA knee OA, absence of axis dislocation, age ≥ 30 years, and clinical treatment for knee OA for > 6 months.
Exclusion criteria	Those who could not read or understand the consent form or the WOMAC questionnaire, and patients with grade II and III or morbid obesity were also not included. Other exclusion criteria were: brace used differently from what was requested, abandonment of the study, non-adaptation to the brace, skin and vascular complications due to brace use, failure to report medication use for the month between signing the consent and brace placement.
Recruitment/selection of patients	Not reported.
Age, gender and ethnicity	Age - Mean (SD): 64.2 (7.8). Gender (M:F): 10M/ 47F. Ethnicity: Not reported
Further population details	1. Age: <75 years (Age 30-70 years). 2. Diagnostic method: Diagnosed with imaging 3. Multimorbidities: Not stated / Unclear (Participants had 2 or more of: overweight or obesity, hyperglycaemia, dyslipidaemia, hyperuricaemia, high blood pressure.).

Study	NCT02984254 trial: Yamamoto 2019[199]
Extra comments	Severity (WOMAC pain at baseline): bracing group: 8.5 (4), sham group: 9.1 (3.3)/ K-L II/III excluded Duration: participants had been receiving treatment for knee OA for > 6 months
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Braces. Patellofemoral functional brace. A knee brace made of neoprene with upper, lower and lateral impact absorption system. Patients were instructed to use the brace for 2 hours in the first day increasing half an hour per day up to a maximum of 12 hours/ day. In case of difficulties with the brace for 12 continuous hours, they were allowed to use it for at least 4 hours with a 2 hour interval (from the second week) and then again returning to bracing. They were to sleep/ rest without the brace(s), and to use their braces during physical activities if under water. All patients attended a half day course on OA and its forms of treatment base on an OA disease group educational programme for patients with knee OA.. Duration 3 months. Concurrent medication/care: Medications for pain control were permitted and recorded.. Indirectness: No indirectness (n=30) Intervention 2: Sham device. Neoprene knee brace with a patellar orifice. A patella- shaped neoprene knee brace with lateral reinforcement. Patients were instructed to use the brace for 2 hours in the first day increasing half an hour per day up to a maximum of 12 hours/ day. In case of difficulties with the brace for 12 continuous hours, they were allowed to use it for at least 4 hours with a 2 hour interval (from the second week) and then again returning to bracing. They were to sleep/ rest without the brace(s), and to use their braces during physical activities if under water.. Duration 3 months. Concurrent medication/care: Medications for pain control were permitted and recorded.. Indirectness: No indirectness
Funding	Equipment / drugs provided by industry (Knee orthoses donated by Salvape Produtos Ortopedicos Ltda. and the sponsorship of the PARQVE program by TRB Pharma Brazil.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRACES versus SHAM DEVICE

Protocol outcome 1: Pain reduction at ≤3- or >3- months
- Actual outcome for Knee: WOMAC pain at 3 months; Group 1: mean 6.5 (SD 4.2); n=28, Group 2: mean 6.4 (SD 4.4); n=29; WOMAC pain subscale 0-20 Top=High is poor outcome; Comments: Baseline values
knee bracing group: 8.5 (4), sham group: 9.1 (3.3)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Open-label ; Group 1 Number missing: 2, Reason: Did not attend the session for knee brace retrieval.; Group 2 Number missing: 1, Reason: Did not attend the session for knee brace retrieval.

Protocol outcome 2: Physical function at ≤3- or >3- months
- Actual outcome for Knee: WOMAC function at 3 months; Group 1: mean 22.9 (SD 14.2); n=28, Group 2: mean 26.4 (SD 15.5); n=29; WOMAC function subscale 0-68 Top=High is poor outcome; Comments: Baseline values
knee brace group: 30.3 (14.3), sham group: 31.6 (10.7)

Study	NCT02984254 trial: Yamamoto 2019[199]
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Blinding details: Open-label ; Group 1 Number missing: 2, Reason: Did not attend the session for knee brace retrieval.; Group 2 Number missing: 1, Reason: Did not attend the session for knee brace retrieval.	
Protocol outcomes not reported by the study	Quality of life at ≤3- or >3- months; Psychological distress at ≤3- or >3- months; Osteoarthritis flare-ups at ≤3- or >3- months; Adverse events at ≤3- or >3- months

Appendix E – Forest plots

E.1 Knee osteoarthritis

E.1.1 Insoles compared to sham devices

Figure 2: Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months

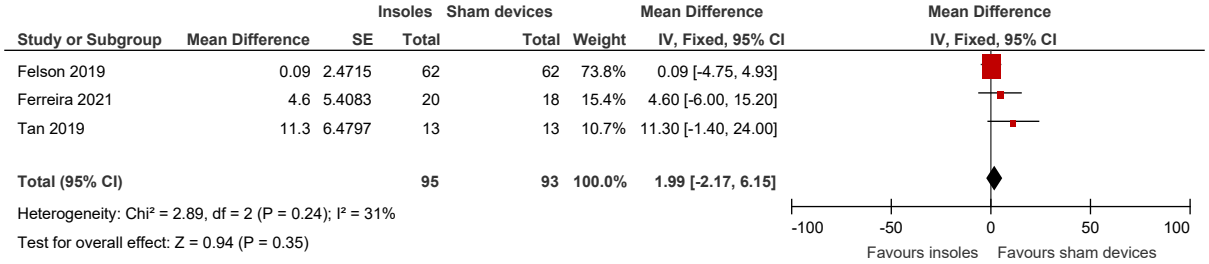


Figure 3: Quality of life (assessment of quality of life instrument, -0.04-1.00, change scores, high is good) at >3 months

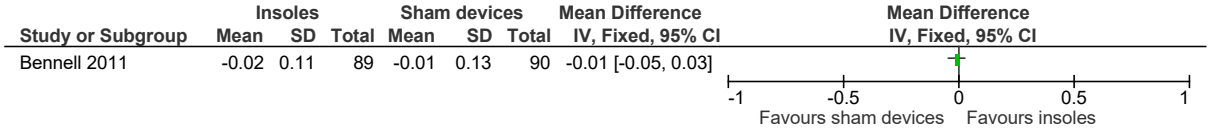


Figure 4: Pain (VAS, 0-100, high is poor, change score, parallel trial) at ≤3 months

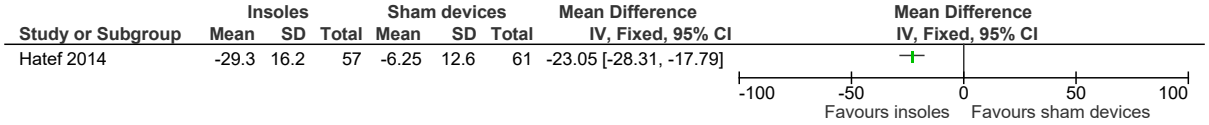


Figure 5: Pain (KOOS, WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months

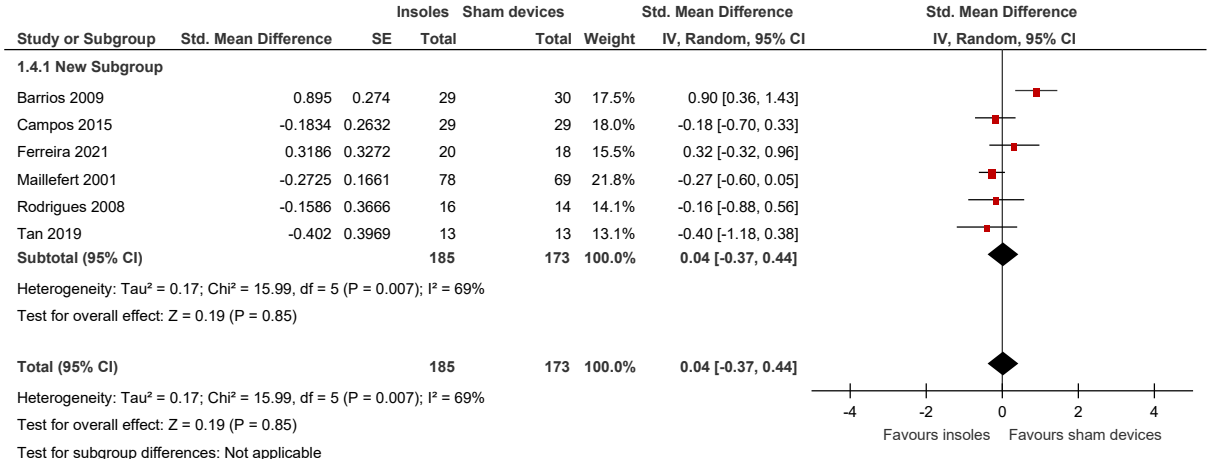


Figure 6: Pain (WOMAC, 0-500, high is poor, mean difference, change score, crossover trial) at ≤3 months

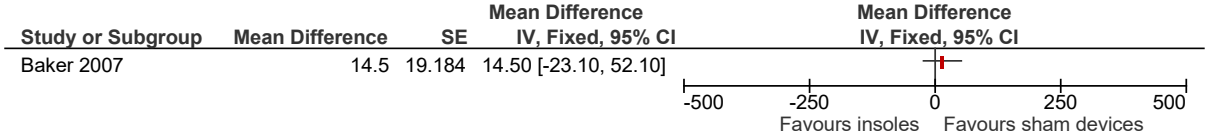


Figure 7: Pain (KOOS, 0-100, high is good, final value, crossover trial) at ≤3 months

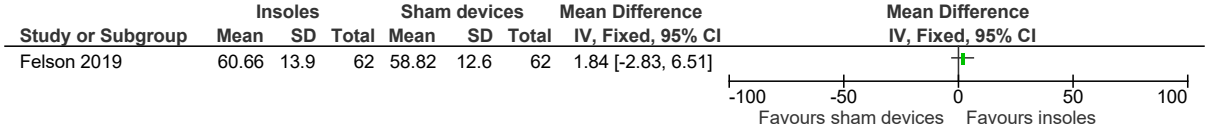


Figure 8: Pain (WOMAC, VAS [different scale ranges], high is poor, final values) at >3 months

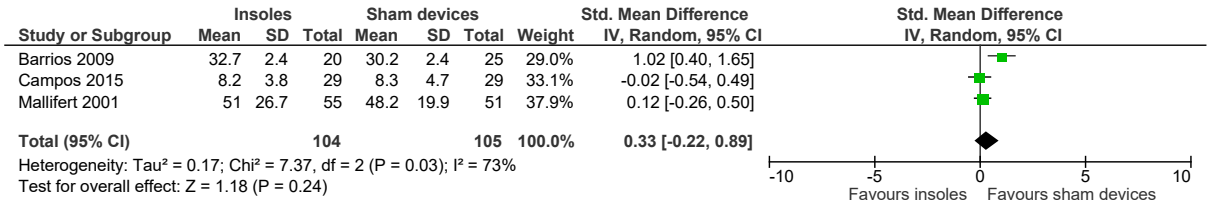


Figure 9: Pain (WOMAC, 0-20, high is poor, change score) at >3 months

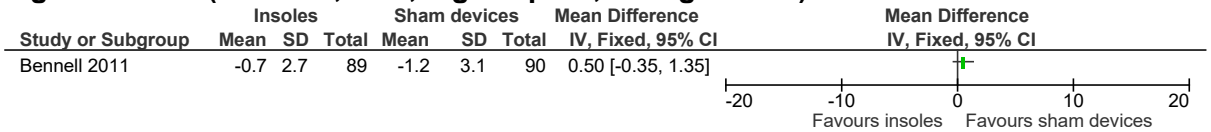


Figure 10: Physical function (KOOS, WOMAC, 0-100, high is poor, final values) at ≤3 months

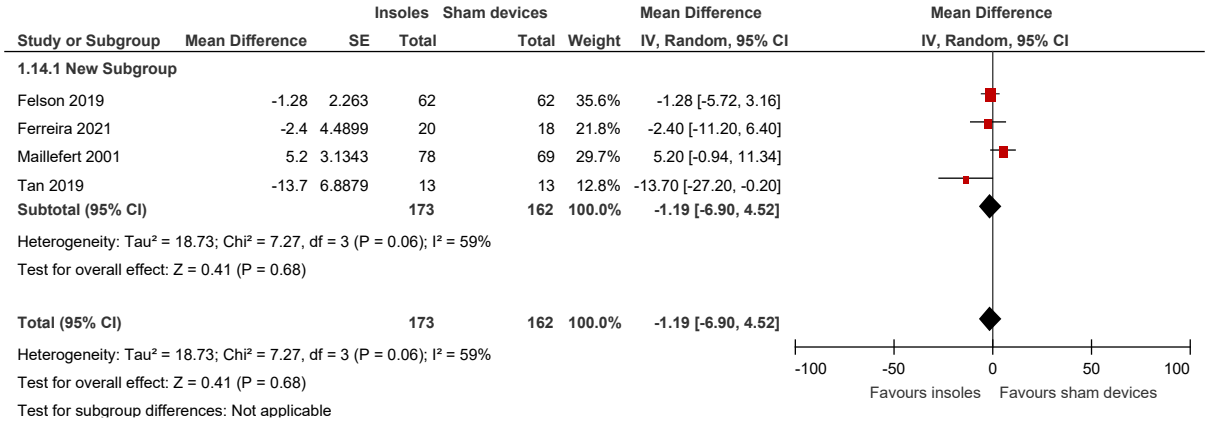


Figure 11: Physical function (WOMAC, Edinburgh Knee Function Scale [different scale ranges], high is poor, change scores) at ≤3 months

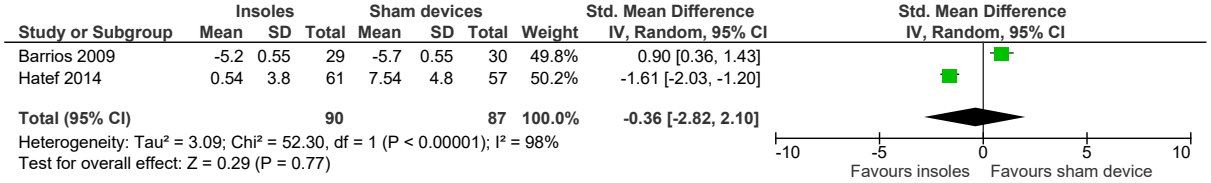


Figure 12: Physical function (WOMAC, 0-100, high is poor, final value) at >3 months

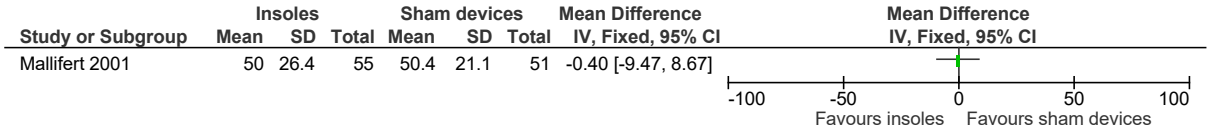


Figure 13: Physical function (WOMAC, high is poor, change scores) at >3 months

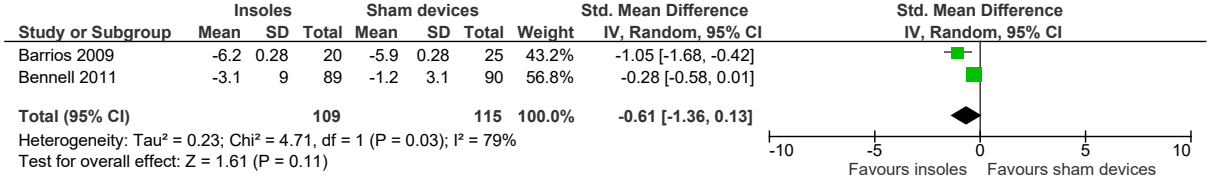


Figure 14: Number of adverse events at ≤3 months

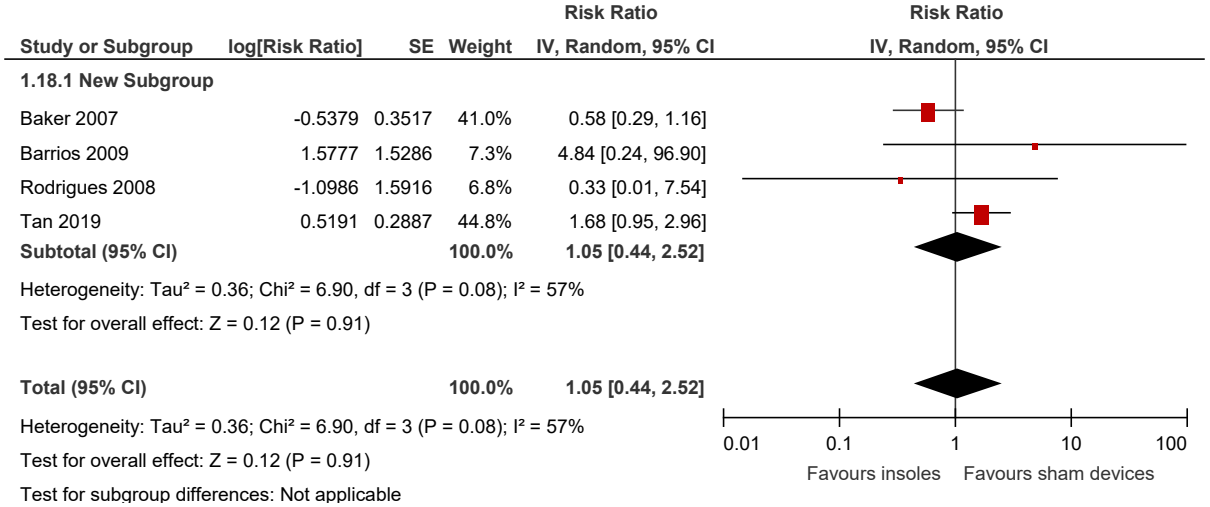
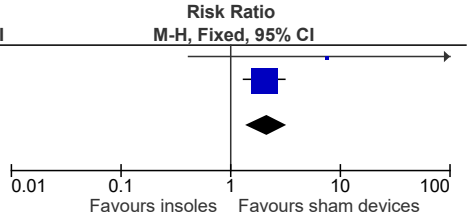


Figure 15: Number of adverse events at >3 months

Study or Subgroup	Insoles Events	Total	Sham devices Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Barrios 2009	3	23	0	25	2.2%	7.58 [0.41, 139.32]
Bennell 2011	42	89	21	90	97.8%	2.02 [1.31, 3.12]
Total (95% CI)		**112**		**115**	**100.0%**	**2.15 [1.40, 3.30]**
Total events	45		21			

Heterogeneity: Chi² = 0.79, df = 1 (P = 0.37); I² = 0%
Test for overall effect: Z = 3.48 (P = 0.0005)



E.1.2 Insoles compared to no device intervention

Figure 16: Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months

Study or Subgroup	Insoles Mean	SD	Total	No device intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Lewinson 2016	42.1	14.3	15	36.1	17.1	18	49.4%	6.00 [-4.71, 16.71]
Salam 2019	70.7	14.58225	20	28.85	9.59317	20	50.6%	41.85 [34.20, 49.50]
Total (95% CI)			**35**			**38**	**100.0%**	**24.13 [-11.00, 59.26]**

Heterogeneity: Tau² = 620.06; Chi² = 28.49, df = 1 (P < 0.00001); I² = 96%
Test for overall effect: Z = 1.35 (P = 0.18)

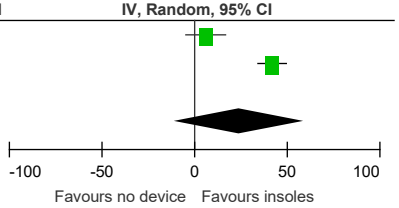


Figure 17: Quality of life (EQ-5D VAS total score, 0-100, high is good, final value) at ≤3 months

Study or Subgroup	Insoles Mean	SD	Total	No device intervention Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Wyndow 2021	80	11	17	86	12	14	-6.00 [-14.18, 2.18]

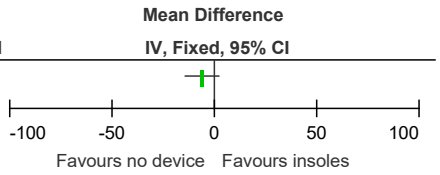


Figure 18: Quality of life (EQ-5D VAS total score, 0-100, high is good, final value) at >3 months

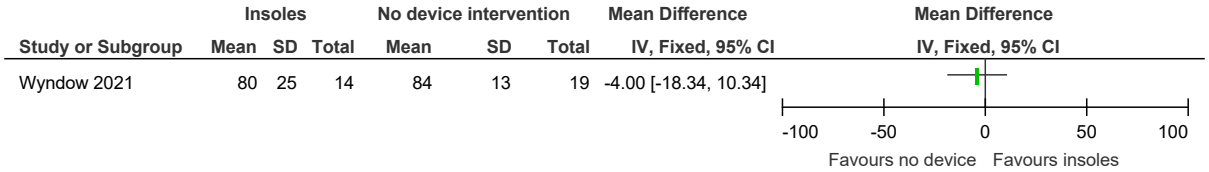


Figure 19: Pain (WOMAC pain subscale and KOOS pain subscale, high is poor, final values) at ≤3 months

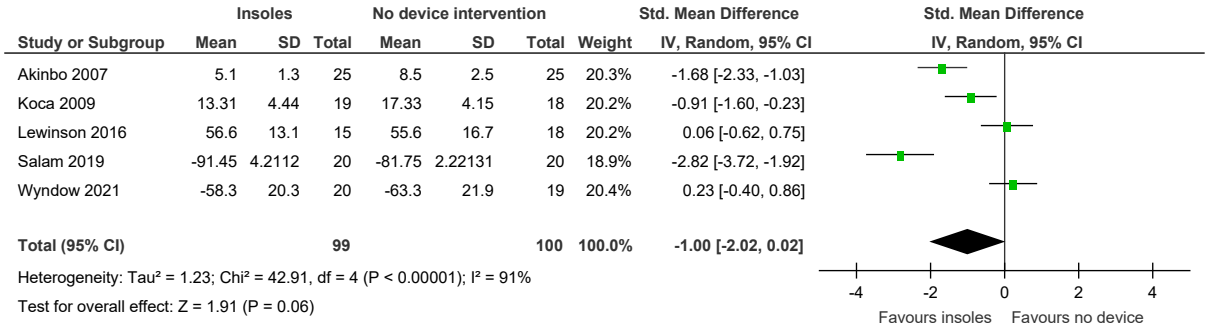


Figure 20: Pain (KOOS, VAS, 0-100, high is good, final values) at >3 months

Study or Subgroup	Insoles Mean	SD	Total	No device intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Sattari 2011	-43	12	20	-59	11	20	54.9%	16.00 [8.87, 23.13]
Wyndow 2021	64	18.8	20	66	22.9	19	45.1%	-2.00 [-15.19, 11.19]
Total (95% CI)			**40**			**39**	**100.0%**	**7.89 [-9.66, 25.44]**

Heterogeneity: Tau² = 132.74; Chi² = 5.54, df = 1 (P = 0.02); I² = 82%

Test for overall effect: Z = 0.88 (P = 0.38)

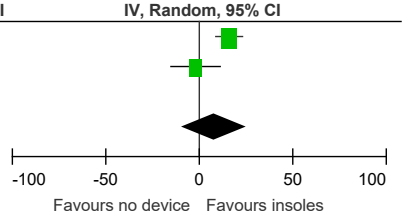


Figure 21: Physical function (WOMAC,KOOS, high is poor, final values) at ≤3 months

Study or Subgroup	Insoles Mean	SD	Total	No device intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Akinbo 2007	16.1	5.2	25	23.3	3.8	25	33.8%	-1.56 [-2.20, -0.92]
Koca 2009	46.16	15.18	19	57.94	13.98	18	33.2%	-0.79 [-1.46, -0.12]
Lewinson 2016	-64	17.8	18	-64	15.2	15	33.0%	0.00 [-0.69, 0.69]
Total (95% CI)			**62**			**58**	**100.0%**	**-0.79 [-1.67, 0.10]**

Heterogeneity: Tau² = 0.50; Chi² = 10.61, df = 2 (P = 0.005); I² = 81%

Test for overall effect: Z = 1.75 (P = 0.08)

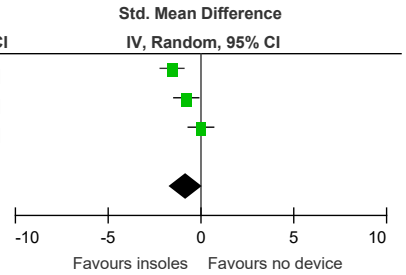


Figure 22: Psychological distress (HADS anxiety, 0-21, high is poor, final values) at ≤3 months

Study or Subgroup	Insoles Mean	SD	Total	No device intervention Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Wyndow 2021	4.8	3.6	18	2.8	3.1	17	2.00 [-0.22, 4.22]

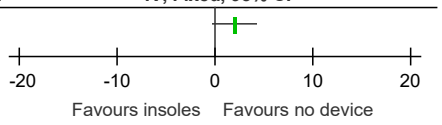


Figure 23: Psychological distress (HADS depression, 0-21, high is poor, final values) at ≤3 months

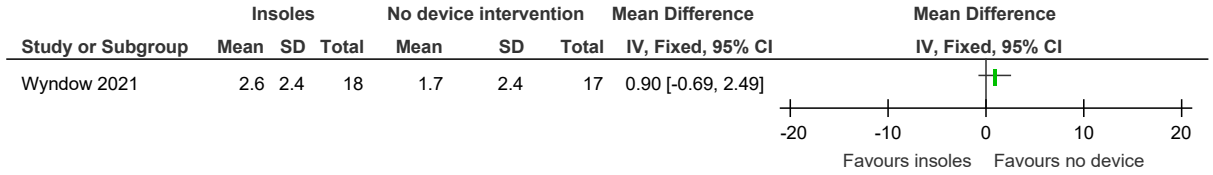


Figure 24: Psychological distress (HADS anxiety, 0-21, high is poor, final values) at >3 months

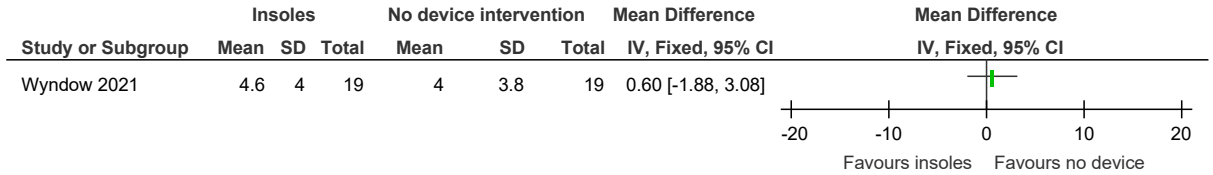


Figure 25: Psychological distress (HADS depression, 0-21, high is poor, final values) at >3 months

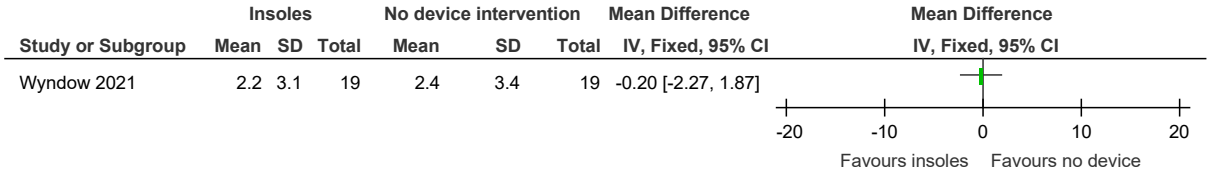
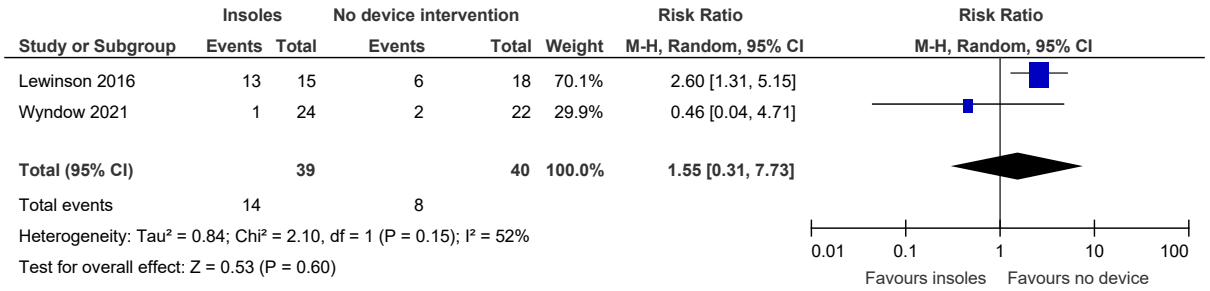


Figure 26: Adverse events at ≤3 months



E.1.3 Shoes compared to sham devices

Figure 27: Quality of life (SF-36 physical component, 0-100, high is good, final values) at ≤3 months

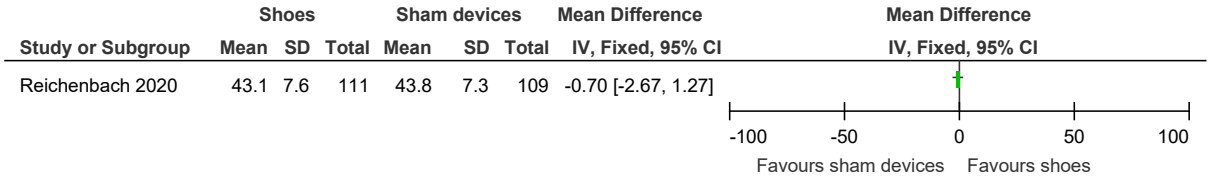


Figure 28: Quality of life (SF-36 mental component, 0-100, high is good, final values) at ≤3 months

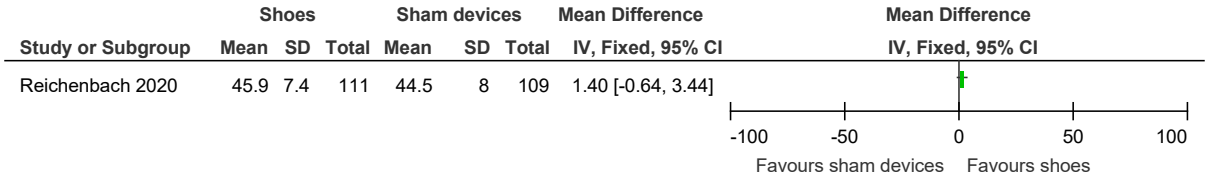


Figure 29: Quality of life (AQoL-6D, -0.04-1, high is good, change scores) at >3 months

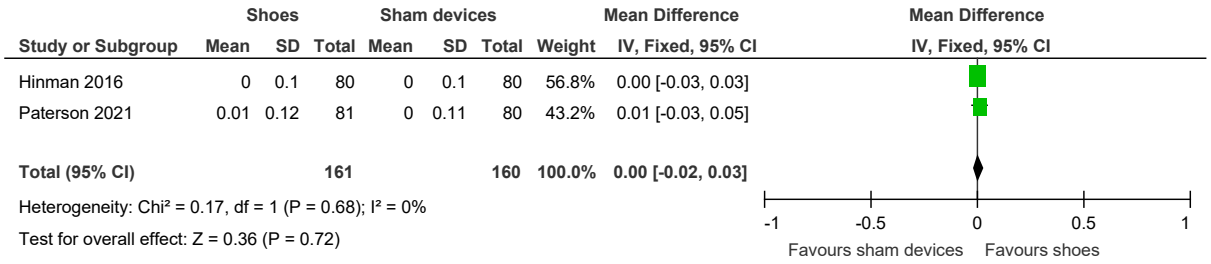


Figure 30: Quality of life (SF-36 physical component, 0-100, high is good, final values) at >3 months

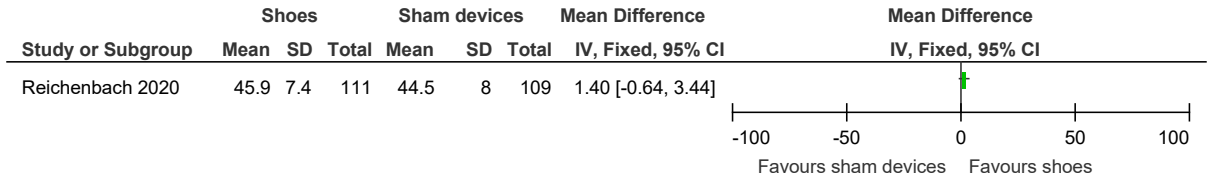


Figure 31: Quality of life (SF-36 mental component, 0-100, high is good, final values) at >3 months

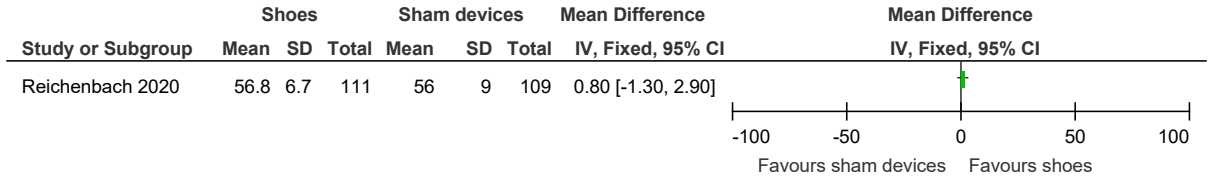


Figure 32: Pain (WOMAC pain [different scale ranges], high is poor, change scores) at ≤3 months

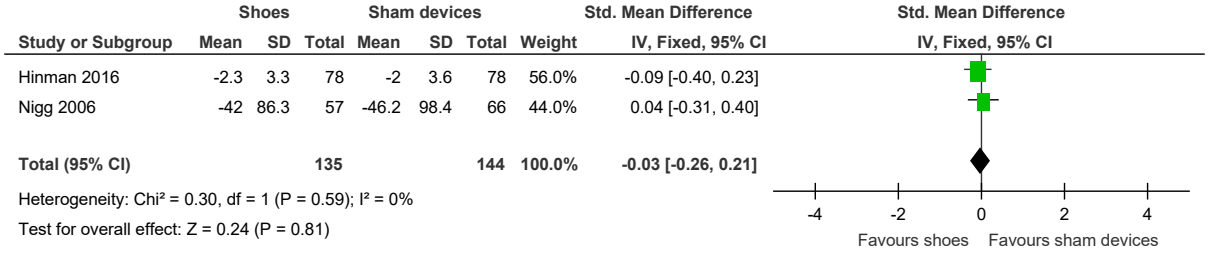


Figure 33: Pain (WOMAC, 0-10, high is poor, final value) at ≤3 months

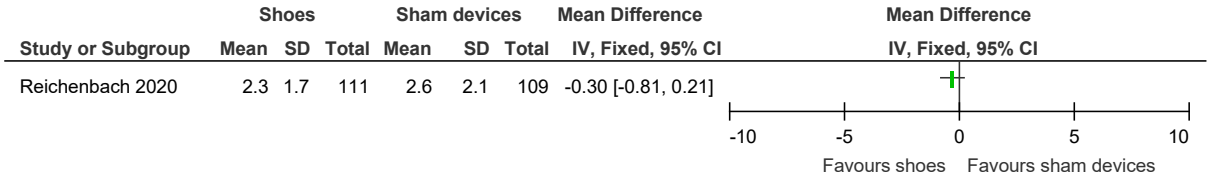


Figure 34: Pain (KOOS, WOMAC [different scale ranges], high is poor, change scores) at >3 months

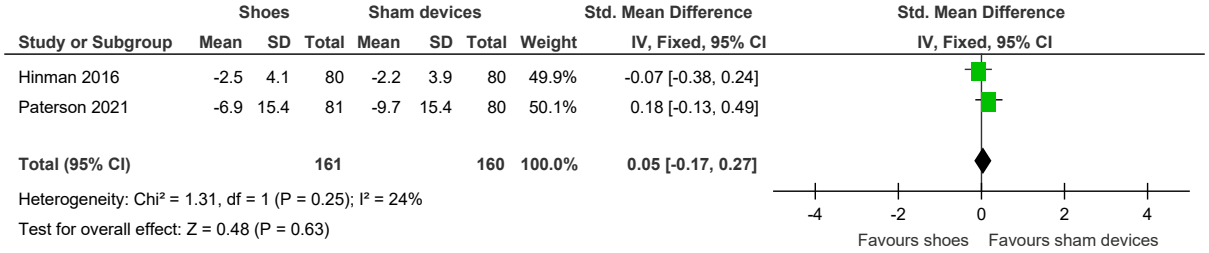


Figure 35: Pain (WOMAC [different scale ranges], high is poor, final values) at >3 months

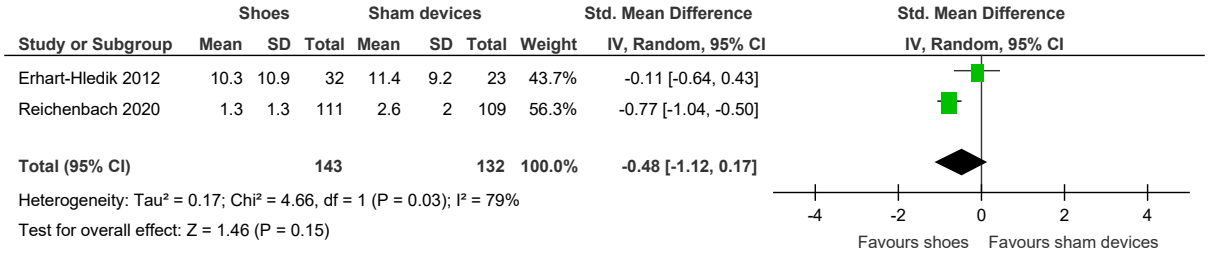


Figure 36: Physical function (WOMAC [different scale ranges], high is poor, change scores) at ≤3 months

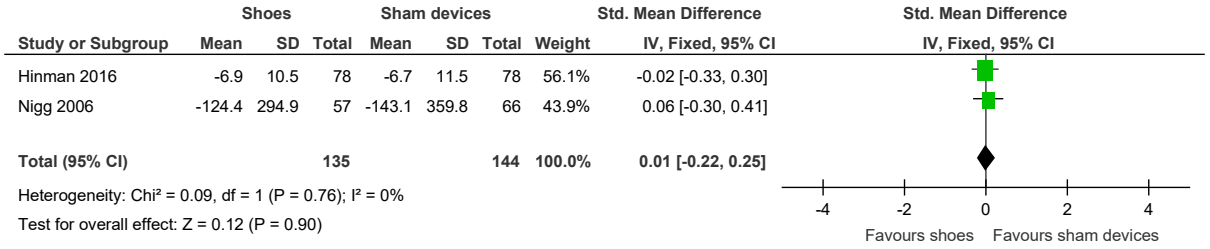


Figure 37: Physical function (WOMAC, 0-10, high is poor, final value) at ≤3 months

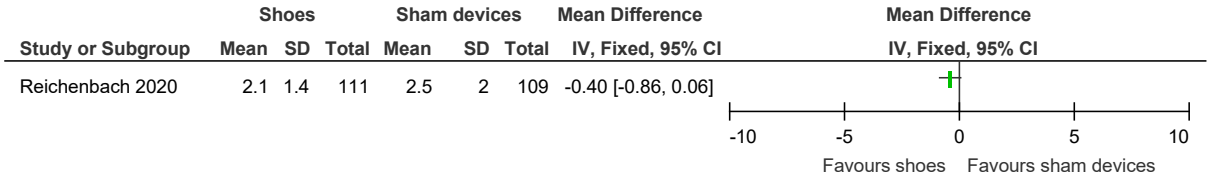


Figure 38: Physical function (WOMAC, 0-68, high is poor, change scores) at >3 months

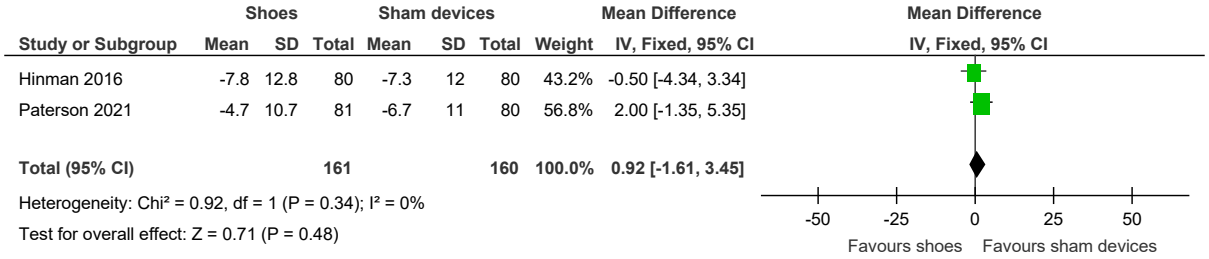


Figure 39: Physical function (WOMAC [different scale ranges], high is poor, final values) at >3 months

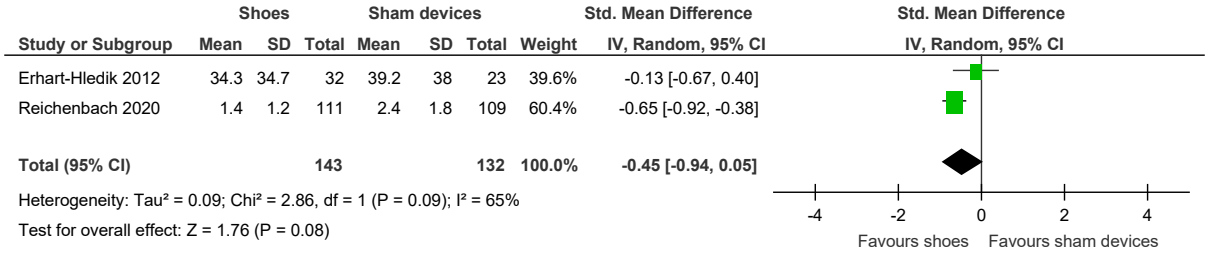
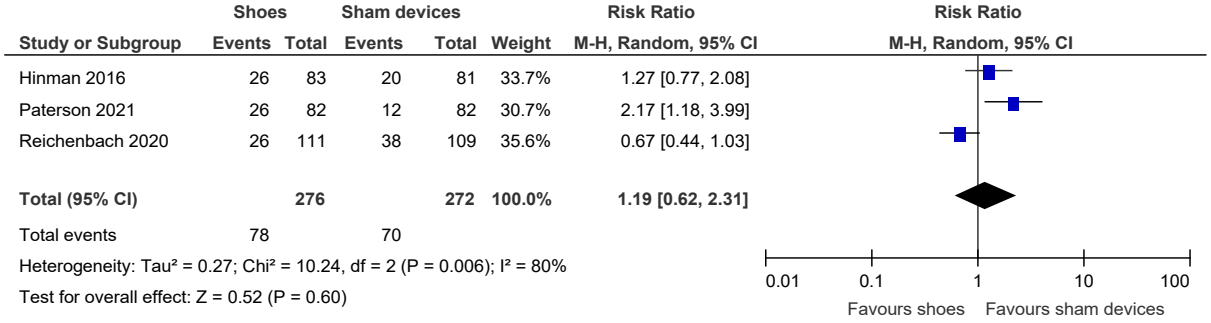


Figure 40: Number of adverse events at >3 months



E.1.4 Braces compared to insoles

Figure 41: Pain (WOMAC, VAS, 0-100, high is poor, final values) at ≤3 months

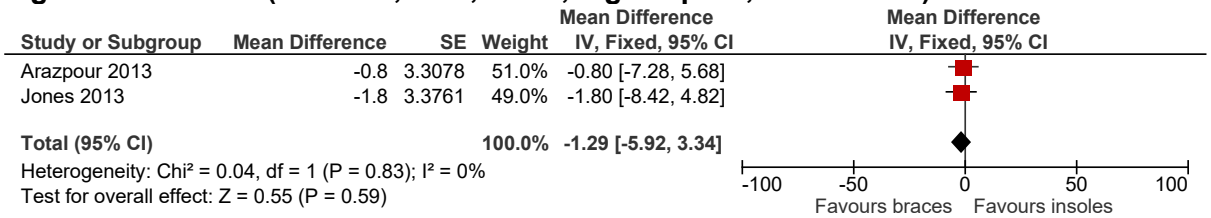


Figure 42: Pain (VAS, 0-10, high is poor, change score and final values) at >3 months

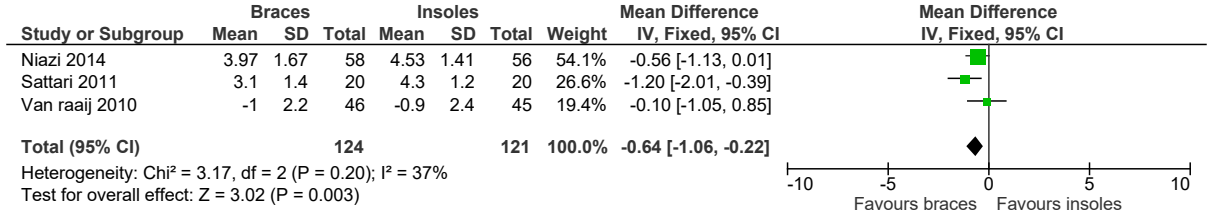


Figure 43: Physical function (WOMAC, 0-100, high is poor, final values) at ≤3 months

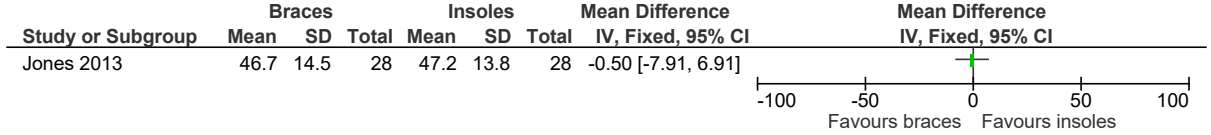


Figure 44: Physical function (WOMAC, 0-100, high is good, change score) at >3 months

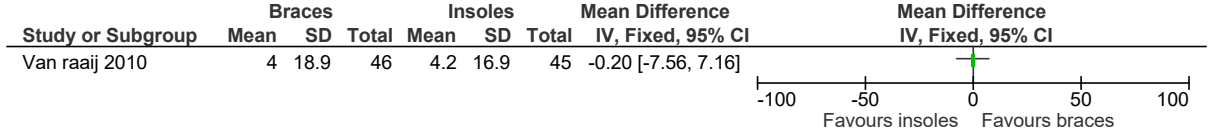
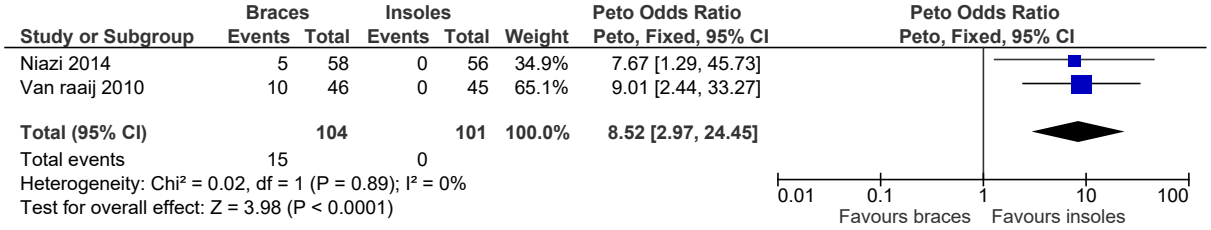


Figure 45: Number of adverse events at >3 months



E.1.5 Braces compared to supports

Figure 46: Pain (WOMAC, 0-500, high is poor, change score) at >3 months

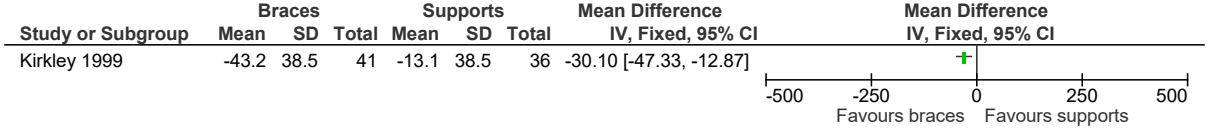
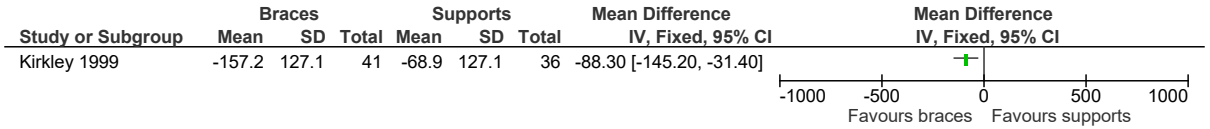


Figure 47: Physical function (WOMAC, 0-1700, high is poor, change score) at >3 months



E.1.6 Braces compared to sham devices

Figure 48: Quality of life (KOOS, 0-100, high is good, change score) at >3 months

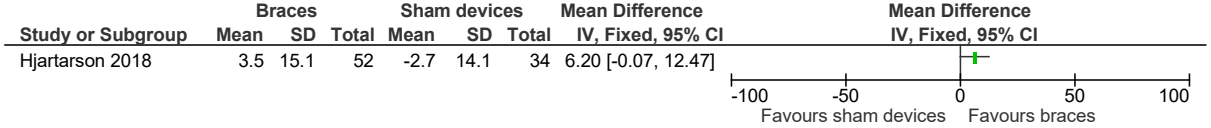


Figure 49: Pain (WOMAC, 0-20, high is poor, final value) at ≤3 months

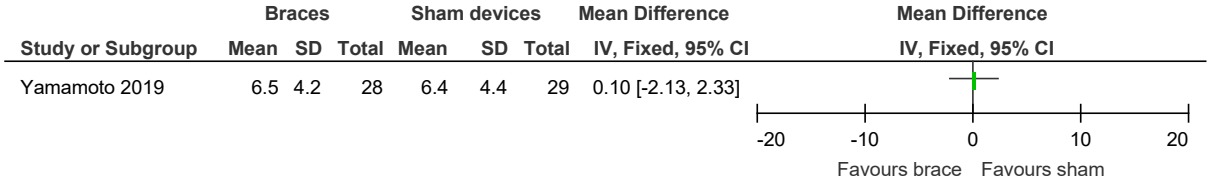


Figure 50: Pain (KOOS, 0-100, high is good, change score) at >3 months

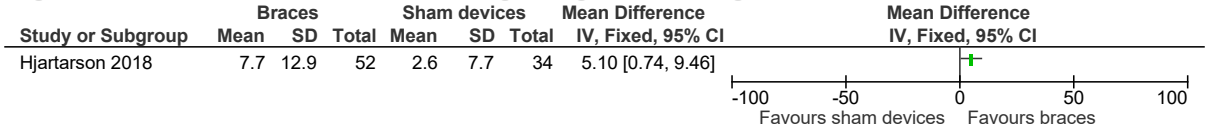


Figure 51: Physical function (WOMAC, 0-68, high is poor, final value) at ≤3 months

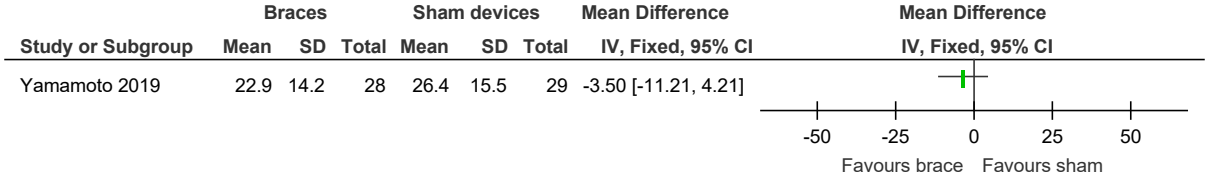
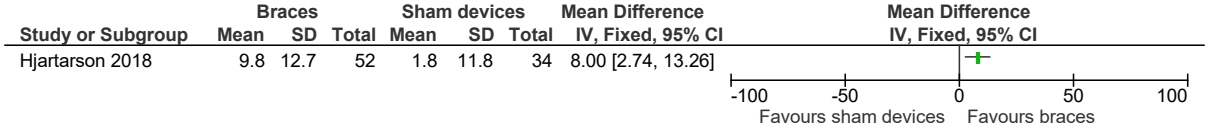


Figure 52: Physical function (KOOS, 0-100, high is good, change score) at >3 months



E.1.7 Braces compared to no device intervention

Figure 53: Quality of life (EQ-5D, mean difference, 0-1, high is good) at ≤3 months

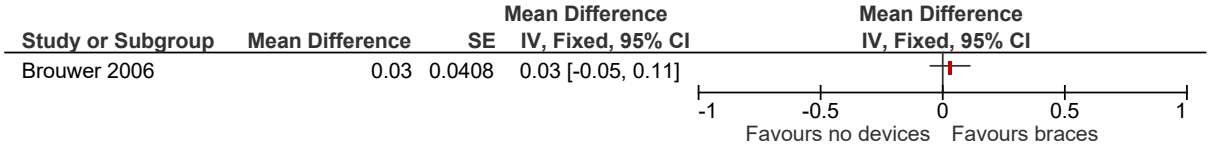


Figure 54: Quality of life (EQ-5D, mean difference, 0-1, high is good) at >3 months

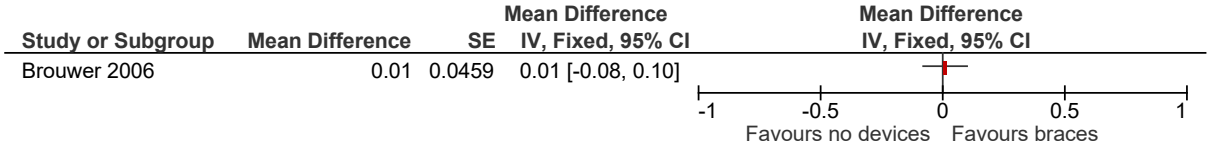


Figure 55: Quality of life (KOOS, 0-100, high is good, change score) at >3 months

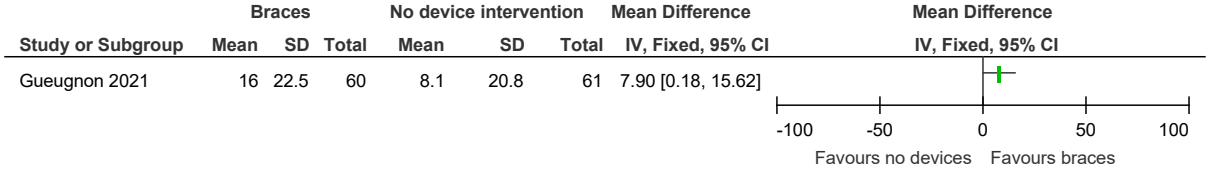


Figure 56: Pain (KOOS pain subscale and visual analogue scale, 0-100, high is poor, final values and change score) at ≤3 months

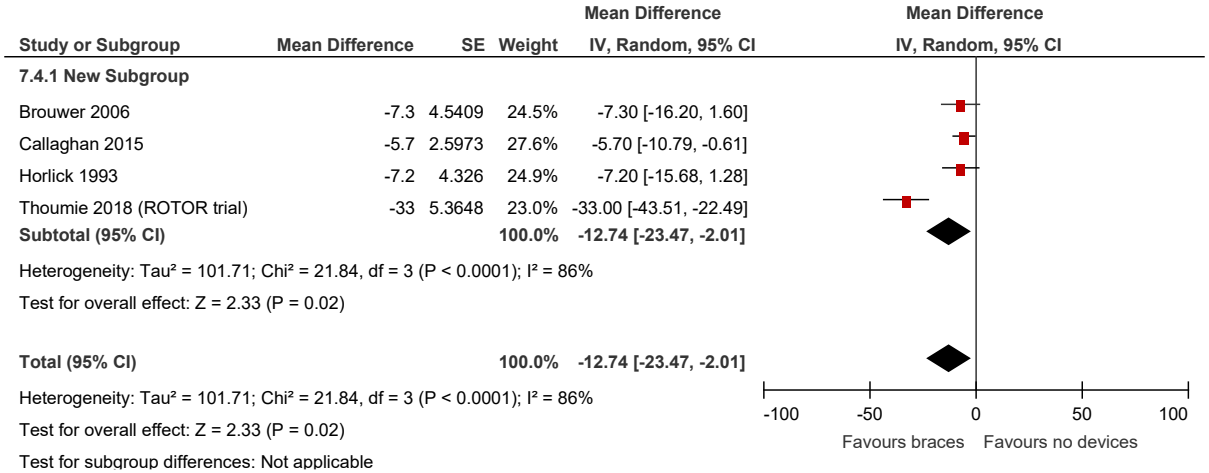


Figure 57: Pain (KOOS pain, WOMAC pain subscale [different scale ranges], high is poor, change scores) at >3 months

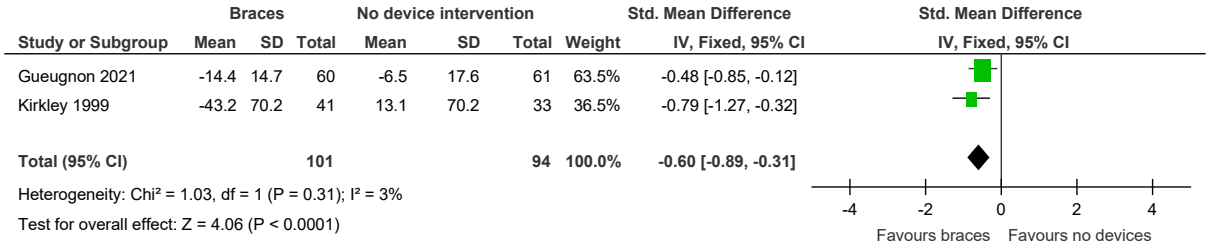


Figure 58: Pain (Visual analogue scale, 0-10, high is poor, final value and change score) at >3 months

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Brouwer 2006	-0.81	0.4847	49.0%	-0.81 [-1.76, 0.14]
Sattari 2011	-2.8	0.3981	51.0%	-2.80 [-3.58, -2.02]
Total (95% CI)			**100.0%**	**-1.82 [-3.77, 0.13]**

Heterogeneity: Tau² = 1.78; Chi² = 10.07, df = 1 (P = 0.002); I² = 90%
Test for overall effect: Z = 1.83 (P = 0.07)

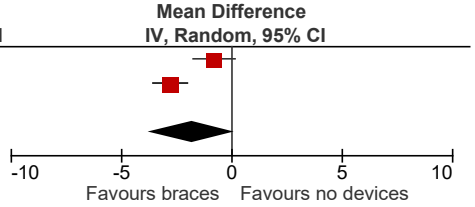


Figure 59: Pain (WOMAC pain subscale, 0-500, high is poor, change score) at >3 months

Study or Subgroup	Braces Mean	SD	Total	No device intervention Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Kirkley 1999	-43.2	70.2	41	13.1	70.2	33	-56.30 [-88.48, -24.12]

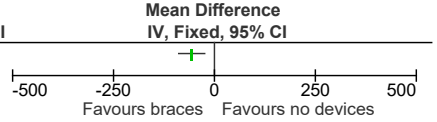


Figure 60: Physical function (KOOS function in activities of daily living, WOMAC physical function subscale [different scale ranges], high is poor, change scores) at >3 months

Study or Subgroup	Braces Mean	SD	Total	No device intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Gueugnon 2021	-12.6	17	60	-5.1	18.9	61	63.2%	-0.41 [-0.77, -0.05]
Kirkley 1999	-157.2	235.4	41	6.5	235.4	33	36.8%	-0.69 [-1.16, -0.22]
Total (95% CI)			**101**			**94**	**100.0%**	**-0.52 [-0.80, -0.23]**

Heterogeneity: Chi² = 0.82, df = 1 (P = 0.37); I² = 0%
Test for overall effect: Z = 3.52 (P = 0.0004)

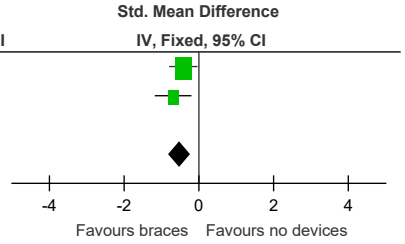


Figure 61: Adverse events at ≤3 months

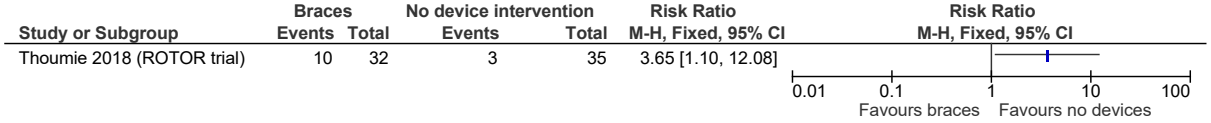
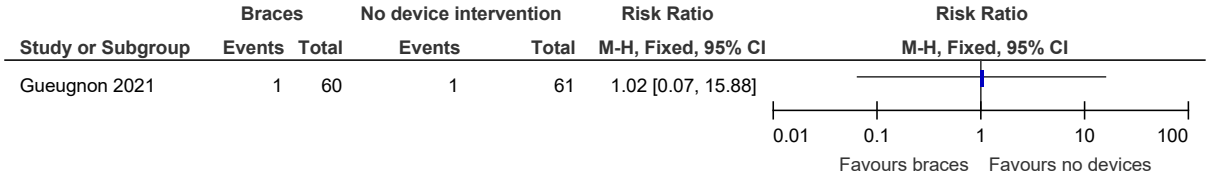


Figure 62: Number of adverse events at >3 months



E.1.8 Supports compared to no device intervention

Figure 63: Pain (WOMAC pain subscale, 0-500, high is poor, change score) at >3 months

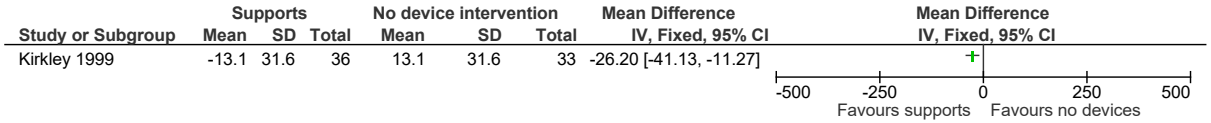
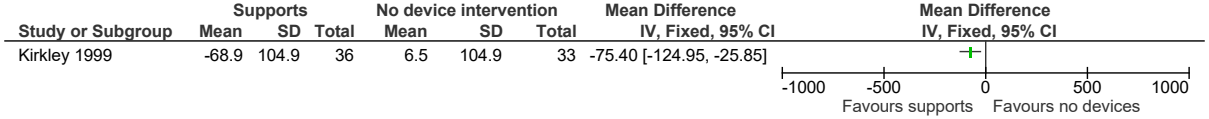


Figure 64: Physical function (WOMAC physical function subscale, 0-1700, high is poor, change score) at >3 months



E.1.9 Tape compared to sham devices

Figure 65: Quality of life (KOOS, Nottingham Health Profile [different scale ranges], high is poor, final values) at ≤3 months

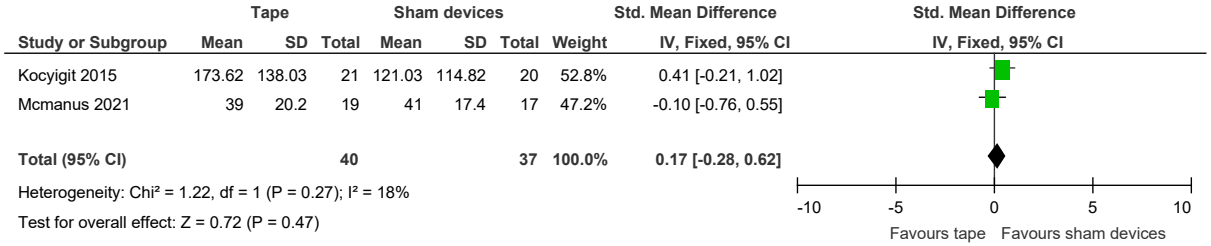


Figure 66: Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months

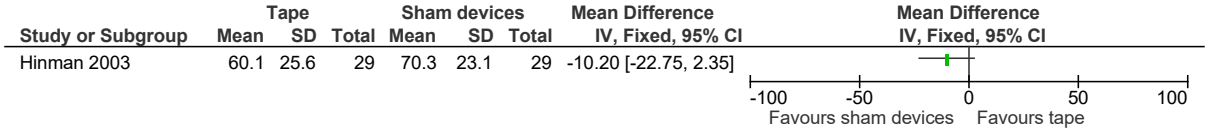


Figure 67: Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months

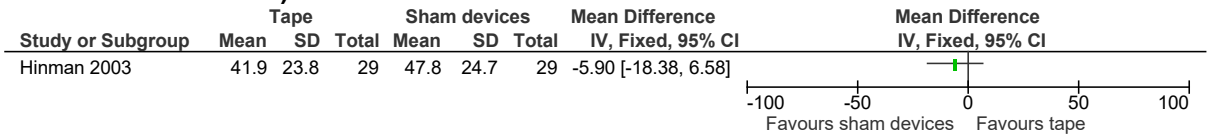


Figure 68: Quality of life (SF-36 physical role subscale, 0-100, high is good, final value) at ≤3 months

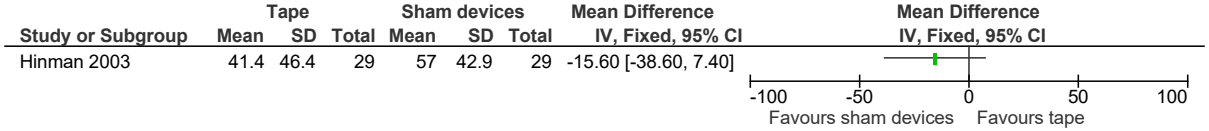


Figure 69: Pain (KOOS, WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months

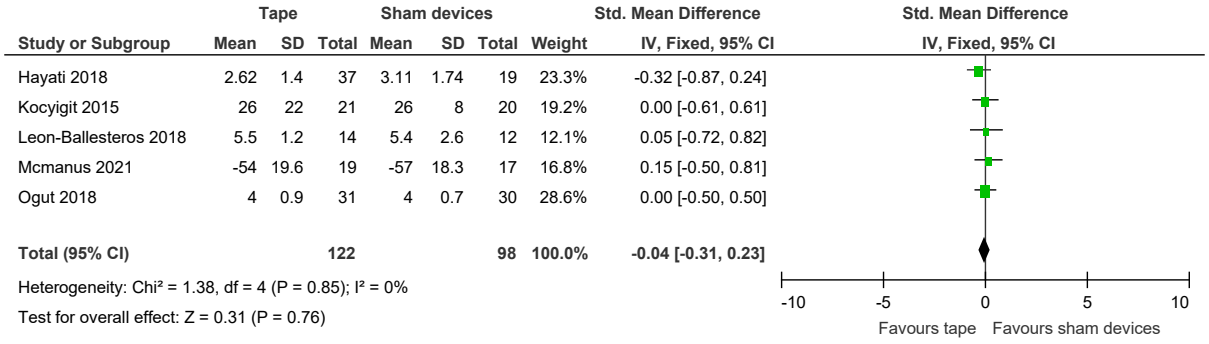


Figure 70: Pain (WOMAC, 0-20, high is poor, final values, crossover trials) at ≤3 months

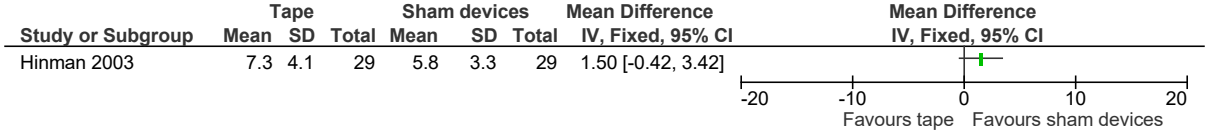


Figure 71: Pain (VAS, 0-10, high is poor, change score) at ≤3 months

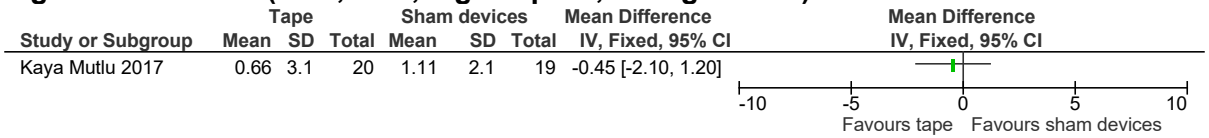


Figure 72: Physical function (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months

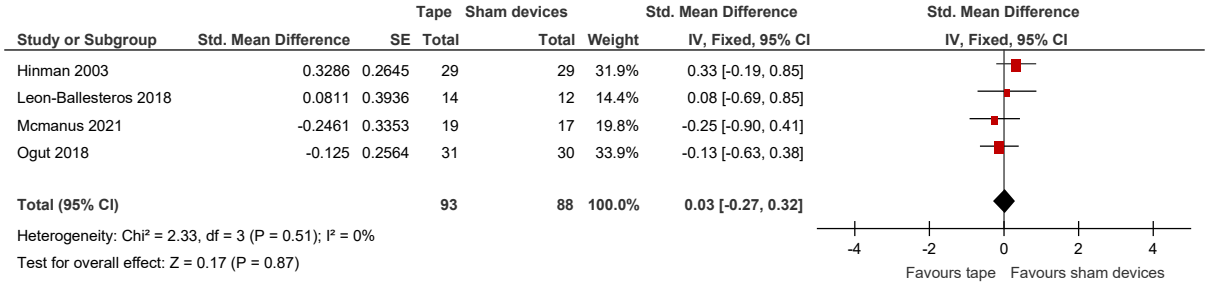
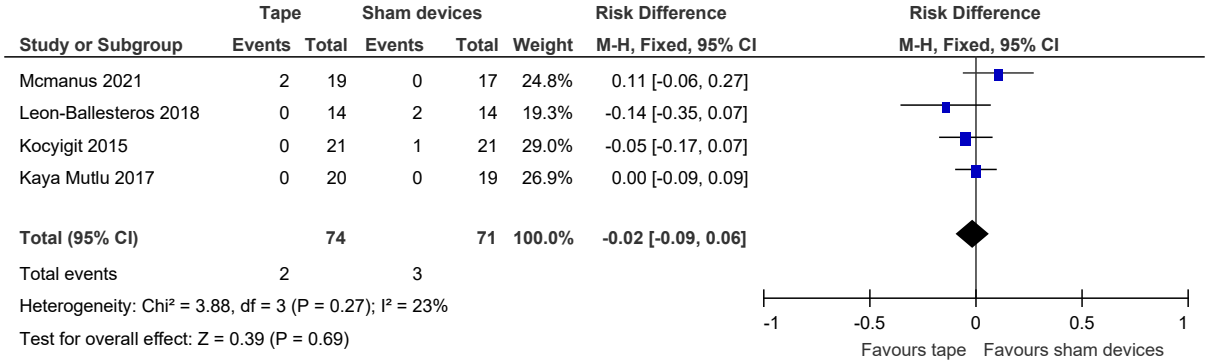


Figure 73: Number of adverse events at ≤3 months



E.1.10 Tape compared to no device intervention

Figure 74: Quality of life (KOOS, 0-100, high is good, final value) at ≤3 months

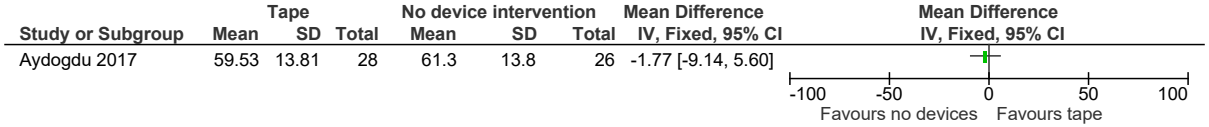


Figure 75: Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months

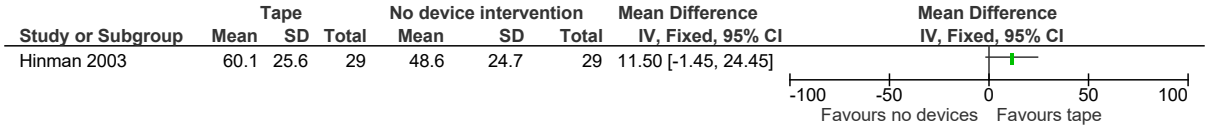


Figure 76: Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months

	Tape			No device intervention			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Hinman 2003	41.9	23.8	29	38.7	25.1	29	3.20 [-9.39, 15.79]	

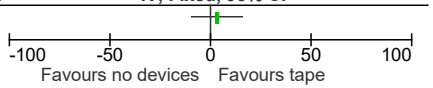


Figure 77: Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months

	Tape			No device intervention			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Hinman 2003	41.4	46.4	29	34.6	44.5	29	6.80 [-16.60, 30.20]	

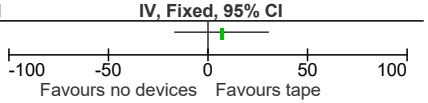


Figure 78: Pain (KOOS, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months

	Tape			No device intervention				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Aydogdu 2017	74.57	10.89	26	73.21	10.43	28	22.1%	0.13 [-0.41, 0.66]	
Gunaydin 2020	3.05	2.36	20	2.74	2.16	20	21.0%	0.13 [-0.49, 0.75]	
Lee 2016	4.3	1.2	15	5.7	0.9	15	18.9%	-1.28 [-2.08, -0.49]	
Oguz 2021	3.55	1.69	11	2.82	1.54	11	18.2%	0.43 [-0.41, 1.28]	
Taheri 2017	2	1.13	20	4.13	2.3	16	19.8%	-1.19 [-1.91, -0.47]	
Total (95% CI)			**92**			**90**	**100.0%**	**-0.34 [-1.01, 0.33]**	

Heterogeneity: Tau² = 0.46; Chi² = 18.95, df = 4 (P = 0.0008); I² = 79%

Test for overall effect: Z = 1.00 (P = 0.32)

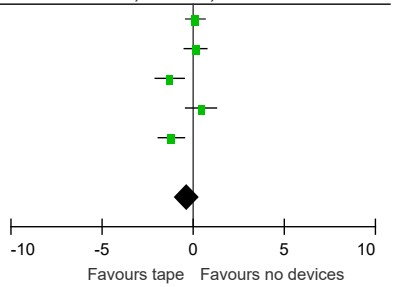


Figure 79: Pain (WOMAC, 0-20, high is poor, final value, crossover trial) at ≤3 months

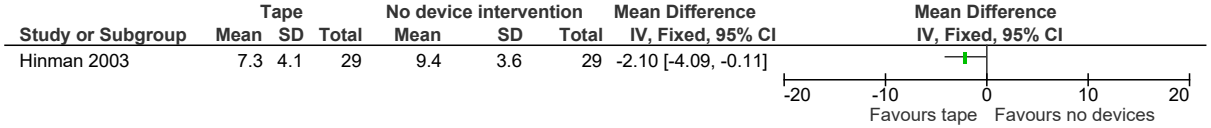


Figure 80: Physical function (KOOS, 0-100, high is good, final value, parallel trial) at ≤3 months

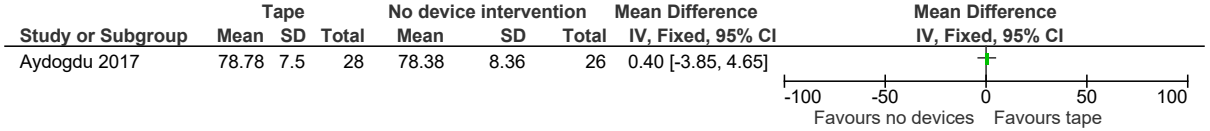


Figure 81: Physical function (WOMAC, 0-68, high is poor, final value, crossover trial) at ≤3 months

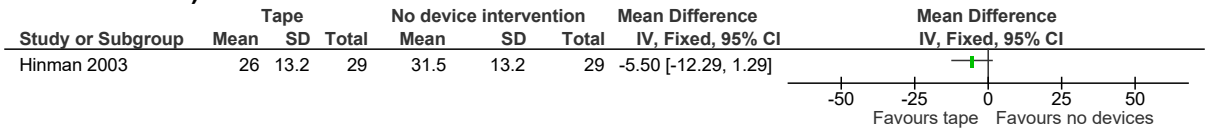
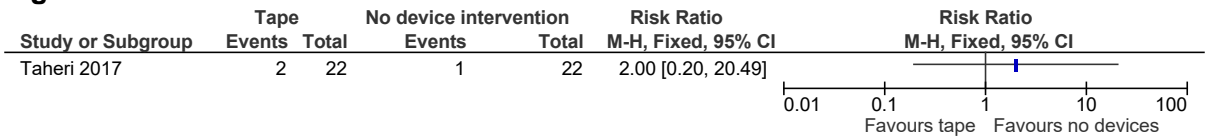


Figure 82: Number of adverse events at ≤3 months



E.1.11 Walking aids versus no device intervention

Figure 83: Quality of life (AQoL, -0.04-1, high is good, change score) at ≤3 months

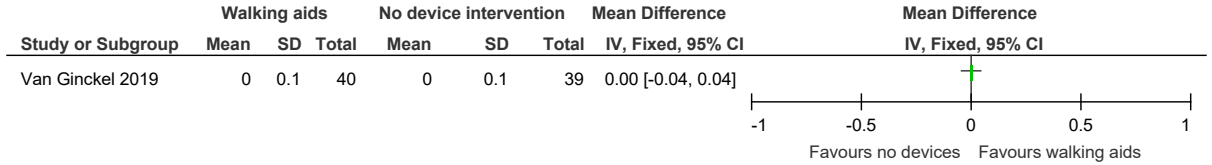


Figure 84: Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months

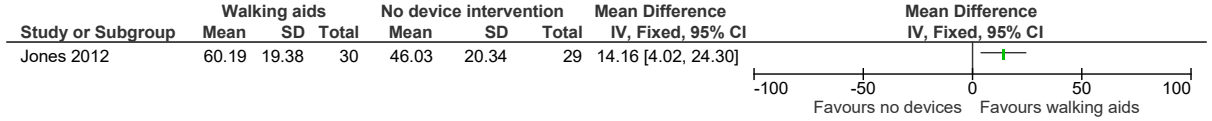


Figure 85: Quality of life (SF-36 general health subscale, 0-100, high is good, final value) at ≤3 months

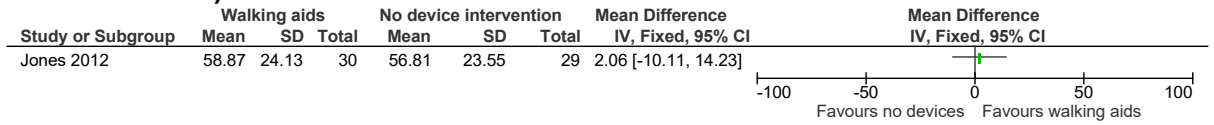


Figure 86: Quality of life (SF-36 mental health subscale, 0-100, high is good, final value) at ≤3 months

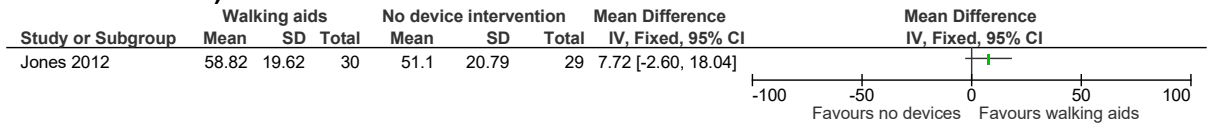


Figure 87: Quality of life (SF-36 physical functioning subscale, 0-100, high is good, final value) at ≤3 months

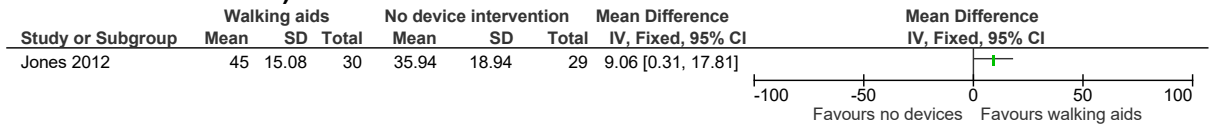


Figure 88: Quality of life (SF-36 role emotional subscale, 0-100, high is good, final value) at ≤3 months

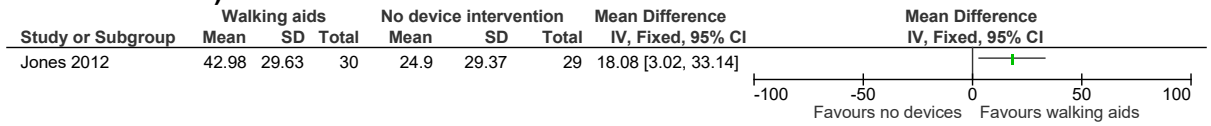


Figure 89: Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months

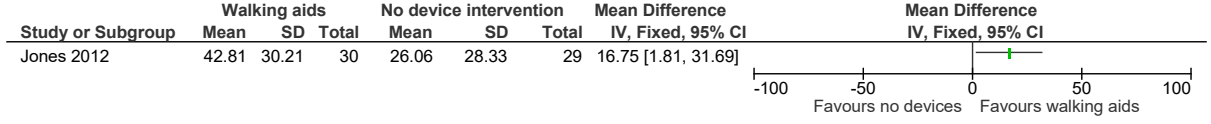


Figure 90: Quality of life (SF-36 social functioning subscale, 0-100, high is good, final value) at ≤3 months

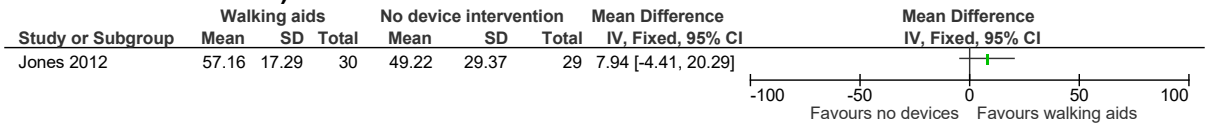


Figure 91: Quality of life (SF-36 vitality subscale, 0-100, high is good, final value) at ≤3 months

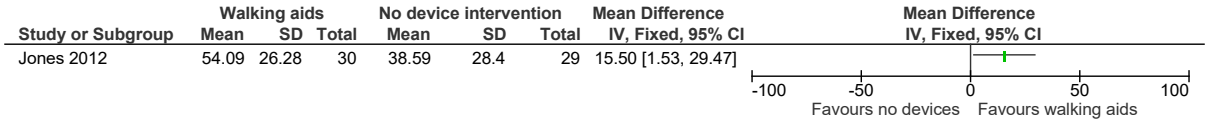


Figure 92: Pain (WOMAC pain, 0-20, high is poor, change score) at ≤3 months

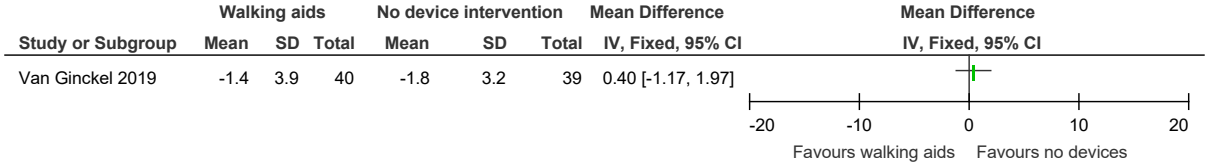


Figure 93: Pain (VAS, 0-10, high is poor, final value) at ≤3 months

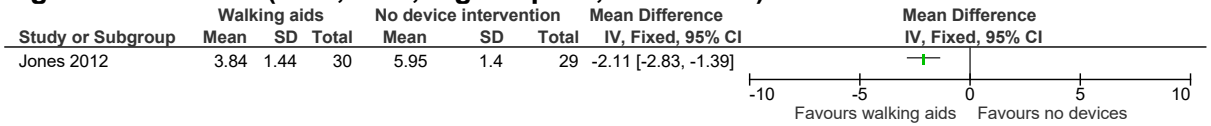


Figure 94: Physical function (WOMAC physical function, 0-68, high is poor, change score) at ≤3 months

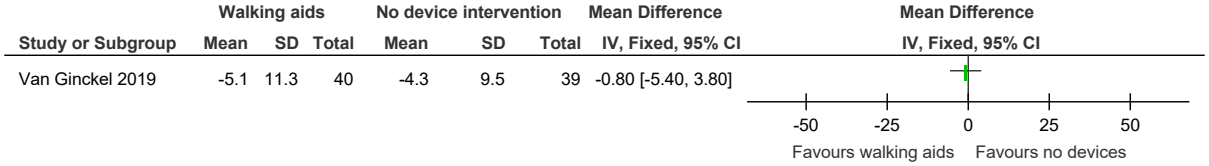
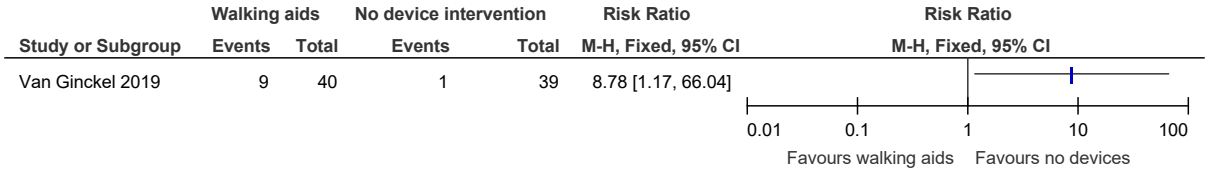


Figure 95: Number of adverse events at ≤3 months



E.2 Thumb osteoarthritis

E.2.1 Splints compared to sham devices

Figure 96: Quality of life (EQ-5D, -0.11-1, high is good, final value) at ≤3 months

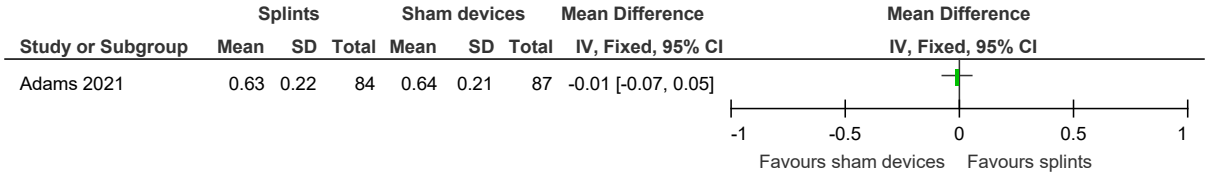


Figure 97: Pain (AUSCAN pain, 0-20, high is poor, final value) at ≤3 months

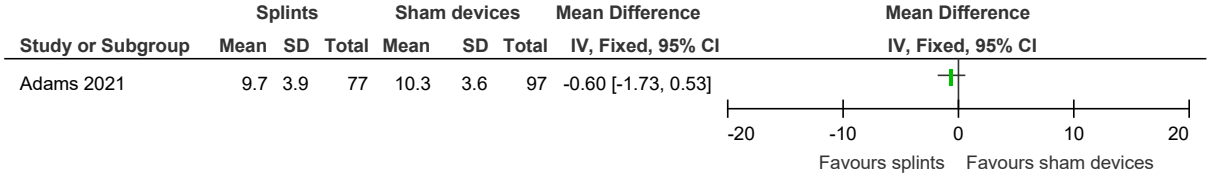


Figure 98: Physical function (AUSCAN function, 0-38, high is poor, final value) at ≤3 months

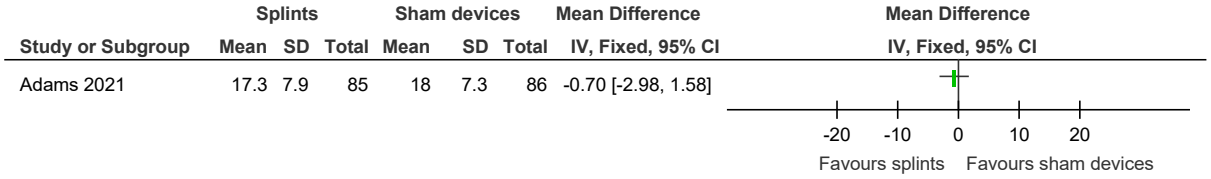
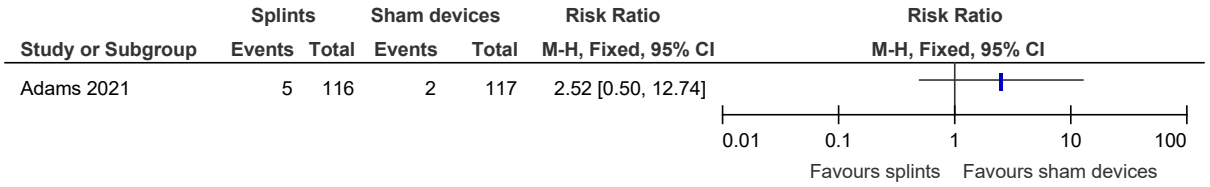


Figure 99: Adverse events at ≤3 months



E.2.2 Splints compared to no device intervention

Figure 100: Pain (visual analogue scale, 0-10, high is poor, final values, parallel and crossover) at ≤3 months

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Arazpour 2017	0.56	0.3705	25.4%	0.56 [-0.17, 1.29]
Bani 2013	-5	0.478	25.1%	-5.00 [-5.94, -4.06]
Gomes Carreira 2010	-2.3	0.6648	24.3%	-2.30 [-3.60, -1.00]
Rannou 2009	0.06	0.4457	25.2%	0.06 [-0.81, 0.93]
Total (95% CI)			**100.0%**	**-1.66 [-4.28, 0.96]**

Heterogeneity: Tau² = 6.90; Chi² = 96.49, df = 3 (P < 0.00001); I² = 97%
Test for overall effect: Z = 1.24 (P = 0.22)

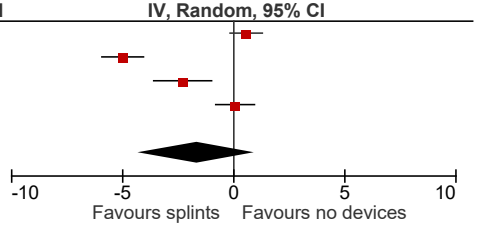


Figure 101: Pain (visual analogue scale, 0-100, high is poor, change score) at >3 months

Study or Subgroup	Splints Mean	SD	Total	No device intervention Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Rannou 2009	-22.2	23.1	52	-7.9	23.5	45	-14.30 [-23.60, -5.00]

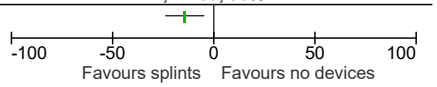


Figure 102: Physical function (MHQ subscale and DASH scale, 0-96 and 0-100, high is poor, final values) at ≤3 months

Study or Subgroup	Splints Mean	SD	Total	No device intervention Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Arazpour 2017	67.81	19.19	16	71.66	18.2	9	37.0%	-0.20 [-1.02, 0.62]
Gomes Carreira 2010	28.6	18	20	35.3	13.2	20	63.0%	-0.42 [-1.04, 0.21]
Total (95% CI)			**36**			**29**	**100.0%**	**-0.34 [-0.83, 0.16]**

Heterogeneity: Chi² = 0.17, df = 1 (P = 0.68); I² = 0%
Test for overall effect: Z = 1.32 (P = 0.19)

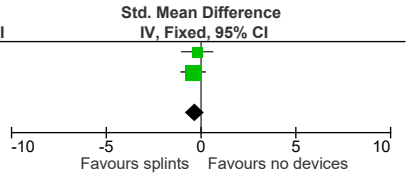


Figure 103: Physical function (DASH scale, 0-100, high is good, final value, crossover trial) at ≤3 months

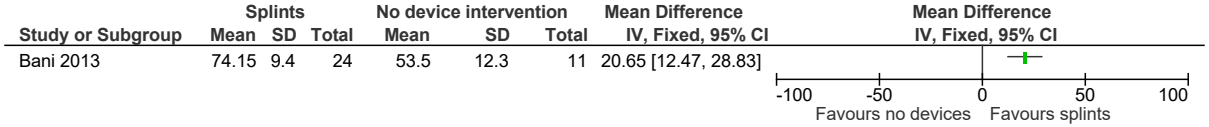


Figure 104: Physical function (Cochin hand function scale, 0-90, high is poor, change score) at ≤3 months

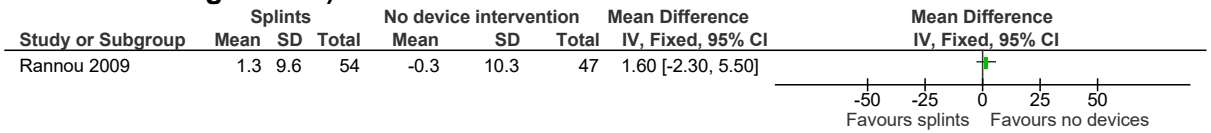
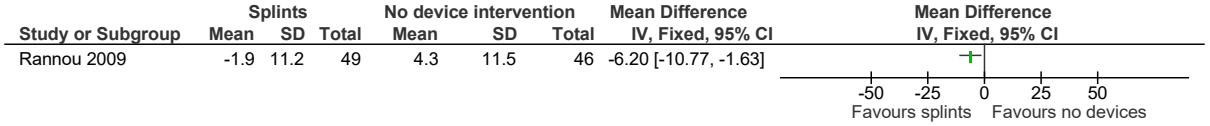


Figure 105: Physical function (Cochin hand function scale, 0-90, high is poor, change score) at >3 months



E.3 Hand osteoarthritis

E.3.1 Splints compared to no device intervention

Figure 106: Pain (AUSCAN, 0-20, high is poor, final value) at ≤3 months

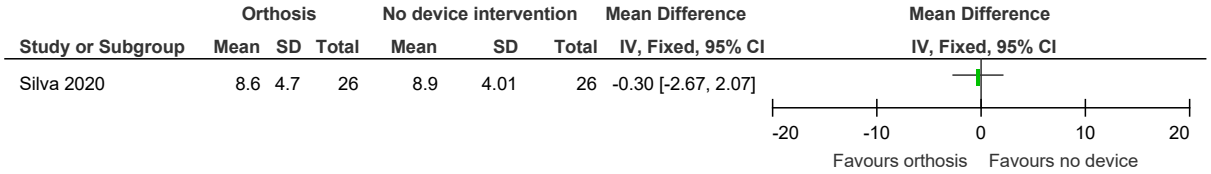


Figure 107: Pain (AUSCAN, 0-20, high is poor, final value) at >3 months

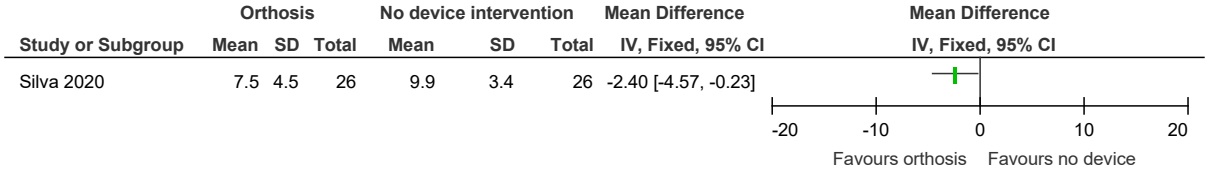


Figure 108: Physical function (AUSCAN, 0-36, high is poor, final value) at ≤3 months

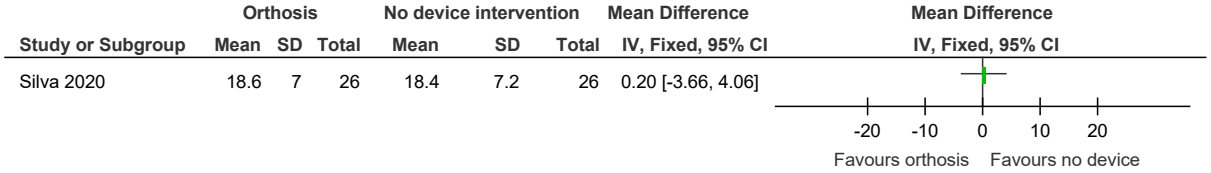
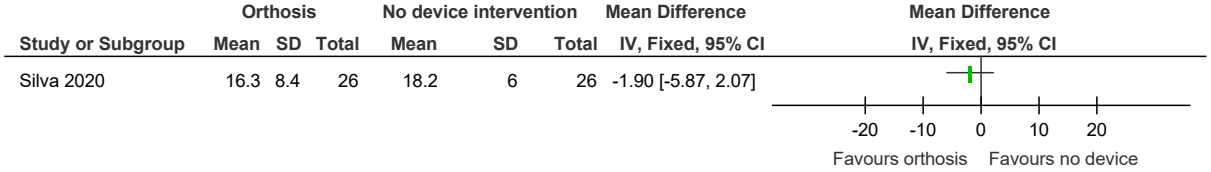


Figure 109: Physical function (AUSCAN, 0-36, high is poor, final value) at >3 months



E.3.2 Tape compared to no device intervention

Figure 110: Pain (VAS, 0-10, high is poor, final value) at ≤3 months

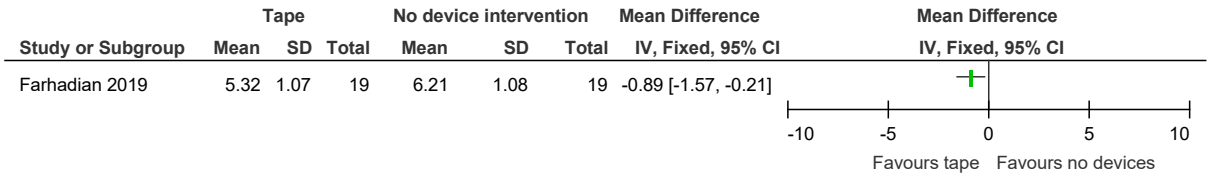
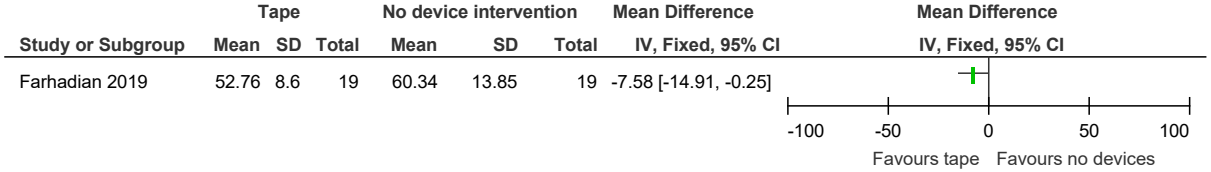


Figure 111: Physical function (DASH, 0-100, high is poor, final value) at ≤3 months



E.4 Finger osteoarthritis

E.4.1 Tape compared to sham devices

Figure 112: Pain (VAS, 0-10, high is poor, final values) at ≤3 months

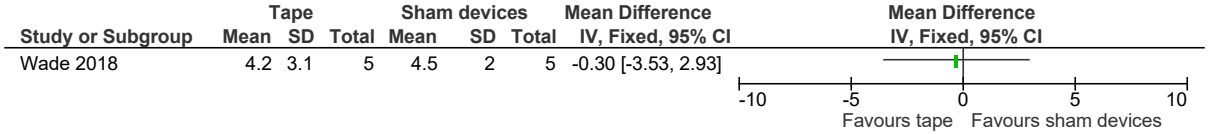
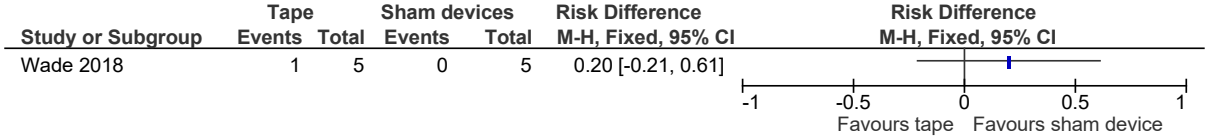


Figure 113: Osteoarthritis flares at ≤3 months



E.5 Foot osteoarthritis

E.5.1 Insoles compared to sham devices

Figure 114: Pain (NRS, 0-10, high is poor, change score) at ≤3 months

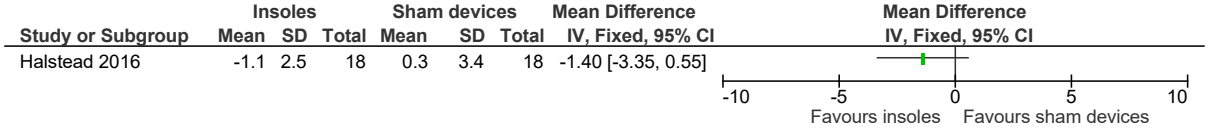
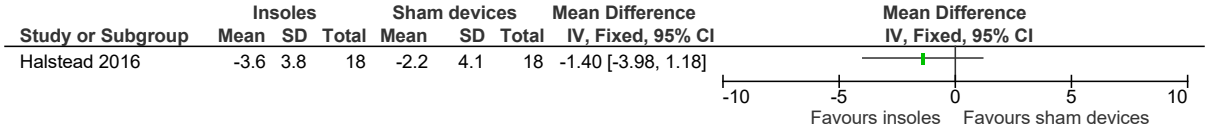


Figure 115: Physical function (MFPDI function subscale, scale not reported, high is poor, change score) at ≤3 months



E.6 Toe osteoarthritis

E.6.1 Shoes compared to insoles

Figure 116: Quality of life (SF-12 physical, 1-100, high is good, final value) at ≤3 months

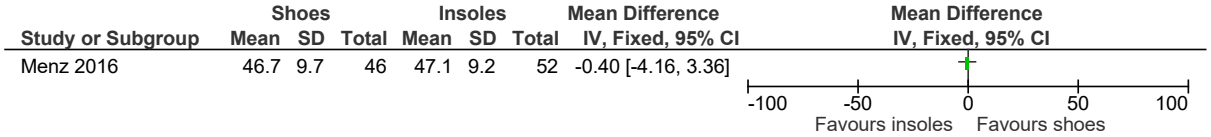


Figure 117: Quality of life (SF-12 mental, 1-100, high is good, final value) at ≤3 months

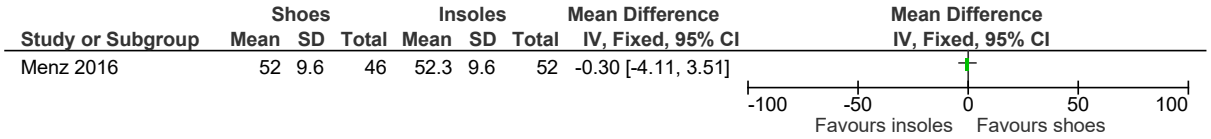


Figure 118: Pain (Foot health status questionnaire pain domain, 1-100, high is good, final value) at ≤3 months

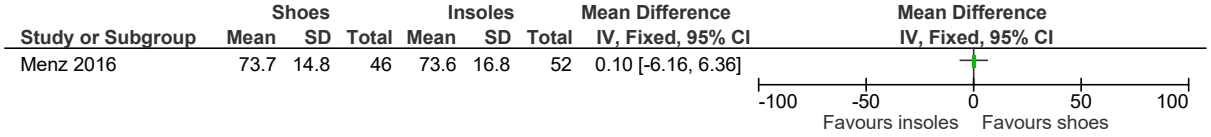


Figure 119: Physical function (Foot health status questionnaire function domain, 1-100, high is good, final value) at ≤3 months

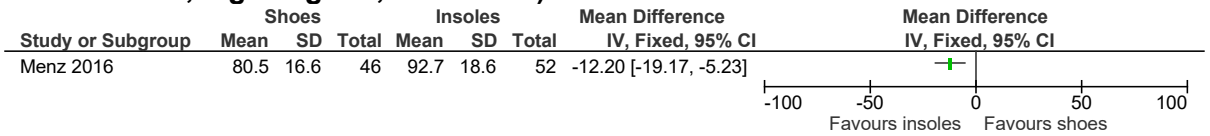
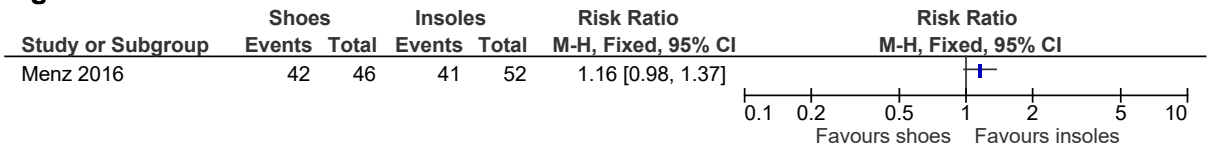


Figure 120: Number of adverse events at ≤3 months



Appendix F – GRADE tables

F.1 Knee osteoarthritis

Table 39: Clinical evidence profile: insoles compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months (follow-up: mean 8 weeks; assessed with: KOOS; Scale from: 0 to 100)												
3	randomised trials	very serious[a]	not serious	not serious	not serious	none	95	93	-	MD **1.99 higher** (2.17 lower to 6.15 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (assessment of quality of life instrument, -0.04-1.00, high is good, change score) at >3 months (follow-up: 12 months; assessed with: assessment of quality of life instrument; Scale from: -0.04 to 1)												
1	randomised trials	not serious	not serious	not serious	not serious	none	89	90	-	MD **0.01 lower** (0.05 lower to 0.03 higher)	⨁⨁⨁⨁ HIGH	CRITICAL
Pain (VAS, 0-100, high is poor, change score, parallel trial) at ≤3 months (follow-up: 8 weeks; assessed with: VAS; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	not serious	none	57	61	-	MD **23.05 lower** (28.31 lower to 17.79 lower)	⨁⨁◯◯ LOW	CRITICAL
Pain (KOOS, WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months (follow-up: mean 8 weeks; assessed with: KOOS, WOMAC, VAS)												
6	randomised trials	serious[a]	serious[b]	not serious	not serious	none	185	173	-	SMD **0.04 SD higher** (0.37 lower to 0.44 higher)	⨁⨁◯◯ LOW	CRITICAL
Pain (WOMAC, 0-500, high is poor, change score, crossover trial) at ≤3 months (follow-up: 6 weeks; assessed with: WOMAC; Scale from: 0 to 500)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	sham devices	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	not serious	not serious	not serious	not serious	none	90	90	-	MD **14.5 higher** (23.1 lower to 52.1 higher)	⨁⨁⨁⨁ HIGH	CRITICAL
Pain (KOOS, 0-100, high is good, final value, crossover trial) at ≤3 months (follow-up: 8 weeks; assessed with: KOOS; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	not serious	none	62	62	-	MD **0.09 higher** (4.75 lower to 4.93 higher)	⨁⨁◯◯ LOW	CRITICAL
Pain (WOMAC, VAS [different scale ranges], high is poor, final values) at >3 months (follow-up: mean 14 months; assessed with: WOMAC, VAS)												
3	randomised trials	very serious[a]	very serious[b]	not serious	serious[c]	none	104	105	-	SMD **0.33 higher** (0.22 lower to 0.89 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (WOMAC, 0-20, high is poor, change score) at >3 months (follow-up: 12 months; assessed with: WOMAC)												
1	randomised trials	not serious	not serious	not serious	not serious	none	89	90	-	MD **0.5 higher** (0.35 lower to 1.35 higher)	⨁⨁⨁⨁ HIGH	CRITICAL
Physical function (KOOS, WOMAC, 0-100, high is poor, final values) at ≤3 months (follow-up: mean 10 weeks; assessed with: KOOS, WOMAC; Scale from: 0 to 100)												
4	randomised trials	very serious[a]	serious[b]	not serious	not serious	none	173	162	-	MD **1.19 lower** (6.9 lower to 4.52 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (WOMAC, Edinburgh Knee Function Scale [different scale ranges], high is poor, change scores) at ≤3 months (follow-up: mean 6 weeks; assessed with: WOMAC, Edinburgh Knee Function Scale)												
2	randomised trials	very serious[a]	very serious[b]	not serious	very serious[c]	none	90	87	-	SMD **0.36 lower** (2.82 lower to 2.1 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (WOMAC, 0-100, high is poor, final value) at >3 months (follow-up: 2 years; assessed with: WOMAC; Scale from: 0 to 100)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	sham devices	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious[a]	not serious	not serious	not serious	none	55	51	-	MD **0.4 lower** (9.47 lower to 8.67 higher)	⨁⨁◯◯ LOW	CRITICAL
Physical function (WOMAC [different scale ranges], high is poor, change scores) at >3 months (follow-up: mean 12 months; assessed with: WOMAC)												
2	randomised trials	serious[a]	very serious[b]	not serious	serious[c]	none	109	115	-	SMD **0.61 lower** (1.36 lower to 0.13 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Number of adverse events (parallel trials and crossover trials) at ≤3 months (follow-up: mean 6 weeks)												
4	randomised trials	serious[a]	serious[b]	not serious	very serious[c]	none	24/145 (16.6%)	25/141 (17.7%)	**RR 1.05** (0.44 to 2.52)	**9 more per 1,000** (from 99 fewer to 270 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Number of adverse events at >3 months (follow-up: mean 12 months)												
2	randomised trials	serious[a]	not serious	not serious	not serious	none	45/112 (40.2%)	21/115 (18.3%)	**RR 2.15** (1.40 to 3.30)	**210 more per 1,000** (from 73 more to 420 more)	⨁⨁⨁◯ MODERATE	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 40: Clinical evidence profile: insoles compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Quality of life (KOOS, 0-100, high is good, final values) at ≤3 months (follow-up: mean 9 weeks; assessed with: KOOS; Scale from: 0 to 100)												
2	randomised trials	very serious[a]	very serious[b]	not serious	not serious	none	35	38	-	MD **24.13 higher** (11 lower to 59.26 higher)	⨁◯◯◯ Very low	CRITICAL
Quality of life (EQ-5D VAS total score, 0-100, high is good, final values) at ≤3 months (follow-up: 8 weeks; assessed with: EQ-5D VAS total score; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	serious[c]	none	17	14	-	MD **6 lower** (14.18 lower to 2.18 higher)	⨁◯◯◯ Very low	CRITICAL
Quality of life (EQ-5D VAS total score, 0-100, high is good, final value) at >3 months (follow-up: 16 weeks; assessed with: EQ-5D VAS total score; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	serious[c]	none	14	19	-	MD **4 lower** (18.34 lower to 10.34 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months (follow-up: mean 9 weeks; assessed with: KOOS, WOMAC)												
5	randomised trials	very serious[a]	very serious[b]	not serious	serious[c]	none	99	100	-	SMD **1 SD lower** (2.02 lower to 0.02 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (KOOS, VAS, 0-100, high is good, final values) at >3 months (follow-up: 7 months; assessed with: KOOS, VAS; Scale from: 0 to 100)												
2	randomised trials	very serious[a]	very serious[b]	not serious	very serious[c]	none	40	39	-	MD **7.89 higher** (9.66 lower to 25.44 higher)	⨁◯◯◯ Very low	CRITICAL
Physical function (KOOS, WOMAC [different scale ranges], high is poor, final values) at ≤3 months (follow-up: mean 10 weeks; assessed with: KOOS, WOMAC)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	no device intervention	Relative (95% CI)	Absolute (95% CI)		
3	randomised trials	very serious[a]	very serious[b]	not serious	serious[c]	none	62	58	-	SMD **0.79 SD lower** (1.67 lower to 0.1 higher)	⨁◯◯◯ Very low	CRITICAL
Psychological distress (HADS anxiety, 0-21, high is poor, final value) at ≤3 months (follow-up: 8 weeks; assessed with: HADS anxiety; Scale from: 0 to 21)												
1	randomised trials	very serious[a]	not serious	not serious	serious[c]	none	18	17	-	MD **2 higher** (0.22 lower to 4.22 higher)	⨁◯◯◯ Very low	IMPORTANT
Psychological distress (HADS depression, 0-21, high is poor, final value) at ≤3 months (follow-up: 8 weeks; assessed with: HADS depression; Scale from: 0 to 21)												
1	randomised trials	very serious[a]	not serious	not serious	serious[c]	none	18	17	-	MD **0.9 higher** (0.69 lower to 2.49 higher)	⨁◯◯◯ Very low	IMPORTANT
Psychological distress (HADS anxiety, 0-21, high is poor, final value) at >3 months (follow-up: 16 weeks; assessed with: HADS anxiety; Scale from: 0 to 21)												
1	randomised trials	very serious[a]	not serious	not serious	serious[c]	none	19	19	-	MD **0.6 higher** (1.88 lower to 3.08 higher)	⨁◯◯◯ Very low	IMPORTANT
Psychological distress (HADS depression, 0-21, high is poor, final value) at >3 months (follow-up: 16 weeks; assessed with: HADS depression; Scale from: 0 to 21)												
1	randomised trials	very serious[a]	not serious	not serious	very serious[c]	none	19	19	-	MD **0.2 lower** (2.27 lower to 1.87 higher)	⨁◯◯◯ Very low	IMPORTANT
Number of adverse events at ≤3 months (follow-up: 3 months)												
1	randomised trials	very serious[a]	not serious	not serious	not serious	none	13/15 (86.7%)	6/18 (33.3%)	**RR 2.60** (1.31 to 5.15)	**533 more per 1,000** (from 103 more to 1,000 more)	⨁⨁◯◯ Low	IMPORTANT
Number of adverse events at >3 months (follow-up: 16 weeks)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	no device intervention	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious[a]	not serious	not serious	very serious[c]	none	1/24 (4.2%)	2/22 (9.1%)	**RR 0.46** (0.04 to 4.71)	**49 fewer per 1,000** (from 87 fewer to 337 more)	⨁◯◯◯ Very low	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 41: Clinical evidence profile: shoes versus sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	shoes	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (SF-36 physical component, 0-100, high is good, final values) at ≤3 months (follow-up: 12 weeks; assessed with: SF-36 physical component; Scale from: 0 to 100)												
1	randomised trials	not serious	not serious	not serious	serious[a]	none	111	109	-	MD **0.7 lower** (2.67 lower to 1.27 higher)	⨁⨁⨁◯ Moderate	CRITICAL
Quality of life (SF-36 mental component, 0-100, high is good, final values) at ≤3 months (follow-up: 12 weeks; assessed with: SF-36 mental component; Scale from: 0 to 100)												
1	randomised trials	not serious	not serious	not serious	serious[a]	none	111	109	-	MD **1.4 higher** (0.64 lower to 3.44 higher)	⨁⨁⨁◯ Moderate	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	shoes	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (AQoL-6D, -0.04-1, high is good, change scores) at >3 months (follow-up: mean 6 months; assessed with: AQoL-6D; Scale from: -0.04 to 1)												
2	randomised trials	not serious	not serious	not serious	not serious	none	161	160	-	MD **0** (0.02 lower to 0.03 higher)	⨁⨁⨁⨁ High	CRITICAL
Quality of life (SF-36 physical component, 0-100, high is good, final values) at >3 months (follow-up: 24 weeks; assessed with: SF-36 physical component; Scale from: 0 to 100)												
1	randomised trials	not serious	not serious	not serious	serious[a]	none	111	109	-	MD **1.4 higher** (0.64 lower to 3.44 higher)	⨁⨁⨁◯ Moderate	CRITICAL
Quality of life (SF-36 mental component, 0-100, high is good, final values) at >3 months (follow-up: 24 weeks; assessed with: SF-36 mental component; Scale from: 0 to 100)												
1	randomised trials	not serious	not serious	not serious	not serious	none	111	109	-	MD **0.8 higher** (1.3 lower to 2.9 higher)	⨁⨁⨁⨁ High	CRITICAL
Pain (WOMAC [different scale ranges], high is poor, change scores) at ≤3 months (follow-up: mean 12 weeks; assessed with: WOMAC)												
2	randomised trials	not serious	not serious	not serious	not serious	none	135	144	-	SMD **0.03 SD lower** (0.26 lower to 0.21 higher)	⨁⨁⨁⨁ High	CRITICAL
Pain (WOMAC, 0-10, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: WOMAC; Scale from: 0 to 10)												
1	randomised trials	not serious	not serious	not serious	not serious	none	111	109	-	MD **0.3 lower** (0.81 lower to 0.21 higher)	⨁⨁⨁⨁ High	CRITICAL
Pain (KOOS, WOMAC [different scale ranges], high is poor, change scores) at >3 months (follow-up: mean 6 months; assessed with: KOOS, WOMAC)												
2	randomised trials	not serious	not serious	not serious	not serious	none	161	160	-	SMD **0.05 SD higher** (0.17 lower to 0.27 higher)	⨁⨁⨁⨁ High	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	shoes	sham devices	Relative (95% CI)	Absolute (95% CI)		
Pain (WOMAC [different scale ranges], high is poor, final values) at >3 months (follow-up: mean 38 weeks; assessed with: WOMAC)												
2	randomised trials	not serious	very serious[b]	not serious	serious[a]	none	143	132	-	SMD **0.48 SD lower** (1.12 lower to 0.17 higher)	⨁◯◯◯ Very low	CRITICAL
Physical function (WOMAC [different scale ranges], high is poor, change scores) at ≤3 months (follow-up: mean 12 weeks; assessed with: WOMAC; Scale from: 0 to 68)												
2	randomised trials	not serious	not serious	not serious	not serious	none	135	144	-	SMD **0.01 SD higher** (0.22 lower to 0.25 higher)	⨁⨁⨁⨁ High	CRITICAL
Physical function (WOMAC, 0-10, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: WOMAC; Scale from: 0 to 10)												
1	randomised trials	not serious	not serious	not serious	not serious	none	111	109	-	MD **0.4 lower** (0.86 lower to 0.06 higher)	⨁⨁⨁⨁ High	CRITICAL
Physical function (WOMAC, 0-68, high is poor, change scores) at >3 months (follow-up: mean 6 months; assessed with: WOMAC; Scale from: 0 to 68)												
2	randomised trials	not serious	not serious	not serious	not serious	none	161	160	-	MD **0.92 higher** (1.61 lower to 3.45 higher)	⨁⨁⨁⨁ High	CRITICAL
Physical function (WOMAC [different scale ranges], high is poor, final values) at >3 months (follow-up: mean 38 weeks; assessed with: WOMAC)												
2	randomised trials	not serious	serious[b]	not serious	serious[a]	none	143	132	-	SMD **0.45 SD lower** (0.94 lower to 0.05 higher)	⨁⨁◯◯ Low	CRITICAL
Number of adverse events at >3 months (follow-up: mean 26 weeks)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	shoes	sham devices	Relative (95% CI)	Absolute (95% CI)		
3	randomised trials	not serious	very serious[b]	not serious	very serious[a]	none	78/276 (28.3%)	70/272 (25.7%)	**RR 1.19** (0.62 to 2.31)	**49 more per 1,000** (from 98 fewer to 337 more)	⨁◯◯◯ Very low	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 42: Clinical evidence profile: braces compared to insoles

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	insoles	Relative (95% CI)	Absolute (95% CI)		
Pain (WOMAC, VAS, 0-100, high is poor, final values) at ≤3 months (follow up: mean 4 weeks; assessed with: WOMAC, VAS; Scale from: 0 to 100)												
2	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	40	40	-	MD **1.29 lower** (5.92 lower to 3.34 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (VAS, 0-10, high is poor, change score and final value) at >3 months (follow up: mean 8 months; assessed with: VAS; Scale from: 0 to 10)												
3	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	124	121	-	MD **0.64 lower** (1.06 lower to 0.22 lower)	⨁◯◯◯ VERY LOW	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	insoles	Relative (95% CI)	Absolute (95% CI)		
Physical function (WOMAC, 0-100, high is poor, final values) at ≤3 months (follow up: 8 weeks; assessed with: WOMAC; Scale from: 0 to 100)												
1	randomised trials	not serious	not serious	not serious	serious [b]	none	28	28	-	MD **0.5 lower** (7.91 lower to 6.91 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Physical function (WOMAC, 0-100, high is good, change score) at >3 months (follow up: 6 months; assessed with: WOMAC; Scale from: 0 to 100)												
1	randomised trials	very serious [a]	not serious	not serious	not serious	none	46	45	-	MD **0.2 lower** (7.56 lower to 7.16 higher)	⨁⨁◯◯ LOW	CRITICAL
Number of adverse events at >3 months (follow up: 6 months)												
2	randomised trials	serious [a]	not serious	not serious	not serious	none	15/104 (14.4%)	0/101 (0.0%)	**OR 8.52** (2.97 to 24.45)	**140 fewer per 1,000** (from 220 fewer to 70 fewer) [c]	⨁⨁⨁◯ MODERATE	IMPORTANT

CI: Confidence interval; **MD:** Mean difference; **OR:** Odds ratio

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Absolute effect calculated by risk difference due to zero events in at least one arm of one study

Table 43: Clinical evidence profile: braces compared to supports

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	supports	Relative (95% CI)	Absolute (95% CI)		
Pain (WOMAC, 0-500, high is poor, change score) at >3 months (follow up: 6 months; assessed with: WOMAC; Scale from: 0 to 500)												
1	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	41	36	-	MD **30.1 lower** (47.33 lower to 12.87 lower)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (WOMAC, high is poor, change score) at >3 months (follow up: 6 months; assessed with: WOMAC; Scale from: 0 to 1700)												
1	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	41	36	-	MD **88.3 lower** (145.2 lower to 31.4 lower)	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **MD:** Mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 44: Clinical evidence profile: braces compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (KOOS, 0-100, high is good, change score) at >3 months (follow-up: 12 months; assessed with: KOOS; Scale from: 0 to 100)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	sham devices	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	52	34	-	MD **6.2 higher** (0.07 lower to 12.47 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (WOMAC, 0-20, high is poor, final value) at ≤3 months (follow-up: 3 months; assessed with: WOMAC; Scale from: 0 to 20)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	28	29	-	MD **0.1 higher** (2.13 lower to 2.33 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (KOOS, 0-100, high is good, change score) at >3 months (follow-up: 12 months; assessed with: KOOS; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	52	34	-	MD **5.1 higher** (0.74 higher to 9.46 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (WOMAC, 0-68, high is poor, final value) at ≤3 months (follow-up: 3 months; assessed with: WOMAC; Scale from: 0 to 68)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	28	29	-	MD **3.5 lower** (11.21 lower to 4.21 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (KOOS, 0-100, high is good, change score) at at >3 months (follow-up: 12 months; assessed with: KOOS; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	52	34	-	MD **8 higher** (2.74 higher to 13.26 higher)	⨁◯◯◯ VERY LOW	CRITICAL

CI: confidence interval; **MD:** mean difference

- Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 45: Clinical evidence profile: braces compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Quality of life (EQ-5D, 0-1, high is good, mean difference) at ≤3 months (follow-up: 12 weeks; assessed with: EQ-5D; Scale from: 0 to 1)												
1	randomised trials	very serious[a]	not serious	not serious	very serious[b]	none	60	57	-	MD **0.03 higher** (0.05 lower to 0.11 higher)	⨁◯◯◯ Very low	CRITICAL
Quality of life (EQ-5D, 0-1, high is good, mean difference) at >3 months (follow-up: 12 months; assessed with: EQ-5D; Scale from: 0 to 1)												
1	randomised trials	very serious[a]	not serious	not serious	very serious[b]	none	60	57	-	MD **0.01 higher** (0.08 lower to 0.1 higher)	⨁◯◯◯ Very low	CRITICAL
Quality of life (KOOS, 0-100, high is good, change score) at >3 months (follow-up: 12 months; assessed with: KOOS; Scale from: 0 to 100)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	60	61	-	MD **7.9 higher** (0.18 higher to 15.62 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (KOOS, VAS, 0-100, high is poor, final values and change score) at ≤3 months (follow-up: mean 8 weeks; assessed with: KOOS, VAS; Scale from: 0 to 100)												
4	randomised trials	very serious[a]	very serious[c]	not serious	serious[b]	none	194	194	-	MD **12.74 lower** (23.47 lower to 2.01 lower)	⨁◯◯◯ Very low	CRITICAL
Pain (KOOS, WOMAC [different scale ranges], high is poor, change scores) at >3 months (follow-up: mean 9 months; assessed with: KOOS, WOMAC)												
2	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	101	94	-	SMD **0.6 SD lower** (0.89 lower to 0.31 lower)	⨁◯◯◯ Very low	CRITICAL
Pain (VAS, 0-10, high is poor, final value and change score) at >3 months (follow-up: mean 11 months; assessed with: VAS; Scale from: 0 to 10)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	braces	no device intervention	Relative (95% CI)	Absolute (95% CI)		
2	randomised trials	very serious[a]	very serious[c]	not serious	very serious[b]	none	80	77	-	MD **1.82 lower** (3.77 lower to 0.13 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (WOMAC, 0-500, high is poor, change score) at >3 months (follow-up: 6 months; assessed with: WOMAC; Scale from: 0 to 500)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	41	33	-	MD **56.3 lower** (88.48 lower to 24.12 lower)	⨁◯◯◯ Very low	CRITICAL
Physical function (KOOS, WOMAC [different scale ranges] high is poor, change score) at >3 months (follow-up: mean 9 months; assessed with: KOOS, WOMAC)												
2	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	101	94	-	SMD **0.52 SD lower** (0.8 lower to 0.23 lower)	⨁◯◯◯ Very low	CRITICAL
Number of adverse events at ≤3 months (follow-up: 6 weeks)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	10/32 (31.3%)	3/35 (8.6%)	**RR 3.65** (1.10 to 12.08)	**227 more per 1,000** (from 9 more to 950 more)	⨁⨁◯◯ Low	CRITICAL
Number of adverse events at >3 months (follow-up: 12 months)												
1	randomised trials	serious[a]	not serious	not serious	very serious[b]	none	1/60 (1.7%)	1/61 (1.6%)	**RR 1.02** (0.07 to 15.88)	**0 fewer per 1,000** (from 15 fewer to 244 more)	⨁◯◯◯ Very low	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 46: Clinical evidence profile: tape compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (Nottingham Health Profile, 0-600, high is poor, final value) at ≤3 months (follow up: 2 weeks; assessed with: Nottingham Health Profile; Scale from: 0 to 600)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	21	20	-	MD **52.59 higher** (24.98 lower to 130.16 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months (follow up: 6 weeks; assessed with: SF-36 bodily pain subscale; Scale from: 0 to 100)												
1	randomised trials	serious [a]	not serious	not serious	very serious [b]	none	29	29	-	MD **10.2 lower** (22.75 lower to 2.35 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months (follow up: 6 weeks; assessed with: SF-36 physical function subscale; Scale from: 0 to 100)												
1	randomised trials	serious [a]	not serious	not serious	very serious [b]	none	29	29	-	MD **5.9 lower** (18.38 lower to 6.58 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 physical role subscale, 0-100, high is good, final value) at ≤3 months (follow up: 6 weeks; assessed with: SF-36 physical role subscale; Scale from: 0 to 100)												
1	randomised trials	serious [a]	not serious	not serious	very serious [b]	none	29	29	-	MD **15.6 lower** (38.6 lower to 7.4 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (WOMAC, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months (follow up: mean 6 weeks; assessed with: WOMAC, VAS)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	sham devices	Relative (95% CI)	Absolute (95% CI)		
4	randomised trials	serious [a]	not serious	not serious	not serious	none	103	81	-	SMD **0.08 lower** (0.38 lower to 0.21 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Pain (WOMAC, 0-20, high is poor, final value, crossover trial) at ≤3 months (follow up: 6 weeks; assessed with: WOMAC; Scale from: 0 to 20)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	29	29	-	MD **1.5 higher** (0.42 lower to 3.42 higher)	⨁⨁◯◯ LOW	CRITICAL
Pain (VAS, 0-10, high is poor, change score) at ≤3 months (follow up: 6 weeks; assessed with: VAS; Scale from: 0 to 10)												
1	randomised trials	not serious	not serious	not serious	serious [b]	none	20	19	-	MD **0.45 lower** (2.1 lower to 1.2 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Physical function (WOMAC, 0-68, high is poor, final values) at ≤3 months (follow up: mean 8 weeks; assessed with: WOMAC; Scale from: 0 to 68)												
3	randomised trials	serious [a]	not serious	not serious	not serious	none	45	42	-	MD **0.03 lower** (1.82 lower to 1.77 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Number of adverse events at ≤3 months (follow up: mean 4 weeks)												
3	randomised trials	not serious	serious [c]	not serious	serious [b]	none	0/55 (0.0%)	3/54 (5.6%)	**RD -0.06** (-0.14 to 0.03)	**60 fewer per 1,000** (from 140 fewer to 30 more) [c,d]	⨁⨁◯◯ LOW	IMPORTANT

CI: Confidence interval; **MD:** Mean difference; **SMD:** Standardised mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Downgraded for heterogeneity due to conflicting number of events in different studies (zero events in one or more studies)

d. Absolute measure calculated by risk difference due to zero events in one or both study arms

Table 47: Clinical evidence profile: tape compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Quality of life (KOOS, 0-100, high is good, final value) at ≤3 months (follow-up: 3-6 weeks; assessed with: KOOS; Scale from: 0 to 100)[a]												
1	randomised trials	very serious[b]	not serious	not serious	serious[c]	none	28	26	-	MD **1.77 lower** (9.14 lower to 5.6 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 6 weeks; assessed with: SF-36 bodily pain subscale; Scale from: 0 to 100)												
1	randomised trials	very serious[b]	not serious	not serious	serious[c]	none	29	29	-	MD **11.5 higher** (1.45 lower to 24.45 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 physical function subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 6 weeks; assessed with: SF-36 physical function subscale; Scale from: 0 to 100)												
1	randomised trials	very serious[b]	not serious	not serious	very serious[c]	none	29	29	-	MD **3.2 higher** (9.39 lower to 15.79 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 6 weeks; assessed with: SF-36 role physical subscale; Scale from: 0 to 100)												
1	randomised trials	very serious[b]	not serious	not serious	very serious[c]	none	29	29	-	MD **6.8 higher** (16.6 lower to 30.2 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (KOOS, VAS [different scale ranges], high is poor, final values, parallel trials) at ≤3 months (follow-up: mean 7 weeks; assessed with: KOOS, VAS)[a]												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	no device intervention	Relative (95% CI)	Absolute (95% CI)		
5	randomised trials	very serious[b]	very serious[d]	not serious	serious[c]	none	92	90	-	SMD **0.34 SD lower** (1.01 lower to 0.33 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (WOMAC, 0-20, high is poor, final value, crossover trial) at ≤3 months (follow-up: 6 weeks; assessed with: WOMAC; Scale from: 0 to 20)												
1	randomised trials	serious[b]	not serious	not serious	serious[c]	none	29	29	-	MD **2.1 lower** (4.09 lower to 0.11 lower)	⨁⨁◯◯ LOW	CRITICAL
Physical function (KOOS, 0-100, high is good, final value, parallel trial) at ≤3 months (follow-up: 3-6 weeks; assessed with: KOOS; Scale from: 0 to 100)[a]												
1	randomised trials	very serious[b]	not serious	not serious	serious[c]	none	28	26	-	MD **0.4 higher** (3.85 lower to 4.65 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (WOMAC physical function subscale, 0-68, high is poor, final value, crossover trial) at ≤3 months (follow-up: 6 weeks; assessed with: WOMAC physical function subscale)												
1	randomised trials	serious[b]	not serious	not serious	serious[c]	none	29	29	-	MD **5.5 lower** (12.29 lower to 1.29 higher)	⨁⨁◯◯ LOW	CRITICAL
Number of adverse events at ≤3 months (follow-up: 6 weeks)												
1	randomised trials	serious[b]	not serious	not serious	serious[c]	none	2/22 (9.1%)	1/22 (4.5%)	**RR 2.00** (0.20 to 20.49)	**45 more per 1,000** (from 36 fewer to 886 more)	⨁⨁◯◯ LOW	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Includes Ayodogu 2017. In this study the intervention arm received treatment for 6 weeks while the control arm received treatment for 3 weeks. Measurements were reported to occur after treatment had finished

b. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

d. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

Table 48: Clinical evidence profile: walking aids compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	walking aids	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Quality of life (AQoL, -0.04-1, high is good, change score) at ≤3 months (follow-up: 12 weeks; assessed with: AQoL; Scale from: -0.04 to 1)												
1	randomised trials	serious[a]	not serious	not serious	not serious	none	40	39	-	MD **0** (0.04 lower to 0.04 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Quality of life (SF-36 physical functioning subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 physical functioning subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	30	29	-	MD **9.06 higher** (0.31 higher to 17.81 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 bodily pain subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 bodily pain subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	not serious	none	30	29	-	MD **14.16 higher** (4.02 higher to 24.3 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Quality of life (SF-36 role physical subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 role physical subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	30	29	-	MD **16.75 higher** (1.81 higher to 31.69 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 vitality subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 vitality subscale; Scale from: 0 to 100)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	walking aids	no device intervention	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	30	29	-	MD **15.5 higher** (1.53 higher to 29.47 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 general health subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 general health subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	very serious[b]	none	30	29	-	MD **2.06 higher** (10.11 lower to 14.23 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Quality of life (SF-36 mental health subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 mental health subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	30	29	-	MD **7.72 higher** (2.6 lower to 18.04 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 role emotional subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 role emotional subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	30	29	-	MD **18.08 higher** (3.02 higher to 33.14 higher)	⨁⨁◯◯ LOW	CRITICAL
Quality of life (SF-36 social functioning subscale, 0-100, high is good, final value) at ≤3 months (follow-up: 8 weeks; assessed with: SF-36 social functioning subscale; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	very serious[b]	none	30	29	-	MD **7.94 higher** (4.41 lower to 20.29 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (WOMAC pain, 0-20, high is poor, change score) at ≤3 months (follow-up: 12 weeks; assessed with: WOMAC pain; Scale from: 0 to 20)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	40	39	-	MD **0.4 higher** (1.17 lower to 1.97 higher)	⨁⨁◯◯ LOW	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	walking aids	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Pain (visual analogue scale, 0-10, high is poor, final value) at ≤3 months (follow-up: 8 weeks; assessed with: visual analogue scale; Scale from: 0 to 10)												
1	randomised trials	serious[a]	not serious	not serious	not serious	none	30	29	-	MD **2.11 lower** (2.83 lower to 1.39 lower)	⨁⨁⨁◯ MODERATE	CRITICAL
Physical function (WOMAC physical function, 0-68, high is poor, change score) at ≤3 months (follow-up: 12 weeks; assessed with: WOMAC physical function; Scale from: 0 to 68)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	40	39	-	MD **0.8 lower** (5.4 lower to 3.8 higher)	⨁⨁◯◯ LOW	CRITICAL
Number of adverse events at ≤3 months (follow-up: 12 weeks)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	9/40 (22.5%)	1/39 (2.6%)	**RR 8.78** (1.17 to 66.04)	**199 more per 1,000** (from 4 more to 1,000 more)	⨁⨁◯◯ LOW	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

F.2 Thumb osteoarthritis

Table 49: Clinical evidence profile: splints compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	splints	sham devices	Relative (95% CI)	Absolute (95% CI)		
Quality of life (EQ-5D, -0.11-1, high is good, final value) at ≤3 months (follow-up: 12 weeks; assessed with: EQ-5D; Scale from: -0.11 to 1)												
1	randomised trials	not serious	not serious	not serious	very serious[a]	none	84	87	-	MD **0.01 lower** (0.07 lower to 0.05 higher)	⨁⨁◯◯ LOW	CRITICAL
Pain (AUSCAN pain, 0-20, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: AUSCAN pain; Scale from: 0 to 20)												
1	randomised trials	not serious	not serious	not serious	not serious	none	77	97	-	MD **0.6 lower** (1.73 lower to 0.53 higher)	⨁⨁⨁⨁ HIGH	CRITICAL
Physical function (AUSCAN function, 0-38, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: AUSCAN function; Scale from: 0 to 38)												
1	randomised trials	not serious	not serious	not serious	not serious	none	85	86	-	MD **0.7 lower** (2.98 lower to 1.58 higher)	⨁⨁⨁⨁ HIGH	CRITICAL
Number of adverse events at ≤3 months (follow-up: 12 weeks)												
1	randomised trials	not serious	not serious	not serious	very serious[a]	none	5/116 (4.3%)	2/117 (1.7%)	**RR 2.52** (0.50 to 12.74)	**26 more per 1,000** (from 9 fewer to 201 more)	⨁⨁◯◯ LOW	IMPORTANT

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

a. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 50: Clinical evidence profile: splints compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	splints	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Pain (VAS, 0-10, high is poor, final values, parallel and crossover) at ≤3 months (follow up: mean 8 weeks; assessed with: VAS; Scale from: 0 to 10)												
4	randomised trials	serious [a]	very serious [b]	not serious	very serious [c]	none	115	86	-	MD **1.66 lower** (4.28 lower to 0.96 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Pain (VAS, 0-100, high is poor, change score) at >3 months (follow up: 12 months; assessed with: VAS; Scale from: 0 to 100)												
1	randomised trials	serious [a]	not serious	not serious	serious [c]	none	52	45	-	MD **14.3 lower** (23.6 lower to 5 lower)	⨁⨁◯◯ LOW	CRITICAL
Physical function (MHQ subscale, DASH scale [different scale ranges], high is poor, final values, parallel trials) at ≤3 months (follow up: mean 9 weeks; assessed with: MHQ subscale and DASH scale)												
2	randomised trials	serious [a]	not serious	not serious	serious [c]	none	36	29	-	SMD **0.34 lower** (0.83 lower to 0.16 higher)	⨁⨁◯◯ LOW	CRITICAL
Physical function (DASH scale, 0-100, high is good, final value, crossover trial) at ≤3 months (follow up: 10 weeks; assessed with: DASH; Scale from: 0 to 100)												
1	randomised trials	serious [a]	not serious	not serious	not serious	none	24	11	-	MD **20.65 higher** (12.47 higher to 28.83 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Physical function (Cochin hand function scale, 0-90, high is poor, change score) at ≤3 months (follow up: 4 weeks; assessed with: Cochin hand function scale; Scale from: 0 to 90)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	splints	no device intervention	Relative (95% CI)	Absolute (95% CI)		
1	randomised trials	serious [a]	not serious	not serious	serious [c]	none	54	47	-	MD **1.6 higher** (2.3 lower to 5.5 higher)	⨁⨁◯◯ LOW	CRITICAL
Physical function (Cochin hand function scale, 0-90, high is poor, change score) at >3 months (follow up: 12 months; assessed with: Cochin hand function scale; Scale from: 0 to 90)												
1	randomised trials	serious [a]	not serious	not serious	serious [c]	none	49	46	-	MD **6.2 lower** (10.77 lower to 1.63 lower)	⨁⨁◯◯ LOW	CRITICAL

CI: Confidence interval; **MD:** Mean difference; **SMD:** Standardised mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

c. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

F.3 Hand osteoarthritis

Table 51: Clinical evidence profile: splints compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	splints	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Pain (AUSCAN, 0-20, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: AUSCAN; Scale from: 0 to 20)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	26	26	-	MD **0.3 lower** (2.67 lower to 2.07 higher)	⨁◯◯◯ VERY LOW	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	splints	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Pain (AUSCAN, 0-20, high is poor, final value) at >3 months (follow-up: 24 weeks; assessed with: AUSCAN; Scale from: 0 to 20)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	26	26	-	MD **2.4 lower** (4.57 lower to 0.23 lower)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (AUSCAN, 0-36, high is poor, final value) at ≤3 months (follow-up: 12 weeks; assessed with: AUSCAN; Scale from: 0 to 36)												
1	randomised trials	very serious[a]	not serious	not serious	very serious[b]	none	26	26	-	MD **0.2 higher** (3.66 lower to 4.06 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (AUSCAN, 0-36, high is poor, final value) at >3 months (follow-up: 24 weeks; assessed with: AUSCAN; Scale from: 0 to 36)												
1	randomised trials	very serious[a]	not serious	not serious	serious[b]	none	26	26	-	MD **1.9 lower** (5.87 lower to 2.07 higher)	⨁◯◯◯ VERY LOW	CRITICAL

CI: confidence interval; **MD:** mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 52: Clinical evidence profile: tape compared to no device intervention

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	no device intervention	Relative (95% CI)	Absolute (95% CI)		
Pain (VAS, 0-10, high is poor, final value) at ≤3 months (follow-up: 8 weeks; assessed with: VAS; Scale from: 0 to 10)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	19	19	-	MD **0.89 lower** (1.57 lower to 0.21 lower)	⨁⨁◯◯ LOW	CRITICAL
Physical function (DASH, 0-100, high is poor, final value) at ≤3 months (follow-up: 8 weeks; assessed with: DASH; Scale from: 0 to 100)												
1	randomised trials	serious[a]	not serious	not serious	serious[b]	none	19	19	-	MD **7.58 lower** (14.91 lower to 0.25 lower)	⨁⨁◯◯ LOW	CRITICAL

CI: confidence interval; **MD:** mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

F.4 Finger osteoarthritis

Table 53: Clinical evidence profile: tape compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	tape	sham devices	Relative (95% CI)	Absolute (95% CI)		
Pain (VAS, 0-10, high is poor, final values) at ≤3 months (follow up: 3 weeks; assessed with: VAS; Scale from: 0 to 10)												
1	randomised trials	very serious [a]	not serious	not serious	very serious [b]	none	5	5	-	MD **0.3 lower** (3.53 lower to 2.93 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Osteoarthritis flares at ≤3 months (follow up: 3 weeks)												
1	randomised trials	very serious [b]	not serious	not serious	very serious [b]	none	1/5 (20.0%)	0/5 (0.0%)	**OR 7.39** (0.15 to 372.38)	**200 fewer per 1,000** (from 610 fewer to 210 more) [c]	⨁◯◯◯ VERY LOW	IMPORTANT

CI: Confidence interval; **MD:** Mean difference; **OR:** Odds ratio

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

c. Absolute effect calculated from risk difference due to zero events in one study arm

F.5 Foot osteoarthritis

Table 54: Clinical evidence profile: insoles compared to sham devices

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	insoles	sham devices	Relative (95% CI)	Absolute (95% CI)		
Pain (NRS, 0-10, high is poor, change score) at ≤3 months (follow up: 12 weeks; assessed with: NRS; Scale from: 0 to 10)												
1	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	18	18	-	MD **1.4 lower** (3.35 lower to 0.55 higher)	⨁◯◯◯ VERY LOW	CRITICAL
Physical function (MFPDI function subscale, range not reported, high is poor, change score) at ≤3 months (follow up: 12 weeks; assessed with: MFPDI function subscale)												
1	randomised trials	very serious [a]	not serious	not serious	serious [b]	none	18	18	-	MD **1.4 lower** (3.98 lower to 1.18 higher)	⨁◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **MD:** Mean difference

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

F.6 Toe osteoarthritis

Table 55: Clinical evidence profile: shoes compared to insoles

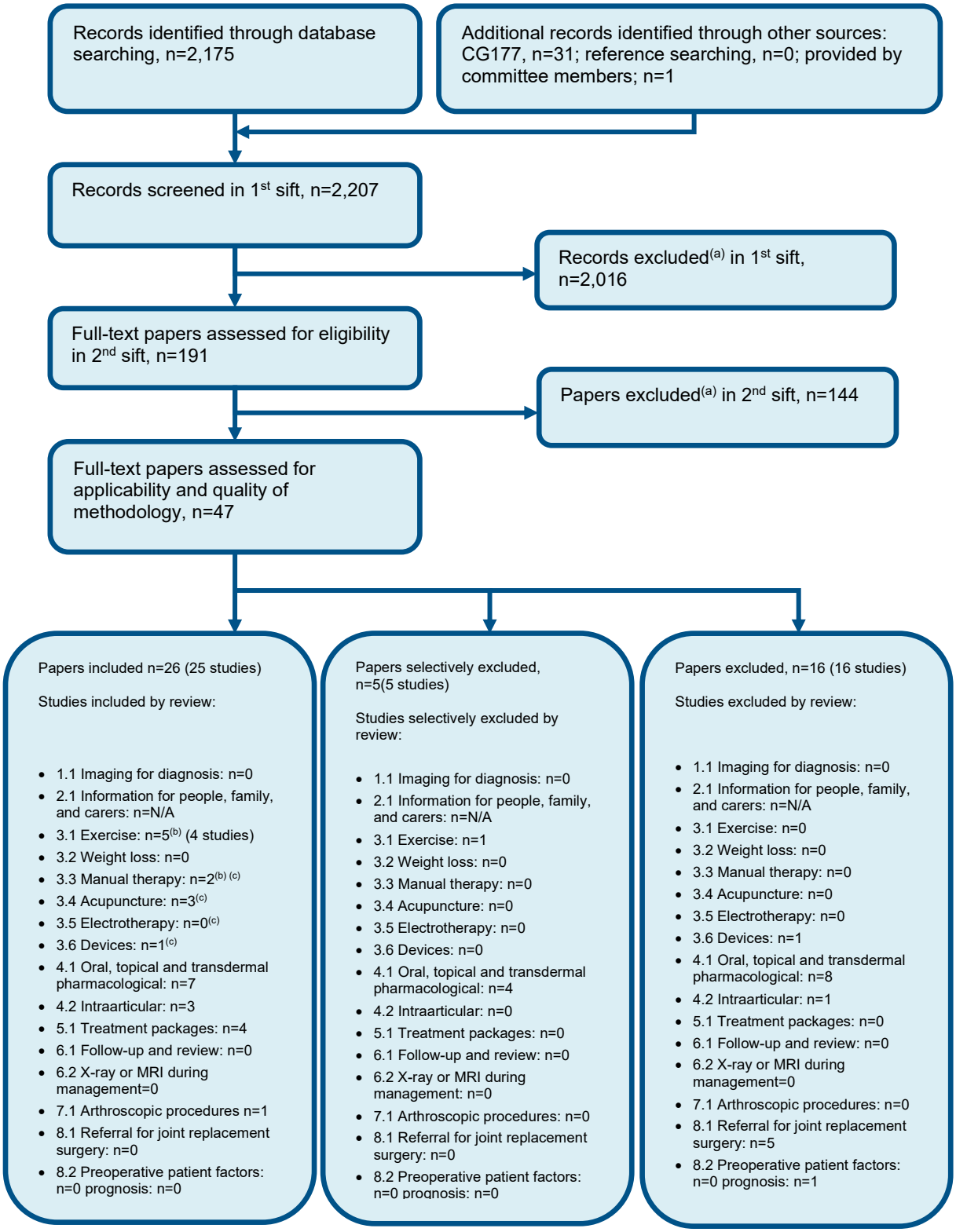
Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	shoes	insoles	Relative (95% CI)	Absolute (95% CI)		
Quality of life (SF-12 physical, 1-100, high is good, final value) at ≤3 months (follow up: 12 weeks; assessed with: SF-12 physical; Scale from: 1 to 100)												
1	randomised trials	serious [a]	not serious	not serious	not serious	none	46	52	-	MD **0.4 lower** (4.16 lower to 3.36 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Quality of life (SF-12 mental, 1-100, high is good, final value) at ≤3 months (follow up: 12 weeks; assessed with: SF-12 mental; Scale from: 1 to 100)												
1	randomised trials	very serious [a]	not serious	not serious	not serious	none	46	52	-	MD **0.3 lower** (4.11 lower to 3.51 higher)	⨁⨁◯◯ LOW	CRITICAL
Pain (Foot health status questionnaire pain domain, 1-100, high is good, final value) at ≤3 months (follow up: 12 weeks; assessed with: Foot health status questionnaire pain domain; Scale from: 1 to 100)												
1	randomised trials	serious [a]	not serious	not serious	not serious	none	46	52	-	MD **0.1 higher** (6.16 lower to 6.36 higher)	⨁⨁⨁◯ MODERATE	CRITICAL
Physical function (Foot health status questionnaire function domain, 1-100, high is good, final value) at ≤3 months (follow up: 12 weeks; assessed with: Foot health status questionnaire function domain; Scale from: 1 to 100)												
1	randomised trials	serious [a]	not serious	not serious	serious [b]	none	46	52	-	MD **12.2 lower** (19.17 lower to 5.23 lower)	⨁⨁◯◯ LOW	CRITICAL
Number of adverse events at ≤3 months (follow up: 12 weeks)												
1	randomised trials	not serious	not serious	not serious	serious [b]	none	42/46 (91.3%)	41/52 (78.8%)	**RR 1.16** (0.98 to 1.37)	**126 more per 1,000** (from 16 fewer to 292 more)	⨁⨁⨁◯ MODERATE	CRITICAL

CI: Confidence interval; **MD:** Mean difference; **RR:** Risk ratio

Explanations

a. Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
b. Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Appendix G – Economic evidence study selection



(a) Non-relevant population, intervention, comparison, design or setting; non-English language.
(b) Two articles identified were applicable to Q3.1 and Q3.3, for the purposes of this diagram they have been included under Q3.1 only.
(c) One article identified was applicable to Q3.3, Q3.4, Q3.5 and Q3.6, for the purposes of this diagram it has been included under Q3.3 only.

Appendix H – Economic evidence tables

Study	Adams 2021[4]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** Within trial analysis of a pragmatic, multi-centre single blinded randomised controlled superiority trial (same paper) **Approach to analysis:** Analysis of individual level data for EQ-5D and resource use. Unit costs applied. **Perspective:** UK NHS **Follow-up:** 12 weeks **Discounting:** Costs: n/a; Outcomes: n/a	**Population:** People with symptomatic basal thumb joint OA **Patient characteristics:** N: 349 Mean age: 63 Male: 21% **Intervention 1:** Therapist supported self-management programme (SSM)* **Intervention 2:** SSM plus a placebo thumb splint (either DMOrthotics thumb sleeve or DMOrthotics thumb sleeve lite) **Intervention 3:** SSM plus a verum thumb splint (either a Procool thumb splint or an Orflight trouser leg splint)	**Total costs (mean per patient):** Intervention 1: £586 Intervention 2: £685 Intervention 3: £738 Incremental (2−1): £99 Incremental (3−1): £152 (95% CI: NR; p=NR) **Currency & cost year:** 2017/18 UK pounds **Cost components incorporated:** Intervention costs, follow-up healthcare resource use costs	**QALYs (mean per patient):** Intervention 1: 0.144 (95% CI: 0.136 to 0.151; p=NR) Intervention 2: 0.144 (95% CI: 0.138 to 0.151; p=NR) Intervention 3: 0.144 (95% CI: 0.136 to 0.151; p=NR) Incremental (2−1): 0.000 Incremental (3−1): 0.000 (95% CI: NR; p=NR)	**ICER (Intervention 2 versus Intervention 1):** Intervention 1 dominates intervention 2 (pa) 95% CI: NR **ICER (Intervention 3 versus Intervention 1):** Intervention 1 dominates intervention 3 (pa) 95% CI: NR Probability Intervention 2 cost effective versus Intervention 1 (£20K threshold): 32% Probability Intervention 3 cost effective versus Intervention 1 (£20K threshold): 28% **Analysis of uncertainty:** Bootstrapping undertaken, results presented above. None other reported

	*All interventions were delivered over 8 weeks. Therapists conducted a 60-minutes assessment at baseline, followed by check-ins at weeks 2, 4 and 8.			
Data sources				
Health outcomes: Self-report questionnaires were completed at baseline, weeks 8 and 12 following randomisation. **Quality-of-life weights:** EQ-5D-5L were converted to EQ-5D-3L via the van Hout mapping algorithm. **Cost sources:** Unit costs were taken from the NHS Reference costs 2017/18 and PSSRU 2017/18.				
Comments				
Source of funding: NR. **Limitations:** The follow-up period was very short at 12 weeks and may not capture the full costs and benefits of the interventions. **Other:**				
Overall applicability:[a] Directly applicable **Overall quality:**[b] Potentially serious limitations				

Abbreviations: 95% CI= 95% confidence interval; CUA= cost–utility analysis; EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER= incremental cost-effectiveness ratio; NR= not reported; pa= probabilistic analysis; QALYs= quality-adjusted life years
(a) Directly applicable / Partially applicable / Not applicable
(b) Minor limitations / Potentially serious limitations / Very serious limitations

<table>
<tr><th>Study</th><th colspan="4">MacPherson 2017[110]</th></tr>
<tr><th>Study details</th><th>Population & interventions</th><th>Costs</th><th>Health outcomes</th><th>Cost effectiveness</th></tr>
<tr>
<td>Economic analysis: CUA (health outcome = QALYs)

Study design: Network meta-analysis based on a systematic review of 88 trials. Three different networks were used:
1. All trials
2. Subset of trials that were graded with a low risk of bias for allocation concealment
3. Same as point 2 but further restricting trials to those that reported outcomes between 3 and 13 weeks.

Approach to analysis: QALY changes from the different networks of analysis were</td>
<td>Population:
Patients reporting pain resulting from OA of the knee

Patient characteristics:
Mean age across all trials = 53-85
Male = NR

Intervention 1: Usual care (specific treatment not described)
Intervention 2: Static magnets
Intervention 3: Insoles
Intervention 4: TENS
Intervention 5: Braces
Intervention 6: Acupuncture
Intervention 7: Heat treatment
Intervention 8: Manual therapy
Intervention 9: PES</td>
<td>Total costs (mean per patient):
<u>All trials</u>
Intervention 1: £0
Intervention 2: £5
Intervention 3: £13
Intervention 4: £31
Intervention 5: £40
Intervention 6: £179
Intervention 7: £297
Intervention 8: £304
Intervention 9: £396
Intervention 10: £481
Intervention 11: £503
Intervention 12: £770
Intervention 13: £1,453

<u>Trials with adequate allocation concealment</u>
Intervention 1: £0
Intervention 2: £5
Intervention 3: £13
Intervention 4: £30
Intervention 5: NR
Intervention 6: £192
Intervention 7: £214
Intervention 8: £276</td>
<td>QALYs gained versus baseline (mean per patient):
<u>All trials</u>
Intervention 1: 0.000
Intervention 2: 0.001
Intervention 3: 0.001
Intervention 4: 0.011
Intervention 5: 0.001
Intervention 6: 0.014
Intervention 7: 0.005
Intervention 8: 0.008
Intervention 9: 0.011
Intervention 10: 0.005
Intervention 11: 0.007
Intervention 12: 0.033
Intervention 13: 0.007

<u>Trials with adequate allocation concealment</u>
Intervention 1: 0.000
Intervention 2: 0.000
Intervention 3: 0.002
Intervention 4: 0.005
Intervention 5: NR
Intervention 6: 0.017
Intervention 7: 0.003
Intervention 8: 0.013</td>
<td>Full incremental analysis[(c)] [(d)]:
<u>All trials</u>
<table>
<tr><th></th><th>Cost</th><th>QALYs</th><th>Inc. Cost</th><th>Inc. QALY</th><th>Cost per QALY</th><th>% most CE at £20 K</th></tr>
<tr><td>1</td><td>£0</td><td>0.000</td><td colspan="2">Baseline</td><td></td><td>0%</td></tr>
<tr><td>2</td><td>£5</td><td>0.001</td><td>£5</td><td>0.001</td><td>ED</td><td>22%</td></tr>
<tr><td>3</td><td>£13</td><td>0.001</td><td>£8</td><td>0.000</td><td>ED</td><td>0%</td></tr>
<tr><td>4</td><td>£31</td><td>0.011</td><td>£31</td><td>0.011</td><td>£2,690</td><td>49%</td></tr>
<tr><td>5</td><td>£40</td><td>0.001</td><td>£9</td><td>-0.01</td><td>D</td><td>6%</td></tr>
<tr><td>6</td><td>£179</td><td>0.014</td><td>£148</td><td>0.003</td><td>ED</td><td>6%</td></tr>
<tr><td>7</td><td>£297</td><td>0.005</td><td>£266</td><td>-0.006</td><td>D</td><td>0%</td></tr>
<tr><td>8</td><td>£304</td><td>0.008</td><td>£273</td><td>-0.003</td><td>D</td><td>0%</td></tr>
<tr><td>9</td><td>£396</td><td>0.011</td><td>£365</td><td>0.000</td><td>D</td><td>0%</td></tr>
<tr><td>10</td><td>£481</td><td>0.005</td><td>£450</td><td>-0.006</td><td>D</td><td>16%</td></tr>
<tr><td>11</td><td>£503</td><td>0.007</td><td>£472</td><td>-0.004</td><td>D</td><td>0%</td></tr>
<tr><td>12</td><td>£770</td><td>0.033</td><td>£739</td><td>0.022</td><td>£33,866</td><td>0%</td></tr>
<tr><td>13</td><td>£1,453</td><td>0.007</td><td>£683</td><td>-0.026</td><td>D</td><td>0%</td></tr>
</table>
</td>
</tr>
</table>

combined with treatment and non-treatment-related costs.

Perspective: UK NHS

Time horizon/ treatment duration: 8 weeks

Discounting: n/a

Intervention 10: NMES
Intervention 11: Laser light therapy
Intervention 12: Interferential therapy
Intervention 13: PEMF

Intervention 9: £410
Intervention 10: NR
Intervention 11: £288
Intervention 12: £1,179
Intervention 13: £577

<u>Trials with adequate allocation concealment and an end point reported at 3-13 weeks</u>

Intervention 1: £0
Intervention 2: £5
Intervention 3: £14
Intervention 4: £30
Intervention 5: NR
Intervention 6: £192
Intervention 7: £213
Intervention 8: £277
Intervention 9: £410
Intervention 10: NR
Intervention 11: £288
Intervention 12: £1,179
Intervention 13: £277

For incremental analyses see cost effectiveness column

Currency & cost year:
2011/12 UK pounds.

Intervention 9: 0.010
Intervention 10: NR
Intervention 11: 0.003
Intervention 12: 0.016
Intervention 13: 0.008

<u>Trials with adequate allocation concealment and an end point reported at 3-13 weeks</u>

Intervention 1: 0.000
Intervention 2: -0.001
Intervention 3: 0.004
Intervention 4: 0.006
Intervention 5: NR
Intervention 6: 0.017
Intervention 7: 0.002
Intervention 8: 0.018
Intervention 9: 0.010
Intervention 10: NR
Intervention 11: 0.003
Intervention 12: 0.017
Intervention 13: 0.007

For incremental analyses see cost effectiveness column

<u>Trials with adequate allocation concealment</u>[(e)]

	Cost	QALYs	Inc. Cost	Inc. QALY	Cost per QALY	% most CE at £20 K
1	£0	0.000	Baseline			0%
2	£5	0.000	£5	0.000	D	26%
3	£13	0.002	£13	0.002	ED	4%
4	£30	0.005	£30	0.005	£6,142	15%
6	£192	0.017	£162	0.012	£13,502	47%
7	£214	0.003	£22	-0.014	D	0%
8	£276	0.013	£84	-0.004	D	7%
11	£288	0.003	£96	-0.014	D	0%
9	£410	0.010	£218	-0.007	D	0%
13	£577	0.008	£385	-0.009	D	0%
12	£1,179	0.016	£987	-0.001	D	0%

<u>Trials with adequate allocation concealment and an end point reported at 3-13 weeks</u>[(e)]

	Cost	QALYs	Inc. Cost	Inc. QALY	Cost per QALY	% most CE at £20 K
1	£0	0.000	Baseline			0%
2	£5	-0.001	£5	-0.001	D	17%
3	£14	0.004	£14	0.004	£3,540	13%
4	£30	0.006	£16	0.002	£9,750	25%
6	£192	0.017	£162	0.011	£14,275	25%

		Cost components incorporated: Physiotherapist's time to conduct weekly sessions, except for TENS, where patients self-administered after an initial physiotherapist visit. Changes in non-treatment-related visits to GPs and specialists arising from changes in EQ-5D score.		

7	£213	0.002	£21	-0.015	D	0%
8	£277	0.018	£85	0.001	£86,964	20%
13	£277	0.007	£0	-0.011	D	0%
11	£288	0.003	£11	-0.015	D	0%
9	£410	0.010	£133	-0.008	D	0%
12	£1,179	0.017	£902	-0.001	D	0%

Analysis of uncertainty:
TENS was the most cost-effective alternative at a £20K threshold when a linear relationship were assumed between EQ-5D treatment effect and session duration. When all the treatment benefit were assumed in the first 20/30 minutes of the session, interferential therapy was the most cost-effective option.

In an analysis of all trials, TENS remained the most cost-effective option when the duration of treatment benefit were extended by 50%.

Data sources

Health outcomes: Study-level reported mean differences in pain as a measure of treatment effectiveness were standardised to the EQ-5D measure for each of the three network meta analyses. **Quality-of-life weights:** Generic EQ-5D quality-of-life scores were mapped from the SF-12 & SF-36 surveys, pain NRD, pain VAS and WOMAC scales. **Cost sources:** The cost to the NHS (physiotherapists time, GP and specialists' consultations) was obtained from the Personal Social Services Research Unit 2012. Equipment administered by physiotherapists (e.g., devices) were not included as the per-patient costs as these were expected to be small. **Resource use:** Estimates of resource use were based on consultations with clinical experts and published literature including trial data and NHS data. Treatment duration was based on a weighted average of the clinical trial data.

Comments

Source of funding: National Institute for Health Research (NIHR). **Limitations:** Unit costs taken from 2011/12 may not reflect current UK NHS practice. The time horizon was only 8 weeks. Adverse events and their downstream consequences were not considered. **Other:** Non-treatment-specific healthcare resource use was assumed to be a function of change in EQ-5D and was taken from the TOIB trial. TENS machine assumed to last for 1 year.

Overall applicability:[a] Partially applicable **Overall quality:**[b] Potentially serious limitations

Abbreviations: CE= cost effective; CI = confidence interval; CUA = cost-utility analysis; D= dominated; ED= extendedly dominated; EQ-5D = Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); GP= general practitioner; ICER = incremental cost-effectiveness ratio; Inc.= incremental; K= thousand; n/a = not applicable; NHS = National Health Service; NMES= neuromuscular electrical stimulation; NR = not reported; NRS = numeric rating scale; OA = Osteoarthritis; PEMF= pulsed

electromagnetic field; PES= pulsed electrical stimulation; QALYs = quality-adjusted life years; SF-12 = short-form health survey 12 items; SF-36= short-form health survey 36 items; TENS= transcutaneous electrical nerve stimulation; UK= United Kingdom; VAS = visual analogue scale; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

(a) Directly applicable / Partially applicable / Not applicable

(b) Minor limitations /Potentially serious limitations / Very serious limitations

(c) Intervention number in order of least to most costly (in terms of cost)

(d) Full incremental analysis of available strategies: first strategies are ruled out that are dominated (another strategy is more effective and has lower costs) or subject to extended dominance (the strategy is more effective and more costly but the incremental cost effectiveness ratio is higher than the next most effective option and so it would never be the most cost effective option); incremental costs, incremental effects and incremental cost effectiveness ratios are calculated for the remaining strategies by comparing each to the next most effective option.

(e) Interventions 5 and 10 not available because these intervention did not provide information to network meta analyses.

Appendix I – Health economic model

No original economic modelling was undertaken.

Appendix J – Excluded studies

Clinical studies

Table 56: Studies excluded from the clinical review

Study	Exclusion reason
Abolhasani 2019[1]	Systematic review; references checked
Abolhasani 2019[3]	Erratum only
Abolhasani 2019[2]	Insufficient follow up (<1 week)
Aebischer 2016[5]	Systematic review: study designs inappropriate
Alfatafta 2021[7]	Systematic review; references checked
Altmis 2018[8]	Inappropriate comparison (mobilisation with movement and taping versus mobilisation with movement and placebo taping)
Amaral 2018[9]	Incorrect interventions (assistive devices versus information)
Anandkumar 2014[10]	Insufficient follow up (<1 week)
Anonymous 2018[11]	Erratum only
Arazpour 2014[13]	Incorrect study design (not randomised)
Ashraf 2014[15]	Incorrect interventions (lateral wedge insoles versus acupuncture)
Atya 2015[16]	No appropriate outcomes reported (in graphical format only)
Baradaran 2018[20]	Systematic review; references checked
Berggren 2001[24]	No usable outcomes (no relevant outcomes)
Berry 1992[25]	No appropriate outcomes reported
Bhosale 2019[26]	Incorrect interventions (pain release phenomenon technique with kinesio taping versus conventional therapy)
Bryk 2011[28]	Incorrect study design (randomised by intervention, not patient)
Buhler 2019[29]	Systematic review: study designs inappropriate
Cantero-tellez 2018[33]	Inappropriate comparison (thumb orthosis with the metacarpophalangeal joint excluded versus thumb orthosis with the metacarpophalangeal joint included.)
Cantero-tellez 2018[32]	Inappropriate comparison (Ballena orthotic versus Colditz orthotic)
Chen 2008[35]	Insufficient follow up (<1 week)
Chen 2011[36]	Inappropriate comparison (Knee wraps with a static magnetic field versus control knee wraps)
Cherian 2016[37]	Incorrect interventions (TENS, NMES)
Cho 2015[38]	Insufficient follow up (<1 week)
Chughtai 2016[39]	No appropriate outcomes reported (no relevant outcomes)
Collins 2017[40]	Incorrect study design (randomisation by intervention)
Collins 2019[41]	Protocol only
Crenshaw 2000[42]	Not guideline condition. Not review population (not osteoarthritis). Incorrect study design (randomised by intervention)
Crossley 2009[43]	No appropriate outcomes reported (no relevant outcomes)
Cudejko 2018[44]	Systematic review: study designs inappropriate
Dammerer 2019[46]	Not review population (post arthroscopic partial meniscectomy)
Danazumi 2021[47]	No usable outcomes (no relevant outcomes)
De 2012[48]	Incorrect interventions (systematic review: surgical and non-surgical therapeutic options for the management of temporomandibular joint osteoarthritis)

Dessery 2014[50]	Inappropriate comparison (valgus brace, unloader brace with valgus and external rotation functions and a functional knee brace).
Dessery 2017[49]	No appropriate outcomes reported (no relevant outcomes)
Donec 2019[52]	Inappropriate population (unit of randomisation was joint rather than person)
Donec 2020[51]	Inappropriate population (unit of randomisation was joint rather than person)
Draganich 2006[53]	No appropriate outcomes reported
Duivenvoorden 2015[54]	Cochrane review; references checked
Edmonds 2016[55]	Incorrect study design (randomised by testing session, not by patient)
Fan 2020[58]	Systematic review; references checked
Frecklington 2018[62]	People with conditions that may make them susceptible to osteoarthritis or often occur alongside osteoarthritis (including: crystal arthritis, inflammatory arthritis, septic arthritis, hemochromatosis, haemophilic arthropathy, diseases of childhood that may predispose to osteoarthritis and malignancy)
Fu 2015[63]	Incorrect study design (cohort study)
Gardner 2016[64]	Inappropriate comparison (effects of lateral wedges in patients with osteoarthritis and healthy volunteers). Incorrect study design
Gohal 2018[65]	Systematic review: study designs inappropriate
Hanafy 2014[70]	Incorrect study design (conditions were randomised rather than participants)
Hart 2016[71]	Incorrect study design (randomised within subject)
Hassan 2002[72]	Inappropriate comparison (standard bandage versus looser bandage)
Hawke 2008[74]	Not guideline condition. Not review population (foot pain, including conditions that are not osteoarthritis)
Hinman 2003[77]	Insufficient follow up (<1 week)
Hinman 2009[78]	No appropriate outcomes reported (no relevant outcomes)
Hinman 2016[80]	Inappropriate comparison (walking shoes with lateral-wedge insoles versus conventional walking shoes)
Hsieh 2016[84]	Inappropriate comparison (rigid versus soft lateral wedge arch support insoles)
Hsieh 2020[83]	Incorrect study design (not randomised)
Hui 2014[85]	Insufficient follow up (<1 week)
Hunter 2011[87]	No appropriate outcomes reported (beta coefficients reported)
Hunter 2012[86]	Wrong comparison (compares multiple orthoses being changed at the same time, not a valid comparison in the protocol)
Ishii 2017[88]	Incorrect study design. Inappropriate comparison (participants with OA versus healthy volunteers)
Jamison 2018[89]	Incorrect interventions (vibrating gloves)
John 2011[90]	No appropriate outcomes reported
Johnson 2013[91]	Incorrect study design (prospective pilot series)
Jones 2015[93]	Insufficient follow up (<1 week)
Kanaujia 2018[95]	Abstract only
Khan 2019[97]	No appropriate outcomes reported (relevant outcomes did not have standard deviations reported, and were not possible to calculate)
Li 2018[106]	Systematic review; references checked

Lu 2018[107]	Systematic review; references checked
Lue 2017[108]	Systematic review is not relevant to review question or unclear PICO (pharmacological and non-pharmacological therapies in patients with hand osteoarthritis)
Machon 2011[109]	No appropriate outcomes reported
Mao 2021[112]	Wrong comparison (includes studies where the treatment effect is examined immediately after treatment therefore <1 week duration)
Matsuno 1997[113]	Incorrect study design (case series)
Mauricio 2018[114]	Incorrect study design (interventions were randomised)
Mehta 2005[116]	Incorrect study design (randomisation not mentioned). No appropriate outcomes reported
Mejersjo 2008[117]	Incorrect interventions (diclofenac sodium versus occlusal splint therapy)
Melese 2020[118]	Systematic review; references checked
Menz 2016[119]	Inappropriate comparison (prefabricated foot orthoses versus specialised footwear)
Menz 2017[121]	Incorrect study design (secondary analysis of an RCT). Inappropriate comparison (prefabricated foot orthoses versus specialised footwear)
Mine 2017[122]	Systematic review; references checked
Mistry 2018[123]	Systematic review: study designs inappropriate (cohort studies)
Molgaard 2018[124]	Not guideline condition. Not review population (patellofemoral pain, including those without OA).
Mont 2015[125]	Inappropriate comparison (compares braces to a range of additional treatments, ranging from exercise to corticosteroid injections with no information provided as to whether this was available to people in the intervention arm).
Moyer 2015[127]	Systematic review; references checked
Moyer 2017[126]	No appropriate outcomes reported
Munteanu 2021[128]	Conference abstract
Nerot 2017[130]	Incorrect study design
Niemela 2012[133]	Not guideline condition. Not review population (Only ~8% in each arm had osteoarthrosis. The rest had other reasons for temporomandibular disorders so may not be relevant)
Ostrander 2016[137]	No appropriate outcomes reported
Ouyang 2018[138]	Systematic review: study designs inappropriate
Parekh 2018[139]	No relevant outcomes
Park 2018[140]	Insufficient follow up (<1 week)
Parkes 2013[141]	Systematic review; references checked
Paterson 2021[142]	Conference abstract
Petersen 2016[145]	Systematic review: study designs inappropriate
Petersen 2019[144]	Inappropriate comparison (ankle-–foot orthosis versus knee unloader brace)
Phillips 2016[147]	Systematic review: study designs inappropriate
Pinheiro 2020[148]	Insufficient follow up period (<7 days)
Rafiaee 2012[149]	Inappropriate comparison (3mm versus 7mm lateral wedge insoles)
Rahlf 2018[150]	Insufficient follow up (<1 week)

Richards 2005[153]	Inappropriate comparison (simple hinged brace versus valgus corrective brace)
Robert-lachaine 2020[154]	Inappropriate comparison (valgus three-point bending system brace versus unloader brace versus stabilizing brace)
Schwarze 2021[158]	No usable outcomes (relevant outcomes reported as median plus IQR)
Segal 2009[159]	Inappropriate comparison (laterally wedged insole versus insole with an ankle support). No appropriate outcomes reported
Sillem 2011[160]	Inappropriate comparison (prefabricated versus custom-made splint)
Snyder-mackler 2011[162]	Commentary only
Steadman 2016[163]	Systematic review: study designs inappropriate
Sudhesh 2013[164]	Incorrect interventions (taping and closed kinetic exercise)
Sutida 2020[165]	Insufficient follow up (<1 week)
Swezey 1979[166]	People with conditions that may make them susceptible to osteoarthritis or often occur alongside osteoarthritis (including: crystal arthritis, inflammatory arthritis, septic arthritis, hemochromatosis, haemophilic arthropathy, diseases of childhood that may predispose to osteoarthritis and malignancy). Inappropriate comparison
Tan 2020[169]	Insufficient follow up period (<1 week)
Tezcan 2017[170]	No appropriate outcomes reported
Thiele 2009[171]	Not guideline condition (chronic risk pain caused by OA and other conditions). Not review population. Inappropriate comparison (custom made versus commercially available splint)
Toda 2001[175]	Inappropriate comparison (insole with elastic subtalar strapping versus a traditional shoe insert wedge insole)
Toda 2002[174]	Inappropriate comparison (subtalar strapping versus ankle support)
Toda 2002[173]	No appropriate outcomes reported (no relevant outcomes)
Toda 2004[177]	Inappropriate comparison (rubber insole versus urethane insole)
Toda 2004[179]	Inappropriate comparison (lateral wedge insole with subtalar strapping versus lateral wedge insole)
Toda 2004[178]	Inappropriate comparison (lateral wedge insole with subtalar strapping of different elevations)
Toda 2005[180]	Inappropriate comparison (lateral wedge with subtalar strapping versus lateral wedge without subtalar strapping)
Toda 2006[176]	Inappropriate comparison (insole with elastic subtalar strapping versus a traditional shoe insert wedge insole)
Trombini-souza 2012[182]	No appropriate outcomes reported (no relevant outcomes)
Trombini-souza 2015[183]	No appropriate outcomes reported (no relevant outcomes)
Trombini-souza 2020[181]	No usable outcomes (no relevant outcomes)
Turpin 2012[184]	Incorrect study design
Van egmond 2017[185]	Inappropriate comparison (two types of valgus unloading brace)
Vegt 2017[188]	Inappropriate comparison (thumb brace versus custom-made orthosis)
Wageck 2016[190]	Insufficient follow up (≤1 week)
Wagner 2018[191]	Systematic review: study designs inappropriate
Wajon 2005[192]	Inappropriate comparison (thumb splint plus exercise versus opens splint plus exercise)
Wallace 2012[193]	Insufficient follow up (≤1 week)

Witteveen 2013[194]	Protocol only
Woods 2017[195]	Cost-effectiveness study, no appropriate clinical outcomes
Wyndow 2017[197]	Protocol only
Xing 2017[198]	Systematic review: study designs inappropriate
Yu 2016[201]	Incorrect study design (observational study)
Yu 2021[200]	Systematic review; references checked
Zafar 2020[202]	Systematic review; references checked
Zhang 2018[203]	Systematic review; references checked

Health Economic studies

Table 57: Studies excluded from the health economic review

Reference	Reason for exclusion
Lee 2016 [103]	Excluded as rated as partially applicable with very serious limitations. Analysis uses non-comparative prospective cohort data for intervention treatment effects, and separate trial for control group. The populations in the two studies are very different and therefore not considered suitable for use in this way. The paper does not consider resource use beyond that required for the device.

Appendix K – Research recommendations – full details

K.1.1 Research recommendation

What is the clinical and cost effectiveness of footwear for the management of lower limb osteoarthritis?

K.1.2 Why this is important

People with lower limb osteoarthritis can have their symptoms worsened if they have the incorrect footwear. Therefore, providing the correct footwear may help to improve the quality of life of people with lower limb osteoarthritis. Current studies investigating this compared use of medical footwear compared to other footwear, which often included providing new footwear which may be more suitable for the person than their previous footwear. During discussion, the committee agreed that this was not an effective sham comparison and so this made the comparison more difficult. The committee agreed that a trial comparing a new footwear to usual care (where a person continues to use their current shoes) may allow for a pragmatic assessment of the benefits of providing new footwear to people using NHS services.

K.1.3 Rationale for research recommendation

Importance to 'patients' or the population	People with osteoarthritis may have their symptoms worsened by the wrong footwear and therefore providing footwear that is suited to the symptoms that the person has may improve their quality of life and reduce adverse events (for example: falls). A variety of footwear that is marketed to improve osteoarthritis symptoms is available commercially, but the evidence of their effectiveness is limited. Therefore, investigating the clinical effectiveness of this is important. If footwear can improve quality of life and daily activity this has the potential to reduce the negative psychological and social impact as well as improve the management of comorbidities associated with osteoarthritis like hypertension and diabetes mellitus.
Relevance to NICE guidance	The current guidance found no evidence comparing shoes to no treatment/usual care. Given that a sham shoe is likely not plausible, and that comparisons will often be better than what is usually available to people with osteoarthritis, additional evidence investigating the effectiveness of shoes compared to usual care would be important to making future recommendations.
Relevance to the NHS	The potential cost of providing footwear may be significant and therefore having an adequate assessment of the cost-effectiveness would be important for ensuring that this is a worthwhile investment.

National priorities	This is not an area of national priority.
Current evidence base	Currently evidence is available comparing shoes to other types of shoes. In this review those have been classified as sham comparisons, but in actuality they are often better than what people normally use for footwear and so are not an adequate sham comparison to the devices being investigated (instead being an adequate comparison of the footwear compared to another footwear). Therefore, in order to understand pragmatically the benefit of providing shoes to people in the NHS, a no treatment comparison study would be necessary.
Equality considerations	Research assessing footwear would need to assess the impact of footwear on occupation, gender, self-efficacy and cultural choices to optimise acceptability and use. To optimise inclusion, removing barriers to application (donning and doffing) of the footwear would need to be considered (for example: elastic laces). The committee noted that the research identified in this review does not appear to represent the diverse population of people with osteoarthritis. They agreed that any further research should be representative of the population, including people from different family backgrounds, and socioeconomic backgrounds, disabled people, and people of different ages and genders. Future work should be done to consider the different experiences of people from diverse communities to ensure that the approach taken can be made equitable for everyone.

K.1.4 Modified PICO table

Population	Inclusion:
	• Adults (age ≥16 years) with osteoarthritis affecting lower limb joints
	• Stratified by joint site(s):
	  ○ Hip osteoarthritis
	  ○ Knee osteoarthritis
	  ○ Ankle osteoarthritis
	  ○ Foot osteoarthritis
	  ○ Toe osteoarthritis
	  ○ Multi-joint osteoarthritis

Intervention	Shoes designed or shoes hypothesised to improve symptoms related to lower limb

	osteoarthritis and daily movement/walking function
Comparator	Usual care (people continue using the shoes they already own)
Outcome	Stratify by ≤/>3 months: • Health-related quality of life [validated patient-reported outcomes, continuous data prioritised] • Pain [validated patient-reported outcomes, continuous data prioritised] • Physical function [validated patient-reported outcomes, continuous data prioritised] • Psychological distress [validated patient-reported outcomes, continuous data prioritised] • Osteoarthritis flare-ups [validated patient-reported outcomes, continuous data prioritised] • Number of adverse events [dichotomous] • Falls [dichotomous]
Study design	Randomised control trial
Timeframe	Long term (at least 1 year)
Additional information	Sample size: This should be based on feasibility studies, which can detect minimally important differences. We also recommend a size large enough to minimise group imbalance in each arm. The committee found studies less than 50 in each arm there were group imbalances and greater risk of study bias. Trials with sufficient blinding (of assessors), adequate randomisation methods and allocation concealment. Studies should collect data on any impact on physical activity and about the benefits and harms to other joints Subgroup analyses: • Presence of multimorbidity (high versus low morbidity score) • Age (≤/> 75 years) • Site of osteoarthritis ○ Hip ○ Knee ○ Ankle ○ Foot ○ Toe ○ ○ Multisite

K.1.5 Research recommendation

What is the clinical and cost effectiveness of devices compared with usual care for the management of painful foot and or ankle osteoarthritis?

K.1.1 Why this is important

There are a large range of medical devices provided for people with peripheral joint osteoarthritis but the efficacy for most of devices are unknown. The aims of these devices are to support or brace the joint, aid function and reduce pain. These are provided by the NHS services for many sites of peripheral osteoarthritis: finger, thumb, wrist, elbow, knee, ankle, foot and toe. The NICE guideline committee found there were a number of studies examining orthoses and braces for painful knee osteoarthritis, but very few device trials compared the outcomes to usual care or self-management.

During discussion, the committee agreed there was a lack of understanding not only patient benefit but also patient harms. Therefore, further research trials are recommended.

The committee recognises there are ongoing osteoarthritis randomised controlled trials that will answer some of the gaps in research found by the review of the current evidence. A large HTA funded trial will examine the efficacy of knee braces compared to self-management care (PROP-OA) as well as a large trial funded by Versus Arthritis to compare thumb braces to usual care (OTTER II).

The committee recognise that there are no randomised controlled trials examining the efficacy of devices for foot or ankle osteoarthritis compared to usual care. It was also not clear if there is a specific sub-group that may be pre-disposed to increased gains like unstable joints or joint deformity. The committee agreed that a trial comparing a device to self-management should be optimal and if a sham is included as an additional arm this should be tested in a feasibility phase to assess the quality of the blinding. Investigating the benefits and cost effectiveness of the devices will enable individual NHS services and national procurement to those with patient benefits and which are cost effective.

K.1.2 Rationale for research recommendation

Importance to ‘patients’ or the population	People with painful foot and ankle osteoarthritis have pain when performing daily functions and activities. Medical devices are provided to aid movement and function and reduce pain but the efficacy of these devices is not understood. Therefore, investigating the clinical effectiveness and improvement of quality of life is important. If medical devices improve quality of life and daily activity, this has the potential to reduce the negative psychological and social impact of osteoarthritis as well as improve the management of comorbidities associated with OA like hypertension and Diabetes.
Relevance to NICE guidance	The current guidance found no evidence comparing foot orthoses or ankle brace devices to no treatment/usual care. Given that a sham may not be plausible, additional evidence investigating the effectiveness of devices

	compared to usual care would be important to making future recommendations.
Relevance to the NHS	These devices are provided to a portion of the NHS patients (depending on local commissioning rules) but there is little evidence to support their ongoing use. Therefore, having an adequate assessment of the cost-effectiveness would be important for ensuring that this is a worthwhile investment.
National priorities	This is not an area of national priority.
Current evidence base	Currently there is no evidence exploring medical devices such as braces for ankle osteoarthritis and limited evidence is available for midfoot osteoarthritis comparing foot orthoses devices to a sham device and, for toe osteoarthritis orthoses were compared to footwear. Therefore, in order to understand pragmatically the benefit of continuing to provide medical devices equitably to people in the NHS, a no treatment comparison study would be necessary.
Equality considerations	Research assessing devices would need to assess the impact on occupation, gender, self-efficacy and cultural to optimise acceptability and use. To optimise inclusion, removing barriers to application (donning and doffing) would need to be considered. The committee noted that the research identified in this review does not appear to represent the diverse population of people with osteoarthritis. They agreed that any further research should be representative of the population, including people from different family backgrounds, and socioeconomic backgrounds, disabled people, and people of different ages and genders. Future work should be done to consider the different experiences of people from diverse communities to ensure that the approach taken can be made equitable for everyone.

K.1.3 Modified PICO table

Population	Inclusion:
	• Adults (age ≥18 years) with osteoarthritis affecting ankle and or foot joints.
	• Stratified by joint site(s):
	  ○ Ankle osteoarthritis
	  ○ Foot osteoarthritis
	  ○ Toe osteoarthritis
	  ○ Multi-joint osteoarthritis

Intervention	Foot orthoses or ankle braces or toe braces designed to improve symptomatic osteoarthritis with a proven therapeutic aims and mechanism of action
Comparator	Usual care (people offered self-management that does include medical devices like braces or orthoses.
Outcome	Stratify by ≤/>3 months: • Health-related quality of life [validated patient-reported outcomes, continuous data prioritised] • Pain [validated patient-reported outcomes, continuous data prioritised] • Physical function [validated patient-reported outcomes, continuous data prioritised] • Psychological distress [validated patient-reported outcomes, continuous data prioritised] • Osteoarthritis flare-ups [validated patient-reported outcomes, continuous data prioritised] • Number of adverse events [dichotomous] • Falls [dichotomous]
Study design	Randomised control trial
Timeframe	Long term (at least 1 year)

Additional information	Sample Size: This should be based on feasibility studies, which can detect minimally important differences. We also recommend a size large enough to minimise group imbalance in each arm. Trials with sufficient blinding (of assessors), adequate randomisation methods and allocation concealment.
	
	Studies should collect data on any impact on physical activity and about the benefits and harms to other joints.
	
	Subgroup analyses:
	• Presence of multimorbidity (high versus low morbidity score)
	• Age (≤/> 75 years)
	• Site of osteoarthritis
	  ○ Ankle
	  ○ Foot
	  ○ Toe
	  ○ Multisite