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Knee braces for knee osteoarthritis: A scoping review and narrative synthesis of interventions in randomised controlled trials



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SUMMARY

Objective: To identify and synthesise the content of knee bracing interventions in randomised controlled trials (RCTs) of knee osteoarthritis (OA).

Design: In this scoping review, three electronic databases (PubMed, Web of Science, Cochrane) were searched up to 10th June 2024. Nineteen previous systematic reviews of knee bracing for knee OA and four recent international clinical practice guidelines were also hand searched. Identified studies were screened for eligibility by two independent reviewers. Information on bracing interventions was extracted from included RCT reports, informed by Template for Intervention Description and Replication (TIDieR) guidelines. Data were synthesised narratively.

Results: Thirty-one RCTs testing 47 different bracing interventions were included. Braces were broadly grouped as valgus/varus, patellofemoral, sleeve, neutral hinged, or control/placebo knee braces. Brace manufacturer and models varied, as did amount of recommended brace use. Only three interventions specifically targeted brace adherence. Information on brace providers, setting, number of treatment sessions, and intervention modification over time was poorly reported. Adherence to brace use was described for 32 (68%) interventions, most commonly via self-report. Several me-

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mechanisms of action for knee braces were proposed, broadly grouped as biomechanical, neuromuscular, and psychological.

Conclusions: Many different knee brace interventions have been tested for knee OA, with several proposed mechanisms of action, a lack of focus on adherence, and a lack of full reporting. These issues may be contributing to the heterogeneous findings and inconsistent guideline recommendations about the clinical effectiveness of knee bracing for knee OA to date.

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Introduction

Symptomatic knee osteoarthritis (OA) affects an estimated 365 million adults worldwide.¹ 11.5 million years lived with disability (YLD) are attributable to knee OA; this represents 1.3% of the total global YLD.¹ This figure is rising, driven by ageing populations and the high prevalence of obesity. Rates of knee replacement continue to increase across much of the world.² There is a need for health systems to implement cost-effective nonsurgical health technologies earlier in care pathways and when joint replacement may not be available, indicated or preferred. Knee braces, encompassing a wide array of valgus/varus unloader, neutral stabilising, and soft sleeve braces for tibiofemoral, patellofemoral, and mixed knee OA presentations, are potential options. However, clinical practice guidelines offer contradictory and conflicting recommendations on their effectiveness.³

Recent clinical guidelines from the American College of Rheumatology/Arthritis Foundation⁴ and the American Academy of Orthopaedic Surgeons⁵ recommend knee bracing for knee OA, although heterogeneous findings and low-quality evidence continue to be noted in these guidelines and in others that have been unable to make a recommendation or have recommended against bracing.^{6,7} In the UK, due to insufficient evidence, current guidance from the National Institute of Health and Care Excellence (NICE) does not support the routine use of braces, unless there is joint instability or abnormal biomechanical loading, or if therapeutic exercise is ineffective or unsuitable without the addition of a brace, and the brace is likely to improve movement and function.⁸

Knee bracing for knee OA represents a class of complex interventions comprising a variety of devices, indications, and proposed mechanisms of action. Knee brace interventions may include different components (e.g. brace selection, brace fitting, encouraging brace adherence), target a range of behaviours (e.g. donning the brace, wearing the brace over time, using the brace within a broader self-management programme), and require varying levels of skill and expertise to apply.⁹ Treatment fidelity, comprising design, training, delivery, receipt, and enactment of interventions, is important for the internal validity of randomised controlled trials (RCTs), but particularly challenging for complex interventions. A review by Borrelli et al of complex interventions in health behaviour research found that only 55% of reviewed studies met treatment fidelity criteria.¹⁰ A full and accurate description of interventions is also a requirement for the successful replication of RCTs and for the faithful translation of complex interventions into 'real world' contexts.^{10,11} In 2013, a review by Hoffman et al. found that non-pharmacological interventions were insufficiently described in more than half of published RCTs.¹² Subsequent reviews of trial interventions reported in orthopaedic¹³ and physical therapy^{14,15} journals and exercise interventions for hip and knee OA^{16,17} suggest improving, but still suboptimal, reporting.

Whilst evidence from RCTs on the efficacy and effectiveness of knee braces for knee OA has been synthesised in many systematic reviews^{eg, 18} limited information is provided on the specific components of the bracing interventions tested or their proposed mechanisms of action. To address this gap, this study aimed to identify and synthesise the content of knee bracing interventions in published RCTs of knee OA. The purpose was to explore possible heterogeneity of intervention content (thus

assisting understanding the results of bracing RCTs), identify aspects of good reporting practice as well as aspects that require improvement, and to increase understanding of the proposed mechanisms of action by which knee braces may improve symptoms among people with knee OA.

Methods

A scoping review was conducted following Joanna Briggs Institute guidance.¹⁹ To identify the content of bracing interventions previously tested in RCTs (concept), for people with knee OA (participants), applicable for use in clinical practice (context), relevant search terms (shown in appendix 1) were run in three electronic databases (Medline (PubMed), Web of Science, and Cochrane Library) from inception to 10th June 2024. Nineteen previous systematic reviews of knee bracing for knee OA^{18,20–37} and four recent international clinical practice guidelines^{4,5,7,8} were also hand searched to identify potentially eligible RCTs. Identified studies were imported into Ryaan where duplicates were removed. Two reviewers (either MAH, MJT or JS) independently screened abstracts and full-text articles against the inclusion and exclusion criteria (Table 1), with disagreements resolved by consensus and, failing this, a third reviewer (GP). To maximise the likelihood of finding relevant information on intervention descriptions for all included RCTs, any separate (linked) publications from the same parent trial were obtained where available (e.g. published protocols, published ancillary studies). Following methods adopted in a previous review,³⁸ these were identified by one author (MAH) checking references of included RCTs, and by searching the publications of all first and last authors via PubMed (appendix 2).

From RCT publications (main and/ or linked publications), data were extracted into tables by one reviewer (either MAH or MM), and then checked by a second reviewer (one of JS, MJT, LH, JQ). These included data on the RCT country of origin, patient population, sample size, interventions, comparator, and the primary outcomes and endpoints. The template for intervention description and replication (TIDieR) checklist³⁹ was used to inform data extraction on the description and reporting of knee bracing interventions. Information on 18 different intervention components were extracted, including 1) intervention name, 2) the brace(s) used (including brace make/ manufacturer, off the shelf or customised brace, recommend brace use, intervention length, additional intervention components, specific adherence enhancing strategies), 3) delivery of the bracing intervention (including who delivered it and with what training, over how many treatment sessions and in what setting), 4) any modifications to the bracing intervention protocol over the course of the RCT, 5) the proposed mechanism of actions of the brace, and 6) how well the intervention happened (assessment and amount of intervention fidelity and brace adherence) (appendix 3). Risk of bias assessment was not undertaken as the focus was on synthesising the content of knee bracing interventions for knee OA only, rather than the reported clinical- or cost-effectiveness of bracing interventions in comparison to controls.

Findings were synthesised narratively. This included grouping proposed mechanisms of action and intervention components into

	Include	Exclude
Types of participants (<i>Adults with symptomatic knee OA</i>)	OA can be self-reported, clinician or radiographically diagnosed, or self-reported knee pain in adults aged 45 years and over. For studies with mixed populations, over 50% need to meet one of the above criteria, or have a mean age of 45 years and over if self-reported knee pain.	Healthy volunteers; non-human, pain not attributable to OA (e.g., rheumatoid arthritis)
Concept (<i>Content of knee bracing interventions</i>) and Context (<i>applicable for use in clinical settings</i>)		
Intervention	Any type of knee brace (e.g., soft-sleeve or unloader-type), either delivered alone or in conjunction with other treatments, intended to be worn for a minimum period of two weeks	Rest orthoses, taping, other biomechanical interventions (e.g., shoe insoles)
Comparator	No treatment, other treatment, or placebo control	
Outcomes	Patient-centred measures (e.g., pain, function) reported as primary or secondary outcomes	Biomechanical/gait parameters only
Setting	Any clinical setting	Gait lab only
Other		
Study design	RCTs (any design, e.g., parallel, crossover, cluster, quasi)	Non-randomised comparative studies; observational studies; case series/reports
Publication type	Full, original published research articles	Conference abstracts, study protocols, correspondence
Language	Any language	Translation not available

Table I

Eligibility criteria.

themes (e.g., braces grouped as off the shelf or custom made) and completing frequency counts to report numbers and percentages.

Results

As shown in Fig. 1, 1136 articles were identified from electronic database searching, and 59 from hand searching existing systematic reviews and recent clinical guidelines. Following removal of duplicates, 800 unique articles were screened for eligibility; 688 of which were excluded based on title/abstract screening. Of 112 full-text manuscripts screened, 81 were excluded, most commonly due to being a conference proceeding/ trial protocol registry record only ($n = 48$) and study design (eight were not RCTs). Thirty-one RCTs were included in the synthesis, reported in 38 manuscripts.^{40–77}

Description of included RCTs

The 31 included RCTs were published between 1992 and 2022 and overall included 2356 participants (range 10–171). The majority of RCTs were conducted in Europe ($n = 12$) and North America ($n = 9$), used a parallel group design ($n = 23$), combined clinical and radiographic criteria to define OA for inclusion ($n = 26$), targeted individuals with tibiofemoral OA ($n = 23$), and followed participants for less than or equal to 3 months ($n = 19$). The comparators against which bracing interventions were tested were usual/ conservative care or education (without the use of a knee brace) ($n = 9$), a different knee brace intervention (including control/ placebo braces) ($n = 11$), lateral wedged insoles ($n = 7$), no brace ($n = 3$), stretching ($n = 1$), and an ankle brace ($n = 1$) (Table II).

Description of knee bracing interventions

Within the 31 RCTs, 47 different bracing interventions were tested. The type of knee braces could broadly be grouped as valgus/varus ($n = 27$, 57%), patellofemoral (categorised as such when a brace was stated by the authors as specifically targeting the patellofemoral joint) ($n = 3$, 6%), sleeve ($n = 6$, 13%), neutral hinged ($n = 3$, 6%), and control/placebo knee braces ($n = 7$, 15%) (any brace type explicitly described as a control/placebo by RCT authors). One intervention issued either a valgus/ varus or neutral hinged knee brace depending on patient presentation.⁵⁹ Brace manufacturer and model varied broadly, although the majority were off the shelf ($n = 36$, 77%) rather

than custom-made knee braces. The brace intervention period ranged from 2 weeks to 1 year, with most interventions lasting up to 3 months ($n = 33$, 70%). The recommended amount of brace use was variable, ranging from a minimum wear time of 3- to 12-hours per day, or all day. Nine (19%) interventions recommended gradually increasing brace wear over time. For valgus/varus braces, the degree of valgus/varus force applied was also variable. This was either dependent on participant perception (including perceived acceptability/ tolerability, or pain reduction) ($n = 9$), or by a set amount (e.g. four degree increase in valgus in the anteroposterior plane) ($n = 5$). However, for many interventions, this was not reported ($n = 13$). Twenty-four interventions (51%) included other treatments alongside the brace, which included varied components of usual or conservative care (e.g., education, exercise, analgesics). Only three interventions had accompanying reports that made it clear the intervention explicitly targeted brace adherence. Strategies to enhance adherence included in two brace interventions by Hunter et al^{54,55} included education, skills training on donning the brace, and issuing a pamphlet addressing common adherence-related concerns. The type of brace included in one bracing intervention in the RCT by van Egmond et al⁷³ was specifically chosen for its expected comfort with the aim of enhancing adherence (the SoftTec OA brace).

Bracing interventions were most provided by orthotists ($n = 9$, 21%) or technicians ($n = 9$, 21%); information on brace provider was not reported for 20 (43%) interventions. Although some brace interventions were reportedly delivered by a trained provider ($n = 6$, 13%), information on what training was undertaken was not reported for any intervention. Brace interventions were provided in both health care (e.g., hospitals, orthotic and outpatient departments) and research (e.g. universities, clinical research units) settings. However, this was often not reported or unclear ($n = 25$, 53%), as was the number of treatment sessions over which brace interventions were delivered ($n = 42$, 89%), and whether bracing interventions were modified over time ($n = 47$, 100%) (see Table III).

Proposed mechanisms of action of knee braces for knee OA

No clear logic model (representing the underlying causal processes through which interventions are thought to produce outcomes in simple, diagrammatical form⁷⁸) was reported for any bracing intervention. As shown in Table IV, several mechanisms of action for knee braces were proposed for each brace type, spanning biomechanical,

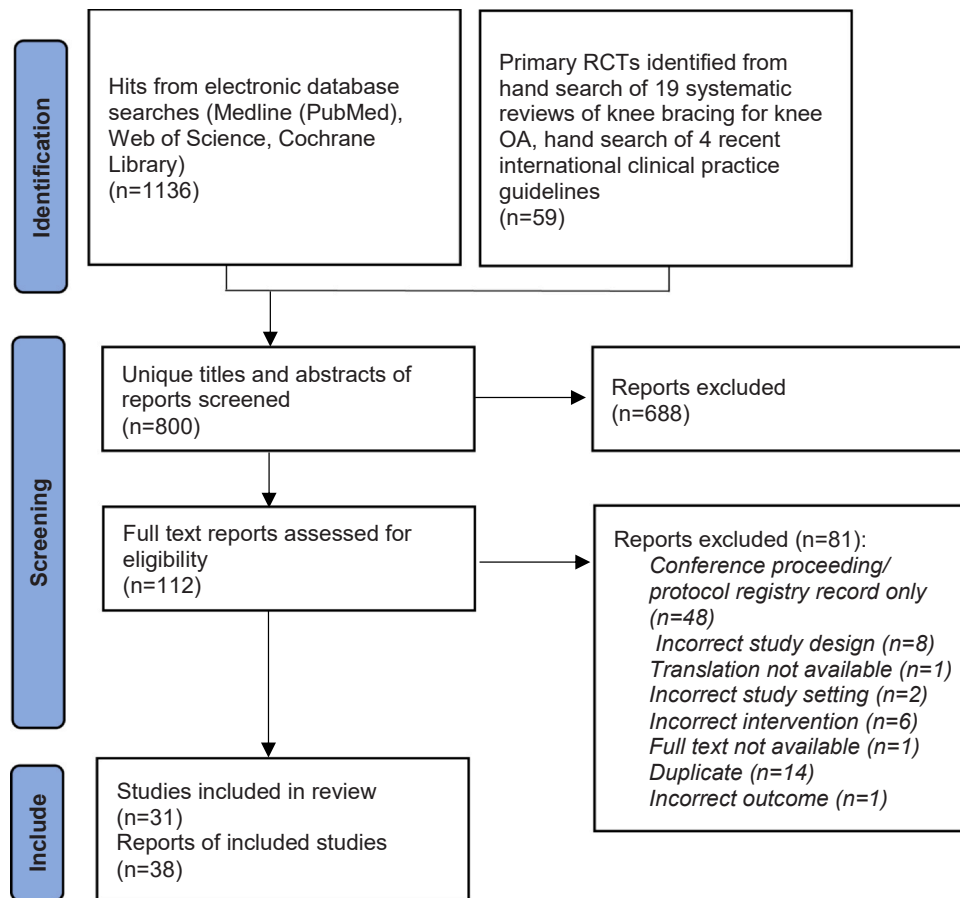


Fig. 1

Review flow diagram.

neuromuscular, and psychological factors. Biomechanical mechanisms of action (reduced load, improved joint alignment, increased stability) were most proposed for valgus/varus, patellofemoral and neutral hinged knee braces. Sleeve braces were predominantly proposed to have neuromuscular mechanisms of action (particularly increased proprioception and improved muscle function/ motor control). RCT papers of two bracing interventions (one valgus/varus knee brace, one neutral hinged knee brace) proposed a psychological mechanism of action (increased confidence in knee stability). Other than the placebo effect, one additional proposed mechanism of action for a control/ placebo knee brace was provided, which was to improve muscle function.

Brace adherence and intervention fidelity

As shown in Table V, adherence to brace use was measured for 32 (68%) brace interventions, predominantly via self-reported brace wear time (e.g., hours per day, days per week). Three brace interventions (all tested in one RCT⁴⁹) captured dichotomous information on whether the brace was being used (yes/no), and one used an objective measure of adherence (an activity monitor strapped to the brace) to capture information on daily step count.⁵¹ Only three interventions (from two RCTs) provided a threshold of required brace use in order to achieve adherence (Mazzucca et al: days the brace was worn for 12 h or more⁶⁰; van Raaij et al: using the brace more than 42 h per week/ 7 days for 6 h/ 75% of the working day^{74,75}).

Overall, the amount of reported brace wear time was variable. Information on treatment fidelity was very rarely explicitly reported (one RCT only⁶⁵).

Overall reporting of bracing interventions

As shown in Appendix 3, none of the bracing interventions were fully reported, according to our TIDieR informed criteria, with the number of components reported ranging from 6 to 12 (35–67%). Nineteen interventions (40%) reported less than 50% of all possible components. Intervention name, components relating to the brace (particularly make/manufacturer, whether it was customised or off the shelf, and recommended brace use), proposed mechanism of action, and brace adherence were generally better reported than components relating to brace delivery (brace provider, provider training, number of treatment sessions, and where treatment sessions were provided), modifications to the bracing intervention over time, and treatment fidelity.

Discussion

This study aimed to identify and synthesise the content of knee bracing interventions in published RCTs of knee OA. We included 31 RCTs that tested 47 different knee bracing interventions. Our findings highlight considerable heterogeneity in the content of knee bracing interventions and poor reporting of some

Author, year, country, trial reg. no.	Patient population	N	RCT design	Brace intervention (s)	Non-brace comparator (s)	Primary outcome (s)/ endpoint (s)
Arazpour 2013, Iran ⁴⁰ -	Medial tibiofemoral OA (C+XR)	24	Parallel group (quasi)	Unloader knee brace	Lateral wedged insole	Pain VAS at 6w
Berry 1992, UK ⁴¹ -	Knee OA (C+XR if needed)	170	Parallel group	Knee support plus conventional conservative management	Conventional conservative management	Pain VAS at rest, during activity, at night at 6w
Brouwer 2006, Netherlands ⁴² -	Medial or lateral tibiofemoral OA (C+XR)	117	Parallel group	Knee brace plus conservative treatment	Conservative treatment	Pain VAS and HSS at 3,6,12 m
Callaghan 2015, UK ISRCTN50380458 ^{43,44}	Patellofemoral OA (C+XR)	126	Parallel group	Patellar brace	No brace	Pain VAS on nominated activity at 6w
Cherian 2015, USA ^{45,46} -	Medial or lateral tibiofemoral OA (C+XR)	52	Parallel group	Pneumatic knee brace	Current standard care	Primary outcome(s) unclear Pain VAS, LEFS, SF-36, physical performance test battery, isokinetic quadriceps and hamstrings at 3 m Normalised adduction moments at 4–5w
Draganich 2006, USA ⁴⁷ -	Medial tibiofemoral OA (C+XR)	10	Crossover (2w washout)	I1: Off the shelf valgus-producing brace I2: Custom made valgus producing brace	-	Static balance at 6 m
Dwarakanathan 2022, India, ⁴⁸ -	Medial tibiofemoral OA (C+XR)	66	Parallel Group	Unloader knee orthosis	Lateral wedged insoles	Pain VAS at 12 m
Guegnon 2021, France NCT02765685 ⁴⁹	Medial tibiofemoral OA (C+XR)	120	Parallel group	Custom made knee brace plus usual standard care	Usual standard care	KOOS, KSS, KSS function at 6w, 12w, 24w,52w
Hjartarson 2018, Sweden NCT03454776 ⁵⁰	Knee OA (C+XR) (but all participants had medial tibiofemoral OA)	149	Parallel group	I1: Unloader brace I2: Look-alike brace (active straps removed)	-	Pain VAS at 6w
Horlick 1993, Canada ⁵¹ -	Medial tibiofemoral OA (C+XR)	39	Crossover (No wash out)	I1: Valgus brace with medial hinge I2: Valgus brace with lateral hinge I3: Brace in neutral	-	Pain VAS and WOMAC Pain at 6w
Hunter 2011, USA NCT00381563 ^{52,53}	Patellofemoral OA (C+XR)	80	Crossover (6w washout)	I1: Realigning patellofemoral brace I2: Non-realigning patellofemoral brace (placebo)	-	WOMAC Pain and WOMAC Function at 12w
Hunter, 2012, Australia NCT00124462 ^{54,55}	Medial tibiofemoral OA (C+XR)	80	Crossover (6w washout)	I1: Multi-modal realignment intervention: valgus knee brace, customised neutral bilateral foot orthoses, shoes designed for motion control I2: Neutral knee brace, unresponsive foot orthoses, shoes with flexible midsole	-	Valgus knee brace
Jones 2013, UK ⁵⁶ -	Medial tibiofemoral OA (C+XR)	28	Crossover (2w washout)	Valgus knee brace	Lateral wedged insole	Peak early stance external knee adduction moment at 2w
Khosravi 2021, Iran ⁵⁷ -	Medial tibiofemoral OA (XR)	21	Parallel group	I1: Valgus brace I2: Valgus brace plus lateral wedge insole	Lateral wedge insole	Primary outcome(s) unclear Pain VAS, WOMAC, gait analysis, knee adduction moment assessment at 6w WOMAC Total at 6 m
Kirkley 1999, Canada ⁵⁸ -	Medial tibiofemoral OA (C+XR)	119	Parallel group	I1: Neoprene sleeve I2: Unloader brace	Standard medical management	Primary outcome(s) unclear Pain VAS average, best, worst; KOS-ADL; PSFS; physical performance test battery; extension ROM; flexion ROM; isometric quadriceps at 6w
Madara 2019, USA ⁵⁹ -	Knee OA (DrDx)	33	Parallel group	Knee brace (type dependent on participant limb alignment) plus stretching	Stretching	Primary outcome(s) unclear WOMAC Pain, Stiffness, Function at 4w
Mazzuca 2004, USA ⁶⁰ -	Tibiofemoral OA (C+XR)	52	Parallel group	I1: Verum sleeve (specially fabricated to retain body heat) I2: Placebo sleeve (standard cotton/elastane sleeve)	-	Primary outcome(s) unclear WOMAC Pain, Stiffness, Function at 4w
Mohd Sharif 2019, Malaysia ⁶¹ -	Knee OA (C+XR)	19	Parallel group (quasi)	I1: Basic knee sleeve I2: Knee sleeve with patella cutout	-	Knee Adduction Moment, WOMAC at 6w
Niazi 2014, Pakistan ⁶² -	Medial tibiofemoral OA (C+XR)	120	Parallel group	Valgus knee brace	Lateral wedged insole	Pain VAS at 6 m

(continued on next page)

Table II (continued)

Author, year, country, trial reg. no.	Patient population	N	RCT design	Brace intervention (s)	Non-brace comparator (s)	Primary outcome (s)/ endpoint (s)
Ostrandler 2016, USA ⁶³ -	Medial tibiofemoral OA (diagnosis method not stated)	50	Parallel group	Medial Unloader brace	No brace	Primary outcome(s) unclear KOOS Pain, Symptoms, Function, Sport & Recreation, Quality of Life across 4,8,16,24w
Pagani 2010, Germany ⁶⁴ -	Medial tibiofemoral OA (XR)	11	Crossover (no washout)	I1. Knee orthosis I2. Modified knee orthosis (neutral/ flexible)	No orthosis	Primary outcome(s) unclear WOMAC, gait analysis, stair-climbing test, 6-minute walk test at 2w
Pajareya 2003, Thailand ⁶⁵ -	Knee OA (C+XR)	128	Parallel group	Elastic knee sleeve plus education and NSAIDs	Education and NSAIDs	Aggregated functional performance time at 8w
Petersen 2019, Germany DRKS00009215 ⁶⁶	Medial tibiofemoral OA (C+XR)	160	Parallel group, non-inferiority	Unloader brace	Knee OA ankle brace	Pain NRS at 8w, 6m
Richards 2005, UK ⁶⁷ -	Medial tibiofemoral OA (C+XR)	12	Crossover (no washout)	I1: Valgus corrective brace I2: Simple hinged brace	-	Primary outcome(s) unclear Knee angle, knee angular velocity, ground reaction forces, Pain VAS, HSS at 6m
Robbins 2020, Australia ACTRN: 12615000227594 ^{68,69}	Medial tibiofemoral OA (XR)	171	Parallel group	Stepped care, including unloader knee brace option	Educational leaflets and encouragement to access the MyJointPain website	Disease remission via PASS at 32w
Robert-Lachaine 2020, Canada NCT01866176 ⁷⁰	Medial tibiofemoral OA (C+XR)	24	Crossover (2w washout)	I1: Valgus three-point bending system brace (V3P-brace) I2: Unloader brace with valgus and external rotation functions (VER-brace) I3: Stabilizing brace used after ligament injuries (ACL-brace)	-	Knee adduction moment, pain VAS at 3m
Sattari 2011, Iran ⁷¹ -	Medial tibiofemoral OA (C+XR)	60	Parallel group	3 point varus correction custom moulded knee brace plus conservative treatment	C1: Conservative treatment C2: Lateral wedge insole plus conservative treatment	Pain VAS, walking distance at 9m
Thoumie 2018, France NCT02021136 ⁷²	Medial tibiofemoral OA (C+XR)	67	Parallel group	Unloading knee brace plus usual care	Usual care	Pain VAS daily across 6w
van Egmond 2017, Netherlands NL32412.091.10, 27-09-2010 ⁷³	Medial tibiofemoral OA (C+XR)	100	Parallel group	I1: Bledsoe thruster brace I2: SofTec OA brace	-	Pain VAS at 2w and 12w
van Raaij 2010, Netherlands ^{74,75} -	Medial tibiofemoral OA (C+XR)	91	Parallel group	Valgus knee brace	Lateral wedged insole	Pain VAS at 6m
Yamamoto, 2019, Brazil NCT02984254 ^{76,77}	Patellofemoral OA (C+XR)	57	Parallel group	I1: Patellofemoral functional brace I2: Neoprene knee brace with a patellar orifice	-	WOMAC, Lequesne, 6MWT, TUG at 1 and 3m

6MWT, 6-minute walk test; C Clinical; DrDx, Physician-diagnosed; HSS, Hospital for Special Surgery score; KOOS, Knee Osteoarthritis Outcome Score; KOS-ADL, Knee Outcome Survey-Activities of Daily Living scale; KSS, Knee Society Score; LEFS, Lower Extremity Function Scale; NRS, Numerical Rating Scale; NSAID, Nonsteroidal anti-inflammatory drugs; OA, Osteoarthritis; PASS, Patient Acceptable Symptom State; PSFS, Patient-Specific Functional Scale; ROM, Range of motion; TUG, Timed Up and Go test; VAS, Visual Analogue Scale; WOMAC, Western Ontario & McMaster Universities Osteoarthritis Index; XR, Xray.

Table II

Descriptive characteristics of included RCTs of knee braces for knee OA.

intervention components. Multiple and varied mechanisms of action of knee braces were proposed, but there was overall lack of clarity regarding the underlying proposed logic model of how braces might effect change in knee OA outcomes. We believe this helps to explain the previous heterogeneous findings on the clinical effectiveness of knee bracing for knee OA,¹⁸ and the inconsistent recommendations on the use of knee braces for knee OA within clinical guidelines.³

Across all brace types, there was large variability in the brace manufacturer and model used, the brace intervention period, and the recommended brace dose (including recommended hours per day of brace usage, and for valgus/varus braces, where reported, the

degree of valgus/varus applied). Information on control/ placebo braces was often sparse and whilst some RCT authors classed a certain brace as a 'control/sham', others did not (e.g. neoprene sleeve could be tested as an 'active' knee brace in some RCTs and a 'control/sham' in others). This highlights considerable uncertainty about knee bracing for knee OA and might mean that whilst some brace interventions have been applied appropriately, others might not have been (if for example a patellofemoral knee brace was provided when valgus/varus stress is needed, or conversely, if a valgus/varus knee brace was provided to an individual with predominant patellofemoral OA). This could lead to underestimation of the comparative effectiveness of knee braces.

STUDY	THE BRACE (What, tailoring, how much)					BRACE DELIVERY (Who, how, where)				MODIFICATIONS		
	Intervention	Type of brace (V/V, V-PE,S,H,C) ^a	Manufacturer and make	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V/V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training		No. treatment sessions	Where treatment sessions were provided ^d
Arazpour 2013	Unloader knee brace	V/V	N/A	C (plaster of paris)	N/A V/V: Patient acceptability.	6 wks	NS Adherence: NS	Orthotist	NS	6	U	NS
Brouwer 2006	Knee brace plus conservative treatment	V/V	OAsys brace, Innovation sports, Irvine, CA, USA	O	NS V/V: Patient acceptability.	NS	Ed., PT, analgesics Adherence: NS	Orth. Tech.	NS	Unclear	U, H	NS
Draganich 2006	11. Off the shelf valgus-producing brace	V/V	OAdjustor; dj Orthopedics; Vista, California)	O	Daily, as long as possible. V/V: Perceived level for optimal pain relief.	35 days	NS Adherence: NS	Brace Rep	NS	1	U	NS
Draganich 2006	12. Custom made valgus producing brace	V/V	Adjustable OA Defiance; dj Orthopedics)	C	Daily, as long as possible. V/V: Perceived level for optimal pain relief.	35 days	NS Adherence: NS	Brace Rep	NS	1	U	NS
Dwarakanathan 2022	Unloader knee orthosis	V/V	Z1 Osteo-align orthotic knee joint (Zodiacal Overseas Private Limited)	Unclear	At least six hrs per da y.V/V: NS	6 m	Comfortable, lightweight sports shoes Adherence: NS	NS	NS	NS	NS	NS
Guegnon 2021	Custom made knee brace plus usual standard care	V/V	ODRA (PROTEOR, Dijon, France)	C	Min 6 hrs per day, 5 days per wk. V/V: NS	1 year	Usual standard OA care Adherence: NS	Orthotist	NS	NS	H	NS
Hjarartson 2018	1. Unloader brace	V/V	Unloader One (Ossur, Iceland)	O	NS V/V: NS	NS	NS	Ortho. Tech.	NS	NS	H	NS
Horlick 1993	1. Valgus brace with medial hinge	V/V	Generation II, (Vancouver, B.C., Canada)	O	Prolonged standing/sport activit y.V/V: additional 10%	6 wks	NS Adherence: NS	NS	NS	NS	NS	NS
Horlick 1993	2. Valgus brace with lateral hinge	V/V	Generation II, (Vancouver, B.C., Canada)	O	Prolonged standing/sport activit y.V/V: additional 10%	6 wks	NS Adherence: NS	NS	NS	NS	NS	NS
Hunter 2012	1. Multi-modal realignment intervention: valgus knee brace, customised neutral bilateral foot orthoses, shoes designed for motion control	V/V	Donjoy OAdjuster (Donjoy Braces, Coconut Creek, Florida, USA)	O	Min 4 hrs per da y.V/V: NS	12 wks	Adherence: Ed., skills training for donning, pamphlet addressing common adherence-related concerns.	Investigator	NS	Unclear	NS	NS

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Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS	
		Type of brace (V/ V, P.E.S.H.C) ^a	Manufacturer and make	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training		No. treatment sessions
Jones 2013	Valgus knee brace	V/V	Valgus knee brace (Donjoy OAAdjuster, DJO, Vista, USA)	O	Daily during activities s.V/V: 6 degrees.	2w	NS	Trained individual	NS	NS	NS
Khosravi 2021	I1: Valgus brace	V/V	NS	C	NS	6w	NS	Orthotist	NS	NS	NS
Khosravi 2021	I2: Valgus brace plus lateral wedge insole	V/V	NS	C	V/V: Acceptability NS	6w	NS	Orthotist	NS	NS	NS
Kirkley 1999	I2: Unloader brace	V/V	Generation II valgus-producing functional knee (unloader) brace (Generation II Orthotics, Richmond, British Columbia, Canada).	C	For troublesome activities s.V/V: additional 4 degrees.	NS (6 mths)	NS	NS	NS	NS	NS
Niazi 2014	Valgus knee brace	V/V	NS	C	1st wk – on/off every 3–4 hrs. Then as long as possible during the day.V/V: NS	6 m	NS	A Doctor	NS	Unclear	H
Ostrand 2016	Medial Unloader brace	V/V	Fusion OA; Breg, Inc	O	Min. 4 hrs per day.V/V: NS	24w	NS	NS	NS	NS	NS
Pagani 2010	I1. Knee orthosis	V/V	Genu Arthro Knee Orthosis 28K20/21, Otto Bock HealthCare, GmbH, Duderstadt, Germany	C	NS	2w	NS	NS	NS	NS	U

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Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS		
		Type of brace (V/ V,PE,S,H,C) ^a	Manufacturer (O)/ Customised (C)	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V/ V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training		No. treatment sessions	Where treatment sessions were provided ^d
Petersen 2019	Unloader brace	V/V	Unloader One; Óssur, Reykjavik, Iceland	0	At least 6 h a day V/V: NS	6 m	Written information OA. Information about the brace provided by manufacturer. Brace function explained. Following co-interventions allowed: ice, ointment dressing, weight reduction, acupuncture, intra-articular injection, bandages, crutches or cane, oral analgesics, PT. Adherence: NS	Ortho. Tech.	NS	NS	Study centre	NS
Richards 2005	1: Valgus corrective brace	V/V	Generation II ADJ Unloader; Gil Orthotics Europe; Eindhoven, The Netherlands	0	All day V/V: NS	6 m	Continue current medication. Instructed in use and care of the brace. Adherence: NS	Technician	Fully trained	NS	NS	NS
Robbins 2020	Stepped care, including knee brace option	V/V	Unloader knee brace (Óssur)	0	First 2 days: minimum of 2 h per day. After, at least 6 h a day during regular activities s.V/V: NS	12w	Step 1: 18w home based exercise and diet program. Step 2: If at 20w remission not achieved + no depression + varus malalignment $\geq 6^\circ$ brace provided. Also had instruction on brace use and maintenance. Adherence: NS	Certified trained practitioner	NS	NS	NS	NS
Robert-Lachaine 2020	11:Valgus three-point bending system brace (V3P-brace)	V/V	OA Brace; Orthoconcept Inc), Laval, QC, Canada	0	Wear as often as possible, increasing the duration of wear for the first 2 week s.V/V: NS	3 m	Adherence: NS	Orthotist	NS	NS	NS	NS

(continued on next page)

Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS		
		Type of brace (V/ V.I.P.E.S.H.C) ^a	Manufacturer (O)/ Customised (C)	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training sessions		No. treatment sessions	Where treatment sessions were provided ^d
Roberts-Lachaine 2020	I2: Unloader brace with valgus and external rotation functions (VER-brace)	V/V	OdrA; Orthoconcept Inc. Laval, QC, Canada	O	Wear as often as possible, increasing the duration of wear for the first 2 week s.V/V: NS	3 mths	NS Adherence: NS	Orthotist	NS	NS	NS	NS
Sattari 2011	3 point varus correction custom moulded knee brace plus conservative treatment	V/V	NS	C	On and off every 2–3 h for the first week. Then for as long as possible during the day, off at nights.V/V: NS	9 mths	Conservative treatment (activity modification, heat, exercise, analgesics when needed) Adherence: NS	Orthotist	NS	Unclear	Outpatient departments of physical medicine and rehabilitation of Isfahan University of Medical Sciences.	NS
Thoumie 2018	Unloading knee brace plus usual care	V/V	REBEL RELIEVER, Manufacturer not stated	O	At least 6hrs a day y.V/V: NS	6 wks	Usual care (analgesics, daily exercise program, information) Adherence: NS Adherence: NS	Orthopaedist-orthotist	NS	NS	NS	NS
van Egmond 2017	I1: Bledsoe Thruster brace	V/V	Bledsoe Thruster Brace; B&Co Inc. N.V., Sint-Antelinks, Belgium	O	Several hours V/V: pressure on knee but comfortable	12 wks	Adherence: NS Adherence: NS	Ortho. Tech.	NS	NS	H	NS
van Egmond 2017	I2: SofTec OA group	V/V	SofTec OA Brace; Bauerfeind AG, Zeulenroda-Triebes, Germany	O	Several hours V/V: pressure on knee but comfortable	12 wks	NS Adherence: brace type selected for comfort Adherence: NS	Ortho. Tech.	NS	NS	H	NS
van Raaij 2010	Valgus knee brace	V/V	MOS Genu1; Bauerfeind AG, Kempen, Germany	O	As much as tolerated. V/V: Degree of malalignment and patient acceptability	6 mths	NS Adherence: NS	Ortho. Tech.	NS	NS	NS	NS
Callaghan 2015	Patellar brace	PF	Bioskin Patellar Tracking Q brace (Ossur UK, Manchester, England)	O	As many hours throughout the day as tolerated	6 wks	NS Adherence: NS	NS	NS	NS	NS	NS
Hunter 2011	I1. Realigning patellofemoral brace	PF	Bioskin Q Brace with realigning T strap intact (Cropper Medical Inc., Ashland)	O	A minimum of 4 h per day	6 wks	Instruction on Donning/ doffing the brace. Adherence: NS	Trained investigator	NS	NS	NS	NS

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Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS		
		Type of brace (V/ V,PPE,S,H,C) ^a	Manufacturer (O)/ Customised (C)	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V/ V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training		No. treatment sessions	Where treatment sessions were provided ^d
Yamamoto 2019	I1: Patellofemoral functional brace	PF	Free knee (manufacturer NS)	0	2 h on the first day, increase by half an hour per day from the second day, up to a maximum of 12 h per day (continuous or at intervals of not less than 4hr). Instructed to sleep without the knee brace(es) and use them when performing physical activities, as long as activities were not performed in water.	3 mths	Half day course on OA and its treatment Adherence: NS	NS	NS	NS	H	NS
Berry 1992	Knee support plus conventional conservative treatment	S	Genutrain, Bauerfeind (UK)	0	Throughout every day, use in bed optional	6 wks	Standard therapy (analgesics and/or NSAIDs and PT) Adherence: NS	NS	NS	NS	NS	NS
Kirkley 1999	I1: Neoprene sleeve	S	NS	0	While awake for troublesome activities	NS (6 mths)	Medical treatment (Ed. leaflet, acetaminophen use, home flexibility program); ed. on brace application/maintenance. Adherence: NS	NS	NS	NS	U	NS
Mazzucca 2004	I1: Verum sleeve (specially fabricated to retain body heat)	S	NS	0	At least 12 hrs per day	28 days	Ed. on sleeve positioning. Instructed to continue to take usual OA medications Adherence: NS	NS	NS	NS	Clinical Research Unit	NS
Mohd Sharif 2019	I1: Basic knee sleeve	S	Drytex Basic Knee Support, DonJoy, USA	0	Daily, for as long as tolerated.	6 wks	NS Adherence: NS	NS	NS	1	Unclear	NS
Mohd Sharif 2019	I2: Knee sleeve with patella cutout	S	Drytex Basic Knee Support, DonJoy, USA	0	Daily, for as long as tolerated.	6 wks	NS Adherence: NS	NS	NS	1	Unclear	NS

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Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS		
		Type of brace (V/ V,PPE,S,H,C) ^a	Manufacturer and make	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Provider training		No. treatment sessions	Where treatment sessions were provided ^d
Pajareya 2003	Elastic knee sleeve plus education and NSAIDs	S	IP support; LP Pointique Int'l Ltd. Bellevue WA, USA	O	From early morning until late evening	8 wks	Instructed to use as little medication as possible. Patient ed. brochure (diagnosis, prognosis, and a knee joint protection programme)	NS	NS	Unclear	NS	Intervention modification over the RCT
Cherian 2015	Pneumatic knee brace	H	OA Rehabilitator TM (Guardian Brace, Pinellas Park, Florida)	O	Minimum 3 h per day when ambulating and exercising	3 mths	Adherence: NS PT. corticosteroid, home exercise, Ed. about the brace, gait re-training.	NS	NS	NS	NS	NS
Richards 2005	I2: Simple hinged brace	H	Bilateral uniaxial hinge B1, Camp Healthcare, Sheffield, UK	O	All day	6 mths	Adherence: NS Instructed in use and care of the brace. Continue current medication.	Technician	Fully trained	NS	NS	NS
Robert-Lachaine 2020	I3: Stabilizing brace used after ligament injuries (ACL-brace)	H	AC Brace; Orthoconcept Inc. Laval, QC, Canada	O	As often as possible, increasing duration over first 2 wks.	3 mths	Adherence: NS NS Adherence: NS	Orthotist	NS	NS	NS	NS
Madara 2019	Knee brace plus stretching	TF/H; dependent on alignment	TF: OA Rehabilitator (unloader braces) N: Sports Rehabilitator, both: Ongoing Care Solutions Inc. Pinellas Park, FL, USA.	O	Increase wear time by 1 hr per day, up to 8 hrs max. as tolerated	6 wks	Leg stretching program (20 mins. at least 3x wk) Adherence: NS	NS	NS	NS	NS	NS
Hjartartson 2018	I2. Look alike brace	C	Unloader one (Dynamic Force Straps removed)	O	NS	NS	NS Adherence: NS	Ortho. Tech.	NS	NS	H	NS
Hortick 1993	I3. Brace in neutral	C	Generation II, (Vancouver, B.C., Canada)	O	Prolonged standing/sporting activity	6 wks	NS Adherence: NS	NS	NS	NS	NS	NS
Hunter 2011	I2. Non-realigning patellofemoral brace (placebo)	C	Bioskin Q Brace (without realigning T strap)	O	Min. 4 hrs per day	6 wks	NS Adherence: NS	Trained investigator	NS	NS	NS	NS

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Table III (continued)

STUDY	Intervention	THE BRACE (What, tailoring, how much)				BRACE DELIVERY (Who, how, where)				MODIFICATIONS			
		Type of brace (V/ V,PE,S,H,C) ^a	Manufacturer (O)/ Customised (C)	Off the shelf (O)/ Customised (C)	Recommended brace use For V/V only: amount of V force applied	Intervention length	Additional intervention components/ Explicit use of strategies to enhance brace adherence ^b	Brace provider ^c	Investigator		Provider training	No. treatment sessions	Where treatment sessions were provided ^d
Hunter 2012	I2. Neutral knee brace (no valgus angulation), foot orthoses, shoes with a flexible mid-sole	C	Donjoy Montana brace with a loosened screw at the hinge allowing varus/valgus laxity	O	Min. 4 hrs per day	12 wks	Adherence: Ed., skills training for donning, pamphlet addressing common adherence-related concerns	Investigator	NS	Unclear	NS	NS	NS
Mazzucca 2004	I2. Placebo sleeve (standard cotton/ elastane sleeve)	C	NS	O	At least 12 hrs per day	28 days	Ed. on sleeve positioning. Instructed to continue to take usual OA medications	NS	NS	NS	Clinical research unit	NS	NS
Pagani 2010	I1. Modified knee orthosis (neutral/ flexible)	C	Genu Arthro Knee Orthosis 28K20/21, Otto Bock, Duderstadt, Germany	C	NS	2w	Adherence: NS. Adherence: NS	NS	NS	NS	U	NS	NS
Yamamoto 2019	I2. Neoprene knee brace with a patellar orifice	C	NS	O	Day 1: 2 h, increase by 30 min from day 2 up to max. 12 hrs per day (continuous or at intervals of not less than 4hrs)	3 mths	Half day course on OA and its treatment	NS	NS	NS	H	NS	NS

^a Brace type: V/V = Valgus/varus, PF = patellofemoral, S = sleeve, H = neutral hinged, C = control/ placebo.

^b Additional interventions: Ed = education, PT = physical therapy, NS = not stated.

^c Brace provider: Ortha Tech = Orthopaedic technician.

^d Where brace provided: H = healthcare setting, U = university setting.

Table III

Description of bracing interventions in included RCTs.



Author, year	Brace intervention	Brace type BRACE TYPE	No mechanism of action described	Clear logic model provided	Placebo	Biomechanical			Neuromuscular			Psychological		Other
						Increase stability	Reduce load	Improve joint alignment	Improve muscle function/ motor control	Improved muscle strength	Increased proprioception	Increase confidence in knee stability		
Arzpour 2013	Unloader brace	V/V				X		X						
Brouwer 2006	Knee brace	V/V				X		X						
Draganich 2006	I1. Off the shelf valgus-producing brace I2. Custom-made valgus-producing brace	V/V				X		X			X			
Draganich 2006	I2. Custom-made valgus-producing brace	V/V				X		X			X			
Dwarakanathan 2022	Unloader knee orthosis	V/V				X		X						
Guegnon 2021	Custom-made brace	V/V				X		X						
Hjartartson 2018	I1. Unloader brace	V/V				X		X						
Horlick 1993	I1: Valgus brace with medial hinge I2: Valgus brace with lateral hinge	V/V				X		X						
Hunter 2012	I1. Valgus brace	V/V				X		X						
Jones 2013	Valgus brace	V/V				X		X			X			
Khosravi 2021	Valgus brace	V/V				X		X						
Khosravi 2021	Valgus brace plus lateral wedge insole	V/V				X		X						
Kirkley 1999	I2: Unloader brace	V/V				X		X			X			
Niazi 2014	Valgus brace	V/V	X					X						
Ostrand 2016	Medial Unloader brace	V/V				X		X		X				
Pagani 2010	I1. Knee orthosis	V/V				X		X						
Petersen 2019	Unloader brace	V/V				X		X		X				
Richards 2005	I1. Valgus corrective brace	V/V				X		X		X			X	
Robbins 2020	Stepped care including unloader knee brace	V/V						X						
Robert-Lachaine 2020	I1. Valgus three-point bending system brace (V3P-brace)	V/V				X		X						
Robert-Lachaine 2020	I2. Unloader brace with valgus and external rotation functions (VER-brace)	V/V				X		X						
Sattari 2011	3-point varus correction custom moulded knee brace	V/V						X		X				
Thoumie 2018	Unloading knee brace	V/V				X		X						
van Egmond 2017	Bledsoe Thruster brace	V/V				X		X						
van Raaij 2010	Softec OA group	V/V				X		X						
Callaghan 2015	Valgus knee brace	V/V				X		X		X				
Hunter 2011	Patellar brace	PF				X		X						Xa
Hunter 2011	I1. Realigning patellofemoral brace	PF				X		X						
Yamamoto 2019	I1. Patellofemoral functional brace	PF				X		X						
Berry 1992	Knee support	S				X								
Kirkley 1999	I1: Neoprene sleeve	S				X					X			

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Table IV (continued)

Author, year	Brace intervention	Brace type BRACE TYPE	No mechanism of action described	Clear logic model provided	Biomechanical			Neuromuscular			Psychological	Other
					Placebo	Increase stability	Reduce load	Improve joint alignment	Improve muscle function/ motor control	Improved muscle strength		
Mazzucca 2004	I1. Verum sleeve (to retain body heat)	S										Xb
Mohd Sharif 2019	I1: Basic knee sleeve	S						X	X	X		Xc,d
Mohd Sharif 2019	I2: Knee sleeve with patella cutout	S						X	X	X		Xd,e
Pajareya 2003	Elastic sleeve	S					X			X		Xf
Cherian 2015	Pneumatic knee brace	H					X		X			
Richards 2005	I2. Simple hinged brace	H					X		X		X	
Robert- Lachaine 2020	I3. ACL-stabilization brace	H				X			X			
Madara 2019	Knee brace	TF/H						X				Xg
Hjartarson 2018	I2. Look alike brace	C				X						
Horlick 1993	I3. Brace in neutral	C				X						
Hunter 2011	I2. Non-realigning patellofemoral brace (placebo)	C				X						
Hunter 2012	I2. Neutral brace	C				X						
Mazzucca 2004	I2. Placebo sleeve	C				X						
Pagani 2010	I2. Modified knee orthosis	C				X						
Yamamoto 2019	I2. Neoprene knee brace with patellar orifice	C	X									

Abbreviations: TF = tibiofemoral; PF = patellofemoral; S = sleeve; H = neutral hinged; C = control/ placebo.

Other: a: Shrink bone marrow lesions b: Heat retention; c: Compression, d: Warmth, e: Controlled movement, f: Gate control theory, g: Promote normal sagittal plane motion by encouraging end range knee extension during gait.

Table IV



Osteoarthritis and Cartilage

Reported mechanisms of action for braces described in included RCT papers.

STUDY	NAME OF BRACE INTERVENTION	BRACE ADHERENCE		
		Any reported assessment of intervention fidelity	Assessment (and method) of brace adherence	Level of brace adherence
Arazpour 2013	Unloader knee brace	NS	Y: Self-report (daily wearing time)	Mean: 7.33 (SD 0.88) hours/day
Berry 1992	Knee support plus conservative management	NS	NS	N/A
Brouwer 2006	Knee brace plus conventional conservative treatment	NS	NS	N/A
Callaghan 2015	Patellar brace	NS	Y: Self-report (daily wearing time after 6 weeks; use of patellar support strap)	Mean: 7.4 (SD: 2.5) hours/day Of those that provided data, 66% chose not to wear the patellar support strap
Cherian 2015	Pneumatic knee brace	NS	NS	N/A
Draganich 2006	I1. Off the shelf valgus-producing knee brace	NS	Y: Self-report (daily wearing time)	Mean: 9.0 (SD: 3.3) hours/day
Draganich 2006	I2. Custom made valgus-producing knee brace	NS	Y: Self-report (daily wearing time)	Mean: 8.8 (SD: 2.5) hours/day
Dwarakanathan 2022	Unloader knee orthosis	NS	NS	N/A
Guegnon 2021	Custom made knee brace plus usual standard care	NS	Y: Self-reported (wearing time over 1 year: no. days per week and hours per day)	Median days per week: 6 (IQR: 5–6.75) Median hours per day: 5.3 (3.7–7)
Hjartarson 2018	I1. Unloader brace	NS	NS	N/A
Hjartarson 2018	I2. Look-alike brace (active straps removed)	NS	NS	N/A
Hortlick 1993	I1. Valgus brace with medial hinge	NS	Y: Self-report (In those who purchased the brace, still using brace 20 months after end of study (y/n))	14/15 (93%)
Hortlick 1993	I2. Valgus brace with lateral hinge	NS	Y: Self-report (In those who purchased the brace, still using brace 20 months after end of study (y/n))	7/12 (58%)
Hortlick 1993	I3. Brace in neutral	NS	Y: Self-report (In those who purchased the brace, still using brace 20 months after end of study (y/n))	NS
Hunter 2011	I1. Realigning patellofemoral brace	NS	Y: Self-report (daily wearing time)	Mean 4.8 h per day
Hunter 2011	I2. Non-realigning patellofemoral brace (placebo)	NS	Y: Self-reported (daily wearing time)	Mean 4.3 h per day
Hunter 2012	I1. Multi-modal realignment intervention: valgus knee brace, customised neutral bilateral foot orthoses, shoes designed for motion control	NS	Y: Self-report (daily wearing time)	Period 1: 3.32 (SD: 1.55) hours per day Period 2: 3.35 (SD: 2.39) hours per day
Hunter 2012	I2. Neutral knee brace, unsupportive foot orthoses, shoes with a flexible mid-sole	NS	Y: Self-report (daily wearing time)	Period 1: 3.99 (SD: 2.82) hours per day Period 2: 3.29 (SD: 1.92) hours per day
Jones 2013	Valgus knee brace	NS	Y: Self-report (daily wearing time)	71% of participants wore the brace for less than 4 h per day
Khosravi 2021	I1. Valgus brace	NS	NS	N/A
Khosravi 2021	I2. Valgus brace plus lateral wedge insole	NS	NS	N/A
Kirkley 1999	I1. Neoprene Sleeve	NS	Y: Self-report (diary about brace use)	NS
Kirkley 1999	I2. Unloader brace	NS	Y: Self-report (diary about brace use)	NS
Madara 2019	Knee brace plus stretching	NS	Y: Objective (activity monitor on the brace)	NS
Mazzucca 2004	I1. Verum sleeve (specially fabricated to retain body heat)	NS	Y: Self-report (days sleeve worn for 12 h or more)	Average steps per day when wearing brace: 3045 ± 1796 Range of average steps per day when wearing brace: 587 ± 522 to 9831 ± 3098
Mazzucca, 2004	I2. Placebo sleeve (standard cotton/elastane sleeve)	NS	Y: Self-report (days sleeve worn for 12 h or more)	Mean: 26.5 (SD: 3.0) days (possible range 0–28)
Mohd Sharif 2019	I1: Basic knee sleeve	NS	Y: Self-report (hrs per day in log book)	Mean: 27.6 (SD: 1.1) days (possible range 0–28)
Mohd Sharif 2019	I2: Knee sleeve with patella cutout	NS	Y: Self-report (hrs per day in log book)	NS
Niazi 2014	Valgus knee brace	NS	NS	N/A
Ostrander 2016	Medial unloader brace	NS	Y: Self-report (daily wearing time)	Average: 6.7 h per day
Pajareya 2003	Elastic knee sleeve plus education and NSAIDs	NS	Y: Self-report: (daily wearing time)	8 weeks: More than 7 h/day: 86.4%; 4–7 h/day: 10.2%; less than 4 h/day: 1.7%
Pagani 2010	I1. Knee orthosis	NS	NS	N/A
Pagani 2010	I2. Modified knee orthosis	NS	NS	N/A

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Table V (continued)

STUDY	NAME OF BRACE INTERVENTION	BRACE ADHERENCE		Level of brace adherence
		Any reported assessment of intervention fidelity	Assessment (and method) of brace adherence	
Petersen 2019	Unloader brace	NS	Y: Self-report: (how often per week; hours per day)	8 weeks: Weekly use: Everyday: 47.44%; > 5 days/week: 21.79%; > 3 days/week: 24.36%; 1–3 days/week 4: 5.13%; Never: 1.28%. Hours per day: < 6hrs: 46.2%; > 6hrs: 53.8% 3 months: Weekly use: Everyday: 39.3%; > 5 days/week: 22%; > 3 days/week: 27.9%; 1–3 days/week: 9.8%; Never: 0. Hours per day: < 6hrs: 55.2%; > 6hrs: 44.8% Patient compliance was not recorded but assumed as high due to most patients benefiting Patient compliance was not recorded but assumed as high due to most patients benefiting. N/A
Richards 2005	I1. Valgus corrective brace	NS	NS	
Richards 2005	I2. Simple hinged brace	NS	NS	
Robbins 2020	Stepped care including unloader knee brace option	NS	NS	
Robert-Lachaine 2020	I1. Valgus three-point bending system brace (V3P-brace)	NS	Y: Self-report (daily recordings): Selection of 1 of 4 options (0 h, 1–3 h, 4–5 h, 6 h and up).	3 months: Frequency of brace wear: 86.2 (+–5.4) days. Mean daily use: 2.3 (+–0.9) hours. (When daily use was averaged over a week, the 10th and 9th week showed that the V3P-brace was less worn than the VER-brace and ACL-brace). 3 months: Frequency of brace wear: 87.7 (+–4.0) days. Mean daily use: 2.6 (+–0.9) hours. 3 months: Frequency of brace wear: 87.3 (+–3.9) days. Mean daily use: 2.5 (+–0.9) hours. N/A
Robert-Lachaine 2020	I2. Unloader brace with valgus and external rotation functions (VER-brace)	NS	Y: Self-report (daily recordings): Selection of 1 of 4 options (0 h, 1–3 h, 4–5 h, 6 h and up).	
Robert-Lachaine 2020	I3. Stabilizing brace used after ligament injuries (ACL-brace)	NS	Y: Self-report (daily recordings): Selection of 1 of 4 options (0 h, 1–3 h, 4–5 h, 6 h and up).	
Sattari 2011	3 point varus correction custom moulded knee brace plus conservative treatment	NS	NS	
Thoumie 2018	Unloading knee brace plus usual care	NS	Y: Self-report: number of days worn the brace	6 weeks: Mean: 44.0 (SD: 10.6) days; >90% of the actual/theoretical wearing days. Mean hours per day 2 weeks: 8.2 (3.7) 12 weeks: 6.7 (3.4)
van Egmond 2017	I1. Bledsoe Thruster brace	NS	Y: Self-report: use of knee brace (diary)	Mean hours per day 2 weeks: 7.9 (3.1) 12 weeks: 6.8 (4.3)
van Egmond 2017	I2. Sofftec OA brace	NS	Y: Self-report: use of knee brace (diary)	6 months: 45% complied with brace treatment. Mean brace use of 38.8 (SD: 32.2) hours per wk.
van Raaij 2010	Valgus knee brace	NS	Y: Self-report: number of hours per week brace worn (compliance defined a priori: using the brace more than 42 h per week; 7 days for 6 h; 75% of the working day)	1 month: 191.5 (145.6) 3 months: 325 (292.2)
Yamamoto 2019	I1. Patellofemoral functional brace	NS	Y: Self-report: use of knee brace (hours) (specific measure not stated) (mean, SD)	1 month: 127.2 (107.2) 3 months: 270 (240.7)
Yamamoto 2019	I2. Neoprene knee brace with a patellar orifice	NS	Y: Self-report: use of knee brace (hours) (specific measure not stated)	

Abbreviations:

N/A: Not applicable; NS: Not stated; Y: Yes.

Table V

Intervention fidelity and adherence to brace use in included RCTs.

Alongside this variability, there was also suboptimal reporting of bracing interventions when explored through the lens of TIDieR guidance.³⁹ Knee bracing for knee OA is a complex intervention and for it to be replicated accurately, all components need to be transparently and fully reported. Although factors relating to the brace itself were generally (but not always) reported, many factors relating to delivery of the brace intervention were not. Information on who delivered the brace intervention with what training, in what setting, over how many treatment sessions, whether additional interventions were delivered alongside the brace, and whether there were modifications to the bracing intervention over time, was often missing. Without this complete description, healthcare professionals cannot reliably implement knee brace interventions for OA in clinical practice. This is likely to mean that in real world settings, delivery of brace interventions will also be highly variable, and might not be being offered in the best way possible to optimise outcomes for patients. Lack of full description also means that other researchers cannot replicate or build on research findings,³⁹ which hinders progress in the field.

Brace adherence, predominantly quantified as the self-reported amount of time that the brace was worn, was described for many bracing interventions. This represents a greater level of reporting compared to adherence to exercise for chronic musculoskeletal conditions including knee OA.^{79,80} Although self-report of brace wear is a simple and inexpensive method of data-collection, reported brace use may be recalled incorrectly, or overestimated by participants in an attempt to be viewed positively by the study team.^{81,82} One intervention used an activity monitor strapped to the brace to objectively monitor daily step count when wearing the brace. Although this overcomes potential recall bias, it may not accurately capture all brace use, for example when wearing it to undertake stationary weight-bearing activity. As with previous RCTs of unsupervised conservative treatments for OA,⁸³ values for quantifying satisfactory adherence were rarely provided. This makes it difficult to determine whether limited treatment effects are due to poor adherence or an ineffective bracing intervention.⁸³

To experience benefits from a knee brace, it seems plausible to assume that people need to wear them. This study shows that people do wear the knee braces provided, but the duration of use and over what time-periods are highly variable. This is likely due, in part, to inconsistent measurement and reporting of brace use, making comparisons between RCTs difficult. Several barriers to knee brace use among people have previously been reported, including skin irritation, swelling, poor fit, lack of symptomatic relief, difficulty donning/doffing the brace, difficulty wearing the brace with clothing, and heaviness/bulkiness of the brace.⁸⁴ However, overall, barriers and facilitators to knee brace use have not been robustly investigated. To optimise the benefits of bracing, there is a continuing role for manufacturers and suppliers to better address obstacles to adherence in brace design (e.g. maximising brace aesthetics, fit and comfort), supply, and customer support. It may also be important for bracing interventions to incorporate behavioural techniques. Only two interventions (tested in one RCT^{54,55}) explicitly targeted brace adherence, utilising education, skills around donning the brace, and a pamphlet addressing common adherence-related concerns. However, their effectiveness as adherence enhancing strategies was not tested. Although the optimal behaviour change techniques to enhance brace adherence among people with OA remain unknown, techniques that effectively promote physical activity in this population (such as behavioural contracts, goal setting, self-monitoring of behaviour and social support) might be of value.⁸⁵

Multiple mechanisms of action were proposed for bracing interventions, including biomechanical, neuromuscular, and psychological factors, although this information was often difficult to extract

from RCT publications (e.g. similar concepts (such as joint ‘unloading’) were described inconsistently, and reported in different locations within manuscripts (background/ methods/ discussion). Whilst biomechanical studies support some of these proposed mechanisms of action, including reduced joint loading, improved joint position sense, and improved static and dynamic balance,^{86,87} findings appear variable. This may be due to differences in study design, but also due to differences in components of knee brace interventions, or patient characteristics.^{86,87} The variability of the published literature and the multiple proposed mechanisms of action of bracing interventions included in this review highlight overall a lack of clarity regarding how braces might affect change in knee OA outcomes. Our findings suggest that mechanisms of action of knee braces for knee OA are likely to be multi-factorial, spanning biomechanical, neuromuscular, and psychological factors across all brace types, including control/placebo braces. This questions the ability to label a control brace as a true “placebo”. It also questions the validity of using a cross-over RCT design to test the effectiveness of knee brace interventions for knee OA. Eight RCTs included in this review had a cross-over design, with either no, or a short wash-out period (between two and six weeks). Given psychological factors like improved confidence and neuromuscular adaptations may persist after removal of the brace, response to subsequent treatments may be altered, thus potentially invalidating comparisons between interventions.⁸⁸ This may further explain the previous heterogeneous findings on the clinical effectiveness of knee bracing for knee OA.¹⁸ Given the overall lack of clarity in mechanisms of action, logic models for bracing interventions might be a useful addition to future bracing RCTs, with embedded mediation analyses to better understand if and how bracing interventions change outcomes for people with knee OA.⁷⁸ Logic models can also be useful to demonstrate intervention logic to research funders and aid the process of knowledge transfer whereby research findings are applied in different settings.⁷⁸

Strengths and limitations

This study offers the most detailed description to date of components of knee bracing interventions for knee OA. Limitations include not registering our protocol a-priori. Restricting inclusion of previous RCTs to those that tested bracing interventions intended to be worn over a minimum period of two weeks may mean that other bracing interventions relevant for use in clinical practice may have been missed. Despite our efforts to identify linked mechanistic/ pilot work for each included RCT, some linked studies may not have been identified. Proposed mechanisms of action of knee braces for knee OA within included RCTs were the stated opinions of RCT authors, and not necessarily supported by mechanistic evidence. Finally, as we did not contact RCT authors for missing information about bracing interventions (e.g. lack of detail about training of brace deliverers), it remains unknown whether this means the variable was not included in the RCT, or whether it was included but not reported.

Comparison to other research

In line with a previous scoping review, our study found that a broad range of bracing models from different manufacturers are used for people with knee OA in RCTs.²¹ Our finding that bracing interventions in RCTs are rarely fully reported mirrors findings from previous reviews showing inadequate reporting of non-pharmacological interventions in RCTs,¹² and poor replicability of exercise interventions for knee OA specifically.¹⁶

Recommendations for future research

This study highlights several important areas for future research. Firstly, large heterogeneity in knee brace interventions for knee OA is unhelpful for the field and indicates considerable uncertainty about how braces may work. To reduce this heterogeneity, consensus could be gained on the components of knee brace interventions most likely to be effective and subsequently tested in high-quality RCTs in different settings. Secondly, intervention logic models with key mediator data collection and analyses, and ancillary mechanistic studies are recommended to better understand how knee braces may work for knee OA. Thirdly, more needs to be done across bracing interventions to assess and address brace adherence. This includes using more robust measures of brace adherence (including objective measures), determining quantifiable values for satisfactory adherence, and testing the effectiveness of behaviour change techniques to enhance brace adherence. Finally, future RCTs of knee bracing for knee OA should use existing best practice recommendations¹⁰ and reporting guidelines such as TIDieR.³⁹ Instead of just focusing on describing ‘the brace’, interventions should be considered as complex, and all aspects should be fully reported in detail including in journal supplements, including other treatments offered alongside the brace, how the brace is delivered, adherence and treatment fidelity, and modifications to the intervention over the course of the study.

Conclusion

Many different knee brace interventions have been tested for knee OA, with several proposed mechanisms of action, and a lack of full and transparent reporting. Although adherence to brace use has been measured, amount of brace use is reported inconsistently and explicit strategies to enhance brace adherence are sparse. These issues may be contributing to the heterogeneous findings and inconsistent guideline recommendations about the clinical effectiveness of knee bracing for knee OA to date.

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Author contributions

MA Holden made substantial contributions to the conception and design of the work; the acquisition, analysis, and interpretation of results; drafting the work; and approved the final version to be published.

M Murphy made substantial contributions to the acquisition of data for the work; reviewing the work critically for important intellectual content; and approved the version to be published.

J Simkins made substantial contributions to the acquisition of data for the work; reviewing the work critically for important intellectual content; and approved the version to be published.

MJ Thomas made substantial contributions to the acquisition of data for the work; reviewing the work critically for important intellectual content; and approved the version to be published.

L Huckfield made substantial contributions to the acquisition of data for the work; reviewing the work critically for important intellectual content; and approved the version to be published.

JG Quicke made substantial contributions to the acquisition of data for the work; reviewing the work critically for important intellectual content; and approved the version to be published.

N Halliday made substantial contributions to the interpretation of results; reviewing the work critically for important intellectual content; and approved the version to be published.

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E Nicholls made substantial contributions to the interpretation of results; reviewing the work critically for important intellectual content; and approved the version to be published.

G Peat made substantial contributions to the conception and design of the work; the acquisition, analysis, and interpretation of results; drafting the work; and approved the final version to be published.

In addition, all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of competing interest

Nothing to disclose.

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Competing interest statement

Nothing to disclose.

APPENDIX 1: SEARCH STRATEGY

Databases (inception to 10/6/24)	Search	Number of hits
Medline (PubMed)	"Osteoarthritis"[Title/Abstract] OR "osteoarthrosis"[Title/Abstract] OR "degenerative joint disease"[Title/Abstract] OR "osteo arthritis"[Title/Abstract] OR "osteo arthrosis"[Title/Abstract] OR "degenerative arthritis"[Title/Abstract] OR "Osteoarthritis"[MeSH Terms] AND "Knee"[Title/Abstract] OR "patellofemoral"[Title/Abstract] OR "patella"[Title/Abstract] OR "tibiofemoral"[Title/Abstract] AND "Orthotic Device"[Title/Abstract] OR "brace*"[Title/Abstract] OR "bracing"[Title/Abstract] OR "orthotic*"[Title/Abstract] OR "orthoses"[Title/Abstract] OR "orthosis"[Title/Abstract] OR "sleeve*"[Title/Abstract] OR "knee support*"[Title/Abstract] OR "Orthotic Devices"[MeSH Terms] AND "randomized controlled trial" OR "controlled clinical trial" OR randomized OR randomly OR random OR random* OR trial	335
Web of Science	(searched by Topic) osteoarthritis OR osteoarthrosis OR "degenerative joint disease" OR "osteo arthritis" OR "osteo arthrosis" OR "degenerative arthritis" AND Knee OR patellofemoral OR patella OR tibiofemoral AND "Orthotic Device" OR brace* OR bracing OR orthotic* OR orthoses OR orthosis OR sleeve* OR "knee support*" AND "randomized controlled trial" OR "controlled clinical trial" OR randomized OR randomly OR random OR random* OR trial	336
Cochrane	osteoarthritis OR osteoarthrosis OR "degenerative joint disease" OR "osteo arthritis" OR "osteo arthrosis" OR "degenerative arthritis" AND Knee OR patellofemoral OR patella OR tibiofemoral AND MeSH descriptor: [orthotic devices] explode all trees OR "Orthotic Device" OR brace* OR bracing OR orthotic* OR orthoses OR orthosis OR sleeve* OR knee NEXT support* Limited to "TRIALS"	472

APPENDIX 2: SEARCH STRATEGY TO IDENTIFY SEPARATE (LINKED) PUBLICATIONS FROM INCLUDED PARENT RCTS

PubMed	"Osteoarthritis"[Title/Abstract] OR "osteoarthrosis"[Title/Abstract] OR "degenerative joint disease"[Title/Abstract] OR "osteo arthritis"[Title/Abstract] OR "osteo arthrosis"[Title/Abstract] OR "degenerative arthritis"[Title/Abstract] AND "Knee"[Title/Abstract] OR "patellofemoral"[Title/Abstract] OR "patella"[Title/Abstract] OR "tibiofemoral"[Title/Abstract] AND "Orthotic Device"[Title/Abstract] OR "brace*"[Title/Abstract] OR "bracing"[Title/Abstract] OR "orthotic*"[Title/Abstract] OR "orthoses"[Title/Abstract] OR "orthosis"[Title/Abstract] OR "sleeve*"[Title/Abstract] OR "knee support*"[Title/Abstract] AND xxxxx[Author] <i>N.B first and last authors for each included RCT were included in the above search strategy. Titles and abstracts of all hits were reviewed by MAH. Where potentially relevant, full texts were reviewed by MAH to see if they linked to the included parent RCT.</i>
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APPENDIX 3: COMPLETENESS OF REPORTING OF BRACING INTERVENTIONS ACCORDING TO CRITERIA INFORMED BY TIDIER GUIDANCE

STUDY	Intervention	Brace type	1. Intervention name	Description of the brace*							Description of delivery of the bracing intervention [^]				Why	How well ⁵				Complete reporting per intervention; number (%) of intervention components reported			
				2. Manufacturer and make	3. Off the shelf (O)/ customised(C)	4a. Recommended brace use	4b. Recommended brace use For V/V only; amount of V/V force	5. Intervention length	6. Additional intervention components	7. Explicit use of strategies to enhance brace adherence	8. Brace provider	9. Provider training	10. No. treatment sessions	11. Where treatment sessions were provided ⁴		12. Intervention modification over the RCT	13. At least one proposed mechanism of action	14. Fidelity assessment	15. Level of fidelity		16. Brace adherence assessment	17. Level of brace adherence	
Arazpour 2013	Unloader knee brace	V/V	Y	N/A	Y	N/A	Y	Y	N	N	Y	N	Y	Y	N	Y	N	N	Y	Y	N	10 (63)	
Brouwer 2006	Knee brace plus conservative treatment	V/V	Y	Y	Y	N	Y	N	Y	N	Y	N	N	Y	N	Y	N	N	N	N	N	N	8 (44)
Draganich 2006	I1. Off the shelf valgus-producing brace	V/V	Y	Y	Y	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	N	12 (67)
Draganich 2006	I2. Custom made valgus producing brace	V/V	Y	Y	Y	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	N	12 (67)
Dwarakanathan 2022	Unloader knee orthosis	V/V	Y	Y	N	Y	N	Y	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	6 (33)
Guegnon 2021	Custom made knee brace plus usual standard care	V/V	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	Y	N	Y	N	N	Y	Y	Y	N	11 (61)
Hjarartson 2018	1. Unloader brace	V/V	Y	Y	Y	N	N	N	N	N	Y	N	N	Y	N	Y	N	N	N	N	N	N	6 (33)
Horlick 1993	1. Valgus brace with medial hinge	V/V	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	Y	N	N	Y	Y	Y	N	9 (50)
Horlick 1993	2. Valgus brace with lateral hinge	V/V	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	Y	N	N	Y	Y	Y	N	9 (50)
Hunter 2012	1. Multi-modal realignment intervention: valgus knee brace, customised neutral bilateral foot orthoses, shoes designed for motion control	V/V	Y	Y	Y	Y	N	Y	Y	Y	Y	N	N	N	N	Y	N	N	Y	Y	Y	N	11 (61)
Jones 2013	Valgus knee brace	V/V	Y	Y	Y	Y	Y	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	Y	N	10 (56)
Khosravi 2021	I1: Valgus brace	V/V	Y	N	Y	N	Y	Y	N	N	Y	N	N	Y	N	Y	N	N	N	N	N	N	7 (39)
Khosravi 2021	I2: Valgus brace plus lateral wedge insole	V/V	Y	N	Y	N	Y	Y	Y	N	Y	N	N	Y	N	Y	N	N	N	N	N	N	8 (44)
Kirkley 1999	I2: Unloader brace	V/V	Y	Y	Y	Y	Y	N	Y	N	N	N	N	Y	N	Y	N	N	Y	N	N	N	9 (50)
Niazi 2014	Valgus knee brace	V/V	Y	N	Y	Y	N	Y	N	N	Y	N	N	Y	N	N	N	N	N	N	N	N	6 (33)
Ostrand 2016	Medial Unloader brace	V/V	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	N	Y	N	N	Y	Y	Y	N	9 (50)
Pagani 2010	I1. Knee orthosis	V/V	Y	Y	Y	N	Y	Y	N	N	N	N	N	Y	N	Y	N	N	N	N	N	N	7 (39)
Petersen 2019	Unloader brace	V/V	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	Y	N	Y	N	N	Y	Y	Y	N	11 (61)
Richards 2005	1: Valgus corrective brace	V/V	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	N	N	Y	N	N	N	N	Y	N	9 (50)
Robbins 2020	Stepped care, including knee brace option	V/V	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	N	N	Y	N	N	N	N	N	N	8 (44)
Robert-Lachaine 2020	I1: Valgus three-point bending system brace (V3P-brace)	V/V	Y	Y	Y	Y	N	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	Y	N	9 (50)
Robert-Lachaine 2020	I2: Unloader brace with valgus and external rotation functions (VER-brace)	V/V	Y	Y	Y	Y	N	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	Y	N	9 (50)

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