Osteoarthritis and Cartilage 32 (2024) 1371–1396

Osteoarthritis and Cartilage

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

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

MA Holden # † *, M. Murphy ‡, J. Simkins # †, MJ Thomas # † §, L. Huckfield # §, JG Quicke # ¶, N. Halliday # ‖, FN Birrell ##, B. Borrelli †† ‡‡, MJ Callaghan §§ ¶¶ |||, K. Dziedzic # †, D. Felson ### †††, NE Foster # ¶, C. Ingram ‡‡‡, C. Jinks # †, S. Jowett # §§§, E. Nicholls # † ‖, G. Peat # ¶¶¶

School of Medicine, Primary Care Centre Versus Arthritis, Keele University, Keele, Staffordshire, UK
† *Centre for Musculoskeletal Research, Keele University, Keele, Staffordshire, UK*
‡ *The Robert Jones Agnes Hunt Orthopaedic NHS Foundation Trust, Oswestry, Shropshire, UK*
§ *Haywood Academic Rheumatology Centre, Midlands Partnership University NHS Foundation Trust, Haywood Hospital, Burslem, Staffordshire, UK*
¶ *Surgical Treatment and Rehabilitation Service (STARS) Education and Research Alliance, The University of Queensland and Metro North Health, Herston, Brisbane, Queensland, Australia*
‖ *Keele Clinical Trials Unit, Keele University, Keele, Staffordshire, UK*
MRC-Versus Arthritis Centre for Integrated Research into Musculoskeletal Ageing, Newcastle University, UK
†† *Henry M Goldman School of Dental Medicine, Boston University, Boston, MA, USA*
‡‡ *Manchester Centre for Health Psychology, Division of Psychology and Mental Health, School of Health Sciences, Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK*
§§ *Faculty of Biology, Medicine and Health, The University of Manchester, Manchester, UK*
¶¶ *Faculty of Health and Education, Manchester Metropolitan University Manchester, UK*
||| *Manchester University Hospitals NHS Foundation Trust, Manchester, UK*
Research in OsteoArthritis Manchester (ROAM), Centre for Epidemiology Versus Arthritis, Centre for Musculoskeletal Research, Institute of Inflammation and Repair, The University of Manchester, Manchester, UK
††† *Boston University School of Medicine, Boston, MA, USA*
‡‡‡ *Research User Group, Keele University, Keele, Staffordshire, UK*
§§§ *Health Economics Unit, Institute of Applied Health Research, University of Birmingham, Birmingham, UK*
¶¶¶ *Centre for Applied Health & Social Care Research (CARe), Sheffield Hallam University, Sheffield, UK*

ARTICLE INFO

Article history:
Received 20 March 2024
Accepted 23 August 2024

Keywords:
Osteoarthritis
Bracing
Knee
Scoping review

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-

* Correspondence to: School of Medicine, Primary Care Centre Versus Arthritis, David Weatherall Building, Keele University, Keele, Staffordshire ST5 5BG, UK.
E-mail addresses: m.holden@keele.ac.uk (M. Holden), m.murphy10@nhs.net (M. Murphy), j.m.simkins1@keele.ac.uk (J. Simkins), m.thomas@keele.ac.uk (M. Thomas), lucyc.huckfield@mpft.nhs.uk (L. Huckfield), j.quicke@uq.edu.au (J. Quicke), n.halliday@keele.ac.uk (N. Halliday), fraser.birrell@ncl.ac.uk (F. Birrell), belindab@bu.edu (B. Borrelli), michael.callaghan@mmu.ac.uk (M. Callaghan), k.s.dziedzic@keele.ac.uk (K. Dziedzic), dfelson@bu.edu (D. Felson), n.foster@uq.edu.au (N. Foster), c.jinks@keele.ac.uk (C. Jinks), s.jowett@bham.ac.uk (S. Jowett), e.nicholls@keele.ac.uk (E. Nicholls), g.peat@shu.ac.uk (G. Peat).

https://doi.org/10.1016/j.joca.2024.08.010

chanisms 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.

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 Foundation[4] and the American Academy of Orthopaedic Surgeons[5] 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 orthopaedic[13] 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) checklist[39] 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 *(Adults with symptomatic knee OA)*		
	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 *(Content of knee bracing interventions)* and **Context** *(applicable for use in clinical settings)*		
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 Osteoarthritis and Cartilage

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 al[73] was specifically chosen for its expected comfort with the aim of enhancing adherence (the SofTec 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 form[78]) 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,

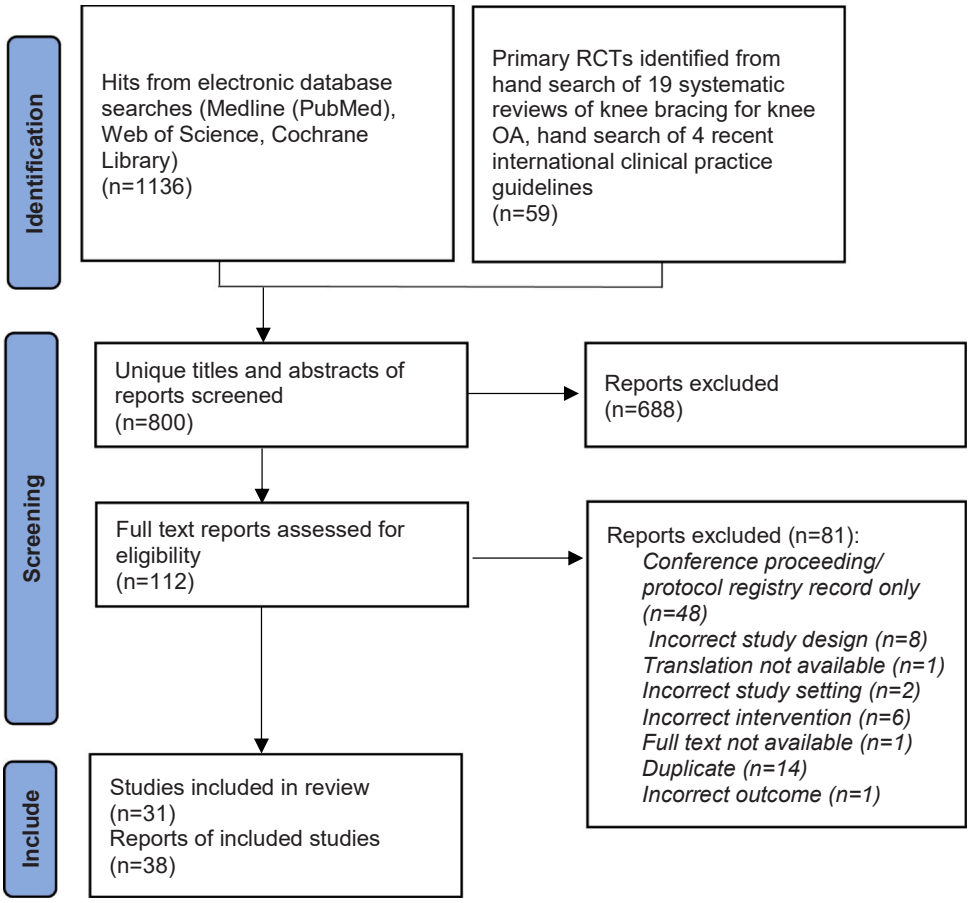

Fig. 1 Osteoarthritis and Cartilage

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 RCT[49]) 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 more[60]; 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) unclearPain VAS, LEFS, SF-36, physical performance test battery, isokinetic quadriceps and hamstrings at 3 m
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	-	Normalised adduction moments at 4–5w
Dwarakanathan 2022, India,[48] -	Medial tibiofemoral OA (C+XR)	66	Parallel Group	Unloader knee orthosis	Lateral wedged insoles	Static balance at 6 m
Gueugnon 2021, France NCT02765685[49]	Medial tibiofemoral OA (C+XR)	120	Parallel group	Custom made knee brace plus usual standard care	Usual standard care	Pain VAS at 12 m
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)	-	KOOS, KSS, KSS function at 6w, 12w, 24w,52w
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 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)	-	Pain VAS and WOMAC Pain at 6w
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, unsupportive foot orthoses, shoes with flexible midsole	-	WOMAC Pain and WOMAC Function at 12w
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
Kirkley 1999, Canada[58] -	Medial tibiofemoral OA (C+XR)	119	Parallel group	I1: Neoprene sleeve I2: Unloader brace	Standard medical management	WOMAC Total at 6 m
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 Pain VAS average, best, worst; KOS-ADL; PSFS; physical performance test battery; extension ROM; flexion ROM; isometric quadriceps at 6w
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)
Ostrander 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, 6 m
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 6 m
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 3 m
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 9 m
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 6 m
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 3 m

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

Osteoarthritis and Cartilage

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	Intervention	THE BRACE (What, tailoring, how much)						BRACE DELIVERY (Who, how, where)				MODIFICATIONS
		Type of brace (V/V,PF,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]	Intervention modification over the RCT
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	I1. 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	I2. 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
Dwarakan-athan 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 Adherence: 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

(*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,PF,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]	Intervention modification over the RCT
Jones 2013	Valgus knee brace	V/V	Valgus knee brace (Donjoy OAdjuster, DJO, Vista, USA)	O	Daily during activitie s.V/V: 6 degrees.	2w	NS Adherence: NS	Trained individual	NS	NS	NS	NS
Khosravi 2021	I1: Valgus brace	V/V	NS	C	NS V/V: Acceptability	6w	NS Adherence: NS	Orthotist	NS	NS	H	NS
Khosravi 2021	I2: Valgus brace plus lateral wedge insole	V/V	NS	C	NS V/V: Acceptability	6w	Lateral wedge insole Adherence: NS	Orthotist	NS	NS	H	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 activitie s.V/V: additional 4 degrees.	NS (6 mths)	Medical treatment (Ed. leaflet, instruction on acetaminophen use, home flexibility program); education on brace application/ maintenance. Adherence: NS	NS	NS	NS	U	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 Adherence: NS	A Doctor	NS	Unclear	H	NS
Ostrander 2016	Medial Unloader brace	V/V	Fusion OA; Breg, Inc	O	Min. 4 hrs per da y.V/V: NS	24w	Conservative OA treatment (NSAIDs, exercises, joint supplements). Adherence: NS	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 V/V: additional 4 degrees valgus.	2w	NS Adherence: NS	NS	NS	NS	U	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,PF,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]	Intervention modification over the RCT
Petersen 2019	Unloader brace	V/V	Unloader One; Össur, Reykjavik, Iceland	O	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; GII Orthotics Europe, Eindhoven, The Netherlands	O	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 (Össur)	O	First 2 days: minimum of 2 h per day. After, at least 6 h a day during regular activitie 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 ≥6° brace provided. Also had instruction on brace use and maintenance. Adherence. NS	Certified trained practitioner	NS	NS	NS	NS
Robert-Lachaine 2020	I1:Valgus three-point bending system brace (V3P-brace)	V/V	OA Brace; 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 m	NS 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,PF,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]	Intervention modification over the RCT
Robert-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 da y.V/V: NS	6 wks	Usual care (analgesics, daily exercise program, information) 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	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	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

(*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,PF,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]	Intervention modification over the RCT
Yamamoto 2019	I1. Patellofemoral functional brace	PF	Free knee (manufacturer NS)	O	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)	O	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	O	While awake for troublesome activities	NS (6 mths)	Medical treatment (Ed. leaflet, instruction on 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	O	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	O	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	O	Daily, for as long as tolerated.	6 wks	NS Adherence: NS	NS	NS	1	Unclear	NS

(*continued on next page*)

Table III (*continued*)

		THE BRACE (What, tailoring, how much)						BRACE DELIVERY (Who, how, where)				MODIFICATIONS
STUDY	Intervention	Type of brace (V/V,PF,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]	Intervention modification over the RCT
Pajareya 2003	Elastic knee sleeve plus education and NSAIDs	S	LP 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) Adherence: NS	NS	NS	Unclear	NS	NS
Cherian 2015	Pneumatic knee brace	H	OA Rehabilitator[IM] (Guardian Brace, Pinellas Park, Florida)	O	Minimum 3 h per day when ambulating and exercising	3 mths	PT, corticosteroid, home exercise, Ed. about the brace, gait re-retraining. Adherence: NS	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	Instructed in use and care of the brace. Continue current medication. Adherence: NS	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	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
Hjarartson 2018	I2. Look alike brace	C	Unloader one (Dynamic Force Straps removed)	O	NS	NS	NS Adherence: NS	Ortho. Tech.	NS	NS	H	NS
Horlick 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

(*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,PF,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]	Intervention modification over the RCT
Hunter 2012	I2. Neutral knee brace (no valgus angulation), unsupportive 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
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 Adherence: NS.	NS	NS	NS	Clinical research unit	NS
Pagani 2010	I1. Modified knee orthosis (neutral/ flexible)	C	Genu Arthro Knee Orthosis 28K20/21, Otto Bock, Duderstadt, Germany	C	NS	2w	NS Adherence: NS	NS	NS	NS	U	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 Adherence: NS	NS	NS	NS	H	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.

Osteoarthritis and Cartilage

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	
Arazpour 2013	Unloader brace	V/V					X	X					
Brouwer 2006	Knee brace	V/V					X	X					
Draganich 2006	I1. Off the shelf 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						
Guegnon 2021	Custom-made brace	V/V					X	X					
Hjarartson 2018	I1. Unloader brace	V/V					X	X					
Horlick 1993	I1: Valgus brace with medial hinge	V/V					X	X					
Horlick 1993	I2: Valgus brace with lateral hinge	V/V					X	X					
Hunter 2012	I1. Valgus brace	V/V						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										
Ostrander 2016	Medial Unloader brace	V/V				X	X	X	X				
Pagani 2010	I1. Knee orthosis	V/V					X						
Petersen 2019	Unloader brace	V/V				X	X	X	X		X		
Richards 2005	I1. Valgus corrective brace	V/V					X			X		X	
Robbins 2020	Stepped care including unloader knee brace option	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		X		
Thoumie 2018	Unloading knee brace	V/V					X	X					
van Egmond 2017	Bledsoe Thruster brace	V/V					X	X					
van Egmond 2017	SofTec OA group	V/V					X	X					
van Raaij 2010	Valgus knee brace	V/V					X	X	X				
Callaghan 2015	Patellar brace	PF				X	X	X					Xa
Hunter 2011	I1. Realigning patellofemoral brace	PF					X	X					
Yamamoto 2019	I1. Patellofemoral functional brace	PF				X	X	X					
Berry 1992	Knee support	S				X							
Kirkley 1999	I1: Neoprene sleeve	S				X					X		

(*continued on next page*)

Table IV (*continued*)

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	
Mazzucca 2004	I1. Verum sleeve (to retain body heat)	S											Xb
Mohd Sharif 2019	I1: Basic knee sleeve	S							X		X		Xc,d
Mohd Sharif 2019	I2: Knee sleeve with patella cutout	S							X		X		Xd,e
Pajareya 2003	Elastic sleeve	S									X		Xf
Cherian 2015	Pneumatic knee brace	H					X		X	X			
Richards 2005	I2. Simple hinged brace	H					X				X	X	
Robert-Lachaine 2020	I3. ACL-stabilization brace	H				X			X		X		
Madara 2019	Knee brace	TF/H					X						Xg
Hjarartson 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

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		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
Horlick 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%)
Horlick 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%)
Horlick 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)	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	I1. Verum sleeve (specially fabricated to retain body heat)	NS	Y: Self-report (days sleeve worn for 12 h or more)	Mean: 26.5 (SD: 3.0) days (possible range 0–28)
Mazzucca, 2004	I2. Placebo sleeve (standard cotton/elastane sleeve)	NS	Y: Self-report (days sleeve worn for 12 h or more)	Mean: 27.6 (SD: 1.1) days (possible range 0–28)
Mohd Sharif 2019	I1: Basic knee sleeve	NS	Y: Self-report (hrs per day in log book)	NS
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	Participants asked to report any changes to the protocol prescribed	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

(*continued on next page*)

Table V (*continued*)

STUDY	NAME OF BRACE INTERVENTION	BRACE ADHERENCE		
		Any reported assessment of intervention fidelity	Assessment (and method) of brace adherence	Level 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%6 months: Weekly use: Everyday: 39.3%; > 5 days/week: 23%; > 3 days/week: 27.9%; 1–3 days/week: 9.8%; Never: 0. Hours per day: < 6hrs: 55.2%; > 6hrs: 44.8%
Richards 2005	I1. Valgus corrective brace	NS	NS	Patient compliance was not recorded but assumed as high due to most patients benefiting.
Richards 2005	I2. Simple hinged brace	NS	NS	Patient compliance was not recorded but assumed as high due to most patients benefiting.
Robbins 2020	Stepped care including unloader knee brace option	NS	NS	N/A
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).
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).	**3 months:** Frequency of brace wear: 87.7 (+−4.0) days. Mean daily use: 2.6 (+−0.9) hours.
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).	3 months: Frequency of brace wear: 87.3 (+−3.9) days. Mean daily use: 2.5 (+−0.9) hours.
Sattari 2011	3 point varus correction custom moulded knee brace plus conservative treatment	NS	NS	N/A
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.
van Egmond 2017	I1. Bledsoe Thruster brace	NS	Y: Self-report: use of knee brace (diary)	Mean hours per day 2 weeks: 8.2 (3.7) 12 weeks: 6.7 (3.4)
van Egmond 2017	I2. SofTec OA 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 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)	6 months: 45% complied with brace treatment. Mean brace use of 38.8 (SD: 32.2) hours per wk.
Yamamot 2019	I1. Patellofemoral functional brace	NS	Y: Self-report: use of knee brace (hours) (specific measure not stated) (mean, SD)	1 month: 191.5 (145.6) 3 months: 325 (292.2)
Yamamot 2019	I2. Neoprene knee brace with a patellar orifice	NS	Y: Self-report: use of knee brace (hours) (specific measure not stated)	1 month: 127.2 (107.2) 3 months: 270 (240.7)

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 adaptions 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 delivers), 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 recommendations[10] 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.

Role of the funding source

There has been no role of any funding source in this publication.

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.

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

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

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

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

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

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

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

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

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

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.

Acknowledgements

The views expressed are those of the authors and not necessarily those of the NHS, National Institute for Health and Care Research (NIHR) or Department for Health and Social Care. NE Foster is supported by a National Health and Medical Research Council (NHMRC) Investigator Grant Leadership 2 (#2018182). JQ is supported through a NHMRC Investigator Grant Leadership 2 (#2018182) awarded to NE Foster. CJ is part funded by the NIHR Collaboration West Midlands (NIHR200165). KD is part funded by the NIHR Applied Health Research Collaboration (ARC) West Midlands (NIHR 200165). KD was also part funded by an NIHR Knowledge Mobilisation Research Fellowship (KMRF-2014-03-002) and is an NIHR Senior Investigator (ID NIHR 205031).

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] *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.*

APPENDIX 3: COMPLETENESS OF REPORTING OF BRACING INTERVENTIONS ACCORDING TO CRITERIA INFORMED BY TIDIER GUIDANCE

				Description of the brace*							Description of delivery of the bracing intervention^					Why	How well$				
STUDY	**Intervention**	**Brace type**	**1. Intervention name**	**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$**	**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**	**Complete reporting per intervention; number (%) of intervention components reported**
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 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	**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	**N 12 (67)**
Dwarakan-athan 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 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	**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 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	**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	**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	**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	**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 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 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 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 6 (33)**
Ostrander 2016	Medial Unloader brace	V/V	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	N	Y	N	N	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 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	**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	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 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	**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	**N 9 (50)**

Sattari 2011	3 point varus correction custom moulded knee brace plus conservative treatment	V/V	Y	N	Y	Y	N	Y	Y	N	Y	N	N	Y	N	Y	N	N	N	N	**N 8 (44)**
Thoumie 2018	Unloading knee brace plus usual care	V/V	Y	Y	Y	Y	N	Y	Y	N	Y	N	N	N	N	Y	N	N	Y	Y	**N 10 (56)**
van Egmond 2017	I1: Bledsoe Thruster brace	V/V	Y	Y	Y	Y	Y	Y	N	N	Y	N	N	Y	N	Y	N	N	Y	Y	**N 11 (61)**
van Egmond 2017	I2: SofTec OA group	V/V	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	Y	N	Y	N	N	Y	Y	**N 12 (67)**
van Raaij 2010	Valgus knee brace	V/V	Y	Y	Y	Y	Y	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	**N 10 (56)**
Callaghan 2015	Patellar brace	PF	Y	Y	Y	Y	-	Y	N	N	N	N	N	N	N	Y	N	N	Y	Y	**N 8 (47)**
Hunter 2011	I1. Realigning patellofemoral brace	PF	Y	Y	Y	Y	-	Y	Y	N	Y	N	N	N	N	Y	N	N	Y	Y	**N 10 (59)**
Yamamot 2019	I1. Patellofemoral functional brace	PF	Y	Y	Y	Y	-	Y	Y	N	N	N	N	Y	N	Y	N	N	Y	Y	**N 10 (59)**
Berry 1992	Knee support plus conventional conservative treatment	S	Y	Y	Y	Y	-	Y	Y	N	N	N	N	N	N	Y	N	N	N	N	**N 7 (41)**
Kirkley 1999	I1: Neoprene sleeve	S	Y	N	Y	Y	-	N	Y	N	N	N	N	Y	N	Y	N	N	Y	N	**N 7 (41)**
Mohd Sharif 2019	I1: Basic knee sleeve	S	Y	Y	Y	Y	-	Y	N	N	N	N	Y	N	N	Y	N	N	Y	N	**N 8 (47)**
Mohd Sharif 2019	I2: Knee sleeve with patella cutout	S	Y	Y	Y	Y	-	Y	N	N	N	N	Y	N	N	Y	N	N	Y	N	**N 8 (47)**
Mazzucca 2004	I1. Verum sleeve (specially fabricated to retain body heat)	S	Y	N	Y	Y	-	Y	Y	N	N	N	N	Y	N	Y	N	N	Y	Y	**N 9 (53)**
Pajareya 2003	Elastic knee sleeve plus education and NSAIDs	S	Y	Y	Y	Y	-	Y	Y	N	N	N	N	N	N	Y	Y	Y	Y	Y	**N 11 (65)**
Cherian 2015	Pneumatic knee brace	H	Y	Y	Y	Y	-	Y	Y	N	N	N	N	N	N	Y	N	N	N	N	**N 7 (41)**
Richards 2005	I2: Simple hinged brace	H	Y	Y	Y	Y	-	Y	Y	N	Y	N	N	N	N	Y	N	N	N	Y	**N 9 (53)**
Robert-Lachaine 2020	I3: Stabilizing brace used after ligament injuries (ACL-brace)	H	Y	Y	Y	Y	-	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	**N 9 (53)**
Madara 2019	Knee brace plus stretching	TF/H	Y	Y	Y	Y	-	Y	Y	N	N	N	N	N	N	Y	N	N	Y	Y	**N 9 (53)**
Hjarartson 2018	I2. Look alike brace	C	Y	Y	Y	N	-	N	N	N	Y	N	N	Y	N	Y	N	N	N	N	**N 6 (33)**
Horlick 1993	I3. Brace in neutral	C	Y	Y	Y	Y	-	Y	N	N	N	N	N	N	N	Y	N	N	Y	N	**N 7 (41)**
Hunter 2011	I2. Non-realigning patellofemoral brace (placebo)	C	Y	Y	Y	Y	-	Y	N	N	Y	N	N	N	N	Y	N	N	Y	Y	**N 9 (53)**
Hunter 2012	I2. Neutral knee brace (no valgus angulation), unsupportive foot orthoses, shoes with a flexible mid-sole	C	Y	Y	Y	Y	-	Y	Y	Y	Y	N	N	N	N	Y	N	N	Y	Y	**N 11 (65)**
Mazzucca 2004	I2. Placebo sleeve (standard cotton/elastane sleeve)	C	Y	N	Y	Y	-	Y	Y	N	N	N	N	Y	N	Y	N	N	Y	Y	**N 9 (53)**
Pagani 2010	I1. Modified knee orthosis (neutral/ flexible)	C	Y	Y	Y	N	-	Y	N	N	N	N	N	Y	N	Y	N	N	N	N	**N 6 (35)**
Yamamot 2019	I2. Neoprene knee brace with a patellar orifice	C	Y	N	Y	Y	-	Y	Y	N	N	N	N	Y	N	N	N	N	Y	Y	**N 8 (47)**
Number (%) of interventions reporting each component			**47 (100)**	**38 (83)**	**46 (98)**	**39 (85)**	**14 (52)**	**42 (89)**	**24 (51)**	**3 (6)**	**27 (57)**	**0**	**5 (11)**	**22 (47)**	**0**	**45 (96)**	**1 (2)**	**1 (2)**	**32 (68)**	**29 (62)**	

Y=Yes, N=No/unclear, NA=Not applicable.
Brace type: V/V= Valgus/varus, PF=patellofemoral, S = sleeve, H = neutral hinged, C = control/ placebo.
* Incorporating the following categories in the TIDierR checklist: what (material), what (procedures), how much, tailoring.
^ Incorporating the following categories in the TIDierR checklist: who provide, how, where, when.
$ Incorporating the following categories in the TIDieR checklist: how well (planned), how well (actual).

References

1. Yang G, Wang J, Liu Y, Lu H, He L, Ma C, *et al*. Burden of Knee Osteoarthritis in 204 Countries and Territories, 1990-2019: results from the Global Burden of Disease Study 2019. Arthritis Care Res 2023 Dec;75(12):2489–500. https://doi.org/10.1002/acr.25158. Epub 2023 Jul 13. PMID: 37221154.
2. OECD 2019 Hip and knee replacement | Health at a Glance; 2019: OECD Indicators | OECD iLibrary (oecd-ilibrary.org).
3. Bichsel D, Liechti FD, Schlapbach JM, Wertli MM. Cross-sectional analysis of recommendations for the treatment of hip and knee osteoarthritis in clinical guidelines. Arch Phys Med Rehabil 2022 Mar;103(3):559–569.e5. https://doi.org/10.1016/j.apmr.2021.07.801. Epub 2021 Aug 16. PMID: 34411512.
4. Kolasinski SL, Neogi T, Hochberg MC, Oatis C, Guyatt G, Block J, *et al*. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Rheumatol 2020 Feb;72(2):220–33. https://doi.org/10.1002/art.41142. Epub 2020 Jan 6. Erratum in: Arthritis Rheumatol. 2021 May;73(5):799. PMID: 31908163.
5. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty). Evidence-Based Clinical Practice Guideline. ⟨https://www.aaos.org/oak3cpg⟩ Published 08/31/2021.
6. The Royal Australian College of General Practitioners. Guideline for the management of knee and hip osteoarthritis. 2nd edn East Melbourne, Vic: RACGP; 2018 Appendix 1. Available at ⟨www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Joint%20replacement/Guideline-for-the-management-of-knee-and-hip-OA-2nd-edition.pdf⟩.
7. Bannuru RR, Osani MC, Vaysbrot EE, Arden NK, Bennell K, Bierma-Zeinstra SMA, *et al*. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage 2019 Nov;27(11):1578–89. https://doi.org/10.1016/j.joca.2019.06.011. Epub 2019 Jul 3. PMID: 31278997.
8. National Institute for Health and Care Excellence. Osteoarthritis in over-16s: diagnosis and management. NICE Guideline NG226. London: Royal College of Physicians; 2022.
9. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al*. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:n2061. https://doi.org/10.1136/bmj.n2061. PMID: 34593508; PMCID: PMC8482308.
10. Borrelli B, Sepinwall D, Ernst D, Bellg AJ, Czajkowski S, Breger R, *et al*. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol 2005 Oct;73(5):852–60. https://doi.org/10.1037/0022-006X.73.5.852. PMID: 16287385.
11. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, *et al*. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol 2004 Sep;23(5):443–51. https://doi.org/10.1037/0278-6133.23.5.443. PMID: 15367063.
12. Hoffmann TC, Erueti C, Glasziou PP. Poor description of non-pharmacological interventions: analysis of consecutive sample of randomised trials. BMJ 2013 Sep 10;347:f3755. https://doi.org/10.1136/bmj.f3755. PMID: 24021722; PMCID: PMC3768250.
13. Anderson JM, Stafford A, Jellison S, Vassar M. Intervention reporting of published trials is insufficient in orthopaedic surgery journals: application of the template for intervention description and replication checklist. Arthrosc Sports Med Rehabil 2021 Apr 24;3(3):e619–27. https://doi.org/10.1016/j.asmr.2020.09.019. PMID: 34195624; PMCID: PMC8220564.
14. Hariohm K, Jeyanthi S, Kumar JS, Prakash V. Description of interventions is under-reported in physical therapy clinical trials. Braz J Phys Ther 2017 Jul-Aug;21(4):281–6. https://doi.org/10.1016/j.bjpt.2017.05.006. Epub 2017 May 19. PMID: 28579012; PMCID: PMC5537478.
15. Yamato TP, Maher CG, Saragiotto BT, Hoffmann TC, Moseley AM. How completely are physiotherapy interventions described in reports of randomised trials? Physiotherapy 2016 Jun;102(2):121–6. https://doi.org/10.1016/j.physio.2016.03.001. Epub 2016 Mar 12. PMID: 27033780.
16. Bartholdy C, Nielsen SM, Warming S, Hunter DJ, Christensen R, Henriksen M. Poor replicability of recommended exercise interventions for knee osteoarthritis: a descriptive analysis of evidence informing current guidelines and recommendations. Osteoarthritis Cartilage. 2019 Jan;27(1):3–22. https://doi.org/10.1016/j.joca.2018.06.018. Epub 2018 Sep 22. PMID: 30248500.
17. Burgess LC, Wainwright TW, James KA, von Heideken J, Iversen MD. The quality of intervention reporting in trials of therapeutic exercise for hip osteoarthritis: a secondary analysis of a systematic review. Trials 2021 Jun 7;22(1):388. https://doi.org/10.1186/s13063-021-05342-1. PMID: 34098998; PMCID: PMC8186100.
18. Duivenvoorden T, Brouwer RW, van Raaij TM, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. Cochrane Database Syst Rev 2015;Mar 16(3), CD004020.
19. Peters MDJ, Godfrey C, McInerney P, Munn Z, Tricco AC, Khalil H. Scoping reviews (2020). In: Aromataris E, Lockwood C, Porritt K, Pilla B, Jordan Z, editors. JBI Manual for Evidence Synthesis JBI; 2024. https://doi.org/10.46658/JBIMES-24-09
20. Moyer RF, Birmingham TB, Bryant DM, Giffin JR, Marriott KA, Leitch KM. Valgus bracing for knee osteoarthritis: a meta analysis of randomized trials. Arthritis Care Res 2015;67:493–501.
21. Phillips S, Li CS, Phillips M, Bischoff M, Ali P, Chahal J, *et al*. Treatment of osteoarthritis of the knee with bracing: a scoping review. Orthop Rev 2016 Jun 27;8(2):6256. https://doi.org/10.4081/or.2016.6256. PMID: 27433297; PMCID: PMC4933815.
22. Mine K, Nakayama T, Milanese S, Grimmer K. The effectiveness of braces and orthoses for patients with knee osteoarthritis: a systematic review of Japanese-language randomised controlled trials. Prosthet Orthot Int 2017 Apr;41(2):115–26. https://doi.org/10.1177/0309364616640926. Epub 2016 Jul 10. PMID: 27117012.
23. Cherian JJ, Jauregui JJ, Leichliter AK, Elmallah RK, Bhave A, Mont MA. The effects of various physical non-operative modalities on the pain in osteoarthritis of the knee. Bone Joint J 2016 Jan;98-B (1 Suppl A):89–94. https://doi.org/10.1302/0301-620X.98B1.36353. PMID: 26733650.
24. Newberry SJ, FitzGerald J, SooHoo NF, *et al*. Treatment of osteoarthritis of the knee: an update review. Comparative Effectiveness Reviews No. 190. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 May.
25. Woods B, Manca A, Weatherly H, Saramago P, Sideris E, Giannopoulou C, *et al*. Cost-effectiveness of adjunct non-pharmacological interventions for osteoarthritis of the knee. PLoS One 2017 Mar 7;12(3), e0172749. https://doi.org/10.1371/journal.pone.0172749. PMID: 28267751; PMCID: PMC5340388.
26. Cudejko T, van der Esch M, van der Leeden M, Roorda LD, Pallari J, Bennell KL, *et al*. Effect of soft braces on pain and physical function in patients with knee osteoarthritis: systematic review with meta-analyses. Arch Phys Med Rehabil 2018 Jan;99(1):153–63. https://doi.org/10.1016/j.apmr.2017.04.029. Epub 2017 Jul 4. PMID: 28687317.

27. Gohal C, Shanmugaraj A, Tate P, Horner NS, Bedi A, Adili A, *et al*. Effectiveness of valgus offloading knee braces in the treatment of medial compartment knee osteoarthritis: a systematic review. Sports Health 2018 Nov/Dec;10(6):500–14. https://doi.org/10.1177/1941738118763913. Epub 2018 Mar 15. PMID: 29543576; PMCID: PMC6204633.
28. Mistry DA, Chandratreya A, Lee PYF. An update on unloading knee braces in the treatment of unicompartmental knee osteoarthritis from the last 10 years: a literature review. Surg J 2018 Jul 2;4(3):e110–8. https://doi.org/10.1055/s-0038-1661382. PMID: 29978048; PMCID: PMC6028281.
29. DeRogatis M, Anis HK, Sodhi N, Ehiorobo JO, Chughtai M, Bhave A, *et al*. Non-operative treatment options for knee osteoarthritis. Ann Transl Med 2019 Oct;7(Suppl 7):S245. https://doi.org/10.21037/atm.2019.06.68. PMID: 31728369; PMCID: PMC6828999.
30. Callaghan MJ, Palmer E, O'Neill T. Management of patellofemoral joint osteoarthritis using biomechanical device therapy: a systematic review with meta-analysis. Syst Rev 2021 Jun 9;10(1):173. https://doi.org/10.1186/s13643-021-01708-3. PMID: 34108025; PMCID: PMC8191025.
31. Khosravi M, Babaee T, Daryabor A, Jalali M. Effect of knee braces and insoles on clinical outcomes of individuals with medial knee osteoarthritis: a systematic review and meta-analysis. Assist Technol 2022 Sep 3;34(5):501–17. https://doi.org/10.1080/10400435.2021.1880495. Epub 2021 Mar 11. PMID: 33507124.
32. Fan Y, Li Z, Zhang H, Hong G, Wu Z, Li W, *et al*. Valgus knee bracing may have no long-term effect on pain improvement and functional activity in patients with knee osteoarthritis: a meta-analysis of randomized trials. J Orthop Surg Res 2020 Sep 1;15(1):373. https://doi.org/10.1186/s13018-020-01917-x. PMID: 32873332; PMCID: PMC7466786.
33. Coudeyre E, Nguyen C, Chabaud A, Pereira B, Beaudreuil J, Coudreuse JM, *et al*. A decision-making tool to prescribe knee orthoses in daily practice for patients with osteoarthritis. Ann Phys Rehabil Med 2018 Mar;61(2):92–8. https://doi.org/10.1016/j.rehab.2018.01.001. Epub 2018 Feb 3. PMID: 29406129.
34. Moller F, Ortíz-Muñoz L, Irarrázaval S. Offloader knee braces for knee osteoarthritis. Medwave 2021 Apr 28;21(3), e8115. https://doi.org/10.5867/medwave.2021.03.8114. PMID: 34038401.
35. Alfatafta H, Onchonga D, Alfatafta M, Zhang L, Boncz I, Lohner S, *et al*. Effect of using knee valgus brace on pain and activity level over different time intervals among patients with medial knee OA: systematic review. BMC Musculoskelet Disord 2021 Aug 12;22(1):687. https://doi.org/10.1186/s12891-021-04513-0. PMID: 34384421; PMCID: PMC8362244.
36. Huang XM, Yuan FZ, Chen YR, Huang Y, Yang ZX, Lin L, *et al*. Physical therapy and orthopaedic equipment-induced reduction in the biomechanical risk factors related to knee osteoarthritis: a systematic review and Bayesian network meta-analysis of randomised controlled trials. BMJ Open 2022 Feb 9;12(2), e051608. https://doi.org/10.1136/bmjopen-2021-051608. PMID: 35140149; PMCID: PMC8830256.
37. Pereira LC, Runhaar J, Favre J, Jolles BM, Bierma-Zeinstra S. Association between changes in the knee adduction moment and changes in knee pain and function in response to non-surgical biomechanical interventions for medial knee osteoarthritis: a systematic review. Eur J Phys Rehabil Med 2021 Dec;57(6):948–58. https://doi.org/10.23736/S1973-9087.21.06828-3. Epub 2021 Sep 1. PMID: 34468109.
38. Quicke JG, Runhaar J, van der Windt DA, Healey EL, Foster NE, Holden MA. Moderators of the effects of therapeutic exercise for people with knee and hip osteoarthritis: a systematic review of sub-group analyses from randomised controlled trials. Osteoarthr Cartil Open 2020 Nov 4;2(4), 100113. https://doi.org/10.1016/j.ocarto.2020.100113. PMID: 36474874; PMCID: PMC9718168.
39. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014 Mar 7;348:g1687. https://doi.org/10.1136/bmj.g1687. PMID: 24609605.
40. Arazpour M, Bani MA, Maleki M, Ghomshe FT, Kashani RV, Hutchins SW. Comparison of the efficacy of laterally wedged insoles and bespoke unloader knee orthoses in treating medial compartment knee osteoarthritis. Prosthet Orthot Int 2013 Feb;37(1):50–7. https://doi.org/10.1177/0309364612447094. Epub 2012 Aug 3. PMID: 22864510.
41. Berry H, Black C, Fernandes L, *et al*. Controlled trial of a knee support (Genutrain) in patients with osteoarthritis of the knee. Eur J Rheumatol Inflamm 1992;12:30–4.
42. Brouwer RW, van Raaij TM, Verhaar JA, Coene LN, Bierma-Zeinstra SM. Brace treatment for osteoarthritis of the knee: a prospective randomized multi-centre trial. Osteoarthritis Cartilage 2006 Aug;14(8):777–83. https://doi.org/10.1016/j.joca.2006.02.004. Epub 2006 Mar 24. PMID: 16563810.
43. Callaghan MJ, Parkes MJ, Hutchinson CE, Gait AD, Forsythe LM, Marjanovic EJ, *et al*. A randomised trial of a brace for patello-femoral osteoarthritis targeting knee pain and bone marrow lesions. Ann Rheum Dis 2015 Jun;74(6):1164–70. https://doi.org/10.1136/annrheumdis-2014-206376. Epub 2015 Jan 16. PMID: 25596158; PMCID: PMC4771926.
44. Swaminathan V, Parkes MJ, Callaghan MJ, O'Neill TW, Hodgson R, Gait AD, *et al*. With a biomechanical treatment in knee osteoarthritis, less knee pain did not correlate with synovitis reduction. BMC Musculoskelet Disord 2017 Aug 10;18(1):347. https://doi.org/10.1186/s12891-017-1691-1. PMID: 28797238; PMCID: PMC5553897.
45. Cherian JJ, Bhave A, Kapadia BH, Starr R, McElroy MJ, Mont MA. Strength and functional improvement using pneumatic brace with extension assist for end-stage knee osteoarthritis: a prospective, randomized trial. J Arthroplasty 2015 May;30(5):747–53. https://doi.org/10.1016/j.arth.2014.11.036. Epub 2014 Nov 29. PMID: 25499679.
46. Chughtai M, Bhave A, Khan SZ, Khlopas A, Ali O, Harwin SF, *et al*. Clinical outcomes of a pneumatic unloader brace for Kellgren-Lawrence Grades 3 to 4 Osteoarthritis: a minimum 1-year follow-up study. J Knee Surg 2016 Nov;29(8):634–8. https://doi.org/10.1055/s-0036-1593616. Epub 2016 Oct 17. PMID: 27750364.
47. Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. J Bone Joint Surg Am 2006 Dec;88(12):2645–52. https://doi.org/10.2106/JBJS.D.02787. PMID: 17142415.
48. Dwarakanathan R, Mohanty RK, Sahoo S, Prasad S. Efficacy of unloader knee orthosis and lateral wedge insole on static balance in medial knee osteoarthritis. J Orthop Trauma Rehabil 2022;29:1–8.
49. Gueugnon M, Fournel I, Soilly AL, Diaz A, Baulot E, Bussière C, *et al*. Effectiveness, safety, and cost-utility of a knee brace in medial knee osteoarthritis: the ERGONOMIE randomized controlled trial. Osteoarthritis Cartilage 2021 Apr;29(4):491–501. https://doi.org/10.1016/j.joca.2020.11.009. Epub 2021 Jan 30. PMID: 33524515.
50. Hjartarson HF, Toksvig-Larsen S. The clinical effect of an unloader brace on patients with osteoarthritis of the knee, a randomized placebo controlled trial with one year follow up. BMC Musculoskelet Disord 2018 Sep 22;19(1):341. https://doi.

org/10.1186/s12891-018-2256-7. PMID: 30243296; PMCID: PMC6151190.
51. Horlick SG, Loomer RL. Valgus knee bracing for medial gonarthrosis. Clin J Sport Med 1993;3:251–5.
52. Hunter DJ, Harvey W, Gross KD, Felson D, McCree P, Li L, *et al*. A randomized trial of patellofemoral bracing for treatment of patellofemoral osteoarthritis. Osteoarthritis Cartilage 2011 Jul;19(7):792–800. https://doi.org/10.1016/j.joca.2010.12.010. Epub 2011 Jan 11. PMID: 21232620; PMCID: PMC3090698.
53. McWalter EJ, Hunter DJ, Harvey WF, McCree P, Hirko KA, Felson DT, *et al*. The effect of a patellar brace on three-dimensional patellar kinematics in patients with lateral patellofemoral osteoarthritis. Osteoarthritis Cartilage 2011 Jul;19(7):801–8. https://doi.org/10.1016/j.joca.2011.03.003
54. Hunter D, Gross KD, McCree P, Li L, Hirko K, Harvey WF. Realignment treatment for medial tibiofemoral osteoarthritis: randomised trial. Ann Rheum Dis 2012 Oct;71(10):1658–65. https://doi.org/10.1136/annrheumdis-2011-200728. Epub 2012 Feb 29. PMID: 22377805.
55. Rezaeian ZS, Smith MM, Skaife TL, Harvey WF, Gross KD, Hunter DJ. Does knee malalignment predict the efficacy of realignment therapy for patients with knee osteoarthritis? Int J Rheum Dis 2017 Oct;20(10):1403–12. https://doi.org/10.1111/1756-185X.12696. Epub 2015 Jul 14. PMID: 26171969.
56. Jones RK, Nester CJ, Richards JD, Kim WY, Johnson DS, Jari S, *et al*. A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis. Gait Posture 2013 Mar;37(3):368–72. https://doi.org/10.1016/j.gaitpost.2012.08.002. Epub 2012 Aug 21. PMID: 22920242.
57. Khosravi M, Arazpour M, Sharafat Vaziri A. An evaluation of the use of a lateral wedged insole and a valgus knee brace in combination in subjects with medial compartment knee osteoarthritis (OA). Assist Technol 2021 Mar 4;33(2):87–94. https://doi.org/10.1080/10400435.2019.1595788. Epub 2019 Apr 4. PMID: 30945994.
58. Kirkley A, Webster-Bogaert S, Litchfield R, Amendola A, MacDonald S, McCalden R, *et al*. The effect of bracing on varus gonarthrosis. J Bone Joint Surg Am 1999 Apr;81(4):539–48. https://doi.org/10.2106/00004623-199904000-00012. PMID: 10225800.
59. Madara K, Aljehani M, Pozzi F, Colonna E, Zeni Jr JA. The effect of extension assist orthosis with pneumatic bladders on pain and function for patients with early knee osteoarthritis. Ann Transl Med 2019 Oct;7(Suppl 7):S247. https://doi.org/10.21037/atm.2019.04.85. PMID: 31728371; PMCID: PMC6829002.
60. Mazzuca SA, Page MC, Meldrum RD, Brandt KD, Petty-Saphon S. Pilot study of the effects of a heat-retaining knee sleeve on joint pain, stiffness, and function in patients with knee osteoarthritis. Arthritis Rheum 2004 Oct 15;51(5):716–21. https://doi.org/10.1002/art.20683. PMID: 15478166.
61. Mohd Sharif NA, Usman J, Wan Safwani WKZ, Siew Li G, Abdul Karim S, Mohamed NA, *et al*. Effects of simple knee sleeves on pain and knee adduction moment in early unilateral knee osteoarthritis. Proc Inst Mech Eng H 2019 Nov;233(11):1132–40. https://doi.org/10.1177/0954411919874614. PMID: 31597554.
62. Niazi N, Niazi S, Niazi K, Siddique M, Iqbal M. Comparison of the effectiveness of knee braces and lateral wedge insole in the management of medial compartment knee osteoarthritis. Pak J Med Health Sci 2014;8:37–40.
63. Ostrander RV, Leddon CE, Hackel JG, O'Grady CP, Roth CA. Efficacy of unloader bracing in reducing symptoms of knee osteoarthritis. Am J Orthop 2016 Jul-Aug;45(5):306–11. PMID: 27552455.
64. Pagani CH, Böhle C, Potthast W, Brüggemann GP. Short-term effects of a dedicated knee orthosis on knee adduction moment, pain, and function in patients with osteoarthritis. Arch Phys Med Rehabil 2010 Dec;91(12):1936–41. https://doi.org/10.1016/j.apmr.2010.09.003. PMID: 21112437.
65. Pajareya K, Chadchavalpanichaya N, Timdang S. Effectiveness of an elastic knee sleeve for patients with knee osteoarthritis: a randomized single-blinded controlled trial. J Med Assoc Thai 2003 Jun;86(6):535–42. PMID: 12924802.
66. Petersen W, Ellermann A, Henning J, Nehrer S, Rembitzki IV, Fritz J, *et al*. Non-operative treatment of unicompartmental osteoarthritis of the knee: a prospective randomized trial with two different braces-ankle-foot orthosis versus knee unloader brace. Arch Orthop Trauma Surg 2019 Feb;139(2):155–66. https://doi.org/10.1007/s00402-018-3040-8. Epub 2018 Sep 25. PMID: 30255369.
67. Richards JD, Sanchez-Ballester J, Jones RK, Darke N, Livingstone BN. A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. J Bone Joint Surg Br 2005 Jul;87(7):937–9. https://doi.org/10.1302/0301-620X.87B7.16005. PMID: 15972906.
68. Robbins SR, Melo LRS, Urban H, Deveza LA, Asher R, Johnson VL, *et al*. Effectiveness of stepped-care intervention in overweight and obese patients with medial tibiofemoral osteoarthritis: a randomized controlled trial. Arthritis Care Res 2021 Apr;73(4):520–30. https://doi.org/10.1002/acr.24148. PMID: 31961489.
69. Robbins SR, Melo LRS, Urban H, Deveza LA, Asher R, Johnson VL, *et al*. Stepped care approach for medial tibiofemoral osteoarthritis (STrEAMline): protocol for a randomised controlled trial. BMJ Open 2017 Dec 26;7(12), e018495. https://doi.org/10.1136/bmjopen-2017-018495. PMID: 29282267; PMCID: PMC5770832.
70. Robert-Lachaine X, Dessery Y, Belzile ÉL, Turmel S, Corbeil P. Three-month efficacy of three knee braces in the treatment of medial knee osteoarthritis in a randomized crossover trial. J Orthop Res 2020 Oct;38(10):2262–71. https://doi.org/10.1002/jor.24634. Epub 2020 Mar 2. PMID: 32077519.
71. Sattari S, Ashraf AR. Comparison the effect of 3 point valgus stress knee support and lateral wedge insoles in medial compartment knee osteoarthritis. Iran Red Crescent Med J 2011 Sep;13(9):624–8. https://doi.org/10.5812/kowsar.20741804.2252. Epub 2011 Sep 15. PMID: 22737536; PMCID: PMC3372008.
72. Thoumie P, Marty M, Avouac B, Pallez A, Vaumousse A, Pipet LPT, *et al*. Effect of unloading brace treatment on pain and function in patients with symptomatic knee osteoarthritis: the ROTOR randomized clinical trial. Sci Rep 2018 Jul 12;8(1), 10519. https://doi.org/10.1038/s41598-018-28782-3. PMID: 30002395; PMCID: PMC6043544.
73. van Egmond N, van Grinsven S, van Loon CJ. Is there a difference in outcome between two types of valgus unloading braces? A randomized controlled trial. Acta Orthop Belg 2017 Dec;83(4):690–9. PMID: 30423680.
74. van Raaij TM, Reijman M, Brouwer RW, Bierma-Zeinstra SM, Verhaar JA. Medial knee osteoarthritis treated by insoles or braces: a randomized trial. Clin Orthop Relat Res 2010 Jul;468(7):1926–32. https://doi.org/10.1007/s11999-010-1274-z. Epub 2010 Feb 23. PMID: 20177839; PMCID: PMC2881986.
75. Duivenvoorden T, van Raaij TM, Horemans HL, Brouwer RW, Bos PK, Bierma-Zeinstra SM, *et al*. Do laterally wedged insoles or valgus braces unload the medial compartment of the knee in patients with osteoarthritis? Clin Orthop Relat Res 2015 Jan;473(1):265–74. https://doi.org/10.1007/s11999-014-3947-5. Epub 2014 Sep 30. PMID: 25267266; PMCID: PMC4390958.
76. Yamamoto GJ, Ocampos GP, Luzo MCM, da Silva CAC, de Farias FES, de Rezende MU. Randomized prospective study on the treatment of femoro-patellar osteoarthritis using bracing. Acta Ortop Bras 2019 Mar-Apr;27(2):85–91. https://doi.org/10.1590/

1413-785220192702208131. PMID: 30988652; PMCID: PMC6442709.
77. Merino MGL, Morale V, Ocampos GP, Luzo MCM, Camargo OP, Rezende MU. One-year results of bracing for patello-femoral osteoarthritis. Prospective randomized study. Acta Ortop Bras 2021 May-Jun;29(3):127–31. https://doi.org/10.1590/1413-785220212903243598. PMID: 34290558; PMCID: PMC8266283.
78. Mills T, Lawton R, Sheard L. Advancing complexity science in healthcare research: the logic of logic models. BMC Med Res Methodol 2019 Mar 12;19(1):55. https://doi.org/10.1186/s12874-019-0701-4. PMID: 30871474; PMCID: PMC6419426.
79. McLean S, Holden MA, Potia T, Gee M, Mallett R, Bhanbhro S, *et al*. Quality and acceptability of measures of exercise adherence in musculoskeletal settings: a systematic review. Rheumatology 2017 Mar 1;56(3):426–38. https://doi.org/10.1093/rheumatology/kew422. PMID: 28013200; PMCID: PMC5410983.
80. Bailey DL, Holden MA, Foster NE, Quicke JG, Haywood KL, Bishop A. Defining adherence to therapeutic exercise for musculoskeletal pain: a systematic review. Br J Sports Med 2020 Mar;54(6):326–31. https://doi.org/10.1136/bjsports-2017-098742. Epub 2018 Jun 6. PMID: 29875278.
81. Nicolson PJA, Hinman RS, Wrigley TV, Stratford PW, Bennell KL. Self-reported home exercise adherence: a validity and reliability study using concealed accelerometers. J Orthop Sports Phys Ther 2018 Dec;48(12):943–50. https://doi.org/10.2519/jospt.2018.8275. Epub 2018 Jul 27. PMID: 30053792.
82. Marks R, Allegrante JP. Chronic osteoarthritis and adherence to exercise: a review of the literature. J Aging Phys Act 2005 Oct;13(4):434–60. https://doi.org/10.1123/japa.13.4.434. PMID: 16301755.
83. Duong V, Daniel MS, Ferreira ML, Fritsch CG, Hunter DJ, Wang X, *et al*. Measuring adherence to unsupervised, conservative treatment for knee osteoarthritis: a systematic review. Osteoarthr Cartil Open 2021 Apr 30;3(2), 100171. https://doi.org/10.1016/j.ocarto.2021.100171. PMID: 36474984; PMCID: PMC9718095.
84. Squyer E, Stamper DL, Hamilton DT, Sabin JA, Leopold SS. Unloader knee braces for osteoarthritis: do patients actually wear them? Clin Orthop Relat Res 2013 Jun;471(6):1982–91. https://doi.org/10.1007/s11999-013-2814-0. Epub 2013 Feb 2. PMID: 23378240; PMCID: PMC3706686.
85. Willett M, Duda J, Fenton S, Gautrey C, Greig C, Rushton A. Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: a systematic review. PLoS One 2019 Jul 10;14(7), e0219482. https://doi.org/10.1371/journal.pone.0219482. PMID: 31291326; PMCID: PMC6619772.
86. Mohd Sharif NA, Goh SL, Usman J, Wan Safwani WKZ. Biomechanical and functional efficacy of knee sleeves: a literature review. Phys Ther Sport 2017 Nov;28:44–52. https://doi.org/10.1016/j.ptsp.2017.05.001. Epub 2017 May 6. PMID: 28673759.
87. Petersen W, Ellermann A, Zantop T, Rembitzki IV, Semsch H, Liebau C, *et al*. Biomechanical effect of unloader braces for medial osteoarthritis of the knee: a systematic review (CRD 42015026136). Arch Orthop Trauma Surg 2016 May;136(5):649–56. https://doi.org/10.1007/s00402-015-2388-2. Epub 2016 Jan 6. PMID: 26739139; PMCID: PMC4842213.
88. Sibbald B, Roberts C. Understanding controlled trials. Crossover trials. BMJ 1998 Jun 6;316(7146):1719. https://doi.org/10.1136/bmj.316.7146.1719. PMID: 9614025; PMCID: PMC1113275.