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To cite this article: Kelly J. Paterson, Alan R. Clough, Katheryn Farry, James W. Virgin, Sean Taylor & Ruth N. Barker (2024) Factors associated with adherence to bracing in Ponseti management of clubfoot: a systematic scoping review, Physical Therapy Reviews, 29:4, 134-152, DOI: [10.1080/10833196.2024.2382014](https://doi.org/10.1080/10833196.2024.2382014)

To link to this article: <https://doi.org/10.1080/10833196.2024.2382014>



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Published online: 07 Aug 2024.



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## Factors associated with adherence to bracing in Ponseti management of clubfoot: a systematic scoping review

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### ABSTRACT

**Background:** Clubfoot management according to the Ponseti method, including 4–5 years of bilateral foot abduction bracing to prevent relapse, is widely accepted as gold standard. Adherence to bracing is often low, despite non-adherence being associated with poor outcomes.

**Objectives:** This systematic scoping review aimed to identify and synthesize factors associated with brace adherence and non-adherence in the Ponseti method, to identify strategies shown to improve adherence, and to provide a clinically meaningful synthesis of available evidence.

**Methods:** This scoping review utilized systematic search and formal guidance on conduct and reporting. Medline, SCOPUS, Informit, EmCare, CINAHL, and PEDro databases were searched for peer-reviewed primary research reporting factors associated with brace adherence or non-adherence during Ponseti management. Factors were identified, then grouped using inductive then deductive methods and reported in a narrative synthesis.

**Results:** A total of 413 studies were identified and 42 were included in the review: 31 quantitative and 11 qualitative, generally of low quality. Meta-analysis was not feasible. Factors associated with non-adherence were identified more often than with adherence, and findings for both were inconsistent. Fifty-three factors were investigated, with conflicting findings common. No studies evaluating strategies to improve brace adherence were identified.

**Conclusions:** Available evidence does not indicate that any one factor or set of factors is consistently associated with adherence or non-adherence to bracing in Ponseti clubfoot management, and so clinically meaningful factors are proposed. Adequately powered longitudinal studies of adherence to bracing are required. Mixed methods approaches would help to inform and evaluate strategies to improve adherence, particularly those routinely recommended in clinical practice.

### ARTICLE HISTORY

Received 24 May 2023

Accepted 14 July 2024

### KEYWORDS

Clubfoot; brace; patient compliance; Ponseti method

### Introduction

Clubfoot, or congenital talipes equinovarus (CTEV), is the most prevalent congenital orthopedic condition, occurring in 0.5–6.8 per 1000 births worldwide [1,2]. Largely idiopathic, clubfoot involves forefoot adductus, midfoot cavus, hindfoot varus and fixed equinus occurring unilaterally or bilaterally [3]. Management of clubfoot to achieve and maintain a straight, flat, flexible and pain-free foot [3,4] requires a lengthy commitment from health services and families alike.

The Ponseti method is gold standard for clubfoot management [5,6], having low need for invasive surgery, low resource cost, high patient satisfaction, and excellent long-term functional outcomes [7–9]. The Ponseti method involves an initial period of manipulations and plaster casts (casting phase) with

percutaneous tenotomy of the Achilles tendon indicated for most children [4,7]. After this initial phase the foot and ankle are flexible, functional and appear normal [10]. To maintain the primary correction, a bilateral foot abduction brace (FAB) prescribed for 4–5 years (bracing phase), is a vital component of the Ponseti method [7]. However, clubfoot relapse is common, occurring in up to 83% of cases [11–14]. Factors associated with relapse are widely reported, with relapse known to be strongly associated with non-adherence to bracing [3,7,15]. Despite this known association, adherence to bracing remains challenging to achieve and non-adherence is common, with rates reported as high as 89% [11].

To improve adherence to bracing, factors influencing adherence and non-adherence, as well as effectiveness of strategies to improve adherence

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need to be understood. Strategies to improve adherence recommended in clubfoot best practice guidelines and protocols are generally based on expert opinion [10,16–20]. A recent scoping review has identified that in low and middle income countries, poverty is a consistent socio-economic factor associated with adherence to the combination of elements related to correction – casting, bracing, drop-out and or recurrence (relapse)[21]. Factors associated with adherence need to be considered in isolation from relapse which can be, but is not always, associated with non-adherence. Factors which are associated with relapse should not be presumed to be associated to adherence, which is a prolonged treatment component rather than an outcome. Brace adherence has multiple dimensions and is a world-wide challenge.

The aim of this study was to review the scope of literature on factors associated with adherence and non-adherence to bracing in Ponseti management of idiopathic clubfoot. The objectives were to determine the quantity, quality, and nature of evidence regarding: (1) factors associated with brace adherence or non-adherence; (2) strategies to increase brace adherence; and (3) to provide a clinically meaningful synthesis of the available evidence.

## Materials and methods

A systematic scoping review was the preferred method for this review, as diverse definitions, methodologies and generally low-quality studies were identified in early searches. As such, a systematic review with meta-analysis was not feasible [22]. The protocol for this scoping review drew upon Joanna Briggs Institute (JBI) scoping review guidance [22,23], and was reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Scoping Extension (PRISMA ScR)[24–26].

A detailed description of the scoping review process undertaken is provided in Table 1. Studies were included that reported: factors associated with adherence to bracing; and intervention studies to improve adherence, that were consistent with Ponseti treatment principles [18]. All studies included were peer-reviewed primary research using any methodology. To increase integrity of findings [29] studies in predatory journals were identified [29] and excluded [30].

Quality appraisal of included studies provided context and transparency regarding methodological strengths and weaknesses [23,31,32]. The Mixed Methods Appraisal Tool (MMAT) version 2018 [33] was used as it provided a single tool for appraisal of multiple study designs (qualitative, RCTs, non-randomized, quantitative descriptive and mixed method).

Data were sourced and extracted, then synthesized by identifying similar factors and: grouping them into ‘Child and Family factors’, or ‘Health Service Provider factors’ (hereafter referred to as ‘family’ or ‘provider’ factors); and grouping them into the World Health Organisation (WHO) dimensions of adherence [34]. Factors were deemed clinically meaningful if they demonstrated statistical significance (quantitative) *and* aligned with views of families or providers (qualitative) *and* were investigated in at least one high quality study (MMAT score of four or five). Finally, the synthesis was presented in a narrative form to explain the findings.

## Results

### Study selection

A total of 413 publications were identified in database searches. After removal of duplicates, 184 publications were screened against inclusion and exclusion criteria; 48 were excluded by title, 65 by abstract. Seventy-one full text publications were reviewed, with 35 studies identified for inclusion plus seven additional studies identified through citation searching. A total of 42 studies were included in the review (Figure 1).

### Study characteristics

Characteristics of included studies are summarized in Table 2 (quantitative) and Table 3 (qualitative). Included studies were published between 2002 and 2022 and conducted in 26 different countries. Across all studies, 53 factors were investigated for association with adherence to bracing (Table 4). Thirty-five family and eighteen provider factors were identified, and all five WHO adherence dimensions were encountered. All studies investigated associations with non-adherence to bracing, while a small number also investigated associations with adherence. No studies differentiated between adherence at initial commencement of bracing and ‘re-adherence’ after a period of non-adherence.

Factors were investigated in quantitative (45 factors) and qualitative (28 factors) studies with some factors investigated in both. Systematic review with meta-analysis was not feasible due to the low quality of quantitative studies and the heterogeneous nature of participants, service settings, factors investigated, definitions of and reporting methods for adherence.

### Quantitative studies

Quantitative studies ( $n = 31$ , Table 2) were observational studies comprising retrospective (25) and prospective (3) cross sectional studies, and historical-

**Table 1.** Systematic scoping review process followed.

PRISMA Scr Item [24]	Item <sup>◇</sup>	Description
Protocol	5	An a priori protocol was developed by authors (KP, RB and AC), but not published, and is available on request.
Eligibility criteria	6	Inclusion: Idiopathic clubfoot Ponseti method of treatment, including use of bilateral foot abduction brace Investigates associations with brace adherence/non-adherence, and/or Investigates strategy for brace adherence (intervention studies) Primary research, peer reviewed, full text Exclusion: If mixed participant group, >50% participants have idiopathic clubfoot Publication in predatory journals
Information sources	7	Databases searched: Medline, SCOPUS, Informit, EmCare, CINAHL and PEDro. Search strategy: Drafted (KP) with experienced university librarian, refined by (RB). Keywords and MESH terms developed with one and reviewed by a second experienced librarian using Peer Review of Electronic Search Strategies (PRESS) checklist [27]. Searches conducted without date limits on 16th June 2022. Search results exported to EndNote (Clarivate X9.2) and duplicates removed by author (KP). Search supplemented by hand-searching reference lists and citations of included studies in relevant reviews.
Search	8	Medline, SCOPUS, Informit, EmCare, CINAHL search strings <sup>◇◇</sup> (combined with AND): 1. Clubfoot OR clubfeet OR 'congenital talipes equinovarus' OR CTEV OR 'structural talipes' OR 'fixed talipes' OR 'rigid talipes' 2. Brace OR splint OR 'foot abduction ortho*' OR 'foot abduction splint' OR 'foot abduction brac*' OR 'Boots and Bar' or 'mitchell boots' OR 'abduction brac*' OR 'ponseti boots' OR 'ponseti splint' 3. Adher* OR complian* OR 'non-complian*' OR 'non complian*' OR obedien* OR refuse OR reject OR cease OR discontinue OR tolerance OR tolerate OR concordance OR 'patient compliance' PEDro search term: 1. Clubf*
Selection of sources of evidence	9	Publications screened at each stage (title, abstract, full text) by two reviewers (KP, KF or JV) to determine eligibility before moving to next stage of screening. Disagreements resolved by third reviewer (RB). Authors of studies contacted to clarify relevant material, as required. Predatory journals identified by a university library Data Repository Officer, and guided by international expert consensus group definition [28] and JBI guidance for predatory journal inclusion in systematic reviews [29].
Data charting process	10	Data charting form developed by two reviewers (KP, RB) Included studies exported to NVivo Version 12 [28] for extraction and analysis. Data extracted by one reviewer (KP), confirmed by second reviewer. Study characteristics extracted to Microsoft Word (Microsoft 365 version 2208)
Data items	11	Author/s; Year of Publication; Country/Countries of Origin; Study aim; Study design; Study quality; Participant number, Participant type (family or provider – qualitative studies); Factors identified; Findings (Quantitative and Qualitative).
Critical appraisal of individual sources of evidence	12	MMAT[31] scored by 2 reviewers (KP, KF) with disagreement resolved by third reviewer (RB). Quality represented by '●' to '●●●●●', with each dot representing one of 5 possible quality criteria met.
Synthesis of results	14	No studies excluded based on quality. Factors grouped: 1. Factors identified and grouped inductively 2. Analogous factors grouped and labelled 3. Factors grouped deductively into 'Child and Family' or 'Health Service Provider' 4. Factors grouped deductively to WHO dimensions of adherence [32]. Factors described by: 1. Association (adherence or non-adherence; positive or negative) 2. Frequency of association 3. Consistency of statistical association 4. Qualitative alignment. Synthesis presented in a narrative form

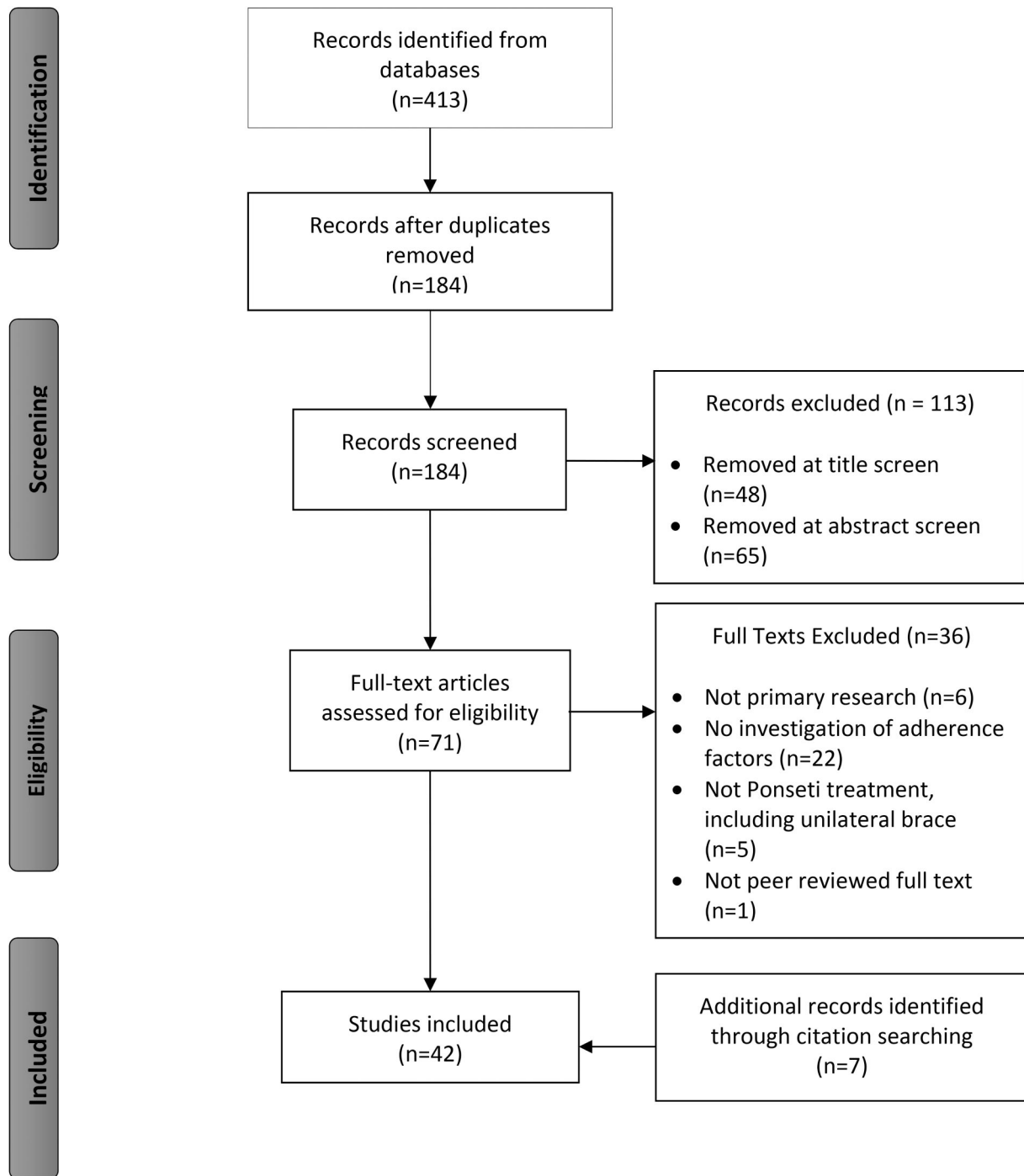
<sup>◇</sup>Note that original PRISMA item 13 'Summary Measures' is not applicable for scoping reviews, as meta-analysis is not a component [24].

<sup>◇◇</sup>MESH headings are underlined.

controlled studies (2). One prospective RCT was identified, although adherence data reported in the study were gathered retrospectively [52]. Data in all 31 studies were derived from clinical records, with additional survey data collected in 12 studies.

Studies were conducted in 17 countries, including nine from the same country (USA), one study that compared two countries (USA and Israel [39]) and one which amalgamated data from seven countries [42]. Lower middle income countries (LMICs) [77] were

represented in five studies [36,56,58,59,61], upper middle income countries (UMICs) in seven studies [40,43,45–48,63] and high income countries (HICs) in 18 studies [35,37–39,41,44,49–55,57,60,62,64,65]. No low income countries (LIC) were studied, and both UMIC and LMICs were represented in one study [42]. Across all quantitative studies, 2407 children with clubfoot were represented (not reported in two studies [42,43]) with sample size ranging from 8–333. Number of feet included was 3920 (not reported in one study



**Figure 1.** PRISMA flow diagram of study selection.

Caption: Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097.

[56]), ranging from 11 to 500. The number of factors investigated in each study ranged from 1 [42,45,52,55,57,58,63] to 17 [53] factors. Each factor was investigated in one to 14 studies, and on average in three studies. Inconsistent findings between studies were common.

Analysis was descriptive only ( $n = 7$ ) or involved bivariate analysis ( $n = 24$ ) and multivariable analysis ( $n = 1$ ). Factors associated with adherence and non-adherence were investigated as a stated aim less often (39% of studies) than reported incidentally (61%).

### Qualitative studies

Qualitative studies ( $n = 11$ , see Table 3) were conducted in 12 different countries with one study across three countries (Chile, Peru, Guatemala [67]). LICs were represented in two studies [71,75], LMICs in four [66,69,70,76], UMICs in two [72,73], HIC in one study [74] and regionally related countries of combined HIC and UMIC in one study [67]. Views of 307 Ponseti providers (nine studies) and 292 parents or caregivers (eight studies), two adults with clubfoot, 40 community leaders and 39 traditional healers [71] were reported. Views of both

Table 2. Quantitative study characteristics.

First author (year), Country	Aim/purpose	Study design	MMAT total <sup>†</sup>	1 <sup>†</sup>	2 <sup>†</sup>	3 <sup>†</sup>	4 <sup>†</sup>	5 <sup>†</sup>	Cases (feet) analyzed <sup>#</sup>	Factors investigated for brace adherence
Abdelgawad [35] (2007) USA	Evaluate effectiveness of Ponseti method in local population	Retrospective audit	●●●	✓	x	✓	✓	✓	83 (127)	<i>Bivariate:</i> Age, number of casts, severity.
Abdullah [36] (2019) Egypt	Evaluate bracing compliance in local clubfoot population	Retrospective medical record audit, Parent questionnaire	●●	✓	x	x	x	✓	40 (60)	<i>Bivariate:</i> Age, gender, parent education, income, number of children <sup>**</sup> , laterality, ability to contact team, difficulty applying brace alone <sup>**</sup> , residence (rural/urban) <sup>**</sup> , 'social relation', body weight; patient, bracing instruction, brace expensive, baby 'compliance' (irritability) <sup>**</sup> , compliance hour <sup>**</sup> , parents 'fed up' <sup>**</sup> , brace changes.
Avilucea [37] (2009) USA	Determine whether distance from site of care affects compliance (with brace), and whether certain patient demographic characteristics predict recurrence.	Prospective observational, Parent questionnaire	●●●	✓	✓	x	x	✓	100 (138)	<i>Bivariate:</i> Gender, Ethnicity <sup>*</sup> , marital status, insurance, education level, income <sup>*</sup> , commute time, age, severity, rurality <sup>*</sup> .
Berger [38] (2018) Germany	Evaluate compliance with unilateral brace design, evaluate effectiveness of unilateral brace design to prevent relapse.	Retrospective observational medical record audit	●	x	x	✓	x	x	45 (75)	<i>Descriptive:</i> Skin problem; sleep disturbance.
Bor [39] (2009) USA & Israel	Compare two clubfoot clinic patient populations; assess association of number of casts with age; assess association of number of casts and severity; assess association of surgery and severity; compare results of early and late presenting patients.	Retrospective audit of medical records, Parent questionnaire	●●	x	✓	x	x	✓	74 (117)	<i>Bivariate:</i> Country; age at presentation <sup>*</sup> ; parent satisfaction.
Bozkurt [40] (2021) Turkey	Determine effect of total number of siblings, younger siblings, complex deformity on brace compliance and recurrence	Retrospective audit	●●	x	✓	x	x	✓	91(130)	<i>Bivariate:</i> Laterality(right) <sup>*</sup> , family history <sup>*</sup> , follow up time <18 m <sup>**</sup> , having younger sibling <sup>*</sup> , complex deformity <sup>*</sup> , gender, age at treatment, treatment center, maternal education, paternal education, Pirani score, number of casts, number of children, having tenotomy.
Chen [41] (2007) USA	Evaluate dynamic orthosis preventing relapse; 2. Determine rate of noncompliance with orthosis; 3. Assess complication rates.	Retrospective audit medical records	●●	x	✓	✓	x	x	28(49)	<i>Bivariate:</i> brace design <sup>**</sup> <i>Descriptive:</i> Skin breakdown, parent work schedule, donning.
de Podesta Haje [42] (2020) Brazil, Mexico, India, Pakistan, Ecuador, Colombia, Egypt	Evaluation of Ponseti treatment of clubfoot and relapse after walking age; evaluate surgical modifications, evaluate age of treatment impact on outcomes.	Retrospective audit	●	x	x	✓	x	x	(401 feet) <sup>‡</sup>	<i>Bivariate:</i> Age at commencement <sup>**</sup>
Eamsobhana [43] (2017) Thailand	Evaluate relationship between brace compliance, evetor muscle grading and recurrence.	Retrospective audit	●●●	✓	✓	x	x	✓	(79 feet)	<i>Descriptive:</i> gender, evetor muscle grade <i>Bivariate:</i> age
Garg [44] (2009) USA	Evaluate adherence, recurrence, and surgery rate with use of dynamic bilateral brace.	Prospective case-control	●●●	x	✓	✓	x	✓	114 (189)	<i>Bivariate:</i> Brace design <sup>**</sup> <i>Descriptive:</i> Severity, skin issues.

(continued)



Table 2. Continued.

First author (year), Country	Aim/purpose	Study design	MMAT total†	1†	2†	3†	4†	5†	Cases (feet) analyzed#	Factors investigated for brace adherence
Göksan [45] (2002) Turkey	Present authors early experience with Ponseti technique in correcting clubfoot and evaluate need for aggressive surgery in first year of life	Retrospective audit	●	x	x	x	x	✓	31(44)	Bivariate: previous treatment (resistant)*
Göksan [46] (2006) Turkey	Evaluate the effectiveness of the Ponseti method in children presenting before 1 year of age with either untreated or complex (initially treated unsuccessfully by other conservative methods) idiopathic clubfeet; to examine the effect of the learning curve, and to identify the factors related to relapses for a successful result in the short-term	Retrospective medical record audit	●●●	✓	x	x	✓	✓	92(134)	Bivariate: Provider experience**, previous treatment; iatrogenic deformity; complexity; iatrogenic and complex; previous treatment and iatrogenic*; cast complications**.
Göksan [47] (2015) Turkey	Investigate patient and parent factors related to relapse; and compliance; parent satisfaction with correction.	Retrospective audit, Parent questionnaire	●●	✓	x	x	x	✓	153(226)	Bivariate: Level of information; parent education*; use of coping strategies**; parent satisfaction; parent belief in brace effectiveness**; periods of discontinuance** Descriptive: child's temper; child & brace; brace; feet moved out of brace; restricted movement; sleeping problems; struck with brace.
Gozen [48] (2015) Turkey	Evaluate outcomes and family factors for local service	Retrospective audit	●●●	✓	x	✓	x	✓	38 (56)	Bivariate: severity (at onset of casting, at commencement of bracing*), previous treatment/complex clubfoot**
Haft [49] (2007) New Zealand	Analyse recurrence and compliance related to specific factors.	Retrospective analysis of prospectively collected patient records.	●●●	✓	x	✓	x	✓	51(73)	Bivariate: (odds ratios): Pirani score (severity mild, mod, severe); number of cast changes; weeks to first cast; family history; ethnicity (Polynesian/other). Descriptive: sleep problems.
Hemo [50] (2011) Israel	Compare clinical outcomes and adherence between two (2) static bilateral designs.	Retrospective audit, Parent questionnaire	●●●	✓	x	x	✓	✓	38 (47)	Bivariate: age, severity*, number of casts*, Descriptive: Cast material.
Hemo [51] (2021) Israel	Evaluate patient variables which may influence or predict relapse and surgery; analyze age of relapse and surgery	Retrospective audit, parent phone survey	●●●●●	✓	✓	✓	✓	✓	333 (500)	
Hui[52] (2014) Canada	Evaluate effect of cast material on outcome, record parent experience with cast material and removal	Prospective RCT (adherence data from survey component only), parental questionnaire.	●●●	✓	x	✓	x	✓	30 (44)	
Jawadi [53] (2015) Saudi Arabia	Determine compliance with bracing in local clubfoot population; identify factors that may predict non-compliance.	Retrospective (cross sectional) audit, Parent questionnaire,	●●●	✓	x	✓	x	✓	108 (158)	Bivariate: Age; gender; laterality*; Number of children*; domestic help; experience with Ponseti; team explained brace; difficulty contacting team*; income; Father's education; Mother's education; likes Ponseti method*; crying**; fell off; waking**; parents fed up**; donning issues**; cost; changing brace; financial impact.

(continued)

Table 2. Continued.

First author (year), Country	Aim/purpose	Study design	MMAT total†	1 <sup>†</sup>	2 <sup>†</sup>	3 <sup>†</sup>	4 <sup>†</sup>	5 <sup>†</sup>	Cases (feet) analyzed <sup>#</sup>	Factors investigated for brace adherence
Kessler [54] (2008) USA	Assess outcomes for patients using flexible bilateral brace	Retrospective, parents asked at each clinic visit re compliance. Parent questionnaire. Retrospective audit	●	x	x	x	✓	x	8(11)	Descriptive: Brace design; brace fit; parents removing; skin issues, child upset.
Little [55] (2019) United Kingdom	Determine whether poor evetor muscle activity is a predictor of clubfoot relapse at 5 years.	Retrospective audit	●●●●	✓	✓	✓	x	✓	104(172)	Bivariate: Evetor muscle activity.
Memon [56] (2014) Pakistan	Determine frequency of early relapse after good initial correction in local clinic; recognize factors relating to poor compliance.	Retrospective audit Parent questionnaire/ interview? reporting reasons for non-compliance	●●	✓	✓	x	x	x	120 (unknown)	Descriptive: Distance to treatment; time taken; discomfort of brace; skin issue; parent conflict; brace fabrication issue; education provision.
Morin [57] (2014) USA	Examine recurrence (particularly in Native American population) after provider adopting a positive style of communication.	Retrospective case-control	●●	✓	x	✓	x	x	69(104)	Bivariate: Clinician's communication style.
Muzzammil [58] (2021) Pakistan	Assess prevalence of malnutrition in clubfoot patients in region; compare nutrition status to outcomes.	Descriptive cross-sectional study	●●●	✓	x	✓	✓	x	153 (248)	Descriptive: Nutritional status.
Pinto[59] (2022) India	Evaluate factors associated with dropping out of clubfoot treatment.	Retrospective audit, parent questionnaire <sup>‡</sup>	●●	✓	✓	x	x	x	137 (190) Interviews = 31 (unknown)	Bivariate: Age*, gender, laterality, Descriptive: cost, caregiver health, child discomfort, loss of wages each visit, household work, child missing school, migration, lack of family support, clinic too far, no transport, clinic crowded/too slow, lack of understanding of treatment, treatment longer than expected, complications in treatment, negative experience with staff, beliefs, preferred traditional treatment.
Ramirez [60] (2011) Puerto Rico	Evaluate factors associated with non-compliance and recurrence in local clubfoot clinic	Retrospective audit	●●●	✓	✓	x	x	✓	53(73)	Bivariate: Gender, age, severity, laterality, previous treatment, number of casts, tenotomy, parent education, income, insurance type.
Rashid [61] (2017) Pakistan	Determine (possible) causes of non-compliance in local outpatient clinic	Retrospective audit Parent questionnaire	●	x	✓	x	x	x	67(97)	Descriptive: Financial; "emotional reason of parents" i.e. baby crying; "ignorance"; skin issues; swelling redness, cosmetic.
Richards [62] (2020) USA	Document orthosis wear time; determine compliance vs prescribed time	Retrospective review of patient registry.	●●	x	x	✓	x	✓	124 (187)	Bivariate: Bilateral/unilateral*, period of brace use (time since bracing commenced).
Sailohit [63] (2020) Thailand	Identify non-compliance rate with brace, and assess stretching exercises impact on correction	Retrospective medical chart audit.	●●	✓	x	✓	x	x	42(63)	Bivariate: Type of bar (dynamic/static).
Thacker [64] (2005) USA	Evaluate outcomes for compliant and non-compliant bracing groups after Ponseti casts	Retrospective audit	●●	x	✓	x	x	✓	30 (44)	Bivariate: age, number of casts, need for tenotomy, severity pre casting, severity pre bracing. Descriptive: Gender

(continued)



Table 2. Continued.

First author (year), Country	Aim/purpose	Study design	MMAT total <sup>†</sup>	1 <sup>†</sup>	2 <sup>†</sup>	3 <sup>†</sup>	4 <sup>†</sup>	5 <sup>†</sup>	Cases (feet) analyzed <sup>#</sup>	Factors investigated for brace adherence
Zionts [65] (2012) USA	Describe outcomes and examine associations to relapse and adherence for clubfoot population using static bilateral brace	Prospective observational	●●●●	✓	✓	✓	✓	✓	57(84)	Bivariate: Gender; laterality; previous treatment; age; family history; parent marital status; parent education; family income; insurance; severity. Multivariate: gender, previous treatment, age, severity of deformity, parent marital status, parent education, income, insurance type (patients*/feet**).

\* $p \leq 0.05$ ; \*\* $p \leq 0.01$  (bivariate without \* indicates no significance found).

✓ = yes, x = no or can't tell for each MMAT criteria 1–5.

<sup>†</sup>For explanation of MMAT criteria 1–5 see: Hong et al.[33].

<sup>#</sup>Only cases/feet analysed for adherence/non-adherence to brace included in this figure, does not include all participants of some studies.

<sup>+</sup> Study included 401 clubfeet with data available for adherence (429 in study overall). Unable to determine if analysis of adherence included those with no access to brace, those with unilateral brace or only those with FAB.

<sup>!</sup>Study deemed quantitative based on nature of results reported.

<sup>^</sup> Variable and analysis type only of adherence-related factors. Other components of study may have other findings or analysis type.

families and providers were reported in six studies [66,68–71,76]. Primary aims of studies were to: investigate barriers to brace adherence ( $n = 1$ [72]), identify reasons for non-adherence to Ponseti management overall (not specific to the bracing phase) ( $n = 2$ [66,67]); identify barriers to introducing the Ponseti method in the region ( $n = 7$ [68–71,73,75,76]); and to identify parents' educational and support needs ( $n = 1$ [74]). Two to 11 factors were investigated in each study.

### Quality appraisal

Quality appraisal against each MMAT criteria is detailed in Table 2 (quantitative studies) and Table 3 (qualitative studies). Quality of all studies (Table 4) ranged from meeting one criteria (represented as ●) to meeting all five (represented as ●●●●●). For quantitative studies, 27 studies (87%) scored ●●● or less, and four studies (13%) scored ●●●● or ●●●●●. Similarly, for qualitative studies, nine studies (82%) scored ●●● or less and two studies (18%) scored ●●●● or ●●●●●.

### Narrative synthesis of results

Results are summarized in Tables 4 and 5.

### Family factors

Family factors were focused on individual (e.g. age at first treatment) and demographic characteristics (e.g. age of parent) and on circumstances and perceptions of families (e.g. family support, concern for pain or discomfort). Numerous (17) different family factors had findings of significance, but of those, eight (47%) had more frequent findings of non-significance than significance for the same factor. Family factors which were frequently assessed, but that were found to have no evidence of association with adherence (or association was outweighed by non-significant findings) were: parent education level, child's gender, parent marital status and age of treatment. No family factors associated with adherence were found to be clinically meaningful. Family factors associated with non-adherence considered to be clinically meaningful were rural/remote location, and culture, religion or ethnicity. These factors were reported by both providers and families.

### Provider factors

Provider factors investigated included provider characteristics (e.g. level of experience), health service characteristics or perceptions (e.g. provision of outreach service or patient travel support, consumer satisfaction) and aspects of Ponseti treatment

Table 3. Qualitative study characteristics.

First author (year), Country	Aim/purpose	Study design/ methods	MMAT total†	1 <sup>†</sup>	2 <sup>†</sup>	3 <sup>†</sup>	4 <sup>†</sup>	5 <sup>†</sup>	Participants <sup>#</sup>	Factors investigated against brace adherence, by participant group
Akintayo [66] (2012) Nigeria	Evaluate Ponseti method and assess impact in Nigeria; identify challenges to diffusion of Ponseti method.	Semi-structured interviews, observations, questionnaires,	••	x	✓	x	x	✓	25 Providers 44 Parents	<i>Families:</i> Transport & lodging cost; lost income; outreach. <i>Providers:</i> Financial constraint; Ignorance, culture & religious practices; brace access; lack of support staff; baby uncomfortable; cultural; family size; paternal role. <i>Both:</i> Understanding treatment.
Boardman [67] (2011) Chile, Peru, Guatemala	Evaluate barriers to diffusion of Ponseti method through this region.	Face to face semi-structured interviews (pre-defined barriers, asked if they agreed)	•	✓	x	x	x	x	28 Providers	<i>Providers:</i> Social stigma; shared experiences; language barrier; financial/cost of brace; parents don't see need for brace; distance and cost of transportation.
Gadhok [68] (2012) India	Evaluate challenges of diffusion and implementation of Ponseti method in urban medical centers in India.	Face to face interviews, questionnaires	•	x	✓	x	x	x	38 Provider questionnaires 15 interviews Providers 19 Parent questionnaires	<i>Families:</i> Brace access; crying; cost of transport; missed wages; cost of medical treatment. <i>Providers:</i> Financial, distance and transportation; quality of care; paternal involvement; lack of education; lack of support staff; no longer looks like needs brace.
Kingau [69] (2015) Kenya	Explore barriers to clubfoot management in Kenya	In depth guided interviews	••••	x	✓	✓	✓	✓	10 providers 10 caregivers	<i>Families:</i> travel distance; travel cost; financial issues; spousal support; cultural (stigma). <i>Providers:</i> nil related to brace adherence.
Lu [70] (2010) China	Identify and evaluate barriers to the clubfoot program throughout China.	Rapid ethnographic; Semi-structured interviews; focus groups & observation.	••	✓	✓	x	x	x	39 Provider interviews Focus groups with 8 'sets of' parents	<i>Providers:</i> Cost, travel difficulties, stigma for family, understanding brace, 'educational gap'
McElroy [71] (2007) Uganda	Identify barriers to adherence to Ponseti method in 8 districts of Uganda.	Rapid ethnographic; semi-structured interviews; focus groups, observation	•••••	✓	✓	✓	✓	✓	42 parents of children with clubfoot 2 adults with clubfoot 40 community leaders 39 traditional healers 38 Ponseti practitioners	<i>Families:</i> Cost, travel difficulties, discomfort for child. <i>NB no distinction between perspectives of providers and families</i> Cost of brace; travel (and cost thereof) to one or more clinics; distance from treatment; availability of brace, financial; women's access to money; family disharmony; caregivers' other responsibilities; length of treatment period; discomfort, pain, crying, or shame for children; outreach; partnership/communication; paternal involvement & family support; high quality care.
Nogueira [72] (2013) Brazil	Identify barriers to bracing compliance and evaluate brace prescribing practices.	Questionnaires with follow up interviews; preset semi-structured questions	••	✓	✓	x	x	x	45 providers	<i>Providers:</i> appropriate prescription of brace; parents feel brace not needed; lack of information; believe it is uncomfortable; child cries; donning issues; parents believe it is painful; cultural reasons and stigma; financial impact; aesthetics; childcare difficulty; access to brace (delay); faulty brace or heavy (brace design).

(continued)

Table 3. Continued.

First author (year), Country	Aim/purpose	Study design/ methods	MMAT total†	1 <sup>‡</sup>	2 <sup>‡</sup>	3 <sup>‡</sup>	4 <sup>‡</sup>	5 <sup>‡</sup>	Participants <sup>#</sup>	Factors investigated against brace adherence, by participant group
Palma [73] (2013) Peru	Evaluate barriers to Ponseti method in Peru.	Semi structured interviews; qualitative description	●●●	✓	✓	x	x	x	32 providers	Providers: Parental understanding of relapse; distance and transportation; cost of brace.
Paulsen-Miller [74] (2011) USA	Identify educational needs of parents of children born with clubfoot and the role of healthcare providers throughout the treatment process.	Preset questions Semi-structured interviews, coded using content analysis techniques; one-on-one interviews, open-ended questionnaire based	●●	x	x	x	✓	✓	30 parents (of 27 children) 30 parents of clubfoot patients >3yrs age who attended appointments	Families: maintaining routine and making it a way of life "just do it", older child – explaining the brace, finding the right swing/stroller/car seat, child assisting to apply brace, take brace everywhere (in diaper bag), clothing mods to suit brace, pad and decorate the brace, activity modification, bedding modification, parents responsibility ("we either do it or we don't"); travel time and time off work, explaining the brace to the public; resistance/self removal; broken equipment; fitting/correct use; redness/blisters; return after relapse/length of bracing period; 'just do it'/routine/take responsibility; involve child; make accommodations to equipment and activities; provide education in more ways and reiterate every appointment; stress long term finish line; additional support and encouragement. Families: Financial issues; transport difficulties; social isolation/shame/fear of rejection; difficulty using brace; brace fabrication issues. Provider: treatment explanation & resources; cultural, affordability, skin issues, crying, burden, understanding brace role (appears normal), lost wages, help from others, cultural & family support (linked).
Ramahenina [75] (2016) Madagascar	Explore reasons for high rate of failure to complete treatment.	Questionnaire-based interviews	●●	✓	✓	x	x	x	20 mothers of children undergoing treatment	
Wu [76] (2012) Vietnam	Evaluate the impact, progress and challenges facing Ponseti practitioners and patient's family members in Vietnam, and to assess web-conferencing for continuing education. Evaluate factors aiding and challenging dissemination of Ponseti method in Vietnam.	Questionnaires Focus groups, Semi-structured interviews	●●	x	✓	x	x	✓	37 Provider questionnaires completed via interview. 99 parents interviewed. 12 parents in focus groups. 47 returned questionnaires	

†For explanation of MMAT criteria 1–5 for each study type see: Hong et al. [33].

#Reported perspectives included only for adherence-related factors. Other study findings are not included.

✓ = yes, x = no or 'can't tell' for each MMAT criteria 1–5.

Factors associated with adherence or non-adherence

*(continued)*



Table 4. Continued.

Factors associated with adherence or non-adherence									
Study	First author (year)	MMAT <sup>†</sup>	Child and family factors				Health Service & Provider factors		
			Patient dimension	Social and economic dimension	Condition dimension	Therapy dimension	Health care team dimension		
	Palma[73] (2013)	●●●	P					P	
	Paulsen-Miller [74] (2011)	●●	F		F	F	F	F	F
	Ramahlenina [75] (2016)	●●	F	F			F	F	
	Wu [76] (2012)	●●		P	F		F	F	
		</							



**Table 5.** Factors associated with adherence by study design (quantitative and qualitative) and quality.

	Quantitative		Qualitative	
	Significant association	Non-significant	Families Support Association	Providers Support Association
<b>FAMILY FACTORS</b>				
<b>Associated with adherence:</b>				
Believe FAB necessary/prevent relapse	◆			◆◆◆◆◆
Coping strategies (non-specific)	◆			
Age treated (older)	◆	◆◆◆◆◆◆◆◆◆◆		
Understanding treatment			◆	◆◆◆
Parent attitude 'just do it'			◆	
Strategy – take brace everywhere			◆	
Strategy – explain and involve child			◆	
Family support				◆
<b>Associated with non-adherence:</b>				
Rural/Remote <sup>#</sup>	◆◆		◆◆	◆
Culture/religion/ethnicity <sup>#</sup>	◆◆	◆◆	◆◆◆	◆◆◆◆
Crying/distress	◆◆		◆◆	◆
Donning/Doffing issues	◆◆		◆◆	
Sibling order/number	◆◆◆	◆		◆
Financial impact treatment			◆◆◆	◆◆◆◆
Paternal involvement (lack)			◆◆	◆◆
Concern for pain/discomfort			◆◆	◆◆
Competing carer responsibilities			◆	
Laterality/Bilateral	◆◆◆	◆◆◆		
Fed up with brace	◆◆			
Sleep concerns	◆			
Severity score (post casting)	◆	◆		
Family history	◆	◆◆		
Socioeconomic indicators (low)	◆	◆◆◆		
Family income (low)	◆	◆◆◆◆		
Education level (caregiver)(lower)	◆	◆◆◆◆◆		
Severity (pre casting)	◆	◆◆◆◆◆◆◆◆		
Gender (male)		◆◆◆◆◆◆◆		
Child removes/resists			◆	
Aesthetic				◆
Childcare issue				◆
Marital status (caregiver)		◆◆◆		
Evertor weakness		◆		
Weight		◆		
<b>PROVIDER FACTORS</b>				
<b>Associated with adherence:</b>				
Consumer satisfaction <sup>#</sup>	◆	◆	◆	
Provider experience	◆			◆
Accessibility of provider	◆	◆		◆◆
Brace type (dynamic)	◆◆	◆		
Provision of education		◆	◆	◆
Access to adaptive equipment			◆	
Peer group support				◆
<b>Associated with non-adherence:</b>				
Lengthy treatment <sup>#</sup>	◆		◆	◆
Cast complications	◆			
Prior treatment/complexity	◆◆◆◆	◆◆◆◆		
Number of casts	◆	◆◆◆◆◆◆		
Outreach/travel support (lack)			◆◆◆◆◆	◆◆◆◆◆
Skin issues (bracing)			◆◆	
Access to reliable brace (lack thereof)		◆	◆◆◆	◆◆
Tenotomy		◆◆◆		
Number brace changes		◆◆◆		
Provider communication		◆		

◆ High quality study (MMAT ●●●● or ●●●●●), ◆ Low quality study (MMAT ●, ●● or ●●●) <sup>#</sup>Clinically meaningful criteria met.

(e.g. bilateral brace design). Adherence was significantly associated with eight factors, however only four factors had findings of significance more frequently than findings of non-significance. These were: cast complications, type of bilateral brace, lengthy treatment and provider experience level. In qualitative studies, some families reported wanting more education[74] while providers believed lack of education to families contributed to non-adherence[72], however in the three quantitative studies

which reported provision of education[45,53,56] no association was found with adherence.

The only provider factor found to be clinically meaningful for non-adherence was lengthy treatment and the only provider factor clinically meaningful for adherence was consumer satisfaction with care, reported by families.

### Strategies to improve adherence to bracing

No true intervention studies were identified. Two studies, described by their authors as interventions,

were case-control studies – one retrospective [57], and one prospective [44].

## Discussion

This is the first study to review factors associated specifically with adherence and non-adherence to bracing in Ponseti management for clubfoot. Forty-two studies (31 quantitative and 11 qualitative) of mixed quality were reviewed. Factors associated with brace adherence were less frequently investigated than factors associated with non-adherence, and findings for both adherence and non-adherence were inconsistent. No studies differentiated between adherence at initial commencement of bracing and ‘re-adherence’ after a period of non-adherence. Clinically meaningful family factors proposed include being rural or remote, and culture, ethnicity or religion, while clinically meaningful provider factors proposed were consumer satisfaction and lengthy treatment. There were no true intervention studies that investigated the efficacy of strategies to improve adherence. The findings of this review highlight that factors associated with adherence to bracing have been investigated in many low-quality studies, but that robust targeted investigation of factors is required to inform strategies to improve adherence. Furthermore, appropriate investigation of strategies being implemented, or being advised to families to improve brace adherence is required to provide an evidence-base for clinical practice recommendations.

Adherence to clubfoot bracing is complex. According to the WHO, it is misleading to presume that patients, in this case parents, are solely responsible for adhering to treatment, and that this perception reflects a misunderstanding of how broader factors can affect behavior and capacity to adhere to long-term medical therapies [34]. Interrelated factors across socioeconomic, health service, child and family or condition and treatment dimensions are likely to affect adherence to bracing, as with other health conditions [34,78,79]. Despite this, many studies included in this review looked to family factors and not provider factors to seek to explain non-adherence. Evaluation of health service models, family engagement strategies or family-centered care practices and their impact on adherence to bracing were rare. A strength-based approach focused on family-identified strategies is needed. Identifying approaches used by families who have been able to adhere throughout the entire bracing phase, or models of care where high adherence rates are observed may inform the design of pilot studies and subsequently, larger powered intervention studies targeting adherence.

Investigation of factors associated with adherence to bracing was incidental as often as targeted and tended to focus on predicting non-adherence rather than achieving adherence. While clinical data provides valuable insights about brace adherence, sample sizes are often not large enough to power studies sufficiently to demonstrate associations with adherence to bracing. Furthermore, research is required to explain adherence, not only non-adherence, to move toward achieving adherence. Factors associated with adherence specific to each phase of management and to adherence over time need to be considered: when commencing bracing; sustaining adherence over time; and resuming brace adherence after relapse and retreatment. As such, longitudinal studies are required to inform potential strategies to support adherence throughout the 4–5-year bracing period.

A variety of factors relating to social, economic and cultural characteristics were perceived to impact adherence to clubfoot bracing. It is known that residing outside urban areas, financial burden of treatment and being from disadvantaged and minority groups negatively impacts access to and engagement with western medical treatment [34,80]. This appears to hold true for clubfoot brace adherence. Clubfoot is more common in disadvantaged populations [1], and yet the Ponseti method, mired in western child rearing ideology, has not been evaluated against non-western or First Nations parenting values, child-rearing beliefs or practices, which can differ widely to western thinking [81,82]. Consideration must be given for culturally safe and responsive decision-making regarding clubfoot management including bracing, and collaborative research methodologies are imperative for future clubfoot research.

Surprisingly, there were no intervention studies identified that investigated the efficacy of implemented strategies to improve adherence to bracing. Additional instruction on brace use, reiterating the risk of relapse and more broadly ‘educating parents’ are strategies repeatedly recommended by experts for overcoming non-adherence [10, 16,17], but none of these strategies have yet been evaluated. Tailored education to ensure clear understanding of the management process when commencing or reinstating bracing is, appropriately, a core element of Ponseti ethos [18,20]. However, while parents have reported having educational needs [74], and providers have reported increased parent confidence in bracing following education [83], change in adherence to bracing as a result of education has not been investigated in any study we identified. The WHO recommends that strategies to foster adherence to medical treatment should be patient-tailored and

target patient decision-making and behavior-change, not didactic instruction [34]. Given the frequency with which 'parent education' is recommended as a strategy to improve brace adherence, it is a priority that educational strategies be adequately described and evaluated with appropriate health education and behavior-change approaches to support this ongoing recommendation.

### Limitations

Review findings were limited by the very small number of studies which met four or more MMAT quality criteria and the inconsistent findings between studies, possibly reflecting the inconsistency in sample size and design of studies. Additionally, the interdependence of many factors within and between domains is undeniable. With limited use of multivariable analysis within studies and insufficient data for meta-analysis, it is not possible to describe this interplay. Accordingly, it is important to acknowledge the limitations of the interpretation of clinical meaningfulness that was applied in this study.

### Implications for future research

Factors associated with adherence (as opposed to non-adherence) remain largely unexplored. It is likely that factors vary across health-care settings and cultures. A mixed methods approach is warranted that begins with, or builds on, qualitative investigations of the experience of families with positive bracing stories. Quantitative studies can then assess evidence of factors associated with successful adherence, thus identifying meaningful strategies to apply in intervention studies. Adequately powered prospective longitudinal studies using appropriate methodologies are needed. Differentiating between factors associated with initial adherence to bracing (implementation adherence), ongoing adherence (persistence adherence) and 're-adherence' after a period of non-adherence is an important area for future research.

### Implications for practice

There is currently insufficient evidence to recommend changes to clinical practice. Instead, this review highlights the importance of providers acknowledging each family's context and their experience with bracing. Our suggestion of clinically meaningful factors might assist providers in identifying a starting point for support, but we must recognize the lack of evidence for any intervention to improve adherence and must not assume that any one approach to maximize adherence will be

effective for any or all families. Population-specific culturally informed and family-focused models of care need to be prioritized.

### Conclusions

Adherence to bracing is a critical element for the success of the Ponseti method for clubfoot management. This review highlights that factors definitively associated with adherence to bracing remain unclear; investigations of adherence are generally of low quality and that evidence-based strategies to improve adherence are lacking.

Clinicians and researchers must be mindful that common recommendations for preventing or improving non-adherence are not supported by evidence. Researchers need to design, implement and evaluate locally relevant approaches to brace adherence underpinned by child and family experiences.

### Acknowledgements

The authors acknowledge the support of James Cook University (JCU) librarians Sam Rannard (assisting development of search terms and search strategy) and Janet Catterall (PRESS guideline review of search strategy), and JCU Library Research and Data Repository Officer Nathan Garvey (predatory journal identification). Miss Paterson acknowledges support and mentorship from the JCU Cohort Program, particularly Dr Karen Cheer and Dr Diana Menzies.

### Contributors

KP, RB, AC and ST conceptualized the study including methodology. KP, RB and AC developed search strategy and KP, KF and JV conducted searching, screening, and critical appraisal with assistance from RB. Analysis was conducted by KP, RB and AC. KP developed first draft of the manuscript with contribution to final manuscript from RB, AC and JV. Revisions were conducted by KP, RB and AC. All authors reviewed and approved the final version of the manuscript.

### Disclosure statement

All authors declare no competing interests.

### Funding

Miss Paterson receives an Australian Government Research Training Program Scholarship. For remaining authors no source of funding is received in support of this study.

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## Data availability statement

The study protocol and full overview of study screening and selection process including title, abstract and full text selections are available upon request from the corresponding author.

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