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COMPREHENSIVE REVIEW

Evidence Mapping and Quality Assessment of Randomized Controlled Trials in Dental Traumatology

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Received: 26 August 2025 | **Revised:** 12 November 2025 | **Accepted:** 19 November 2025

Keywords: bibliometric analysis | dental trauma | randomization | randomized controlled trial | tooth injury

ABSTRACT

Background/Aims: This evidence mapping (EM) and quality assessment of randomized controlled trials (RCTs) in *Dental Traumatology* (DT) aimed to identify the RCTs, distribute them in different domains and subdomains, analyze their methodological characteristics, and assess their quality.

Methods: A protocol was developed as per the principles of Global-Evidence-Mapping (EM) and registered in open-sciences-framework. A systematic electronic search was performed in the PubMed, SCOPUS, EMBASE, Web of Science, LILACS, and COCHRANE on September 30, 2025. Grey literature and reference searches were also performed. RCTs with intervention arms with/without a control group, having details of randomization related to any domain of DT, were included after screening of titles, abstracts, and full-text articles. Studies were distributed in domains and subdomains, and data related to demographic and methodological characteristics were extracted and analyzed. Risk of bias (ROB) was assessed using the Cochrane risk-of-bias tool for randomized trials (RoB-2) and details were presented in the form of an abacus EM plot.

Results: The study identified 30 RCTs in four domains of DT, with the highest in the therapeutic domain and subdomain of treatment protocols in permanent dentition. Seven studies were published before 2010, nine between 2010 and 2019, and 14 others from 2020 to date. They represented 13 countries, with the highest from China, the United Kingdom, and India. A protocol was registered in 10 studies, and the majority of the studies had not followed Consolidated Standards of Reporting Trials (CONSORT) guidelines. Only three RCTs were found to have a low ROB.

Conclusion: The majority of studies exhibited a lack of methodological robustness in defining their hypothesis, sample size estimation, randomization, and statistical evaluation of outcomes. This was the reason for 27 of them being graded as having high ROB or some concerns. The results of this EM may help researchers in identifying the areas for future research and guide them to follow the best practices in the planning and conduct of RCTs.

1 | Introduction

Evidence-based practice integrates the best quality evidence with clinicians' acumen for making clinical decisions [1]. Randomized controlled trials (RCT) are regarded as interventional studies of the highest quality, as they attempt to identify the confounding factors, minimize the possibilities of chance findings, and increase the generalizability of results [2]. They aim to establish a direct cause-and-effect relationship rather than providing an interpretation of observational trends. Their essential requisites include random distribution of participants in groups, concealment of allocation, blinding, standardization of eligibility criteria and outcome assessment, and uniform reporting as per the Consolidated Standards of Reporting Trials

(CONSORT) checklist [3]. PRIRATE 2020 is a specialized guideline for reporting randomized clinical trials in endodontics, developed through expert consensus to improve transparency and reproducibility, which has been endorsed by the *Dental Traumatology* (DT) journal as well [4, 5].

High-quality evidence through well-designed RCTs has been a lucid dream of trauma researchers globally. The trauma situations and cases often preclude inclusion of the ideal protocols of RCTs in research designs [6]. These are the accidental and unique nature, making it difficult to predict the number of eligible cases that may report during the trial period. There are ethical concerns, especially for randomization, allocation concealment, and blinding, that may not allow conceptualization of a trial. The trauma research also witnesses significant attrition of samples during follow-up [7].

Such problems exist in all realms of trauma research and not just in DT. Andreasen and Andersson in 2011 had elucidated the concerns associated with designing in vivo research studies in dental trauma [8]. The most prominent ones were significant flaws in design, methodology, and reporting of the trials. Other concerns stated were difficulties in sampling, sample size estimation, and heterogeneity. They emphasized appropriate recording of pre-injury, injury, treatment, and post-injury factors for conducting a good quality RCT. A pragmatic trial was suggested as a more practical approach for dental trauma research. Pragmatic trials have broader eligibility criteria, and they are flexible in the choice of treatment protocols, resulting in more generalizable results. They are also cost-effective and permit an interim analysis [8, 9]. However, this comes at the cost of loss of homogeneity among the included participants and a reduced precision of the outcome estimates [10].

The global evidence mapping (EM) principles were developed to map the available evidence in a field after establishing its boundary conditions or domains and subdomains [11]. Some of the researchers have utilized this approach with specific study designs such as systematic reviews or RCTs along with assessment of their quality [12–14]. The EM has the potential to propel future research in the domains that lack evidence and improve their methodological characteristics [13, 14].

Clinical researchers in the field of DT have always believed that RCTs are impossible in this science. Hence, this EM and quality assessment of RCTs in DT aimed to identify the RCTs, distribute them in different domains and subdomains, analyze their methodological characteristics, and assess their quality.

2 | Methods

2.1 | Protocol Development and Literature Search

A protocol of this EM study was developed as per the guidelines of global EM [11]. It was registered in the Open Science Framework (10.17605/OSF.IO/X8CAK). A search strategy was formulated as per the aim of the study. Keywords and Medical Subject Headings (MeSH) terms related to different types of TDI were used with the Boolean operator "OR" as one field, and the terms related to RCT as the second field. The fields were combined using the Boolean operator "AND." Another field search was planned to combine the Keywords and MeSH terms related to therapeutic paradigms used in the management of TDI and their sequelae with the previous search using the Boolean operator "AND." The strategy was modified as per the requirements of various databases. This systematic electronic search was performed by two authors (N.T. and G.J.) in PubMed, SCOPUS, EMBASE, Web of Science, LILACS, and COCHRANE on September 30, 2025. There were no limitations set for language or the year of publication (Data S1). Search results were saved in EndNote online (Clarivate, USA), and duplicates were removed. A search of grey literature was done in Google Scholar and Open Grey, and reference searching of the included studies was also performed. Dental Traumatology, International Endodontic Journal, Journal of Endodontics, and International Journal of Pediatric Dentistry were manually searched as well.

2.2 | Eligibility Criteria

The RCTs related to any domain of DT having intervention arms with or without a control group were included if they had performed randomization of the subjects. Non-randomized trials, any other study design such as case-control studies, cohort studies, case reports, case series, and systematic reviews were excluded. It was decided that the authors of conference abstracts or the clinical trials lacking the necessary details would be contacted and would be excluded if it were not provided (Data S1).

2.3 | Screening

The screening of titles and abstracts (stage one) and later full text studies (stage two) was performed by two authors (G.J. and A.R.) with excellent agreement in both stages (Cohen's Kappa value of 0.88 for stage one and 0.84 for stage two). In event of disagreement, the third author (N.T.) was consulted for consensus.

2.4 | Data Extraction and Analysis

A self-designed data extraction sheet was prepared to collect information about the demographics of the included trials and their methodological characteristics, such as their registration, use of the CONSORT checklist, number of authors, details of randomization, allocation concealment, and blinding, number of intervention arms and design, the hypothesis tested, details of sample size estimation, attrition in samples, and the statistical analysis.

It was pre-piloted in five studies, which also allowed calibration of the authors who extracted the data (G.J., A.R.). The aims of the trials were discerned into the elements of Population (P), Intervention (I), Comparator (C), and Outcomes (O). The collected data was analyzed by all the authors to finalize its presentation. Studies were distributed in various domains and subdomains of DT through a group discussion with absolute

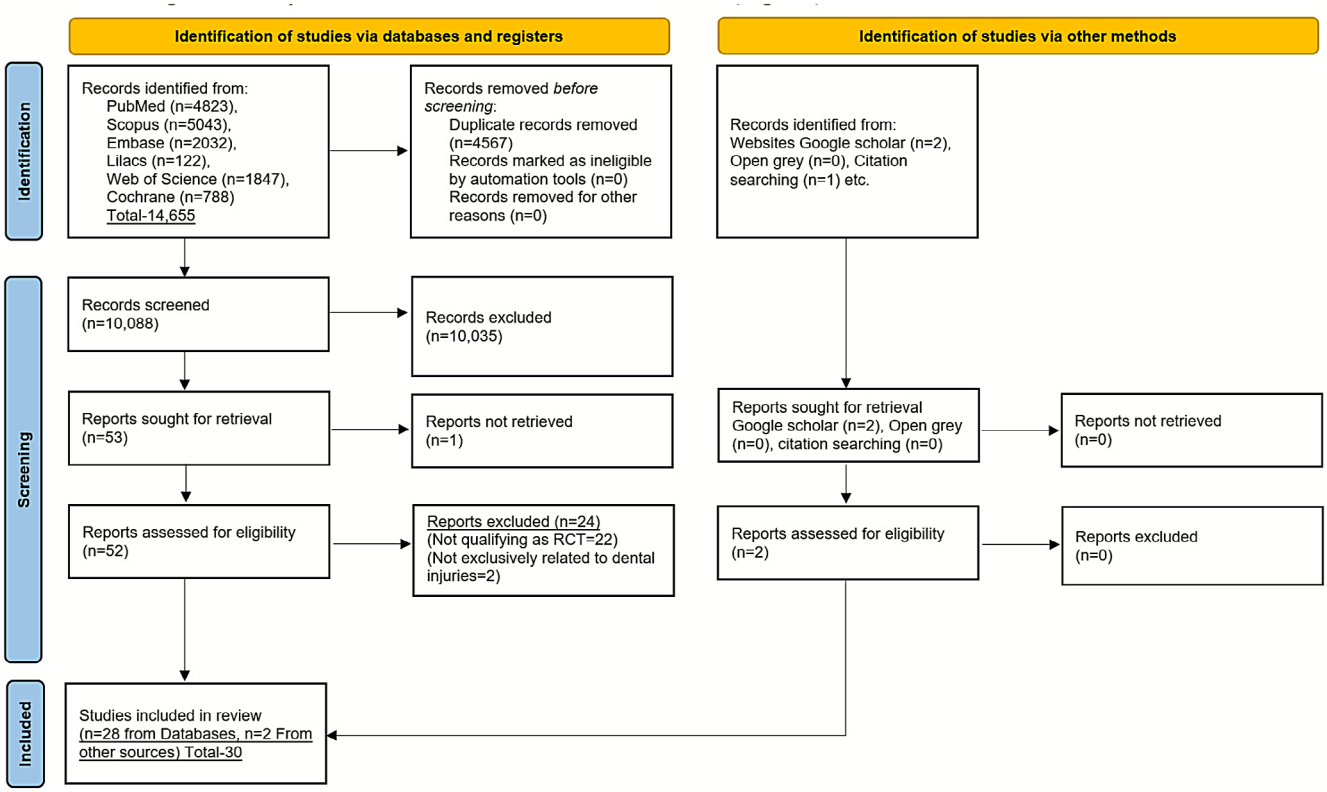

FIGURE 1 | PRISMA diagram showing details of search.

consensus. Intervention and outcomes of the studies were the primary consideration in this categorization.

2.5 | Risk of Bias Assessment

Two reviewers (G.J. and N.T.) independently assessed the methodological quality of the included studies using the Cochrane Risk of Bias (RoB 2.0) tool [15] (Cohen's Kappa: 0.74–0.92). In case of any disagreement, the opinion of the third author, V.M., was considered final. The Abacus EM plot was used for the visual presentation of the distribution of RCTs in domains and their quality. The *X*-axis of the Abacus plot represented the domains of MIH, while the *Y*-axis displayed the grades of ROB as per RoB-2: low, some concerns, and high ROB. Within each grade, the studies were represented as white beads (unregistered protocols) and black beads (registered protocols), with a unique identification number, arranged according to the year of publication.

3 | Results

3.1 | Search Results

The total number of records identified from the database search was 13,448. The scrutiny of titles and abstracts was performed in 9422 of them, and full texts of 43 were evaluated. This resulted in the inclusion of 28 RCTs. Two more articles qualifying the eligibility criteria were identified from other sources (Figure 1, Data S1). The list of excluded studies and the reasons for exclusion are reported in Data S2.

3.2 | Distribution in Domains and Subdomains

The 30 RCTs [16–45] could be categorized in the diagnostic (subdomain—clinical assessment), therapeutic (subdomains—treatment protocols in primary dentition, permanent dentition, or both), prognostic (subdomain—healing response in permanent dentition), and preventive domains (subdomains—awareness of prevention and emergency management of TDI and sports injury prevention). The therapeutic domain and subdomain of treatment protocols in permanent dentition had the highest number of RCTs ($n = 14$) [18–31] (Table 1, Figure 2).

3.3 | Study Characteristics

The earliest RCT included in this EM was published by von Arx et al. [18] from Switzerland in the year 2001. This study compared the titanium trauma splint (TTS) with three other types of splints in healthy human volunteers. Seven studies were published before 2010 [16, 18–20, 33, 40, 41], nine between 2010 and 2019 [17, 21–25, 30, 37, 38, 42], and 14 others from 2020 to date [26–32, 34–36, 39, 43–45]. The *Dental Traumatology* Journal published 13 studies [16–19, 22, 26, 28, 30, 36, 38, 39, 41, 42], The published RCTs are from 14 countries, with the highest number of RCTs from China [20, 25, 31, 37], United Kingdom [16, 21, 22, 43], and India ($n = 4$) [23, 27, 29, 35] followed by United States of America ($n = 3$) [32, 38, 42]. There were two studies each from Sweden [34, 36], Switzerland [18, 19], Turkey [24, 39], Egypt [26, 30] and Spain [41, 45], (Table 1, Figure 3). Day et al. performed the highest number ($n = 3$) of RCTs, with two comparing the intracanal medicaments in avulsed permanent

TABLE 1 | Details of included randomized controlled trials—domain and subdomain of dental traumatology, author (first author), journal, country, aim as per population, intervention, comparator, outcomes, registration of protocols, use of reporting checklist, and number of authors.

Code	Author, year	Journal	Country	Aim	Registration	CONSORT used	Number of authors
B Diagnostic							
Clinical assessment							
B1	Day et al. (2006) [14]	Dental Traumatology	UK	P—General Dentists and post graduate students in pediatric dentistry, vocational trainees, I—a computer database (CD) developed for this study, C—a plain paper unstructured history (USH) and structured histories (SH), O—effectiveness in recording of important prognostic factors for simulated dento-alveolar trauma	No	No	5
C Therapeutic							
Treatment protocols in primary dentition							
C1	Pinto et al. (2011) [15]	Dental Traumatology	Brazil	P—Primary teeth with pulp necrosis secondary to trauma, I—Root canal filling material Calcium hydroxide and polyethylene glycol-based paste (Calen), C- Zinc oxide and eugenol cement (ZOE), O—Clinical and radiographic success	No	No	4
Treatment protocols in permanent dentition							
C2	von Arx et al. (2001) [16]	Dental Traumatology	Switzerland	P—Healthy human volunteers, I—Titanium Trauma Splint C—Wire composite splint, Button bracket splint, Resin Splint, O—Tooth mobility, probing depth, plaque index, bleeding on probing index, chair side time for application and removal.	No	No	3
C3	Filippi et al. (2002) [17]	Dental Traumatology	Switzerland	P—Healthy human volunteers, I—Titanium Trauma Splint C—Wire composite splint, Button bracket splint, Resin Splint, O—patient reported sensitivity of splinted teeth, irritation of gingival margin and lips, impairment of speech, eating, and oral hygiene.	No	No	3
C4	Loo et al. (2008) [18]	Am J Em Med	China	P—Replanted avulsed permanent teeth, I—thymosin alpha root surface treatment, C—Saline treatment of root surface, O—short-term and long-term effects such as survival, mobility, ankylosis, periodontal healing	No	No	4

(Continues)

TABLE 1 | (Continued)

Code	Author, year	Journal	Country	Aim	Registration	CONSORT used	Number of authors
C5	Day et al. (2011) [19]	JOE	UK	P—Replanted avulsed permanent teeth, I—Ledermix as intracanal medicament, C—Ultra Cal XS as intracanal medicament, O—Discoloration	Yes	No	9
C6	Day et al. (2012) [20]	Dental Traumatology	UK	P—Replanted avulsed permanent teeth, I—Ledermix as intracanal medicament, C—Ultra Cal XS as intracanal medicament, O—Periodontal Healing	Yes	Yes	7
C7	Damle et al. (2012) [21]	Journal of Clinical Pediatric Dentistry	India	P—Non vital traumatized permanent maxillary anterior teeth I—MTA group C—Calcium hydroxide group O—clinical and radiographic outcome of apexification	No	No	3
C8	Ulusoy et al. (2019) [22]	JOE	Turkey	P—Maxillary incisors with a complicated crown fracture, showing clinical and radiographic diagnosis of pulp necrosis I- PRP, PRF, and PP, C- BC O—clinical and radiographic outcomes	No	No	4
C9	Xuan et al. (2019) [23]	Science Translational Medicine	China	P- Pulp necrosis after traumatic dental injuries I—human deciduous pulp stem cell (hDPSC) implantation C—traditional apexification O—ability to regenerate lost three-dimensional (3D) pulp tissue, restore pulp function, and promote root development.	No	No	15
C10	Mohammed et al. (2021) [24]	Dental Traumatology	Egypt	P—Permanent teeth with crown root fracture (surgically extruded), I—Splint removed after Periotest values were similar to the contralateral uninjured tooth (three consecutive readings in a single visit), C—splint removal at 2-weeks, O- Tooth mobility, tooth loss, ankylosis, root resorption, marginal bone loss	No	No	5
C11	Jayadevan et al. (2021) [25]	Journal of Clinical Experimental Dentistry	India	P—Traumatized immature non-vital teeth I—A-PRF C—PRF O—Periapical healing, and root development	No	No	5
C12	Raza et al. (2023) [26]	Dental Traumatology	Pakistan	P—Permanent teeth with luxation injuries, I—Bulk-fill composite wire splint, C—Conventional packable composite wire splint, O—Retention, adhesive point dimension, application and removal times, tooth mobility	Yes	PRIRATE	6

(Continues)

TABLE 1 | (Continued)

Code	Author, year	Journal	Country	Aim	Registration	CONSORT used	Number of authors
C13	Siddiqui et al. (2023) [27]	Int J Burn Trauma	India	P—Permanent anterior teeth with uncomplicated crown fractures, I—Putty Index Technique for direct composite restoration, C—Custom Template Technique for Direct Composite restoration, O—Clinical performance	Yes	Yes	6
C14	Abo- Heikal et al. (2023) [28]	Dental Traumatology	Egypt	P—Immature traumatized necrotic maxillary anterior teeth I—i-PRF C—PRP O—regenerative potential in terms of radiographic outcomes	Yes	Yes PRIRATE	4
C15	Yang et al. (2024) [29]	Journal of Peking University	China	P: Traumatized immature permanent teeth requiring pulp capping I: iRoot BP Plus C: CaOH O: Clinical and radiographic success at 3 years	No	No	5
Treatment protocols in primary and permanent dentition							
C16	Huh et al. (2022) [30]	Pediatric Emergency Care	USA	P—Medical students and Pediatric Dentists, I—Dental trauma clinical decision support tool (CDST) by mobile application, C—Print applications, O—improvement in knowledge, effectiveness	No	No	4
D Prognostic							
Healing responses in permanent dentition							
D1	Pasini et al. (2006) [31]	EJPD	Italy	P—Patients with luxation injuries, I—Specific oral hygiene protocol managed by dental hygienist weekly till 6 weeks, C— Oral hygiene protocol with hygienist involved at 1st and 6th week, O—Plaque index assessment	No	No	5
D2	Wikstrom et al. (2024) [32]	Journal of Oral Microbiology	Sweden	P: Traumatized immature necrotic teeth I: 2% chlorhexidine gluconate gel C: Calcium hydroxide pastes O: Microbiological assessment of microbial load and success or failure	No	Yes	6

(Continues)

TABLE 1 | (Continued)

Code	Author, year	Journal	Country	Aim	Registration	CONSORT used	Number of authors
D3	Mutalikdesai et al. (2025) [33]	Lasers in Medical Science	India	P—Patients with radiographic evidence of trauma-induced periapical lesion I: Nonsurgical endodontic treatment with intracanal CaOH and extra-canal Nd:YAG 1064nm PBMT C: Nonsurgical endodontic treatment with intracanal CaOH-Iodoform paste O: Improvement in vascular perfusion, reduction in size, volume area and echogenicity of the lesion	Yes—Clinical Trials Registry India	No	7
D4	Wilkstrom et al. (2025) [34]	Dental Traumatology	Sweden	Traumatized immature necrotic teeth I: 2% chlorhexidine gluconate gel C: Calcium hydroxide pastes O: Clinical and radiographic success	No	Yes- PRILE	6
E Preventive							
Awareness of prevention and emergency management of TDI							
E1	Young et al. (2014) [35]	PLOS One	Hong Kong	P—Secondary school students, I—Educational poster for awareness regarding emergency management of dental trauma, C—No intervention (waiting for two weeks) O— Effectiveness in terms of improving knowledge	Yes	Yes	3
E2	Iskander et al. (2016) [36]	Dental Traumatology	USA	P—Parents of patients with dental trauma, I—Mobile health care application, C—Poster for awareness, O—Accuracy in answering a survey about dental trauma management, user preference for mode of delivery of information	No	No	4
E3	Koc et al. (2025) [37]	Dental Traumatology	Turkey	P: Fourth year dental students I: Theoretical instruction and simulation training using 3D-printed models C: Theoretical instruction O: Anxiety, stress, self- confidence and knowledge	No	Yes	3
Sports injury prevention							
E4	Braham et al. (2004) [38]	J Sci Med Sport	Australia	P—Senior and Junior teams of community football, I—Three protective devices (Headgear, Custom Fitted MG, Both Headgear and Custom Fitted), C—Usual protective equipment practice, O—Compliance	No	No	2

(Continues)

TABLE 1 | (Continued)

Code	Author, year	Journal	Country	Aim	Registration	CONSORT used	Number of authors
E5	Duarte-Pereira et al. (2008) [39]	Dental Traumatology	Spain	P—Rugby players, I—Custom fitted mouth guards, C—Self-adapted mouth guards, O—comfort, wearability, physiological effects, physical performance	No	No	8
E6	Duddy et al. (2012) [40]	Dental Traumatology	USA	P—Collegiate athletes (Rowing) while performing aerobic and anaerobic exercises, I- Custom-made mouthguard, C- Boil and Bite (O—flow Max Under armor), O—satisfaction, breathing difficulties, speech problems, restriction in athletic performance	No	No	6
E7	Kalra et al. (2022) [41]	EJO	UK	P—Patients undergoing orthodontic treatment with fixed appliances involved in sports activities, I—MG1, custom-made laboratory constructed, C—MG2, mouth-formed OPRO Gold Braces, and MG3, pre-fabricated Shock Doctor Single Brace, O—Wearability and preference	Yes	Yes	5
E8	Azizzadeh et al. (2023) [42]	EAPD	Iran	P—11–17-year-old Karate and Taekwondo athletes, I—An educational pamphlet regarding prevention and emergency management of sport-related traumatic dental injuries (TDIs), C—A mobile application regarding prevention and emergency management of sport-related traumatic dental injuries (TDIs), O—Knowledge and self-reported preventive practices and reason for not using mouth guard	Yes	No	6
E9	Qin et al. (2024) [43]	International Journal of Prosthodontics	Spain	P: Rugby Union Players I: Labial reinforced customized mouthguard C: Conventional mouthguard O: Discomfort, satisfaction, functional interference, protection and general satisfaction	Ye—US Clinical Trials Registry	Yes	4

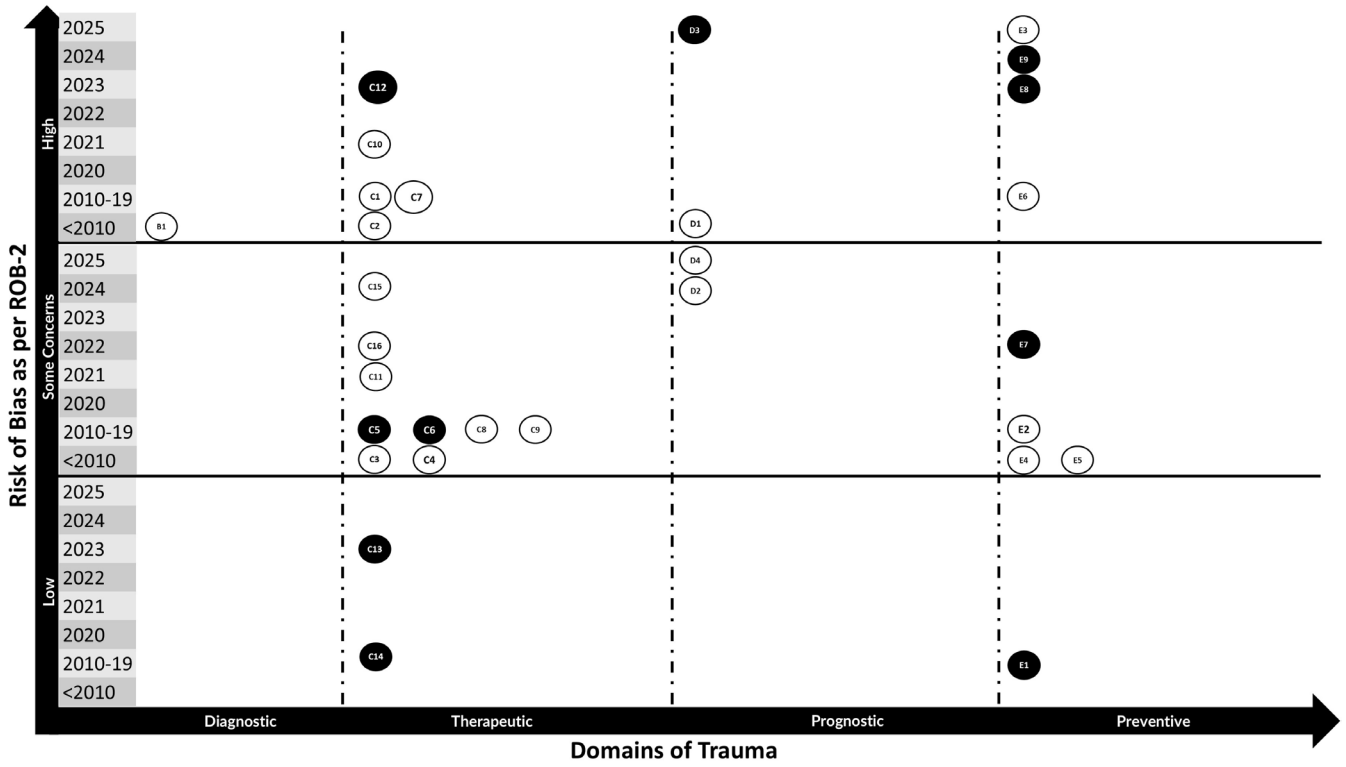

FIGURE 2 | Abacus EM plot showing the included RCTs distributed in different domains of dental traumatology, with the *X*-axis showing the domains and the *Y*-axis showing the categories of risk of bias as per RoB-2 (Low, Some Concerns, High). The RCTs are represented by black (protocol registered) and white (protocol not registered) beads, with each having a unique identification number.

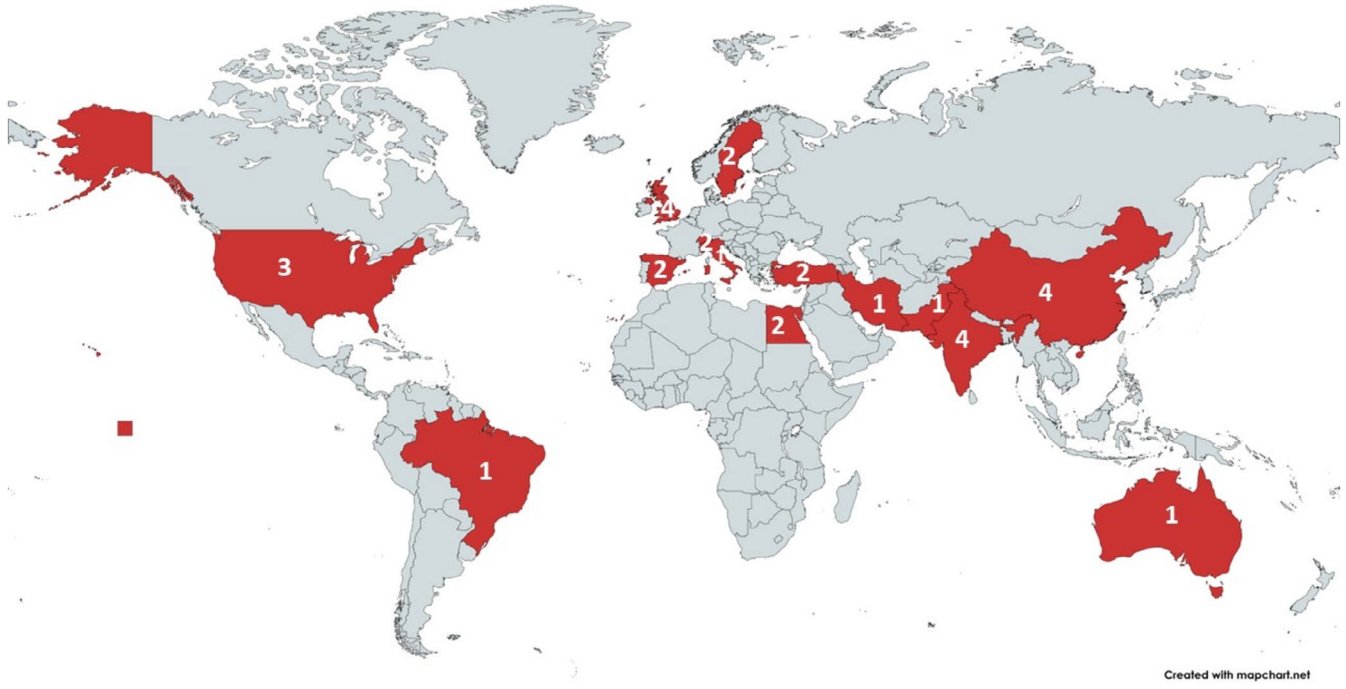

FIGURE 3 | Showing the risk of bias among the included RCTs as per RoB-2.

teeth [21, 22], and one related to the effectiveness of different methods of recording the prognostic factors in simulated cases of dento-alveolar trauma [16]. Protocol registration was done in 10 RCTs [21, 22, 28–30, 35, 37, 43–45] while the CONSORT checklist was used in seven RCTs [22, 29, 34, 37, 39, 43, 45]. Two of the studies had used the Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) guidelines for reporting the trial [28, 30] whereas one study had used Preferred Reporting Items for Laboratory studies in Endodontology (PRILE) guidelines [36]. The number of authors ranged from 2 to 16 (Table 1).

3.4 | Methodological Characteristics

Simple randomization was the most common method used for randomizing the participants in different groups ($n = 22$) [16–21, 23–28, 30–33, 35, 41–44]. Block randomization was used in six studies [22, 29, 34, 36, 39, 45]. The remaining two studies, categorized in the preventive domain of DT, used cluster randomization [37, 40]. Though randomization is the cornerstone for conducting a good RCT, the allocation concealment further reduces the elements of selection bias. It was done in only six of the included studies [22, 26, 29, 30, 37, 43]. Similarly, the blinding was performed in nine studies [17, 20, 22, 26, 28–31, 37]. Among them, one was a triple-blinded trial [37], three were double-blinded [20, 26, 28], and five were single-blinded trials [17, 22, 29–31]. Most of the trials had parallel arms ($n = 24$) [16, 17, 20–40, 44] except for six trials, which were crossover in design [18, 19, 41–43, 45].

It is important for RCTs to clearly state the hypothesis being tested. This results in describing a trial as superiority, non-inferiority, and equivalence. Only three studies stated their design as an equivalence trial [31, 39, 45] and one study each as a non-inferiority trial [33] and superiority trial each [32], while this information was missing in the majority of the studies. The type of hypothesis testing also governs the statistical method of sample size estimation, and it was not surprising to see that the details of this step were stated in 14 studies only [24, 28–31, 34–37, 39, 42–45]. There was no attrition of the samples from baseline to follow-ups in the trials by Day et al. [16], von Arx et al. [18], Filippi et al. [19], Loo et al. [20], Abo- Heikal et al. [30], and Duarte-Pereira et al. [41]. The attrition in 19 other studies ranged from 0.67% [32] to 76.9% [17]. The details of statistical analysis of Intention to Treat (ITT) and/or Per Protocol (PP) were mentioned in nine trials [18–20, 22, 23, 28]. ITT had been used in three [26, 28, 33], PP in four [27, 35, 37, 42], and both ITT and PP in two of them (Table 2) [29, 31].

3.5 | Risk of Bias Analysis

ROB was found to be low in three RCTs [29, 30, 37] while 14 each were graded to have some concerns [19–22, 24, 27, 31, 32, 34, 36, 38, 40, 41, 43] and 13 had high ROB [16–18, 23, 25, 26, 28, 33, 35, 39, 42, 44, 45]. Most of the studies had problems related to the description of randomization, allocation concealment, and blinding. The Abacus EM plot showed that the quality of RCTs was not associated with the year of publication; however, both studies with low ROB had registered their protocol. The proportion of studies with high ROB was highest in the Diagnostic domain (100%, $n = 1$), followed by the Preventive Domain (44.4%, $n = 4$), Therapeutic Domain (31.2%, $n = 5$) and prognostic domain (25%, $n = 1$), (Figures 2 and 4).

4 | Discussion

EM is an effective way of understanding the diversity of research in an area and understanding the quality of studies [11]. The first step includes identifying an area to be studied and establishing its boundary conditions. Principles of qualitative research are used to establish domains and subdomains of the area. The first EM of systematic reviews in DT was done in the year 2020 [13] and has recently been updated [14]. It was successful in establishing the domains and subdomains of DT. EMs are different from bibliometric analyses as the former follow a protocol-driven systematic methodology and aim to map evidence and its quality; the latter attempt to discern the publication trends, keywords, and author correlations [11, 12].

Since RCTs in DT are like lucid dreams to several researchers who don't even attempt to perform trials with pertinent research questions [8]. As a result, most of the evidence is derived from cohort studies or non-randomized pilot trials, which is a concern in the present era of evidence-based medicine [13, 14]. This EM was conceptualized to highlight all the RCTs done in DT and understand their limitations. It was believed that investigators would get inspired and not consider such studies as impossible. As expected, only 30 studies could qualify for final analysis with maximum numbers in the therapeutic domain. However, the RCTs were mapped even in the diagnostic, preventive, and prognostic domains. Most of the research questions were related to splinting and luxation injuries [18, 19, 26, 28, 33]. Two of the earliest RCTs came from Switzerland where the research group of von Arx and Fillipi compared the effects of TTS with wire composite splint, button bracket splint, and resin splint in healthy human volunteers [18, 19]. It was an interesting work and may be regarded as a phase-I trial where safety in humans was being assessed and the participants with TDI were not included. Raza et al. [28] evaluated the efficacy of bulk fill composite over conventional packable composite while performing wire composite splinting in luxation injuries of permanent teeth. The outcomes were retention, adhesive point dimension, application and removal times, and tooth mobility. Pasini et al. [33] also selected a similar design but evaluated the efficacy of a hygiene protocol controlled by a dental hygienist during the splinting period. Such trials in DT seem to be more feasible as the outcomes are assessed at short intervals and do not look at the overall prognosis of the injured tooth. Another popular area in the therapeutic domain was replantation of the avulsed tooth. The trials done in Leeds compared Ledermix with a calcium hydroxide-based medicament as an intracanal medicament after pulp extirpation in terms of periodontal healing and discoloration [21, 22]. While Loo et al. [20] evaluated the efficacy of thymosin alpha-based root surface treatment prior to replantation and compared it to a placebo (normal saline) in terms of survival, mobility, ankylosis, and periodontal healing. The RCT by Mohammed et al. [26] tested the effect of splinting duration in teeth with crown-root fractures on the long-term survival, mobility, ankylosis, root resorption, and marginal bone loss, while Siddiqui et al. [29] compared two methods of direct composite restoration in permanent incisors with uncomplicated crown fractures. Several studies were related to the management of traumatized immature permanent teeth. Yang et al. [31] compared the clinical and radiographic success of iRoot BP Plus and calcium hydroxide in pulp capping as a vital pulp therapy in such teeth. Among the trials related to traumatized non-vital immature permanent teeth, only one trial compared the conventional calcium hydroxide apexification with Mineral Trioxide Aggregate (MTA) apexification [23] while the rest of them were related to regenerative endodontic therapy [24, 27, 30, 34, 36]. Two of the recent trials assessed the methods of endodontic disinfection in regenerative endodontic therapy and nonsurgical endodontic healing [34, 35]. One trial initially compared the reduction in microbial load with two intracanal medicaments: 2% chlorhexidine digluconate gel

TABLE 2 | Methodological details of included randomized controlled trials—randomization, allocation concealment, blinding, arms (number of groups), hypothesis, basis of sample size estimation, attrition in samples, and statistical analysis used.

Code	Author	Randomization (Yes/no and method)	Allocation concealment	Blinding	Type—Arms (Number of groups)	Type—hypothesis	Sample size basis stated	Attrition in samples	ITT/PP
B Diagnostic									
Clinical assessment									
B1	Day et al. 2006 [14]	Yes—Simple randomization	No	No	3—Parallel	NM	No	No attrition	NM
C Therapeutic									
Treatment protocols in primary dentition									
C1	Pinto et al. (2011) [15]	Yes—Simple randomization	No	Yes—Single blind	2—Parallel	NM	No	Initial: 26 patients and31 teeth (15 in Group1 and 16 in Group 2), Final: 6 patients lost to follow-up (Attrition—76.9%)	NM
Treatment protocols in permanent dentition									
C2	von Arx et al. (2001) [16]	Yes—Simple randomization	No	No	3—Crossover	NM	No	No attrition	NM
C3	Filippi et al. (2002) [17]	Yes—Simple randomization	No	No	3—Crossover	NM	No	No attrition	NM
C4	Loo et al. (2008) [18]	Yes—Simple randomization	No	Yes—Double blind	2—Parallel	NM	No	Baseline: Group 1: 29, Group 2: 44 (No attrition for short-term outcomes, no data given for long-term outcomes)	NM
C5	Day et al. (2011) [19]	Yes—Simple randomization	No	No	2—Parallel	NM	No	Baseline: 22, Final: 21 (Attrition—4.5%)	NM
C6	Day et al. (2012) [20]	Yes—Block randomization	Yes	Yes—Single blind	2—Parallel	NM	No	Baseline: 28, Last follow-up: 22 (Attrition—21.4%)	NM

(Continues)

TABLE 2 | (Continued)

Code	Author	Randomization (Yes/no and method)	Allocation concealment	Blinding	Type—Arms (Number of groups)	Type—hypothesis	Sample size basis stated	Attrition in samples	ITT/PP
C7	Damle et al. (2012) [21]	Yes—simple randomization	No	No	2—parallel	NM	No	NM	NM
C8	Ulusoy et al. (2019) [22]	Yes—simple randomization	No	No	4—parallel	NM	Yes	NM	NM
C9	Xuan et al. (2019) [23]	Yes—simple randomization	No	No	2—parallel	NM	No	Group 1: baseline—30 Final—20 (Attrition—33.3%) Group 2: No attrition	NM
C10	Mohammed et al. (2021) [24]	Yes—Simple randomization	Yes	Yes—Double blind	2—Parallel	NM	No	Baseline: 22 (11 in each group), 9 at each follow-up (Attrition: 18.1%)	ITT
C11	Jayadevan et al. (2021) [25]	Yes—Simple randomization	NM	No	2—parallel	NM	NM	Group 1: Baseline—15 Final—11 Attrition: 26.6%, Group 2: Baseline-15, Final-10, Attrition: 66.6%	PP
C11	Raza et al. (2023) [26]	Yes—Simple randomization	No	Yes—Double blind	2—Parallel	NM	Yes	Baseline: 45 per group, Follow-up: 44 per group, 1 lost to follow-up (Attrition: 2.2%)	ITT
C12	Siddiqui et al. (2023) [27]	Yes—Block randomization	Yes	Yes—Single blind	2—parallel	Equivalence trial	Yes	Baseline: 49,51 For analysis: 15,24 (Attrition: 69.3%, 52.9%)	Both
C13	Abo-Heikal et al. (2023) [28]	Yes—simple randomization	Yes	Yes—single blinded	2—parallel	Superiority trial	Yes	No attrition	NM

(Continues)

TABLE 2 | (Continued)

Code	Author	Randomization (Yes/no and method)	Allocation concealment	Blinding	Type—Arms (Number of groups)	Type—hypothesis	Sample size basis stated	Attrition in samples	ITT/PP
C14	Yang et al. (2024) [29]	Yes—Simple randomization	NM	Yes—Single blind	2—parallel	Non- inferiority	Yes	Group 1: 13.5%, Group 2: 15.4%	Both
Treatment protocols in primary and permanent dentition									
C15	Huh et al. (2022) [30]	Yes—Simple randomization	No	No	2—Parallel		No	Initial: 149, Final: 148 (Attrition—0.67%)	NM
D Prognostic									
Healing responses in permanent dentition									
D1	Pasini et al. (2006) [31]	Yes—Simple randomization	No	No	2—parallel	NM	No	Baseline: 41 each Follow-up: Group A: 41 and Group B: 35 (Attrition 14.6% in group B)	ITT
D2	Wikstrom et al. (2024) [32]	Yes—Block randomization	NM	No	2—parallel	NM	Yes	NM	NM
D3	Mutalikdesai et al. (2025) [33]	Yes—Simple randomization	No	NM	2—parallel	NM	Yes	Group 1 and 2: 2/12 (16.7%)	PP
D4	Wilkstrom et al. (2025) [34]	Yes—Block randomization	NM	No	2—parallel	NM	Yes	NM	NM
E Preventive									
Awareness of prevention and emergency management of TDI									
E1	Young et al. (2014) [35]	Yes—Cluster randomization	Yes	Yes—Triple blind	2—Parallel	Equivalence trial	Yes	Baseline: 427 students in Group 1 and 357 students, Analysis: 364 students in Group 1 and 303 students in Group 2	PP
E2	Iskander et al. (2016) [36]	Yes—Simple randomization	No	No	2—Parallel	NM	No	Initial: 101, Final: 89 (Attrition- 11.9%)	NM

(Continues)

TABLE 2 | (Continued)

Code	Author	Randomization (Yes/no and method)	Allocation concealment	Blinding	Type—Arms (Number of groups)	Type—hypothesis	Sample size basis stated	Attrition in samples	ITT/PP
E3	Koc et al. (2025) [37]	Yes- Block randomization	No	No	2—Parallel	NM	Yes	Group 1 and 2: 4/38 (10.5%)	NM
Sports injury prevention									
E4	Braham et al. (2004) [38]	Yes—Clustered randomization	No	No	2—Parallel	NM	No	Baseline: 301, Final: 135 (Attrition-55%)	NM
E5	Duarte-Pereira et al. (2008) [39]	Yes—Simple randomization	No	No	3—Crossover	NM	No	No attrition	NM
E6	Duddy et al. (2012) [40]	Yes—Simple randomization	No	No	3—Crossover	NM	Yes	NM	NM
E7	Kalra et al. 2022 [41]	Yes—Simple randomization	Yes	No	6—Crossover	Equivalence trial	Yes	Initial: 30, Final: 21 (Attrition: 30%)	PP
E8	Azizzadeh et al. (2023) [42]	Yes—Simple randomization	No	No	2—Parallel	NM	Yes	Baseline: 295, Final: 108 (Attrition-63%)	NM
E9	Qin et al. (2024) [43]	Yes—Block randomization	No	No	2—crossover	NM	Yes	Group 1: No attrition, Group 2: 2/12 (16.75)	NM

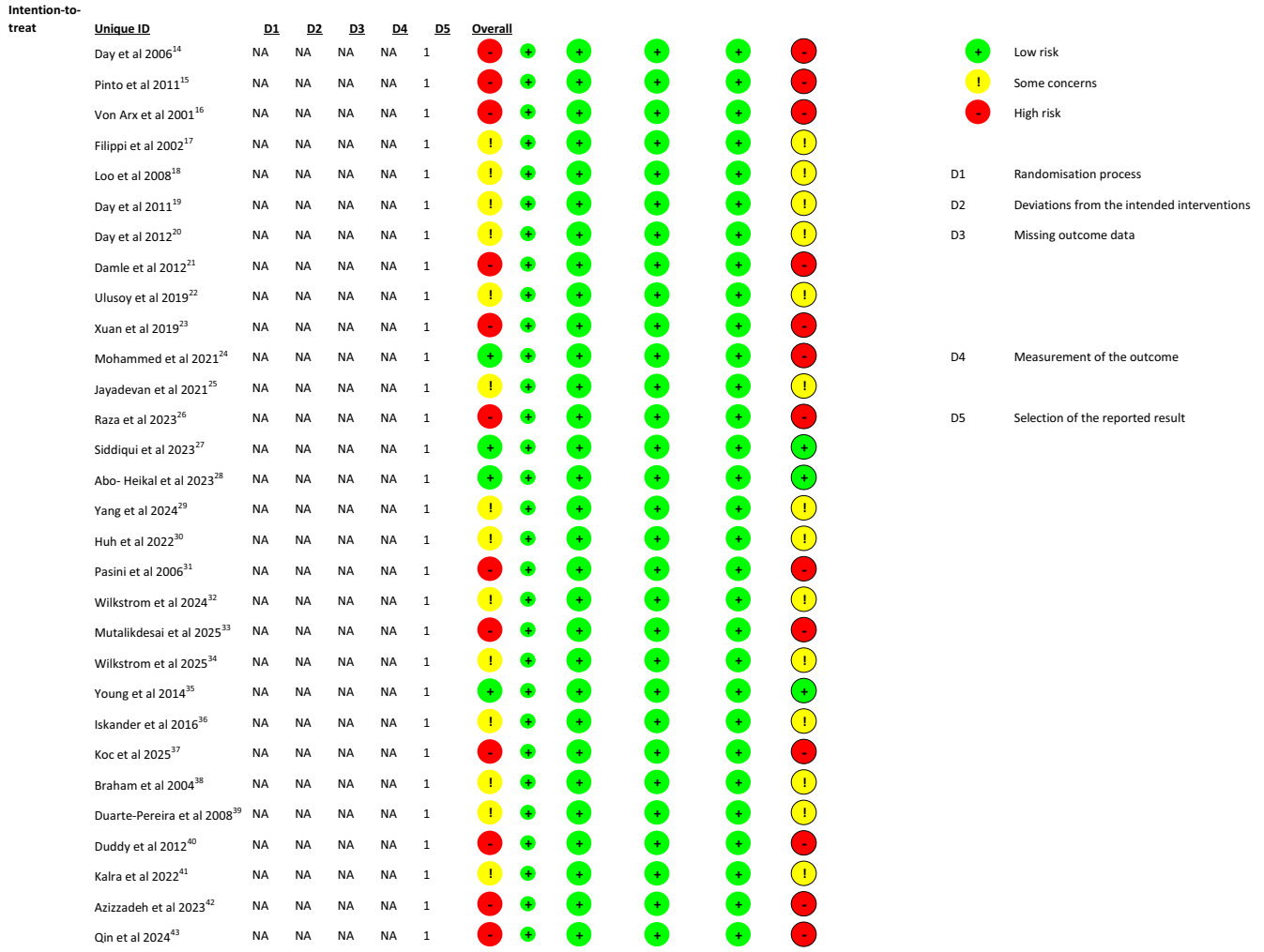

FIGURE 4 | World map showing details of countries of origin of included trials.

with calcium hydroxide paste [34] and then the same population was followed up to evaluate clinical and radiographic success [36]. Three trials had compared various scaffolds used in regenerative endodontic treatment [24, 27, 30], while, one trial had compared the traditional apexification and implantation of human deciduous pulp stem cells for their regenerative potential [25]. Since the traditional apexification procedure does not allow regeneration of damaged pulpal tissue or continued root development, it may not be rational to compare it with regenerative endodontic procedures in terms of changes in root length or dentin thickness. The only trial related to the injured primary teeth was done by Pinto et al. [17], who compared two root canal filling materials for clinical and radiographic success. Such types of trials are common in pediatric endodontics and usually have an age group that is compliant with treatment and follow-ups.

Several RCTs were related to the education of school children [37], parents of injured children [38], medical students and pediatric dentists, dental students [39], and 11–17-year-old Karate and Taekwondo athletes [44]. Young et al. [35] had evaluated the effectiveness of educational posters for the emergency management of dental trauma and compared it with a control group without any educational intervention. Other studies had interventions based on mobile applications and varied control groups. Studies in the preventive domain also compared custom-made mouth guards with other types of mouth guards for comfort, wearability, physiological effects, physical/athletic performance, compliance, satisfaction, functional interference, and preference [40–43]. The sports covered were community football (soccer) [40], rugby [41, 45], and aerobic and anaerobic exercises (collegiate athletes of rowing) [42]. One trial included patients undergoing orthodontic treatment and active in sports [43]. Both aspects are important for the longer public health-centric goals for holistic dental trauma care. The participants of such trials are more predictable to recruit, to standardize, or to randomize; still such community-based trials are difficult to design and execute. The only study in the clinical assessment subdomain of the diagnostic domain tested the effectiveness of a computer database in recording prognostic factors and compared it with structured and unstructured paper forms [16].

The highest number of RCTs was from the United Kingdom, China, and India. Another bibliometric analysis of avulsion of permanent teeth had shown the highest number of publications from the United States. However, only one of them was RCT [46]. On the contrary, another bibliometric and altimetric review on trends and perspectives on dental fragment reattachment showed Brazil had the highest number of publications, with only two of them being clinical trials [47]. In recent years, a large number of research articles have been contributed from

countries such as Brazil, India, and Turkey. This study identified four RCTs from India [29, 35] and two from Turkey [24, 39] and one from Brazil [17]. Further, the Scandinavian research groups that have been active in DT from that region contributed only two RCTs [34, 36]. This may be attributed to the concerns for confounding factors and adequate design, as was emphasized by Andersson and Andreasen [8].

This EM could find some crucial paucities in the RCTs, which were reflected in their quality analysis too. Several journals have made it mandatory to register a priori protocol before commencing an RCT [48, 49]. This is an important step, as it makes the work transparent and allows the reviewers and readers to make judgments about the deviations that may have happened during the course of the conduct of the trial. The Cochrane Risk of Bias Tool (RoB-2) identifies this as a critical bias as well and grades the studies that lack comparisons with the protocol or statistical plan as poor quality [50]. It was observed that 66.6% of RCTs had not registered their protocols. This must be addressed by future researchers to improve the quality of trials. Similarly, CONSORT has been globally recognized as a checklist for reporting trials [3]. This too is often a required checklist for submission in a journal. The PRIRATE checklist had been proposed for the RCTs related to endodontics [49]. One of the RCTs reporting microbial loads in traumatized immature teeth and their impact on the treatment outcomes of regenerative endodontic treatment used the PRILE checklist. Though not intended for RCTs, authors seem to have used it due to the kind of reporting that was expected in the study [36]. This EM identified a lack of compliance with checklists as a common avoidable methodological error. Similarly, Nagendrababu et al. showed that the clinical trials published in journals that adhered to the CONSORT guidelines had significantly better quality scores compared to those that did not. They also stated that clinical trials with a priori protocol registration had a greater proportion of studies with "High" scores of quality [49].

There are several essential features of well-designed RCTs. Randomization is considered to be the core of its design and varies as per the research question [51]. The most commonly used techniques are simple randomization, block randomization, and clustered randomization [52]. Simple randomization, as the name suggests, is the simple allocation of the randomization unit into either the intervention or control group. It was also the most commonly used randomization method among the included studies. The advantages are complete randomization and equal distribution. However, it has limitations in studies with small sample sizes as it cannot completely address all the confounding factors and results in a lower statistical power [53]. The problem of confounding can be overcome by stratification, and this type of randomization may either involve stratification prior to random allocation to the study groups or after it. However, it has been emphasized that stratification without blocking is ineffective. Block randomization aims at equal distribution of participants in all the study groups by creating random blocks of sequences. Cluster randomization is preferred when the unit of randomization is a collective system, such as school students or sports athletes, rather than an individual. Trials testing an educational intervention or related to health promotion often utilize cluster randomization, as such designs are not able to avoid interaction between the participants of the control and intervention groups. Therefore, cluster randomization is helpful in reducing type II error. However, the limitation of cluster randomization is the requirement of a larger sample size, complex statistical analysis, risk of selection bias, and difficulties in concealment of allocation [54].

Trials require clearly defined hypotheses for designing the best methods of testing. It provides a structured framework and direction to the study, and allows direct comparison between the intervention and control [55]. Based on the type of hypothesis, RCTs can be classified as superiority, non-inferiority, and equivalence trials. Sample size calculation, data analysis, and interpretation of results are dependent on the hypothesis [56]. Sample size varies inversely with the "effect size" or the smallest quantitative, clinically important difference between the study groups. The superiority and non-inferiority trials (one-tailed) require a relatively small sample size compared to an equivalence trial that requires a two-tailed test. A non-inferiority trial requires an even smaller sample size than a superiority trial based on the expected effect size. Cost, time, and feasibility are some of the other factors that influence sample size calculation [56]. Attrition is associated with the loss of participants during the course of a study. It often occurs due to changes in personal circumstances, difficulty with study procedures, or the feeling that the study is not relevant to their needs [57]. It has a significant impact on the validity of the study results by introducing a selection bias and affecting their external validity or generalizability. It also makes the trial more expensive [57]. In trials with a high attrition rate, it is difficult to interpret the standard approach in clinical trials—the ITT analysis, where all the randomized participants are included in the analysis, regardless of their adherence to the study protocol. Another method of analysis is the per protocol analysis (PP), where the data from participants who strictly followed the study protocol and completed all treatment procedures are included in the analysis [58]. CONSORT considers ITT as the gold standard approach but recommends reporting of both ITT and PP analysis together to facilitate comparisons and identify potential effectiveness and limitations of the intervention [3]. ITT reflects real-world treatment effectiveness, while PP examines the treatment effect under ideal adherence conditions. The details about the analysis were mentioned in only 9 studies [26–29, 31, 33, 35, 37, 43].

Three studies included in this EM deserve special mention, especially in the context of, their robust methodology [28, 29, 31]. The study by Raza et al. was a double-blinded, non-inferiority trial that compared bulk-fill flowable composite with conventional packable composite for retention of wire composite splint in 90 patients with luxation injuries. Sample size estimation and ITT analysis were done. The trial was reported as per PRIRATE guidelines [28]. Similarly, the trial by Siddiqui et al. was a parallel two-arm equivalence trial on 100 teeth to compare the Putty Index Technique and the Custom Template Technique for direct composite restoration of uncomplicated crown fractures in permanent anterior teeth. It had both ITT and PP analysis and was reported as per CONSORT guidelines [29]. Meanwhile, Yang et al. [31] performed a parallel two-arm non-inferiority single-blind trial comparing two methods of pulp capping in vital traumatized immature permanent teeth and used both ITT and PP analyses. These research questions have greater feasibility for designing RCTs with clear objectives

and outcome variables, and may be the reason for the adoption of better design characteristics.

In addition to improvement in methodology and reporting of the conventional trials, the concept of pragmatic trials may be viewed as a suitable approach to overcome the barriers associated with other approaches in dental trauma research. Such trials are grounded in real-world scenarios that are feasible and ethical due to their broader patient selection criteria, flexibility in treatment procedures, and outcomes that are important for clinicians and patients.

5 | Conclusion

The study identified 30 RCTs in four domains of DT, with the highest in the therapeutic domain and subdomain of treatment protocols in permanent dentition, especially the splinting and management of avulsed teeth. Studies were published in 14 countries between 2001 and 2023. Protocol registration was done in 10 RCTs, while a reporting checklist was used in 10 RCTs. The majority of studies lacked methodological robustness in defining the hypothesis, sample size estimation, randomization, and statistical evaluation of outcomes. The clinical, pathophysiological, and ethical concerns limit the conduct of RCTs in dental traumatology, with pragmatic trials as a possible solution. The results of this study may help the DT researchers in addressing the methodological concerns and improving the quality of studies in the future.

Author Contributions

All the authors have substantially contributed to the manuscript. All the authors have read and approved the final version of the manuscript.

Acknowledgements

The authors have nothing to report.

Funding

The authors have nothing to report.

Disclosure

Permission to reproduce material from other sources: Not applicable.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data from the study is available in the form of tables and annexures (Data S3).

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** Details of Aim, secondary objective, inclusion and exclusion criteria, search strategy, and search results from different databases. **Data S2:** List of excluded studies. **Data S3:** edt70040-sup-0003-DataS3.docx.