Physical Treatments Reduce Pain in Children with Tension-Type Headache: A Systematic Review and Meta-Analysis

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Submitted Sepember 14, 2019; accepted February 26, 2020. ©2020 by Quintessence Publishing Co Inc. Aims: To assess the effectiveness of a variety of physical treatments in the management of tension-type headache (TTH) in children. Methods: This review is reported in accordance with the PRISMA guidelines and was registered in the PROSPERO database (CRD42014015290). Randomized and nonrandomized controlled trials that examined the effects of all treatments with a physical component in the management of TTH in children and compared these treatments to a placebo intervention, no intervention, or a controlled comparison intervention were included. The Physiotherapy Evidence Database (PEDro) criteria for bias assessment and the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group criteria were used to assess the guality of the body of evidence. The outcome measures were pain, functioning, and quality of life. Only RCTs were included in the meta-analyses. Results: An initial search produced 10,464 published articles. Of these, 17 were relevant trials, including 1,815 participants. The overall GRADE rating of the included studies was moderate, and 11 of the 17 studies could be used in the meta-analyses. The effectiveness of physical treatments in terms of a reduction of pain of 50% or more showed a risk ratio (RR) of 2.37 (95% CI: 1.69 to 3.33). Relaxation training was the most evaluated intervention and proved to be significantly effective (RR: 3.00 [95% CI: 1.94 to 4.63]). In children having TTH combined with temporomandibular disorders, occlusal appliances were effective (RR: 2.58 [95% CI: 1.37 to 4.85]). Conclusion: This review supports the use of physical treatments to reduce pain in children with TTH. J Oral Facial Pain Headache 2020;34:240-254. doi: 10.11607/ofph.2575

Keywords: child, headache, meta-analysis, myofascial, pain, systematic review, temporomandibular disorders, therapeutics, therapy, treatment

Tension-type headache (TTH) is the most common headache type and the second most common health complaint among children and adults.^{1,2} The prevalence of TTH varies depending on diagnostic criteria and age. The estimated 1-year prevalence of TTH among children and adolescents aged between 6 and 17 years is 37.9%.³ The prevalence rates are higher for girls and increase with age.⁴

TTH is essentially defined as a bilateral headache of a pressing or tightening quality without a known medical cause.⁵ TTH does not worsen with routine physical activity, but can negatively affect the ability to participate in various activities in school, sport, social, and home settings, especially when the headache becomes chronic and more frequent.^{3,5} TTH is classified according to its clinical presentation and symptoms, with both peripheral and central pain mechanisms most likely playing a role.⁵⁻⁷ Children with headache can be more sensitive to normal stimuli such as touch, heat, cold, smell, noise, or light. They are also less tolerable to pain signals and have lower pain thresholds, with increased pericranial tenderness as the most significant finding.⁵

Both pharmacologic and nonpharmacologic interventions are available for treatment of children with TTH. Psychologic and physical treatments are the main nonpharmacologic interventions. Two recent Cochrane reviews documented the effectiveness of psychologic interventions for the management of children and adolescents with chronic and recurrent pain, including headache.^{8,9} Cognitive behavioral treatment and relaxation especially were effective. As for physical treatments, most national and international treatment guidelines recommend some sort of physical treatment for headache, and most children currently receive physical treatment, though evidence for its effectiveness in children with headache is limited. Results of a systematic review and meta-analysis study among adults suggest that physical treatment seems beneficial for the reduction of most headache symptoms.¹⁰

When conducting this review, the authors aimed to assess the evidence for physical treatments in the management of TTH in children, as no such review exists. The objective of this systematic review and meta-analysis was to synthesize the outcomes, in terms of pain, functioning, and quality of life (QoL), of controlled trials (randomized [RCTs] and nonrandomized [CCTs]) that studied the effectiveness of physical treatments in the management of children with TTH.

Materials and Methods

This systematic review is reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines¹¹ and was registered in the PROSPERO (Prospective Register of Systematic Reviews) database (CRD42014015290).

Search Strategy

An electronic search in the PubMed, Embase, CINAHL, Web of Science, and Cochrane Library databases was conducted and completed on January 8, 2020. The PubMed search string can be found in Fig 1. An equivalent search was conducted in the other databases as well. Words and medical subject headings were identified with the assistance of a librarian who specialized in health science databases. The computerized search contained three aspects: TTH; children up to 18 years of age; and study design. The most sensitive search strategy was used, and all possible synonyms for the term "TTH" were included. Following the electronic search, citations were tracked and reference lists of

- 1 "Tension-Type Headache"[Mesh] OR contraction headache*[tiab] OR paediatric headache*[tiab] OR pediatric headache*[tiab] OR pressure headache*[tiab] OR Tension-Vascular Headache*[tiab] OR Psychogenic Headache*[tiab] OR Tension Headache*[tiab] OR Stress Headache*[tiab] OR Idiopathic Headache*[tiab] OR Tension Type Headache*[tiab]
- 2 ("Headache Disorders"[Mesh] OR "Headache"[Mesh] OR
 OR headache*[tiab] OR cephalalgia*[tiab] OR migraine*[tiab]) AND
 ("Temporomandibular Joint Disorders"[Mesh] OR "Craniomandibular Disorders"[Mesh] OR temporomandibular*[tiab] OR tmj[tiab] OR tmjs[tiab]
 OR craniomandibular*[tiab])
- 3 infant[MeSH] OR adolescent[MeSH] OR child[MeSH] OR preschool*[tw]
 AND OR puberty[tw] OR teenager*[tw] OR teens[tw] OR teen[tw] OR
 youth*[tw] OR girlhood[tw] OR girls[tw] OR girl[tw] OR boyhood[tw] OR
 boys[tw] OR boy[tw] OR paediatr*[tw] OR pediatri*[tw] OR adolescen*[tw]
 OR infan*[tw] OR schoolchild*[tw] OR child*[tw]
- 4 "Comparative Study"[pt] OR clinical trial[pt] OR randomized controlled AND trial[pt] OR controlled clinical trial[pt] OR random allocation[MeSH] OR clinical trials as topic[mesh:noexp] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Single-Blind Method"[Mesh] OR "Double-Blind Method"[Mesh] OR "Placebos"[Mesh] OR "Research Design"[Mesh] OR
 - "Evaluation Studies as Topic"[Mesh:noexp] OR "Cohort Studies"[Mesh] OR "Therapeutics"[Mesh] OR therapeutic use[sh] OR therapy[sh] OR management*[tiab] OR therap*[tiab] OR treatment*[tiab] OR Retrospective[tiab] OR Prospective[tiab] OR Follow-Up[tiab] OR Longitudinal stud*[tiab] OR Cohort[tiab] OR Single-Blind[tiab] OR Double-Blind[tiab] OR placebo*[tiab] OR random*[tiab] OR (clinical[tiab] AND trial[tiab]) OR groups[tiab]) NOT (animals[mh] NOT humans[mh])



Design

- Controlled trials (randomized and nonrandomized)
- Published in a peer-reviewed scientific journal

Participants

- Patients with a maximum age of 18 years or the study sample had a mean age of 17 years or younger
- Tension-type headache as classified by the International Headache Society with or without other headache types
- No previous surgery in the head or neck region
- No serious comorbid conditions (eg, fracture in head or neck region, cancer, neurologic disease)

Intervention

- All treatments with a physical component
- Not restricted to therapy delivered by physical therapists

Outcome measures

- Pain
- Functioning
- Quality of life

Comparisons

Physical treatment in one arm of the study and waiting list, placebo, or education in the other arm

Fig 2 Inclusion criteria.

publications were searched manually. New relevant articles found through this manual search were added to the systematic review.

Eligibility Criteria

Articles were selected independently by the two first reviewers (M.B. and A.W.) based on title and abstract using the criteria shown in Fig 2. If selection could not be decided from reading the abstract, the full paper was retrieved and reviewed. To be select-

ed, a paper had to meet all the inclusion criteria of this systematic review. If no consensus was reached, a third researcher (J.P.) was consulted. Cohen kappa statistics were applied to determine the level of agreement between the first two researchers on the inclusion of articles before consensus.

To be included, studies needed to be controlled trials (RCTs or CCTs) that examined the effect of physical treatment in the management of TTH in children and to compare one or more types of physical treatment to a placebo, waiting list, or patient education intervention.

Outcome Measures

The outcomes of interest for this systematic review were based on the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMMPACT) of 2008.¹²

This systematic review was open to all evaluation intervals (posttreatment and short-term to long-term follow-up).

When the outcome parameter could be dichotomized as a pre-post reduction of 50% or more on a pain index, this outcome (improved vs not improved) was considered suitable for pooling. In the case of continuous outcomes for pain, functioning, or QoL, a study was considered suitable for pooling if the precision of the difference between groups was reported (95% confidence interval [CI] of difference, standard error [SE] of difference, or difference and *P* value).

Data Extraction and Management

Relevant information from each included study was extracted and entered into a Microsoft Word file. Data on study characteristics were extracted, including the study design; number and type of participants; inclusion and exclusion criteria for participation; type of headache; intervention and comparison; outcome measures at posttreatment and/or follow-up; loss to follow-up; and dropouts. Any mention of adverse events was also recorded.

Methods for Assessment of Quality and Level of Evidence

The quality of the body of evidence was assessed using the criteria for levels of evidence as presented by the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) Working Group.¹³

The quality of evidence was initially considered high and then downgraded as a result of limitations due to risk of bias, inconsistency, indirectness, imprecision, or publication bias.

Risk of Bias. The PEDro (Physiotherapy Evidence Database) criteria¹⁴ were used to estimate the risk of bias. Two reviewers (M.B. and A.W) assessed the

methodologic quality of the included studies independently and discussed their findings with two additional reviewers (E.M.P. and E.B.). Cohen kappa statistics were applied to determine the level of agreement between the first two researchers for the PEDro criteria.

Individual studies were downgraded for risk of bias if one or more items of the PEDro criteria may have affected the study outcomes and biased the results.

In the case of pooled data, the level of evidence was downgraded when more than 25% of the sample came from studies with a risk of bias.

Inconsistency. The quality of evidence was downgraded when the l² value was more than 45%, which indicated that a study was very heterogenous.

Indirectness. Downgrading on this item was only applied if the relevant question was not directly answered by evidence.

Imprecision. Imprecision was downgraded only if there was no statistically significant difference and the analysis showed wide CIs, based on the convention of considering effect sizes of \geq 0.8 as large and > 1.2 as very large. This meant that one point was downgraded for a CI width of a standardized mean difference (SMD) of 1.6 or more, and two points for a CI width of 2.4 or more. If the upper and lower borders differ by more than a factor of 1.67, the GRADE handbook considers this as imprecise for a risk ratio (RR) (eg, an interval for the RR of 0.9 to 1.5 is borderline for downgrading, as 1.5/0.9 = 1.67). A definition for "very imprecise" is not given in the GRADE handbook, so this was chosen in parallel with the criteria for the SMD, and the ratio was set at 1.5 imes 1.67= 2.5 as the threshold for downgrading two points for precision. In case of multiple outcomes, the most precise outcome was chosen for the GRADE score of imprecision.

Publication Bias. In the case of multiple articles (more than five), possible publication bias was assessed using funnel plots.

Measures of Treatment Effect. All physical treatments were designated as treatment, and waiting list, placebo, and education control conditions were designated as control. The meta-analyses of the socalled "mixed" treatment comparisons were conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions. When a single study had multiple intervention groups, the intervention arms were separately compared to the control group(s) in individual analyses and simultaneously compared to the control group(s) in meta-analyses.

Pain, functioning, and QoL measures were identified and labeled for each included study when possible. Posttreatment assessments were reported up to 8 weeks after treatment when a headache diary was kept. Follow-up assessment points varied from 3 to 12 months posttreatment. In the case of multiple follow-up points, the point closest to 6 months after treatment was chosen.

Data Analysis

All studies were described separately in a GRADE table. Data analysis was performed according to type of intervention and type of outcome. For analysis of dichotomous outcome data, the RR with 95% CI was used to pool data. For analysis of continuous outcome data, the mean difference (MD) with 95% CI was used. When necessary, these statistics were derived from the data reported to allow the effects to be summarized. Authors were contacted if there were insufficient published data for analysis.

Review Manager (RevMan) version 5.3 software was used to summarize the effect measures (ie, pooled MD and RR values), construct forest plots for all comparisons, and construct funnel plots for pooled data.

Results

The computerized search was finalized on January 8, 2020, and resulted in the collection of 10,464 articles. Four more articles were found through a manual search. After duplicates were removed, 6,605 articles remained. After screening titles and abstracts, 54 articles were considered to be potentially relevant. Observer agreement for this selection was $\kappa = 0.87$, which, according to Byrt's criteria, is very good.¹⁵ After screening the full texts of these articles, 38 studies were excluded: 30 did not meet the inclusion criteria, 3 combined previous published data, 4 were found to be dissertation abstracts, and 1 did not present data from a comparison between groups. The remaining 16 articles were included in this systematic review (Fig 3).16-31 The studies included were not homogenous in presenting the data, and some studies presented their data without showing the differences between the intervention and control groups, leaving 11 articles suitable for meta-analysis.

Characteristics of Included Trials

A total of 1,732 participants, 1,189 (68%) girls and 543 (32%) boys, were involved in the included studies. The number of participants in the studies ranged from 26 to 900. Participants were recruited via advertisements at a school or hospital clinic. Physical treatments in the included studies consisted of relaxation training, biofeedback training, breathing techniques, mobilization and manipulation techniques,

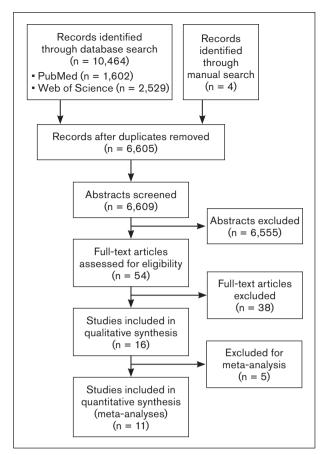


Fig 3 Flowchart of study selection protocol.

massage treatment, stretching techniques, exercise treatment, lifestyle education, occlusal appliances, and acupuncture.

The characteristics of the included studies are shown in Table 1.

Intervention Groups

The majority of included studies (n = 13) used relaxation treatment as the main intervention with or without other interventions, such as massage, stretching, biofeedback, and music therapy.^{16,18-20,22-28,30,31} Two of these 13 studies had two intervention arms: One compared relaxation treatment in one intervention arm to biofeedback in the other arm,²³ and the other compared relaxation treatment to occlusal appliances.³¹ One study used manual therapy¹⁷ and another used exercise treatment²⁹ as the main intervention. Finally, one study used acupuncture.²¹

Control Groups

Eleven studies^{16,19,20,23-28,30,31} included a waiting list or a nonintervention control group. Four studies used a sham treatment in a placebo-controlled design.^{17,18,21,22} One study included education on physical awareness and lifestyle.²⁹

Table 1 Characteristics of Included Studies (N = 16)

Study (y), type	Participant data: n (% F), recruitment	Age range (mean), y	Inclusion criteria	Exclusion criteria
Albers et al ¹⁶ (2015), RCT	900 (60), public grammar schools, 8 th –10 th grade	12–19	IHS criteria Migraine (20%), TTH (32%), migraine + TTH (17%), or other headache (31%)	Pre-intervention headache at T ₁
Borusiak et al ¹⁷ (2010), RCT	56 (60), neuropediatric clinic	7–15 (11.6)	IHS criteria Primary headache and cervicogenic headache Occurring ≥ 1 wk, duration ≥ 6 mo	Secondary headache, previous MT, current therapy
Bussone et al ¹⁸ (1998), RCT	35 (48.5), headache center	11–15	IHS criteria Occurring ≥ 1 wk	Pathology in medical examination, use of preventive medication
Fichtel and Larsson ¹⁹ (2001), RCT	36 (70), secondary schools + advertisements in newspaper	13–18 (15.4)	IHS criteria Frequent migraine or migraine + TTH Duration ≥ 6 mo, occurring ≥ twice/mo	Secondary headache
Fichtel and Larsson ²⁰ (2004), CCT	104 (96), 10 secondary schools (11 school nurses)	(15.6)	IHS criteria Headache diagnosis of TTH, migraine, or both	NR
Gottschling et al ²¹ (2008), RCT	48 (70), 2 medical centers	0–17 (12.3)	IHS criteria Migraine (50%) or TTH (50%) with duration ≥ 12 mo	< 8 TTH d/mo, use of analgesics, organic or mental disorder
Koenig et al ²² (2013), RCT	78 (74), newspaper advertisements	12–17	IHS criteria Migraine (41%), TTH (73%), both (14%) Frequency ≥ 5 d/mo	Psychiatric diagnosis, other headaches, psychotherapeutic treatment
Kröner-Herwig et al ²³ (1998), RCT	50 (60), general hospital	8–14	IHS criteria TTH (70%) or combined headaches (30%) ≥ 2 headache episodes during last mo	Somatic etiology
Larsson and Melin ²⁴ (1986), RCT	33 (94), recruited after an investigation of headache prevalence	16–18	Vahlquist criteria TTH (84%), migraine + TTH (16%) Occurring ≥ 1 wk, duration > 12 mo	NR
Larsson et al ²⁵ (1987), RCT	46 (87), 3 high schools	16–18	Vahlquist criteria Migraine (5%), TTH (71%), or TTH + migraine (24%) Duration ≥ 1 wk ≥ 1 y	Present treatment, somatic/psychologic diseases
Larsson et al ²⁶ (1987), RCT	36 (94), 3 high schools	16–18	Vahlquist criteria TTH (85%), migraine + TTH (15%) Duration ≥ 1 wk ≥ 1 y	Present treatment, somatic diseases
Larsson and Carlsson ²⁷ (1996), RCT	26 (96), 3 high schools	10–15	IHS criteria Chronic TTH Duration ≥ 1 wk ≥ 6 mo	No chronic TTH, presence of somatic disease
Larsson et al ²⁸ (1990), RCT-CO	48 (90), 4 high schools	16–18	IHS criteria TTH Duration ≥ 1 wk ≥ 1 y	Medication dose not stabilized, somatic/psychologic disease
Tornøe et al ²⁹ (2016), RCT	49 (100), headache clinic	9–18 (13.4)	IHS criteria TTH	Migraine ≥ 1 episode/mo, secondary headache, social or developmental disabil- ity, prophylactic medication

CALI = Child Activity Limitations Interview; CBT = cognitive behavioral treatment; CCT = controlled clinical trial; CDI = Children's Depression Inventory; FDI = Functional Disability Inventory (15 functional disability items, 5-point Likert scale, parent and child versions); H-diary = headache diary; IHS = International Headache Society; JIA = juvenile idiopathic arthritis; KIDSCREEN-27 = quality of life questionnaire for children and adolescents; KINDL-R = generic instrument for assessing health-related quality of life in children and adolescents; MT = manual therapy; NA = Not Applicable; NR = not reported; NRS = numeric rating scale; PCS-C = Pain Catastrophizing Scale for Children; PedMIDAS = Pediatric Migraine Disability Assessment; PedsQL= Pediatric Quality of Life Inventory; PI = pain index; RCT = randomized clinical trial; RCT-CO = RCT with a crossover design; RDC/TMD = Research Diagnostic Criteria for Temporomandibular Disorders; RT = relaxation training; SDQ = Strengths and Difficulties Questionnaire; SES = German pain perception scale; TTH = tension-type headache; WL = waiting list.

+ indicates improvement on this outcome; = indicates no effect on this outcome; - indicates worsening effect on this outcome.

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Intervention groups, no. of patients (dropouts)	Comparison groups, no. of patients (dropouts)	Outcome measures	Results available at posttreatment	Results available at follow-up (mo)
Prevention lesson (RT, CBT, exercise, lifestyle, and headache education), 450 (35)	WL: 450 (36)	Headache cessation	NA	Headache cessation: + (7)
MT: 28 (4)	Placebo MT: 28 (0)	H-diary, school absence	H-diary: = School absence: =	NA
RT + BF: 20 (2)	Placebo RT: 15 (1)	H-diary (PI)	NA	H-diary (PI): = (6, 12)
RT: 20	WL: 16	H-diary (PI)	H-diary (PI): +	NA (8, 12)
RT + self-help RT: 30 (0) RT: 33 (0)	Post hoc WL: 41 (0)	H-diary (PI)	H-diary (PI): =	NA (6)
Active acupuncture laser treatment: 24 (2)	Placebo laser treatment: 24 (3)	H-diary	NA	NA (4)
RT music therapy: 40 (6)	Attention placebo: 38 (1)	H-diary, SDQ, KIDSCREEN, SES	H-diary: = SDQ: NR KIDSCREEN: NR SES: NR	H-diary: = SDQ: NR KIDSCREEN: NR SES: NR (6)
RT: 20 (0-2) BF: 20 (0-2)	WL: 10 (0–2)	H-diary (PI)	H-diary (PI): =	NA (6)
RT + self-help: 11 (2) Education: 12 (3)	WL: 7	H-diary (PI)	H-diary (PI): =	H-diary (PI): = (6)
RT: 14 (2) Self-help RT: 16 (2)	WL: 11 (1)	H-diary (PI); anxiety, depression, and stress; school absence	H-diary (PI): = Anxiety, depression, and stress: NR School absence: NR	H-diary (PI): +, RT Anxiety, depression, and stress: NR School absence: NR (5)
Self-help RT: 12 (0) CBT: 10 (0)	WL: 12 (2)	H-diary (PI); anxiety, depression, and stress; school absence	H-diary (PI): + (better results on self-help RT) Anxiety, depression, and stress: NR School absence: NR	H-diary (PI): + (better results, self-help RT) Anxiety, depression, and stress: NR School absence: NR (6)
RT: 13 (0–2)	WL: 13 (0-2)	H-diary (PI)	H-diary (PI): +	NA (6)
Self-help RT: 31 (NR) Chlormezanone 200 mg twice/d: 46 (5)	WL: 46 (NR) 3-wk washout period: 17 (NR)	H-diary (PI); anxiety, depression, and stress; school absence	H-diary (PI): + (better results on RT) Anxiety, depression, and stress: – (for medication) School absence: NR	NA (5)
Education + self-help strength training: 24 (4)	Education: 25 (6)	H-diary (PI), PedsQL, PedMIDAS	H-diary (PI): = PedsQL: NR PedMIDAS: NR	NA (3)

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Table 1 Characteristics of Included Studies (N = 16) (continued)

Study (y), type	Participant data: n (% F), recruitment	Age range (mean), y	Inclusion criteria	Exclusion criteria
Trautmann and Kröner-Herwig ³⁰ (2010), RCT	65 (55), recruited through several sources (websites and newsletters)	10–18 (12.7)	IHS criteria Migraine (60%), TTH (28%), or both (12%) Duration ≥ 2 mo Personal internet	Prophylactic medication or psychotherapeutic treatment
Wahlund et al ³¹ (2003), RCT	122 (76), TMD clinic	12–18 (15.3)	TMD diagnosis (RDC/TMD) for ≥ 3 mo ≥ 1 pain attack/wk IHS criteria if TMD was combined with headache TTH (91%)	JIA, migraine, current orthodontics

CALI = Child Activity Limitations Interview; CBT = cognitive behavioral treatment; CCT = controlled clinical trial; CDI = Children's Depression Inventory; FDI = Functional Disability Inventory (15 functional disability items, 5-point Likert scale, parent and child versions); H-diary = headache diary; IHS = International Headache Society; JIA = juvenile idiopathic arthritis; KIDSCREEN-27 = quality of life questionnaire for children and adolescents; KINDL-R = generic instrument for assessing health-related quality of life in children and adolescents; MT = manual therapy; NA = Not Applicable; NR = not reported; NRS = numeric rating scale; PCS-C = Pain Catastrophizing Scale for Children; PedMIDAS = Pediatric Migraine Disability Assessment; PedsQL= Pediatric Quality of Life Inventory; PI = pain index; RCT = randomized clinical trial; RCT-CO = RCT with a crossover design; RDC/TMD = Research Diagnostic Criteria for Temporomandibular Disorders; RT = relaxation training; SDQ = Strengths and Difficulties Questionnaire; SES = German pain perception scale; TTH = tension-type headache; WL = waiting list.

+ indicates improvement on this outcome; = indicates no effect on this outcome; - indicates worsening effect on this outcome.

Table 2 PEDro Scores (Risk of Bias) of the Included Studies

Study	Eligibility criteria specified?	Random allocation?	Concealment of allocation?	Group comparability?	Blinding patient?	Blinding care provider?	Blinding outcome assessors?	Measures of 85% or more of allocated subjects?	Intention-to-treat analyses?	Between-group statistical comparisons?	Point measures and measures of variability presented?	GRADE: Risk of bias
									•	•		Not serious/
	1	2	3	4	5	6	7	8	9	10	11	serious/ very serious
Albers et al ¹⁶	+	+	_	+	_	_	_	_	+	+	+	Very serious
Borusiak et al ¹⁷	+	+	+	+	+	-	-	+	+	+	+	Not serious
Bussone et al ¹⁸	+	+	-	+	+	-	-	-	+	+	+	Very serious
Fichtel and Larsson ¹⁹	+	+	+	+	-	-	-	+	+	+	+	Not serious
Fichtel and Larsson ²⁰	+	-	-	+	-	-	-	+	+	+	+	Serious
Gottschling et al ²¹	+	+	+	+	+	+	+	+	+	+	+	Not serious
Koenig et al ²²	+	+	+	+	+	-	+	+	+	+	+	Not serious
Kröner-Herwig et al ²³	+	+	-	+	-	-	-	+	+	+	+	Not serious
Larsson and Melin ²⁴	+	+	+	+	-	-	-	+	+	+	+	Not serious
Larsson et al ²⁵	+	+	+	+	-	-	-	+	+	+	+	Not serious
Larsson et al ²⁶	+	+	+	+	-	-	-	+	+	+	+	Not serious
Larsson and Carlsson ²⁷	+	+	-	+	-	-	-	+	+	+	+	Not serious
Larsson et al ²⁸	+	+	+	+	-	-	-	+	+	+	+	Serious
Tornøe et al ²⁹	+	+	+	+	-	-	-	-	+	+	+	Serious
Trautmann and Kröner-Herwig ³⁰	+	+	+	+	-	-	+	+	+	+	+	Not serious
Wahlund et al ³¹	+	+	+	+	-	-	+	+	+	+	+	Not serious
κ coefficient	1.00	0.43	0.46	0.12	0.56	0	0.46	0.52	0.31	0	0.18	Total κ: 0.52 (moderate agreement)

+ = meets the criterion; - = does not meet the criterion.

Intervention groups, no. of patients (dropouts)	Comparison groups, no. of patients (dropouts)	Outcome measures	Results available at posttreatment	Results available at follow-up (mo)
Internet-delivered RT, exercises: 24 (0–14) RT: 22 (0–14)	WL (education): 19 (0–14)	H-diary (PI), PCS-C, CDI, SDQ, KINDL-R	H-diary: = PCS-C: NR CDI: NR SDQ: NR KINDL-R: =	NA (6)
Occlusal appliance: 42 (5) RT + self-help: 41 (7)	WL (education): 39 (0)	Pain diary (PI), clinical examination (RDC/TMD), bruxism, school absence, use of medication	Pain diary (PI): + for occlusal appliance and + for RT Clinical examination (RDC/TMD): NR Bruxism: NR School absence: NR Use of medication: NR	NA (6)

Methodologic Quality

The quality of the methodology of the studies was assessed with the GRADE assessment criteria. The risk of bias of the included studies was assessed on the PEDro scale, and the results are presented in Table 2. As not all studies included in the review were present in the PEDro database, all included studies were scored. The interobserver reliability between the two reviewers was moderate ($\kappa = 0.52$) according to Byrt's criteria.¹⁵ After the consensus meeting, no disagreement persisted.

The overall quality of evidence for the individual studies is presented in the GRADE evidence profiles in Table 3. Downgrading for item inconsistency and publication bias was not applied because these issues were not applicable to individual studies. The overall rating of the evidence was moderate, and the individual ratings of the studies ranged from very low to high. The most problematic areas in terms of quality of evidence were mainly related to imprecision, with risk of bias in second place.

Effectiveness of Physical Treatments

Pain index, intensity, frequency, and duration were the only outcome measures that allowed for data pooling.

Effectiveness of Physical Treatments at Posttreatment

Eleven of the 16 studies compared physical treatments to a waiting list or placebo control group in terms of pain index at posttreatment.^{19,22–31} In the pooled analysis of these 11 studies, physical treatments were associated with a significantly higher percentage of successful results posttreatment: (RR: 2.37 [1.69 to 3.33]; number needed to treat [NNT]: 4.2). The pooled analysis is reported in Table 4, and the forest plot in Fig 4.

Results for the continuous outcomes headache intensity, frequency, and duration could be used for meta-analysis in the case of two studies.^{17,30} The results were not significant for intensity (MD = 0.20 [-0.55 to 0.95]), frequency (MD = -0.65 [-9.73 to 8.43]), or duration (MD = 0.25 [-4.13 to 4.63]).

Effectiveness of Physical Treatments at Follow-up

Three of the 16 studies compared physical treatments to a waiting list or placebo control group in terms of pain index at follow-up.^{22,24,25} In the pooled analysis, the results were no longer significant (RR = 1.38 [0.78 to 2.43]). The pooled analysis is shown in Table 5, and the forest plot in Fig 5.

Results for the continuous outcomes headache intensity, frequency, and duration could be used for meta-analysis at follow-up in the case of all three of these studies.^{22,24,25} Physical treatments were associated with a significantly higher percentage of successful results in these analyses for the outcomes reduction in headache frequency (MD = 2.26 [1.70 to 2.82]) and reduction in headache duration (MD = 0.55 [0.22 to 0.89]). The results were not significant for the outcome reduction in headache intensity (MD = 0.42 [-0.20 to 1.04]). The pooled analyses consisted of only relaxation treatment vs control, as shown in the forest plot in Fig 6.

Table 3 GRADE Evidence	Profiles	of the Ir	ncluded \$	Studies		
Quality assessment				Sumn	nary of finding	S
No. of participants included in analysis Posttreatment/follow-up Outcome measure	Risk of bias	Indirect- ness	Impreci- sion	Overall quality of evidence	Number needed to treat (benefit)	Posttreatment/follow-up measure (95% CI); P in absence of effect size; MD [interval size]
Albers et al ¹⁶ (2015): RCT, relaxati	on training	g vs waitin	g list			
900 Follow-up: 7 mo Headache cessation (reduction of 100% on pain index)	Very seriousª	Not serious	Not serious	⊕⊕⊖⊖ (low)	16	Follow-up OR: 1.77 (1.08 to 2.90)
Borusiak et al ¹⁷ (2010): RCT, manu	ual therapy	/ vs placeb	00			
52 Posttreatment Headache diary 2 mo 1. Intensity: 0–10 NRS (n = 39) 2. Frequency: % d (n = 52) 3. Duration: h/2 mo (n = 37) % d missed at school (n = 51)	Not serious	Not serious	Not serious	⊕⊕⊕⊕ (high)	NA	1. MD: 0.20 (-0.55 to 0.95) [1.28] 2. MD: 0.30 (-10.02 to 10.62) [1.09] 3. MD: 0.90 (-15.33 to 17.13) [1.29] MD: -2.20 (-6.19 to 1.79) [1.11]
Bussone et al ¹⁸ (1998): RCT, relax	ation train	ina + biofe	edback v	s placebo re	elaxation traini	, , , , , ,
30 Follow-up: 6 and 12 mo Headache diary 1 mo (pain index)	Serious ^b	Not serious	Very serious ^c	⊕⊖⊖⊖ (very low)	NA	Statistically significant differences at 6 mo ($P = .01$) and 12 mo ($P = .02$)
Fichtel and Larsson ¹⁹ (2001): RCT,	relaxation	n training v	s waiting l	ist		
36 Posttreatment Headache diary 1 mo (pain index)	Not serious	Not serious	Not serious	⊕⊕⊕⊕ (high)	2.6	RR: 4.00 (1.02 to 15.72)
Fichtel and Larsson ²⁰ (2004): CCT	, relaxatio	n training	vs post ho	c untreated	l participants	
104 Posttreatment Headache diary 1 mo (pain index)	Serious ^d	Not serious	Very serious ^e	⊕○○○ (very low)	8.3	RR: 2.60 (0.78 to 8.66)
Gottschling et al ²¹ 2008: RCT, acu	puncture	vs placebo)			
43 Posttreatment and follow-up: 3–4 mo Headache diary 1 mo 1. Intensity: 10-cm VAS 2. Frequency: d 3. Duration: d	Not serious	Not serious	Very serious ^c	⊕⊕⊖⊖ (low)	NA	The mean number of headaches per mo decreased significantly by 6.4 d in the treated group ($P < .001$) and by 1.0 d in the placebo group ($P = .22$). Headache severity and monthly hours with headache decreased significantly at all time points compared to baseline ($P < .001$) and were significantly lower than those of the placebo group at all time points ($P < .001$).
Koenig et al ²² (2013): RCT, music	relaxation	treatment	vs placeb	0		
71 Posttreatment and follow-up: 6 mo Headache diary 2 mo (pain index)	Not serious	Not serious	Very serious ^e	⊕⊕⊕⊖ (moderate)	1. NA	1. Posttreatment RR not estimable 1. Follow-up RR: 0.32 (0.01 to 7.55)
1. Intensity: 0–10 NRŠ 2. Frequency: d					 Posttreat- ment: 50 Follow-up: NA 	2. Posttreatment RR: 1.11 (0.41 to 3.00) 2. Follow-up RR: 0.68 (0.34 to 1.34)

CCT = controlled clinical trial; CI = confidence interval; KINDL-R = generic instrument for assessing health-related quality of life in children and adolescents; MD = mean difference; NA = not applicable; NRS = numeric rating scale; OR = odds ratio; RCT = randomized controlled trial; RR = risk ratio; VAS = visual analog scale.

^aConcealment of allocation is, in the present authors' opinion, a crucial limitation of this study. In addition, this study had 35% to 36% loss to follow-up. ^bAlthough this study had 33.33% loss to follow-up in the control group, the study precsely complied with the 2:1 ratio on allocated subjects as intended, and 85% or more of subjects allocated was accomplished overall. Therefore, the criterion was met.

^cThis study was downgraded by two points as a result of imprecision because the presented data could not be analyzed and used in RevMan 5.3. ^dThis study is a CCT with a post hoc waiting list group consisting of randomly selected participants from a waiting list group of a previous RCT with the same eligibility criteria.

^eThis study was downgraded by two points as a result of imprecision because all analyses had very wide CI (a factor of 2.5 or more between the upper and lower limits).

^fFailure to blind the outcome assessor is, in the present authors' opinion, a serious limitation of this study, and therefore the risk of bias was downgraded. ^gThe criterion measure of 85% or more of subjects allocated has not been accomplished.

^hThis study was downgraded for imprecision because all analyses had wide CI (a difference of 1.6 or more between the upper and lower limits). ⁱParticipants were TMD patients, 91% of which had tension-type headache.

Table 3 GRADE Evidence Profiles of the Included Studies (continued)

Quality assessment				Sumn	nary of finding	S
No. of participants included in analysis Posttreatment/follow-up Outcome measure	Risk of bias	Indirect- ness	Impreci- sion	Overall quality of evidence	Number needed to treat (benefit)	Posttreatment/follow-up measure (95% CI); P in absence of effect size; MD [interval size]
Kröner-Herwig et al ²³ (1998): RCT	, relaxatio	n treatmer	nt vs biofee	dback vs v	vaiting list	
43 Posttreatment Headache diary 1 mo (pain index) Relaxation training vs waiting list: 1. Intensity: 0–10 NRS (n = 23) 2. Frequency: d/mo (n = 26) 3. Duration: h (n = 28)	Not serious	Not serious	Very serious ^e	⊕⊕⊖⊖ (low)	1. 4.3 2. 9.1 3. 4.8	1. RR: 1.47 (0.69 to 3.13) 2. RR: 1.22 (0.56 to 2.68) 3. RR: 1.53 (0.66 to 3.55)
Biofeedback vs waiting list: 1. Intensity: 0–10 NRS (n = 25) 2. Frequency: d/mo (n = 24) 3. Duration: h (n = 25)					1. 2.3 2. 2.6 3. 2.1	1. RR: 1.88 (0.93 to 3.80) 2. RR: 1.75 (0.85 to 3.59) 3. RR: 2.17 (0.99 to 4.75)
Larsson and Melin ²⁴ (1986): RCT, r	elaxation	vs waiting	list			
18 Posttreatment and follow-up: 6 mo Headache diary 3 wk, pain index Headache: 1. Intensity: 0–6 NRS 2. Frequency: d/wk 3. Duration: h	Not serious	Not serious	Not serious	⊕⊕⊕⊕ (high)	Posttreat- ment: 1.2 Follow-up: 3.8	Posttreatment RR: 1 2.67 (0.85 to 188.37) Follow-up RR: 1.91 (0.53 to 6.93) 1. Follow-up MD: -0.10 (-0.96 to 0.76) [1.90] 2. Follow-up MD: 2.80 (0.81 to 4.79) [2.11] 3. Follow-up MD: 0.30 (-0.36 to 0.96) [1.91]
Larsson et al ²⁵ (1987): RCT, relaxa	tion treat	ment vs se	lf-help rela	axation trea	itment vs waiti	· · · · · ·
41 Posttreatment and follow-up: 5 mo Headache diary 1 wk (pain index) Relaxation vs waiting list: Pain index (n = 25) 1. Intensity: 0–6 NRS 2. Frequency: d/wk 3. Duration: h	Not serious	Not serious	Not serious	⊕⊕⊕⊕ (high)	Posttreat- ment: 2.4 Follow-up: 1.6	Posttreatment RR: 5.50 (0.79 to 38.30) Follow-up RR: 15.20 (0.98 to 235.55) 1. Follow-up MD: 0.20 (-5.10 to 5.50) [1.58] 2. Follow-up MD: 2.60 (1.57 to 3.63) [1.90] 3. Follow-up MD: 0.40 (-0.00 to 0.80) [1.65]
Self-help relaxation vs waiting list: Pain index (n = 27)	Not serious	Not serious	Very serious ^e	⊕⊕⊖⊖ (low)	Posttreat- ment: 3.6 Follow-up: 2.0	Posttreatment RR: 4.13 (0.57 to 29.67) Follow-up RR: 12.00 (0.76 to 188.61)
Larsson et al ²⁶ (1987): RCT, self-h	elp relaxa	tion treatm	nent vs wai	ting list		
24 Posttreatment and follow-up: 6 mo Headache diary 1 wk (pain index) Headache: 1. Intensity: 0–6 NRS 2. Frequency: d/wk 3. Duration: h	Not serious	Not serious	Not serious	⊕⊕⊕ (high)	Posttreat- ment: 2.4	Posttreatment RR: 6.00 (0.85 to 42.59) 1. Follow-up MD: 1.00 (0.09 to 1.91) [1.68] 2. Follow-up MD: 1.50 (-0.25 to 3.25) [1.65] 3. Follow-up MD: 0.70 (0.08 to 1.32) [1.69]

CCT = controlled clinical trial; CI = confidence interval; KINDL-R = generic instrument for assessing health-related quality of life in children and adolescents; MD = mean difference; NA = not applicable; NRS = numeric rating scale; OR = odds ratio; RCT = randomized controlled trial; RR = risk ratio; VAS = visual analog scale.

^aConcealment of allocation is, in the present authors' opinion, a crucial limitation of this study. In addition, this study had 35% to 36% loss to follow-up. ^bAlthough this study had 33.33% loss to follow-up in the control group, the study precsely complied with the 2:1 ratio on allocated subjects as intended, and 85% or more of subjects allocated was accomplished overall. Therefore, the criterion was met.

^cThis study was downgraded by two points as a result of imprecision because the presented data could not be analyzed and used in RevMan 5.3. ^dThis study is a CCT with a post hoc waiting list group consisting of randomly selected participants from a waiting list group of a previous RCT with the same eligibility criteria.

^eThis study was downgraded by two points as a result of imprecision because all analyses had very wide CI (a factor of 2.5 or more between the upper and lower limits).

¹Failure to blind the outcome assessor is, in the present authors' opinion, a serious limitation of this study, and therefore the risk of bias was downgraded. ⁹The criterion measure of 85% or more of subjects allocated has not been accomplished.

^hThis study was downgraded for imprecision because all analyses had wide CI (a difference of 1.6 or more between the upper and lower limits). Participants were TMD patients, 91% of which had tension-type headache.

Table 3 GRADE Evidence Profiles of the Included Studies (continued)

Quality assessment				Sumn	nary of findings	
No. of participants included in analysis Posttreatment/follow-up Outcome measure	Risk of bias	Indirect- ness	Impreci- sion	Overall quality of evidence	Number needed to treat (benefit)	Posttreatment/follow-up measure (95% Cl); <i>P</i> in absence of effect size; MD [interval size]
Larsson and Carlsson ²⁷ (1996): R	CT, relaxat	ion techni	que vs wai	ting list		
26 Posttreatment Headache diary 3 wk (pain index)	Not serious	Not serious	Not serious	⊕⊕⊕⊕ (high)	1.6	RR: 9.00 (1.32 to 61.24)
Larsson et al ²⁸ (1990): RCT, self-h	elp relaxa	tion techn	ique vs wa	iting list		
48 Posttreatment Headache diary 3 wk (pain index)	Serious ^f	Not serious	Very serious ^e	⊕○○○ (very low)	5.3	RR: 7.31 (0.44 to 122.42)
Tornøe et al ²⁹ (2016): RCT, educa	tion + SHF	RT vs educ	ation			
39 Posttreatment Headache diary, 1 mo (pain index)	Serious ^g	Not serious	Very serious ^e	⊕○○○ (very low)	NA	RR: 0.63 (0.21 to 1.90)
Trautmann and Kröner-Herwig ³⁰	(2010): RC	T, RT vs W	L			
32 Posttreatment Headache diary 1 mo: 1. Intensity: 0–10 NRS 2. Frequency: d/mo 3. Duration: h	Not serious	Not serious	Serious ^h	⊕⊕⊕⊖ (moderate)	NA	1. MD: -0.30 (-1.57 to 0.97) [1.43] 2. MD: -1.10 (-6.44 to 4.24) [1.30] 3. MD: 0.20 (-4.35 to 4.75) [1.37]
KINDL-R (quality of life)						MD: 0.10 (-0.22 to 0.42) [1.30]
Wahlund et al ³¹ (2003): RCT, occl	usal applia	nce vs rela	axation tre	atment vs v	vaiting list	
110 Posttreatment Headache diary 2 wk (pain index) Occlusal appliance vs waiting list: (n = 76)	Not serious	Serious ⁱ	Not serious	⊕⊕⊕⊖ (moderate)	2.8	RR: 2.58 (1.37 to 4.85)
Relaxation training vs waiting list: ($n = 73$)	Not serious	Serious ⁱ	Very serious ^e	⊕⊕⊖⊖ (low)	11.1	RR: 1.40 (0.66 to 2.97)

CCT = controlled clinical trial; CI = confidence interval; KINDL-R = generic instrument for assessing health-related quality of life in children and adolescents; MD = mean difference; NA = not applicable; NRS = numeric rating scale; OR = odds ratio; RCT = randomized controlled trial; RR = risk ratio; VAS = visual analog scale.

^aConcealment of allocation is, in the present authors' opinion, a crucial limitation of this study. In addition, this study had 35% to 36% loss to follow-up. ^bAlthough this study had 33.33% loss to follow-up in the control group, the study precsely complied with the 2:1 ratio on allocated subjects as intended, and 85% or more of subjects allocated was accomplished overall. Therefore, the criterion was met.

^cThis study was downgraded by two points as a result of imprecision because the presented data could not be analyzed and used in RevMan 5.3. ^dThis study is a CCT with a post hoc waiting list group consisting of randomly selected participants from a waiting list group of a previous RCT with the same eligibility criteria.

"This study was downgraded by two points as a result of imprecision because all analyses had very wide CI (a factor of 2.5 or more between the upper and lower limits).

¹Failure to blind the outcome assessor is, in the present authors' opinion, a serious limitation of this study, and therefore the risk of bias was downgraded. ⁹The criterion measure of 85% or more of subjects allocated has not been accomplished.

^hThis study was downgraded for imprecision because all analyses had wide CI (a difference of 1.6 or more between the upper and lower limits).

Participants were TMD patients, 91% of which had tension-type headache.

Effectiveness of Relaxation Treatments

Ultimately, 9 of the 11 studies in this meta-analysis used relaxation treatment as one of the main interventions,^{19,23–28,30,31} of which 2 studies showed statistically significant effects without pooling.^{19,28} The quality of evidence of the study showing the results of therapist-assisted relaxation training was high¹⁹; the other study reporting the effectiveness of a selfhelp relaxation training program²⁸ was of very low quality of evidence.

The pooled data of the nine studies concerning relaxation treatment showed positive effects (RR: 3.00 [1.94 to 4.63]; NNT: 3.3). Six of the nine studies on relaxation training recruited their participants from secondary schools (RR: 6.23 [2.82 to 13.76]; NNT = 2.4).^{19,24-28}

Effectiveness of Occlusal Appliances

When TTH was combined with temporomandibular disorders (TMD), occlusal appliances were shown to be effective in relieving pain compared to a waiting list control group (RR: 2.58 [1.37 to 4.85]; NNT: 2.831).³¹ This improvement was well maintained at the 6-month follow-up evaluation. Patients in this study, of which 91% had TTH, were recruited from a specialized TMD clinic. Occlusal appliances were found to be superior to both relaxation treatment and to brief information regarding pain reduction.

Table 4 GRADE Evidence Table for Physical Treatment vs Control (Waiting List of Placebo) in Terms of Pain Index at Posttreatment

Quality assessment	Summary of findings											
No. of studies No. of participants included in analysis Outcome measure	Risk of bias	Inconsis- tency	Indirect- ness	Impreci- sion	Publica- tion bias	Overall quality of evidence	Number needed to treat (benefit) (NNTB)	Posttreatment (95% Cl)				
11 495 Pain index	Not serious	Not serious	Not serious	Not serious	Seriousª	⊕⊕⊕⊖ (moderate)	4.2	RR: 2.37 (1.69 to 3.33)				

CI = confidence interval; RR = risk ratio.

^aOne point on the publication bias item was downgraded based on the funnel plot.

	Interve	ntion	Cont	trol	Weight	RR	MD (95% CI)
Study or subgroup	Events	Total	Events	Total	(%)	M-H Fixed, 95% CI	IV, Fixed
Fichtel and Larsson ¹⁹	10	20	2	16	5.6	4.00 (1.02, 15.72)	
Koenig et al ²²	7	40	6	38	15.6	1.11 (0.41, 3.00)	_
Kröner-Herwig et al ²³	27	32	4	8	16.2	1.69 (0.83, 3.43)	+ -
Larsson and Melin ²⁴	9	11	0	7	1.5	12.67 (0.85, 188.37)	
Larsson et al ²⁵	13	30	1	11	3.7	4.77 (0.70, 32.29)	
Larsson et al ²⁶	6	12	1	12	2.5	6.00 (0.85, 42.59)	
Larsson and Carlsson ²⁷	9	13	1	13	2.5	9.00 (1.32, 61.24)	
Larsson et al ²⁸	6	31	0	17	1.6	7.31 (0.44, 122.42)	
Tornøe et al ²⁹	4	20	6	19	15.6	0.63 (0.21, 1.90)	e
Trautmann and Kröner-Herwig ³⁰	6	19	2	16	5.5	2.53 (0.59, 10.83)	
Wahlund et al ³¹	33	71	9	39	29.5	2.01 (1.08, 3.76)	
Total		299		196	100.0	2.37 (1.69, 3.33)	•
Total events	130		32				
Heterogeneity: $\chi^2 = 14.84$, df = 10 Test for overall effect: $z = 4.99$ (P	P = .14), ² =	33%			0.01 0.	1 1 10 100
$\frac{1}{2}$	< .0001)					Favors	control Favors intervention

Fig 4 Effect size of physical treatment vs control in terms of pain index at posttreatment. RR = risk ratio; M-H = Mantel-Haenszel; fixed = fixed-effects model; CI = confidence interval; df = degrees of freedom.

Effectiveness of Exercise Treatments

One study on strength training vs education of lifestyle changes and physical awareness was included. Both education and the strength training program for a period of 10 weeks had a significant effect on headache frequency and duration, with no significant between-group differences. The 2-year follow-up on health-related QoL questionnaires revealed consistent improvements over time.²⁹

Effectiveness of Music Treatments

There was one study that concerned music treatment. Music treatment was not superior to an attention placebo.²²

Effectiveness of Manual Therapy

One study with a high quality of evidence compared manipulation techniques to placebo. The sham treatment in the placebo group consisted of a light touch of specific spinal segments so that the placebo treatment was identical to the active treatment except for the low amplitude, high-velocity thrust, giving the impression of a cervical manipulation that was not directed to correct the assumed cervical blockage. No significant difference between groups was reported.¹⁷

Effectiveness of Acupuncture

One study with a low quality of evidence compared laser acupuncture to placebo. Headache frequency, intensity, and duration decreased at all time points compared to baseline, and all were lower for the intervention group.²¹

Adverse Events

Only one study reported adverse events, all minor: Dizziness, hot skin, and increased headache frequency and intensity for up to 4 days were reported

Table 5 GRADE Evidence Table for Physical Treatment vs Control (Waiting List or Placebo) in Terms of Pain Index at Follow-up

Quality assessment	Summary of findings										
No. of studies No. of participants included in analysis Outcome measure	Risk of bias	Inconsis- tency	Indirect- ness	Impreci- sion	Publica- tion bias	Overall quality of evidence	Number needed to treat (benefit)	Follow-up effect (95% Cl)			
3 137 Pain index	Not serious	Very serious ^a	Not serious	Very serious ^b	Not applicable	⊕⊖⊖⊖ (very low)	9.1	RR: 1.38 (0.78 to 2.43)			

CI = confidence interval; RR = risk ratio.

^aTwo points were downgraded due to inconsistency in results among studies.

^bTwo points were downgraded as a result of imprecision because all analyses had very wide CI (a factor of 2.5 or more between upper and lower limits).

	Interve	ntion	Cont	trol	Weight	RR	MD (95% CI)
Study or subgroup	Events	Total	Events	Total	(%)	M-H Fixed, 95% CI	IV, Fixed
Koenig et al ²²	10	40	14	38	81.9	0.68 (0.34, 1.34)	
Larsson and Melin ²⁴	6	11	2	7	13.9	1.91 (0.53, 6.93)	
Larsson et al ²⁵	17	30	0	11	4.1	13.55 (0.88, 207.94)	
Total		81		56	100.0	1.38 (0.78, 2.43)	•
Total events	33		16				
Heterogeneity: $\chi^2 = 7.12$, df = 2 (<i>F</i> Test for overall effect: $z = 1.11$ (<i>F</i>	P = .03), I = .27)	² = 72	%			0.01 0.1 Favors control	1 10 100 Favors intervention

Fig 5 Effect size of physical treatment vs control in terms of pain index at follow-up. RR = risk ratio; M-H = Mantel-Haenszel; fixed = fixed-effects model; CI = confidence interval; df = degrees of freedom.

D) Total 11 30 12 53 P = .23); I ² = .18)	0.4 (0.82) 0.5 (8.73) 0.2 (0.82)	7 11 12	Weight (%) 9.2 0.3 8.2	t MD (95% Cl) IV, Fixed -0.10 (-0.96, 0.76) 0.45 (-4.71, 5.61)		MD (95% CI) IV, Fixed
5) 30 12 53 P = .23); 1 ²	0.5 (8.73) 0.2 (0.82)	11 12	0.3	. , ,		
5) 30 12 53 P = .23); 1 ²	0.5 (8.73) 0.2 (0.82)	11 12	0.3	. , ,		
12 53 P = .23); l ²	0.2 (0.82)	12		0.45 (-4.71, 5.61)-		
53 P = .23); I ²	- (/		0.0			
^D = .23); I ²	2 - 2206	00	8.2	1.00 (0.09, 1.91)		
^D = .23); l ⁱ = .18)	2 _ 220%	30	17.7	0.42 (-0.20, 1.04)		◆
	- = 33%					
11	0.6 (2)	7	1.7	2.80 (0.81, 4.79)		
) 30	0.2 (0.52)	11	17.8	2.30 (1.68, 2.92)		
12	0.9 (0.61)	12	2.2	1.50 (-0.25, 3.25)	-	
53		30	21.8	2.26 (1.70, 2.82)		\bullet
□ = .60); l ⁱ = .001)	² = 0%					
6) 11	0	7	15.6	0.30 (-0.36, 0.96)	-	┼╍──
30	-0.2 (0.52)	11	27.2	0.60 (0.10, 1.10)		
12	0.2 (0.61)	12	17.7	0.70 (0.08, 1.32)		
53		30	60.6	0.55 (0.22, 0.89)		
	² = 0%					
				-4	_2	0 2
						Favors intervention
ł	6) 11 30 12 53	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$

Fig 6 Effect size of physical treatment vs control in terms of pain intensity, frequency, and duration at follow-up. IV = inverse variance; fixed = fixed-effects model; CI = confidence interval; df = degrees of freedom.

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as side effects in 8 out of 28 patients in the treatment group and 6 out of 28 patients in the sham intervention group. All patients recovered spontaneously with no reported sequelae.¹⁷

As adverse events were not a registered outcome in the other included articles, underreporting of adverse events is likely.

Discussion

The present study is the first systematic review with meta-analyses on the effectiveness of a variety of physical treatments in the management of TTH in children. For this reason, the present authors consider this review a useful addition to previously reported reviews^{8,9,32} on psychologic and pharmacologic treatments in the management of TTH in children. Physical therapists aim to reduce disability, restore functioning, and improve activity and participation levels in headache conditions.

Strengths and Limitations

A strength of this review is that it conformed to the PRISMA guidelines.¹¹ Other strengths of the review include the use of a sensitive search strategy and two independent reviewers for qualitative and quantitative analyses. The GRADE system was adapted, taking size and precision of estimates into account. The PEDro scale was used for the risk of bias analyses above others because this scale was constructed for rating intervention studies with physical treatments. All studies were reported separately, and, when possible, the data were pooled together in a meta-analysis.

A limitation of this review is that 5 out of 10 items on the PEDro scale did not attain a κ > 0.4 regarding congruence between the reviewers.

Another limitation was that many of the included studies were small trials that individually would not be powerful enough to detect statistically significant effects of interventions.

Various studies included children having TTH, migraine, or both, which is likely to result in an underestimation of the treatment effect in "pure" TTH, since migraine is a more severe headache. It was decided to include studies with participants having migraine or both migraine and TTH because a clear differentiation between the two types of headache in children is difficult to achieve in clinical practice. Included patients thus reflect clinical practice and simplify the implementation of these recommendations in clinical practice.

The conclusion about the size of effects was based on a reduction of pain; however, physical treatments are not initially intended to treat pain, but rather to promote functionality and participation. This means that this review can be seen as only a partial evaluation of the effectiveness of physical treatments.

Another limitation of this study is the variety of additional treatments added to the intervention under study. For example, through relaxation treatment, the child learns to differentiate increased muscle tension from normal muscle tension by tensing and relaxing muscle groups.^{16,19,23–28,30,31} Frequently, additional treatments provided are breathing techniques, stretching techniques, and (auto)massage techniques to further increase muscle relaxation.

Further limitations are differences in the frequency and duration of treatment and in follow-up times, the variety in reporting pain diary scores in terms of duration (from 1 to 8 weeks) or frequency (once daily to four times daily), and a pain index based on a decline (yes/no) of 50% that included one or more pain characteristics (frequency, intensity, duration).

Reduction of pain was the only outcome measure that allowed data pooling. At present there is too little information to support or reject the use of physical treatments for improving functioning and/ or QoL in children with TTH. For this reason, functioning and QoL can be recommended as primary outcomes in future research—for example, by applying the Pediatric Migraine Disability Assessment (pedMIDAS) and Pediatric Quality of Life Inventory (PedsQL) indices.¹²

Clinical Implications

TTH is a multifactorial condition, and a range of treatment options are available to reduce pain and decrease disabilities. A team composed of physician, patient, and parent(s) must decide on the most appropriate treatment plan, which may include one or more treatment options for the individual situation. Pharmacologic, psychologic, or physical treatments might all be part of a personalized rehabilitation or multidisciplinary treatment plan. For pharmacologic treatment, off-label use of drugs is the norm in almost all settings of headache treatment among children.³² For psychologic treatment, cognitive behavioral treatment and relaxation treatment especially were effective in a headache reduction of 50% or more, and the therapeutic gains appeared to be maintained.9 Promising results can also be seen in remotely delivered psychologic treatments.8

For physical treatment, relaxation treatment and occlusal appliances especially were shown to be effective for a headache reduction of 50% or more. Physical treatments aim to maximize children's QoL by maintaining and restoring maximum movement and functional abilities in headache conditions. The second goal is to gain control of the pain.

Conclusions

Although more high-quality evidence and future replication studies are likely to increase the confidence of the effect, this systematic review supports the use of physical treatments to reduce pain in children with TTH. This conclusion concerns relaxation treatment especially as the most evaluated and effective intervention. When headache is combined with TMD among children, occlusal appliances were shown to be effective.

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