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## Educational interventions to prevent paediatric abusive head trauma in babies younger than one year old: A systematic review and meta-analyses

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### ABSTRACT

**Background:** Paediatric abusive head trauma (AHT) occurs in young children due to violent shaking or blunt impact. Educational and behavioural programmes modifying parent/infant interactions may aid primary prevention. This systematic review aims to assess the effectiveness of such interventions to prevent AHT in infants.

**Methods:** We searched Embase, MEDLINE, PsycINFO, The Cochrane library, CINAHL databases and trial registries to September 2021, for studies assessing the effectiveness of educational and behavioural interventions in preventing AHT. Eligible interventions had to include messaging about avoiding or dangers of infant shaking. Randomised controlled trials (RCTs) reporting results for primary (AHT, infant shaking) or secondary outcomes (including parental responses to infant crying, mental wellbeing), and non-randomised studies (NRSs) reporting primary outcomes were included. Evidence from combinable studies was synthesised using random-effects meta-analyses. Certainty of evidence was assessed using GRADE framework. PROSPERO registration CRD42020195644.

**Findings:** Of 25 identified studies, 16 were included in meta-analyses. Five NRSs reported results for AHT, of which four were meta-analysed (summary odds ratio [OR] 0.95, 95 % confidence intervals [CI] 0.80–1.13). Two studies assessed self-reported shaking (one cluster-RCT, OR 0.11, 95 % CI 0.02–0.53; one cohort study, OR 0.36, 95 % CI 0.20–0.64, not pooled). Meta-analyses of secondary outcomes demonstrated marginal improvements in parental response to inconsolable crying (summary mean difference 1.58, 95 % CI 0.11–3.06, on a 100-point scale) and weak evidence that interventions increased walking away from crying infants (summary incidence rate ratio 1.52, 95 % CI 0.94–2.45). No intervention effects were found in meta-analyses of parental mental wellbeing or other responses to crying.

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*Interpretation:* Low certainty evidence suggests that educational programmes for AHT prevention are not effective in preventing AHT. There is low to moderate certainty evidence that educational interventions have no effect or only marginally improve some parental responses to infant crying.

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## 1. Introduction

Paediatric abusive head trauma (AHT) is an injury inflicted on young children, usually through either a direct blow to the head or violent shaking. Most victims are younger than six months (Blumenthal, 2002), and perpetrators are usually parents, in particular fathers or father figures (Starling, Holden, & Jenny, 1995). The incidence in under one year olds in high income countries is 21–35 cases per 100,000 infants (Minns, Jones, & Mok, 2008). Around 18–25 % die due to the injuries sustained, and up to 80 % of survivors are left with lifelong cognitive or neurological impairment (Barr, 2012), such as damaged vision and hearing. AHT is associated with significant financial impact to health and social care, legal costs related to safeguarding processes, and societal costs related to long-term care needs of survivors (Beaulieu, Rajabali, Zheng, & Pike, 2019; Miller, Steinbeigle, Lawrence, et al., 2018; Stabile & Allin, 2012).

The pathway from education to changing behaviour first requires learning and knowledge, which in turn may change attitudes, leading to behaviour change (Ajzen & Fishbein, 1980). Educational and behavioural programmes aim to prevent AHT by modifying carer/infant interactions, particularly during times of peak infant crying (Dias, Cappos, Rottmund, et al., 2021). Most preventive interventions therefore focus on educating carers on patterns of infant crying, and the dangers of shaking their infant (Barr, n.d.; Altman et al., 2011; Bechtel et al., 2011; Bechtel, Gaither, & Leventhal, 2020; Dias et al., 2005; Groisberg, Hashmi, & Girardet, 2020). One such intervention, implemented in New York State and evaluated in an uncontrolled observational study, reported a large reduction in cases (Altman et al., 2011; Dias et al., 2005). These findings were followed by development and implementation of similar programmes, including “The Period of PURPLE Crying” (Barr, n.d.), “I promise”, Take 5 (Bechtel et al., 2011) and the ICON programme (ICON, 2020).

Evaluations of these programmes have been limited in size and scope. They have been implemented and maintained with varying success, with one of the key challenges being a paucity of robust evidence on their effectiveness. Identifying whether any of these programmes are effective in reducing this catastrophic injury is essential to inform preventive policies.

We aimed to systematically review preventative strategies, evaluating the effectiveness of educational interventions aimed at reducing AHT in infants younger than one year old.

## 2. Methods

The study protocol was registered on PROSPERO prior to full text screening (CRD42020195644) (Scott, Davies, Savovic, Dawson, & Mamluk, 2020). Results are reported according to PRISMA guidelines (Page, McKenzie, Bossuyt, et al., 2021).

### 2.1. Study eligibility criteria

#### 2.1.1. Study design

We included Randomised Controlled Trials (RCTs). Comparative non-randomised intervention studies (NRSs) were also included if they reported our primary outcomes (AHT, incidence of infant shaking), as AHT is a rare outcome which is rarely measured in RCTs. We excluded uncontrolled before-after/pre-post designs as studies without a comparison group cannot provide estimates of intervention effectiveness.

#### 2.1.2. Participants

The target population included parents, expectant parents, and carers of children under one year old (at the point of enrolment or start of intervention). We also included studies where an intervention was delivered to health and/or social care professionals supporting parents and carers (e.g. training to enable delivery of messages about shaking and AHT), provided the study reported outcomes in infants and/or parents.

#### 2.1.3. Interventions

We included educational or behavioural interventions aimed at preventing AHT. Interventions primarily focused on managing infant crying were also included if the intervention included messaging about the dangers of infant shaking, or instructions to not shake the baby. Studies did not have to state an explicit aim of preventing AHT. Eligible settings included primary, secondary and community health/social care.

#### 2.1.4. Comparators

We included studies that compared interventions with either no intervention, standard/usual care, or an alternative educational/behavioural intervention. The comparison group could also include some elements of AHT education as in many countries this constitutes standard care.

### 2.1.5. Outcomes

The primary outcomes were the incidence of AHT and the incidence of infant shaking (e.g. self-reported by parent or carer). Secondary outcomes in parents/carers were (i) response to inconsolable crying, (ii) mental health (e.g. anxiety and depression), (iii) confidence/self-efficacy, (iv) emotional regulation (e.g. use of coping strategies), (v) stress/frustration, and (vi) frequency of seeking support (e.g. from GP or health visitor). Secondary outcomes in infants were (i) frequency of crying, (ii) sleep patterns (e.g. hours of continuous or total sleep), (iii) other forms of abuse (including maltreatment or neglect), and (iv) mortality. We did not explore knowledge and learning based outcomes (e.g. knowledge of shaken baby syndrome). Whilst learning is an important step on the pathway to behaviour change, the measurement of the behaviour change itself is required to assess the effectiveness of educational interventions. Outcomes were not used as an eligibility criterion for RCTs, but NRSs were only included if they reported one of the primary outcomes.

### 2.2. Literature search

We searched Ovid Embase, MEDLINE, PsycINFO, The Cochrane library and CINAHL from inception to September 2021, without language or date restrictions. We also searched trial registries ([ClinicalTrials.gov](https://clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform) and grey literature (Open Grey, Google Scholar, theses, and dissertation databases). Search terms were developed by an information specialist (SD) with the study team and adapted for each database (Appendix 1). We supplemented these searches by examining reference lists of included studies, reviews of similar topics, citation searches on Web of Science and Google Scholar, and contacting experts.

### 2.3. Study selection

Identified titles and abstracts were double-screened for relevance. Discrepancies were resolved through discussion or escalation of the discrepant record to full-text assessment. For the potentially relevant records, full-text articles were obtained, and each was independently assessed against the inclusion criteria by two reviewers, with any discrepancies resolved through consensus and, if necessary, by referral to a third reviewer.

### 2.4. Data extraction

Data extraction forms were developed in a custom-built Microsoft Access database and piloted on two studies prior to use. For each study, we extracted information on study design, location, population characteristics, intervention details, outcomes, and estimates of intervention effectiveness. Data extraction was carried out by one reviewer and checked by another; discrepancies were resolved through discussion. When necessary, authors were contacted for additional information or clarification.

### 2.5. Risk of bias assessments

Risk of bias in RCTs was assessed using the Cochrane risk of bias tool “RoB-2” (Sterne, Savovic, Page, et al., 2019) for key results included in the meta-analyses. For NRSs, we used the “ROBINS-I” tool (Sterne, Hernan, Reeves, et al., 2016). We pre-specified key confounding factors expected to be relevant for most NRSs in this review: socioeconomic status, ethnicity or race, parent’s age, sex of the parent and/or partner, parental substance misuse, mother’s pre-existing /acute mental illness, and previous safeguarding concerns. The effect of interest was assignment to the intervention (i.e. intention to treat), for risk of bias assessment of both RCTs and NRSs. Risk of bias assessments were carried out independently, in duplicate, by two co-authors and final judgements agreed through consensus.

We used the pilot version of the “RoB-ME” (Risk of Bias due to Missing Evidence) tool (Page, JAC, Boutron, et al., 2020) to explore the potential impact of evidence unavailable for synthesis due to selective non-reporting (e.g. non-significant results not reported in study publications). Constructing funnel plots to consider the possibility of small-study effects, missing evidence, and/or publication bias was not feasible due to small number of included results (Sterne, Sutton, Ioannidis, et al., 2011). Instead, we contacted authors of registered but unpublished studies to informally assess the approximate volume of unavailable results (see detailed methods in Appendix 2).

### 2.6. Synthesis and certainty of evidence

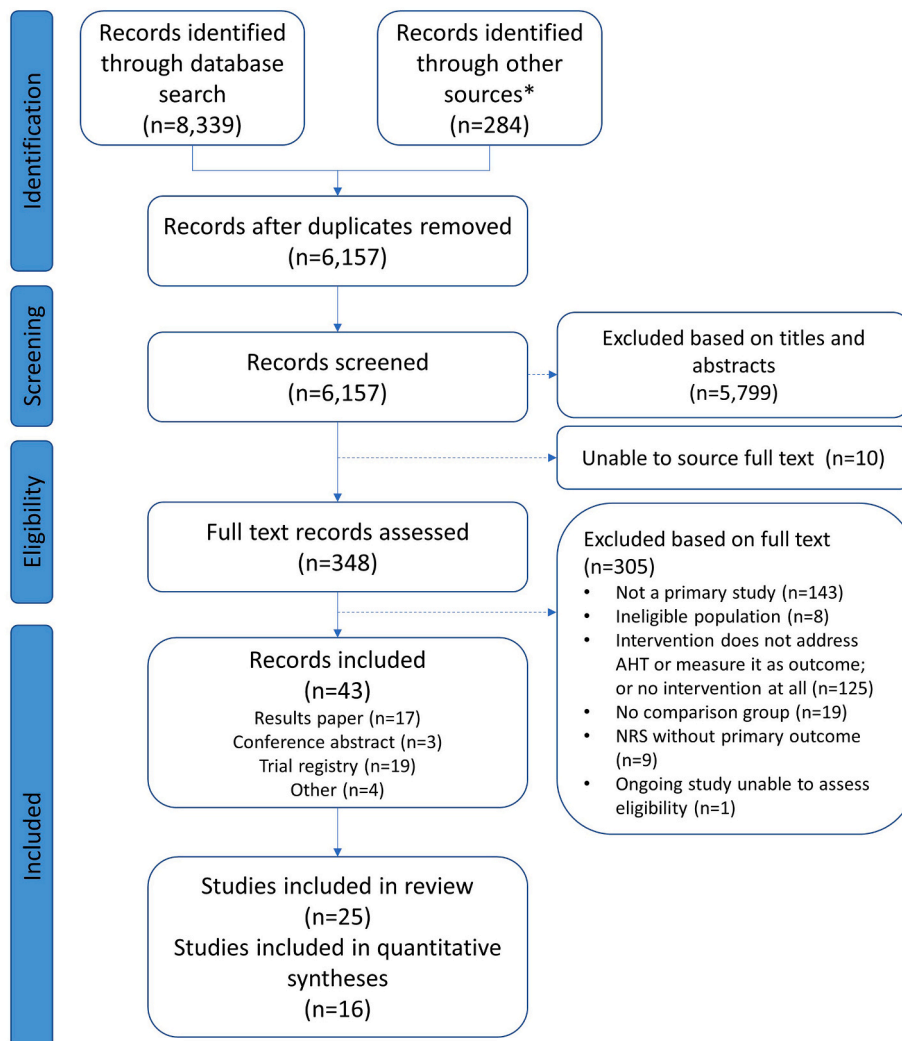
We narratively summarised data from all included studies, grouped by outcomes of interest. Meta-analyses were carried out where study design, interventions and outcomes were similar enough to combine results. Primary analyses used random-effects meta-analyses, due to anticipated heterogeneity between studies (e.g. interventions were expected to differ in content, mode of delivery, settings, dosing and timing), with fixed-effects models provided as sensitivity analyses (with both estimates shown on the same forest plot when feasible). The ‘meta summarize’ and ‘meta forestplot’ user-built commands in Stata Statistical Software: Release 16 (StataCorp. 2019. College Station, TX) were used to generate and present summary estimates of effect, 95 % confidence intervals (CIs), and the percentage of variation across studies due to heterogeneity ( $I^2$ ) for the analysed results (see detailed methods in Appendix 2).

We rated the certainty in the overall body of evidence by applying the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework for our main synthesised outcomes (Guyatt, Oxman, Vist, et al., 2008). We followed the revised GRADE guidelines which propose that when using ROBINS-I tool to assess risk of bias, NRSs can start at “high certainty” (same as

RCTs) and be downgraded for identified limitations (Schunemann, Cuello, Akl, et al., 2019). We used the GRADE-Pro web application to construct our summary of findings table (GRADEpro, 2020).

### 3. Results

Our searches identified 6157 records, after removing duplicates. Title and abstract screening resulted in exclusion of 5799 irrelevant records, leaving 358 records requiring full text assessment. Of these, 10 publications could not be obtained and 305 were excluded after full text assessment (Appendix 3). We included 25 studies, reported in 43 records. We extracted outcome data for 16 studies: ten were RCTs (Arshadi, Mostafa, & Saiedi, n.d.; Barr et al., 2009a; Barr, Rivara, Barr, et al., 2009b; Bishe, Aziznejadrosan, Mojaveri, Hajiahmadi, & Bishe, 2020; Cala, Kelly, Ramos, VanVleet, & High, 2020; Fujiwara et al., 2012; Fujiwara, Isumi, Sampei, et al., 2020a; Groisberg et al., 2020; Lou, D'Souza, Chen, & Barr, 2011; McRury & Zolotor, 2010), including one cluster-RCT (Fujiwara et al., 2020a). Of the six NRSs, three were state/region-wide controlled before-and-after (CBA) studies (Dias, Rottmund, Cappos, et al., 2017; Vinchon, Rakza, Karnoub, & Gobert, 2020; Zolotor, Runyan, Shanahan, et al., 2015), two were case-control studies (Bechtel et al., 2020; Keenan & Leventhal, 2010), and one was a cohort study (Fujiwara, Isumi, Sampei, Yamada, & Miyazaki, 2020b). Of the remaining nine; four (ChiCtr, 2019; JPRN-UMIN000038940, 2020; NCT04568538, 2020; NCT04608877, 2021) were trial registry records of ongoing RCTs, one RCT registry record (JPRN-UMIN000012445, n.d.) was for a completed RCT which had not yet published results, two published RCT protocols (Cook, Seymour, Giallo, et al., 2015; Obikane, Baba, Shinozaki, et al., 2021) had not published



\*Trial registers, theses, backward and forward citations.

Fig. 1. PRISMA flowchart.

AHT = abusive head trauma; NRS = non-randomised study.

**Table 1**  
Characteristics of included randomised controlled trials.

First author/PI (year)	Country	Population	Parental age	Parent ethnicity	Sample size: randomised/analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Arshadi (2015) (Arshadi et al., n.d.)	Iran	Mothers	Intervention: mean = 29 (SE = 6) Control: mean = 29 (SE = 6)	Not reported	92/92	R: Secondary care D: Secondary care	Not stated	“Discharge planning”. Two training sessions with practical training and lectures, and videotape training for months of premature infants. Materials include mention of AHT.	Standard care	Post-birth, pre-hospital discharge	On discharge	Stress.	None.
Barr (2009a) (Barr et al., 2009a)	Canada	Mothers	<25: 8 % 25–30: 23 % 30–35: 37 % >35: 29 %	Not reported	1833/1279	R: Secondary care D: Home	PURPLE crying	An 11-page booklet and a DVD on crying behaviours and advice around unsoothable crying and the dangers of shaking your baby.	Two brochures and a DVD about infant safety.	0–2 weeks post-birth	8 weeks post-birth	Response to crying. Stress. Emotional regulation.	Knowledge (e.g. about crying and shaking). Information sharing.
Barr (2009b) (Barr et al., 2009b)	USA	Mothers & expectant mothers	18–24: 15 % 25–29: 26 % 30–34: 35 % 35–54: 24 %	Not reported	2738/2373	R: Primary/Secondary care D: Home	PURPLE crying	An 11-page booklet and a 12-min DVD on crying behaviours and advice around unsoothable crying and the dangers of shaking your baby.	Two brochures and a DVD about infant safety.	Child “new-born”	Two-months post-birth	Frequency of crying. Response to crying. Stress. Emotional regulation.	Knowledge (e.g. about crying and shaking). Information sharing.
Bishe (2020) (Bishe et al., 2020)	Iran	Mothers	Intervention: mean = 29 (SD = 6) Control: mean = 29 (SD = 7)	Not reported	70/?	R: Unclear D: Home	Not stated	“Premature infant care training package” was presented at home during four sessions, twice a week with an	Unclear, probably just routine hospital care.	Post-hospital discharge	One month post-intervention end	Anxiety.	None.

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Table 1 (continued)

First author/PI (year)	Country	Population	Parental age	Parent ethnicity	Sample size: randomised/analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Cala (2020) (Cala et al., 2020)	USA	Mothers	Intervention: mean = 27 (SD = 5) Control: mean = 28 (SD = 6)	Non-Hispanic white: 28 % Non-Hispanic Black: 12 % Asian: 4 % Hispanic: 51 % American Indian/ Native Alaskan: 1 % Other: 4 %	300/115	R: Secondary care D: Secondary care/home	Not stated	average time of 60 min (30 min practical and 30 min theoretical) according to previous coordination with their mothers. Fourth session included AHT prevention. A bilingual ABC (all babies cry) DVD and corresponding bilingual booklet explaining crying as part of normal infant behaviour, highlighting signs of parental distress and providing strategies to soothe parents and their children.	A bilingual DVD and bilingual booklet addressing the benefits of reading, talking, and playing with young children, as well as a new children's board book.	Post-birth, pre-hospital discharge	2–5 month post-birth	Emotional regulation.	Knowledge (e.g. about crying and shaking). Changes in use of soothing strategies.
Fujiwara (2012) (Fujiwara et al., 2012)	Japan	Mothers	<25: 10 % 25–29: 20 % 30–34: 38 % >34: 29 %	Not reported	230/201	R: Secondary care D: Home	PURPLE crying	An 11-page booklet and a DVD on crying behaviours and advice around unsoothable crying and the dangers of shaking your baby.	A DVD about infant safety.	Post-birth, pre-hospital discharge	2 months post-birth	Response to crying. Stress. Emotional regulation.	Knowledge (e.g. about crying and shaking). Information sharing.

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Table 1 (continued)

First author/PI (year)	Country	Population	Parental age	Parent ethnicity	Sample size: randomised/analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Fujiwara (2020a) (Fujiwara et al., 2020a) (Cluster RCT)	Japan	Mothers	<25: 10 % 25–29: 24 % 30–34: 35 % >34: 31 %	Not reported	45 clusters/ 2655	R: Secondary care D: Secondary care	PURPLE crying	The PURPLE crying DVD	Standard care. Wait list control. Receive intervention at 1 month.	Post-birth, pre-hospital discharge	1 month post-birth	Self-reported shaking. Response to crying. Emotional regulation. Depression.	Knowledge (e.g. about crying and shaking). Information sharing.
Groisberg (2020) (Groisberg et al., 2020)	USA	Parents (4 % fathers)	Intervention: median = 29 Control: median = 25	Hispanic: 43 % African-American: 32 % Caucasian: 14 % Asian: 2 %	271/164	R: Secondary care D: Secondary care	PURPLE crying	Firstly, verbal instruction from the trainee about general newborn care, excluding information about infant crying. They then reviewed the PURPLE crying brochure with the paediatric resident or medical student and watched the PURPLE crying video on a mobile computer.	Verbal newborn discharge instructions provided by the trainee which included pertinent information about infant crying and the dangers of shaking a baby. I. e. same information, different method of delivery.	Post-birth, pre-hospital discharge	5–8 weeks post-hospital discharge	Self-reported shaking. Frequency of crying. Stress.	Knowledge (e.g. about crying and shaking). Information sharing. Advice seeking.
Lopes (2017) (Lopes, 2017)	Brazil	Health care professionals (3 nurses, 6 paediatricians, 3 nursing technicians, 1 dentist)			34/13	R: Unclear D: Unclear	Not stated	Four x 2 h in-person sessions, including multimedia resources covering violence in the home, head trauma and crying management. The video and pamphlet were developed by the shaken	Wait list control. No detail about when they received it.	Received during working hours	Immediately post intervention.	None.	Knowledge (e.g. about crying and shaking). Beliefs about baby care.

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Table 1 (continued)

First author/PI (year)	Country	Population	Parental age	Parent ethnicity	Sample size: randomised/analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Lopes (2018) (Lopes et al., 2018)	Brazil	Parents and expectant parents (159 pregnant women, 36 expectant partners, 39 mothers, 18 fathers)	Mean = 27 (SD = 7)	Not reported	252/183	R: Unclear D: Unclear	Not stated	baby prevention project team at Children's Hospital at Westmead, Australia, and translated and adapted into Portuguese. 15 min intervention. Video "Responding to Crying Baby", followed by reading of a pamphlet and a brief discussion based on a prepared script. The video and pamphlet were developed by the shaken baby prevention project team at Children's Hospital at Westmead, Australia, and translated and adapted into Portuguese.	Standard care. Wait list control. No detail about when they received it.	Expectant parents - 2 years post-birth	Immediately post intervention.	None.	Knowledge (e.g. about crying and shaking). Beliefs about baby care.
Lou (2011) (Lou et al., 2011) (abstract)	Canada	Expectant mothers	Not reported	Not reported	33/33	R: Unclear D: Unclear	PURPLE crying	The PURPLE crying DVD.	A DVD about infant safety.	Pregnant mothers. Pre-birth.	Immediately post-intervention	Stress.	Likelihood of using strategies to cope with crying.

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Table 1 (continued)

First author/PI (year)	Country	Population	Parental age	Parent ethnicity	Sample size: randomised/analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
McRury (2010) ( <a href="#">McRury &amp; Zolotor, 2010</a> )	USA	Mothers	Intervention: mean = 29 (SD = 6) Control: mean = 29 (SD = 4)	Not reported	51/35	R: Secondary care D: Home	The Happiest baby	A 30-min videotape demonstrating the happiest baby method for calming newborn infants. Caregivers were reminded to first try feeding, holding, and changing their newborn when he/she cried. If none of these was effective, they were encouraged to try a detailed swaddling technique. Caution is given never to shake an infant.	A 30-min videotape entitled "Begin with Love" by Civitas. This videotape provides 5 standard recommendations for taking care of normal newborns: 1. Take care of yourself. 2. Provide a warm and loving environment. 3. Talk, sing, and read to your baby. 4. Create a predictable world with routines. 5. Respond to your baby's needs; a newborn infant cannot be spoiled. Again, this included advice never to shake your baby.	Post-birth, pre-hospital discharge	6 & 12 weeks post-birth	Frequency of crying. Stress. Sleep patterns.	None.

Table 2

Characteristics of included non-randomised studies (NRSS).

First author/PI (year)	Country	Study type	Population	Parental age	Parent ethnicity	Sample size: analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Bechtel (2020) ( <a href="#">Bechtel et al., 2020</a> )	USA	Case-control	Unclear	Not reported	White: 48 % Black: 10 % Other: 42 % (Baby's ethnicity)	77	R: Unclear D: Unclear	Take 5	Take 5 messaging. The approach of teaching parents how to recognise their feelings of frustration with their infants' crying and to walk away from the crying infant, as a way to interrupt the dangerous relationship between infant crying and caregiver shaking. Advise included putting baby down, walking away, doing something to calm down, don't return to infant until calm.	Standard care.		<12 months post-birth		
Dias (2017) ( <a href="#">Dias et al., 2017</a> )	USA	Controlled before & after study	Parents (break-down not provided)	Not reported	Not reported	.	R: Secondary care D: Secondary care	Not stated	"Pennsylvania Shaken Baby Syndrome Prevention Program". A brochure, an 8 min video, ask questions of nurse, sign commitment statement. Also, posters saying 'never, never, never shake a baby' around hospital.	Standard care. There was no AHT prevention program running in the five control states.	Post-birth, pre-hospital discharge	12 months post-birth	AHT.	Knowledge (e.g. about crying and shaking). Information sharing. Learning beliefs.
Fujiwara (2020b) ( <a href="#">Fujiwara et al., 2020b</a> )	Japan	Cohort	Mothers & expectant mothers	<25: 6 % 25-29: 23 % 30-34: 37 % >34: 34 %	Not reported	5961	R: Community D: Home	Not stated	An 11-min education video including 1) features of infant crying, 2) danger of shaking, 3) a simulation of the	Standard care (missed video control group).	Second trimester and/or 2 months post-birth	4 months post-birth	Self-reported shaking. Other abuse. Response to crying.	Knowledge (e.g. about crying and shaking). Information sharing.

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Table 2 (continued)

First author/PI (year)	Country	Study type	Population	Parental age	Parent ethnicity	Sample size: analysed	Setting of recruitment (R) and delivery (D)	Intervention name	Intervention details	Control details	Timing of intervention	Timing of outcomes	Outcomes included in review	Outcomes not included in review
Keenan (2010) (Keenan & Leventhal, 2010)	USA	Case-control	Mothers	Cases: 25 (median), 21–29 (IQR) Control: 29 (median), 25–32 (IQR)	Cases: 91 % white (5 % missing), 18 % Hispanic Control: 96 % white (1 % missing), 5 % Hispanic	653	R: Secondary care D: Secondary care	Not stated	anatomical mechanism of shaken baby syndrome using computer graphics and an anatomical doll, 4) danger of smothering, and 5) how to respond to crying (coping strategies from PURPLE crying material) Verbal info delivered by nurse to mother and other available caregivers, the viewing of 1 of 2 videos (Elijah's story or Portrait of a Promise) about the consequences of SBS, and written materials, including refrigerator magnets and posters in maternity wards	Standard care (no viewing of video).	Post-birth, pre-hospital discharge.	2 years post-birth	AHT.	None.
Vinchon (2020) (Vinchon et al., 2020)	France	Controlled before & after study (abstract only)	Parents (break-down not reported)	Not reported	Not reported		R: Secondary care D: Secondary care	Crying Plan	Prevention program based on the "Crying plan" in maternity words	Standard care. Control regions did not receive intervention.	Post-birth, pre-hospital discharge	Unclear	AHT.	None
Zolotor (2015) (Zolotor et al., 2015)	USA	Controlled before & after study	Parents (break-down not reported)	Not reported	Not reported		R: Secondary care D: Secondary care	PURPLE crying	PURPLE crying DVD and booklet, and 3 min of education from nurse before hospital discharge. Also, reinforcement messages in primary care offices and media campaigns.	Standard care. Control states did not receive PURPLE crying education.	Post-birth, pre-hospital discharge	<12 months post-birth	AHT.	Changes to call rate to after hours nurse advice line about crying.

results, and two studies did not report any of our outcomes of interest (Fig. 1) (Lopes, 2017; Lopes, Gorni, Mattar, & de Albuquerque Williams, 2018).

### 3.1. Summary of included studies

Characteristics of included studies are shown Table 1 (RCTs) and Table 2 (NRSs). Ongoing and unpublished studies (all study designs) are presented in Appendix 4 Table S1. Nine studies were conducted in the USA (Barr et al., 2009b; Bechtel et al., 2020; Cala et al., 2020; Dias et al., 2017; Groisberg et al., 2020; Keenan & Leventhal, 2010; McRury & Zolotor, 2010; NCT04608877, 2021; Zolotor et al., 2015), six in Japan (JPRN-UMIN000012445, n.d.; Fujiwara et al., 2012; Fujiwara et al., 2020a; Fujiwara et al., 2020b; JPRN-UMIN000038940, 2020; Obikane et al., 2021), two in Canada (Barr et al., 2009a; Lou et al., 2011), two in Iran (Arshadi et al., n.d.; Bishe et al., 2020), two in Brazil (Lopes, 2017; Lopes et al., 2018), and one in France (Vinchon et al., 2020), Australia (Cook et al., 2015), Turkey (NCT04568538, 2020), and China (ChiCtr, 2019). The intervention was delivered in a hospital setting in eight studies (Arshadi et al., n.d.; Dias et al., 2017; Fujiwara et al., 2020a; Groisberg et al., 2020; Keenan & Leventhal, 2010; NCT04608877, 2021; Vinchon et al., 2020; Zolotor et al., 2015), at home in eight studies (Barr et al., 2009a; Barr et al., 2009b; Bishe et al., 2020; Cook et al., 2015; Fujiwara et al., 2012; Fujiwara et al., 2020b; McRury & Zolotor, 2010; Obikane et al., 2021), in hospital and/or at home in two studies (Cala et al., 2020; NCT04568538, 2020), and seven studies did not provide details (JPRN-UMIN000012445, n.d.; Bechtel et al., 2020; ChiCtr, 2019; JPRN-UMIN000038940, 2020; Lopes, 2017; Lopes et al., 2018; Lou et al., 2011). Outcome assessments ranged from immediately after the intervention to two years post-intervention, though most were at less than three months.

Seven studies (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012; Fujiwara et al., 2020a; Groisberg et al., 2020; Lou et al., 2011; Zolotor et al., 2015) investigated the proprietary intervention “Period of PURPLE Crying”, compared with standard care (with or without alternative education on child safety). The following proprietary interventions were assessed by one study each: “The Happiest Baby” (McRury & Zolotor, 2010), the “Cry Baby” (Cook et al., 2015), the “SmartMama” (Obikane et al., 2021), the “Crying plan” (Vinchon et al., 2020), and the “Take 5 safety plan” (Bechtel et al., 2020). The remaining studies did not specify a proprietary intervention name. In 13 studies (Arshadi et al., n.d.; Barr et al., 2009a; Barr et al., 2009b; Bishe et al., 2020; Cala et al., 2020; Fujiwara et al., 2012; Fujiwara et al., 2020a; Fujiwara et al., 2020b; Keenan & Leventhal, 2010; Lou et al., 2011; McRury & Zolotor, 2010; NCT04568538, 2020; Obikane et al., 2021) the interventions were delivered only to mothers and/or expectant mothers, in nine studies (JPRN-UMIN000012445, n.d.; ChiCtr, 2019; Cook et al., 2015; Dias et al., 2017; Groisberg et al., 2020; Lopes et al., 2018; NCT04608877, 2021; Vinchon et al., 2020; Zolotor et al., 2015) to both parents, in one study to health care professionals (Lopes, 2017), and in two it was not clear (Bechtel et al., 2020; JPRN-UMIN000038940, 2020).

### 3.2. Risk of bias

Risk of bias assessments for 14 outcomes from 10 included RCTs are presented in Table 3. Three studies (Arshadi et al., n.d.; Fujiwara et al., 2020a; Groisberg et al., 2020) were at high risk of bias, two (Barr et al., 2009a; Barr et al., 2009b) at low risk of bias (each with two assessed outcomes), and the remaining RCTs had some concerns for bias. The most frequent reasons for bias concerns were (i) no mention of attempts to conceal the random sequence, (ii) unblinded outcome assessments, (iii) high levels of missing data, and (iv) evidence or suspicion of selective reporting of results. Risk of bias assessments for NRSs are presented in Table 4. One non-randomised CBA study (Vinchon et al., 2020) was judged to be at critical risk of bias as no attempt was made to control for confounding, and results were reported as a proportion of the national AHT cases from the intervention region compared with another region, which rendered them unusable. The remaining study results were at serious risk of bias. The most common issues were inadequate control of confounding, selection bias, issues with classification of intervention status or outcome measurement, and potential selective reporting.

Assessment of risk of bias due to missing evidence (RoB-ME) identified one pilot RCT (Cook et al., 2015), which remains unpublished due to problems with collection of their primary outcome (not an outcome of interest for our review); the reason for missing results was unrelated to the values of the results required for our synthesis and was thus not considered at risk of bias. Two published studies measured, but did not report, parental depression and/or anxiety, and the reasons for non-reporting were unclear (Barr et al., 2009b; Fujiwara et al., 2012). One study author confirmed the unreported result was ‘non-significant’ (Fujiwara et al., 2012). Two studies measuring parental stress were available as a conference abstract only (Lou et al., 2011) and a protocol only (JPRN-UMIN000012445, n.d.). We therefore reached a judgement of “some concerns” for missing evidence for syntheses of parental depression, anxiety, and stress. There was no clear evidence of risk of bias due to missing evidence for other syntheses. Recently registered unpublished RCTs were assumed ongoing and not considered as missing evidence. The matrix of reported results used for RoB-ME assessments is presented in Appendix 4, Table S2.

### 3.3. AHT and incidence of infant shaking

No RCTs reported results for AHT. Two USA-based case-control studies (Bechtel et al., 2020; Keenan & Leventhal, 2010), and two CBA studies (Dias et al., 2017; Zolotor et al., 2015) comparing introduction of two different state-wide programmes with five control US states, were included in the meta-analysis for AHT and found no evidence of reduction in AHT associated with the intervention (summary OR 0.95, 95 % CI 0.80 to 1.13,  $I^2 = 2\%$ ; Fig. 2). The subgroup estimate from two larger and more robust state-level CBA studies is consistent with no effect (OR 1.01, 95 % CI 0.85 to 1.19,  $I^2 = 0\%$ ). Estimates from the two small case-control studies suggest an intervention benefit but with a very wide CI, consistent with both benefit and harm (Fig. 2). One further CBA study (Vinchon et al.,

**Table 3**  
Risk of bias assessments for randomised controlled trials (using RoB2 tool).

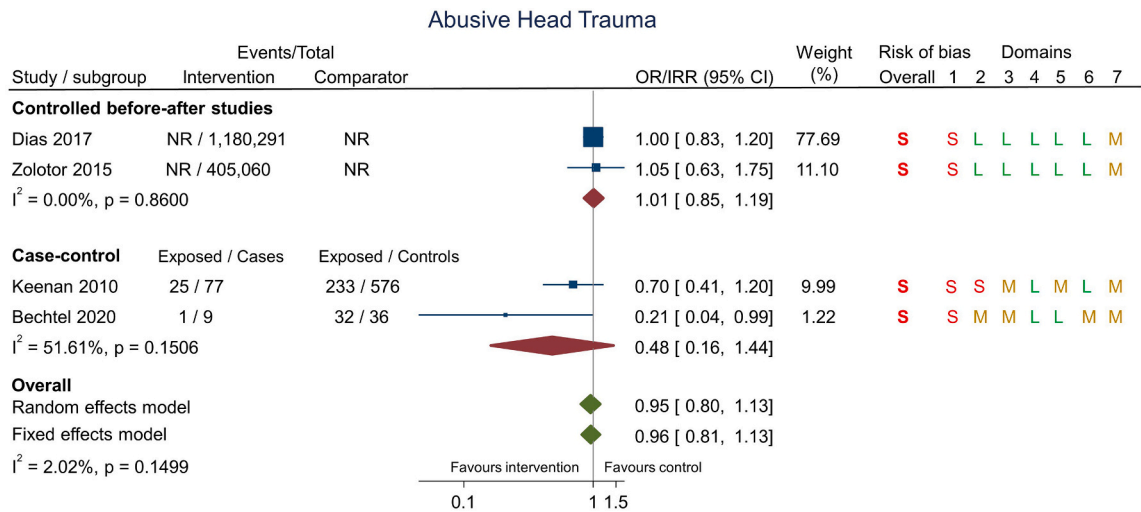
First author Year	Country	Outcome source	Risk of bias domains and judgements					Overall risk of bias	Reasons for concerns
			Randomisation	Deviation from interventions	Missing data	Outcome measurement	Selective reporting		
Arshadi 2015	Iran	Questionnaire	Some concerns	High	High	Low	Some concerns	<b>High</b>	No information on randomisation, blinding, non-completers or drop-outs
Barr 2009	Canada	Interview	Low	Low	Low	Low	Low	<b>Low</b>	No concerns
Barr 2009	Canada	Diary	Low	Low	Low	Low	Low	<b>Low</b>	No concerns
Barr 2009	USA	Interview	Low	Low	Low	Low	Low	<b>Low</b>	No concerns
Barr 2009	USA	Diary	Low	Low	Low	Low	Low	<b>Low</b>	No concerns
Bishe 2020	Iran	Questionnaire	Some concerns	Some concerns	Low	Low	Some concerns	<b>Some concerns</b>	No information on concealment, not blinded, no protocol or SAP
Cala 2020	USA	Interview	Low	Low	Some concerns	Low	Some concerns	<b>Some concerns</b>	Missing data likely to be associated with outcome, no protocol or SAP
McRury 2010	USA	Interview	Low	Low	Some concerns	Some concerns	Some concerns	<b>Some concerns</b>	Significant loss of data, missing outcome data possibly associated with outcome, follow-up data collected unblinded, no protocol, trial registry or SAP available
McRury 2010	USA	Diary	Low	Low	Some concerns	Low	Some concerns	<b>Some concerns</b>	Significant loss of data, missing outcome data possibly associated with outcome, no protocol, trial registry or SAP available
Fujiwara 2012	Japan	Interview	Some concerns	Low	Some concerns	Low	Low	<b>Some concerns</b>	No information on concealment, missing data could be associated with outcome
Fujiwara 2012	Japan	Diary	Some concerns	Low	Some concerns	Low	Low	<b>Some concerns</b>	No information on concealment, missing data could be associated with outcome
Fujiwara 2020a	Japan	Questionnaire	Low	High	High	Low	Low	<b>High</b>	Not blinded, control group likely to cross-over to intervention group, subjective outcome (self-reported shaking) at risk of bias. Cluster RCT.
Groisberg 2020	USA	Interview	High	Low	High	Some concerns	Some concerns	<b>High</b>	Not randomised properly (first come first serve), missing outcome data not addressed and likely to be associated with outcome
Lou 2011	Canada	Questionnaire	Some concerns	Low	Low	Low	Some concerns	<b>Some concerns</b>	Little information on randomisation and concealment (possibly due to limited content in conference abstract) and no protocol, trial registry or SAP available

SAP: statistical analysis plan. Individual domain and overall 'Low' risk of bias judgements are coloured green, 'Some concerns' risk of bias judgements are coloured yellow, and 'high' risk of bias judgements are coloured red. Further, all overall risk of bias judgements are in bold to help guide the reader to the importance of this column.

**Table 4**  
Risk of bias assessments for non-randomised studies (using ROBINS-I tool).

First author Year	Country	Outcome	Risk of bias domains and judgements								Overall risk of bias	Reasons for concerns
			Confounding	Classification of interventions	Selection into the study	Deviation from interventions	Missing data	Outcome measurement	Selective reporting			
Cohort or controlled before and after studies												
Dias 2017	USA	AHT	Serious	Low	Low	Low	Low	Low	Moderate	<b>Serious</b>	No control of confounding, but the comparison populations thought to be fairly comparable. Protocol not available, possibility of selective reporting cannot be ruled out.	
Fujiwara 2020b	Japan	Infant shaking (self-report)	Serious	Serious	Serious	Low	Low	Serious	Moderate	<b>Serious</b>	Adjusted for post-intervention variables. Possible misclassification of intervention as this was based on self-reported watching of video at 4-month check-up. Concerns for selection bias due to exclusion of participants who did not return valid Q-res. Intervention could have influenced whether carers honestly self-reported instances of infant shaking outcome. Protocol not available, possibility of selective reporting cannot be ruled out.	
Vincho 2020	France	AHT (not in MA)	Critical	Low	Low	Low	Low	Moderate	Serious	<b>Critical</b>	No attempt to control confounding. Some concerns that being in the intervention area could affect reporting of AHT cases. Protocol not found (abstract only), reported result could have been selected on the basis of the result.	
Zolotor 2015	USA	AHT (unadjusted)	Serious	Low	Low	Low	Low	Low	Moderate	<b>Serious</b>	Unadjusted rates used for synthesis, but comparison populations thought to be fairly comparable. Protocol not available, possibility of selective reporting cannot be ruled out.	
Case-control studies												
Bechtel 2020	USA	AHT	Serious	Moderate	Moderate	Low	Low	Moderate	Moderate	<b>Serious</b>	Did not adjust for all key confounders. Concerns that the delivery/recording of the intervention may have been affected by the perceived safeguarding risks at birth. Some concerns over possible collider bias due to the 'test-negative' design. Concerns about the possibility of misclassification of case / control status. Protocol not available, possibility of selective reporting cannot be ruled out.	
Keenan 2010	USA	AHT	Serious	Serious	Moderate	Low	Moderate	Low	Moderate	<b>Serious</b>	Negative controls for outcome and exposure suggest serious unmeasured confounding. Recall bias cannot be ruled out. Some concerns for selection bias over exclusion of cases with uncertain intervention status. Missing confounder data was differential for cases and controls. Protocol not available, possibility of selective reporting cannot be ruled out.	

Individual domain and overall 'Low' risk of bias judgements are coloured green, 'Some concerns' risk of bias judgements are coloured yellow, and 'high' risk of bias judgements are coloured red. Further, all overall risk of bias judgements are in bold to help guide the reader to the importance of this column.

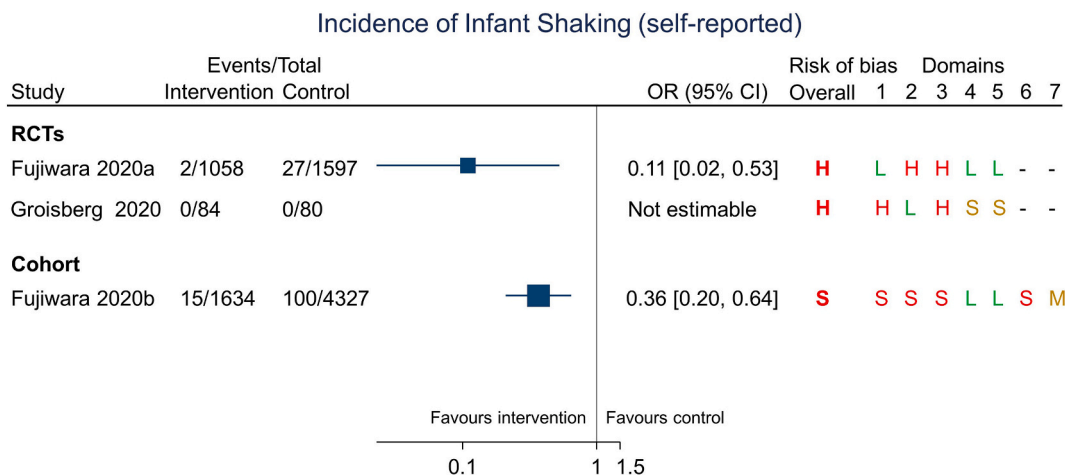


**Fig. 2.** Meta-analysis of controlled before-after study and case-control study results for abusive head trauma, by subgroup and overall. OR: odds ratios; IRR: incidence rate ratios CI: confidence interval; Overall and domain-level risk of bias judgments for the presented result from ROBINS-I tool: L: low, M: moderate, S: serious, C: critical. Risk of bias domains from ROBINS-I tool: 1: Confounding; 2: Classification of interventions; 3: Selection into the study; 4: Deviations from intended interventions; 5: Missing data; 6: Outcome measurement; 7: Selective reporting.

2020), at critical risk of bias, reported a non-significant reduction in AHT, from 18.8 to 13.6 cases/year in the intervention region. One cluster RCT (Fujiwara et al., 2020a) and one NRS (Fujiwara et al., 2020b) found that fewer mothers in the intervention groups admitted to shaking their baby “violently” or “hard”. Another RCT (Groisberg et al., 2020) had no reported instances of parents shaking their babies in either group ( $n = 164$ ; non-estimable). These results were not meta-analysed due to the different study designs, but are presented separately in a forest plot (Fig. 3). Whether any reported shaking events led to AHT was not reported in any study.

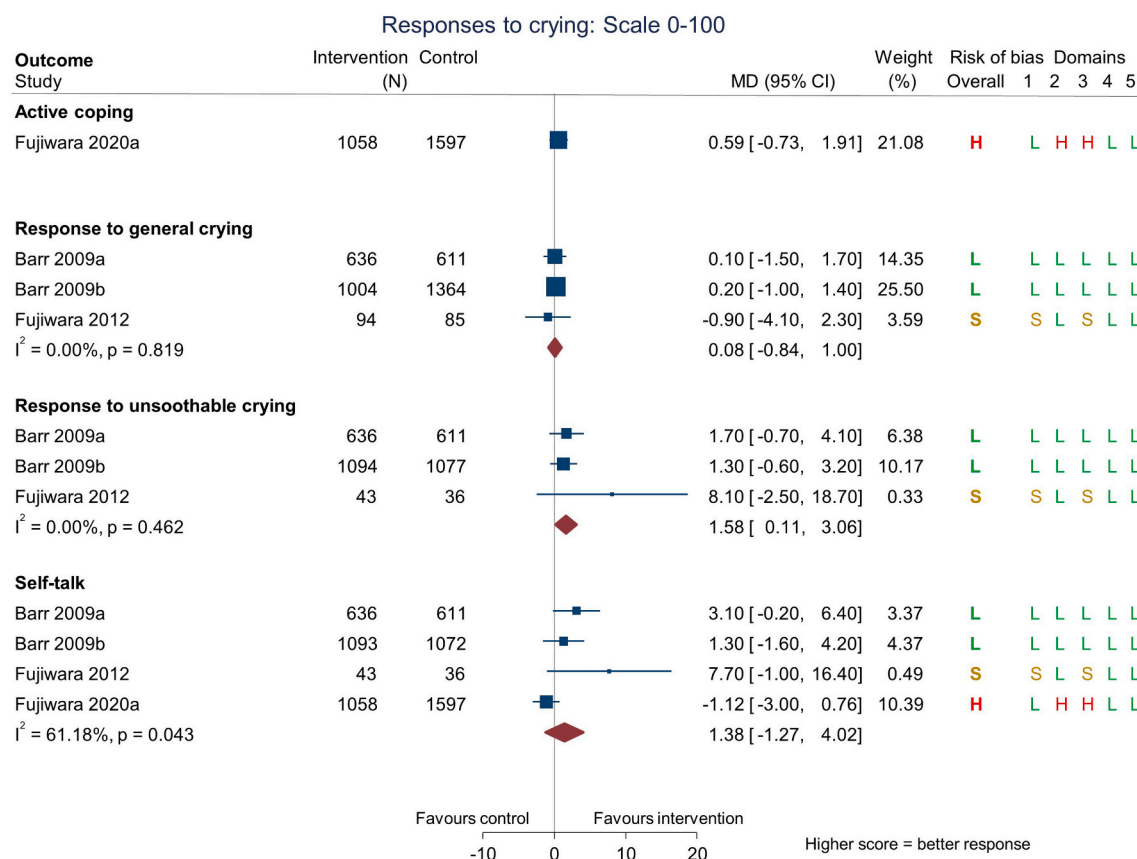
### 3.4. Parental responses to infant crying

Four RCTs evaluating the PURPLE crying intervention (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012; Fujiwara et al., 2020a) measured four coping responses to infant crying, which the trialists transformed into a scale of 0–100 (higher score indicated



**Fig. 3.** Forest plot of self-reported infant shaking (meta-analysis was not performed). OR: odds ratios; CI: confidence interval. Risk of bias judgments for the presented RCT result using RoB2 tool: L: low, S: some concerns, H: high. Risk of bias domains from RoB2 tool for RCTs: 1: Randomisation; 2: Deviations from intended interventions; 3: Missing data; 4: Outcome measurement; 5: Selective reporting. Risk of bias judgments for the presented NRS result using ROBINS-I tool: L: low, M: moderate, S: serious, C: critical. Risk of bias domains from ROBINS-I tool: 1: Confounding; 2: Classification of interventions; 3: Selection into the study; 4: Deviations from intended interventions; 5: Missing data; 6: Outcome measurement; 7: Selective reporting. For Fujiwara, Isumi, Sampei, et al., 2020, event numbers were calculated from percentages and totals presented in the paper.





**Fig. 4.** Meta-analyses (random-effects) of all response to crying outcomes measured on scale 0–100.

MD: mean difference; CI: confidence interval. Risk of bias judgments for the presented RCT result using RoB2 tool: L: low, S: some concerns, H: high. Risk of bias domains from RoB2 tool for RCTs: 1: Randomisation; 2: Deviations from intended interventions; 3: Missing data; 4: Outcome measurement; 5: Selective reporting.

response in the desired direction). One cluster-RCT measured ‘Active coping’ (Fujiwara et al., 2020a), and found no difference between groups (MD 0.59 points on the 1–100 scale, 95 % CI -0.73 to 1.91,  $n = 2655$ ). Three RCTs (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012) found no improvement in the ‘response to general crying’ (summary MD 0.08 95 % CI -0.84 to 1.00;  $n = 3794$ ,  $I^2 = 0\%$ ). The same three RCTs found a negligibly small improvement in the intervention group for the ‘response to unsoothable crying’ (summary MD 1.58, 95 % CI 0.11 to 3.06,  $n = 3497$ ,  $I^2 = 0\%$ ). All four RCTs (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012; Fujiwara et al., 2020a) assessed ‘self-talk’ in response to inconsolable crying (e.g. telling yourself the crying would end or that there was nothing that could be done); the summary estimate suggested no difference between groups (MD 1.38, 95 % CI -1.27, 4.02,  $n = 6146$ ,  $I^2 = 61\%$ ). Forest plots with summary estimates for these meta-analyses are presented in Fig. 4 (fixed effects models shown in Appendix 4 Fig. S1).

The same four RCTs also measured the number of times per day the mother walked away from her inconsolable child (as recorded in participant diaries), a behaviour encouraged as a coping strategy. This occurred more frequently in the intervention group compared with control (summary incidence rate ratio [IRR] from three trials (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012) was 1.52, 95 % CI 0.94 to 2.45,  $n = 3049$ ,  $I^2 = 61\%$ ; Appendix 4 Fig. S2). The fourth RCT (Fujiwara et al., 2020a) dichotomised this outcome (ever vs. never), and found weak evidence of more frequent walking away in the intervention group (37.8 % vs. 34.6 %, RR 1.09, 95 % CI 0.96 to 1.24,  $n = 2655$ ). Another RCT (Lou et al., 2011) measured likelihood of maternal walking away using a five-point scale (in a lab based setting), and found that mothers in the intervention group were more likely to do so ( $t = 2.1$ ,  $p = 0.04$ ).

Three RCTs (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012) assessed the average number of times per day the child was picked up when distressed or crying; no difference was found between groups (summary IRR 1.02, 95 % CI 0.96 to 1.07,  $n = 3049$ ,  $I^2 = 0\%$ ; Appendix 4 Fig. S3).

One study (Cala et al., 2020) comparing “all babies cry” (ABC) material to other educational material measured change in number of calming strategies employed for parenting stress from enrolment to follow-up and found no difference between groups (MD 0.3, 95 % CI -0.2 to 0.8,  $n = 115$ ,  $p = 0.256$ ).

### 3.5. Parental stress/frustration

This outcome was measured in seven RCTs. In three RCTs (Barr et al., 2009a; Barr et al., 2009b; Fujiwara et al., 2012) evaluating PURPLE crying, mothers rated frustration related to infant crying on a six-point Likert scale; there was no difference between groups (summary SMD  $-0.01$ , 95 % CI  $-0.08$  to  $0.05$ ,  $n = 2999$ ,  $I^2 = 23$  %; Appendix 4 Fig. S4). Another RCT (Groisberg et al., 2020), evaluating different methods of delivering PURPLE crying material, reported the weekly frequency of parental frustration, and found no difference between groups ( $p = 0.66$ ,  $n = 164$ ). One RCT (McRury & Zolotor, 2010) ( $n = 35$ ) comparing “Happiest baby” intervention to other material reported parenting stress index at 6 and 12 weeks, and found higher stress in the intervention group at both time points ( $p = 0.07$  and  $p = 0.01$ , respectively; effect estimates not reported). One RCT (Arshadi et al., n.d.), evaluating impact of hospital discharge planning found that maternal stress (using the Parental Stress Scale) was lower in the intervention group ( $p < 0.001$ ,  $n = 92$ ). A final RCT (Lou et al., 2011), assessing the effect of PURPLE crying material on mean frustration levels (rated on a 0–100 scale) when a 10-min audio of a child crying was played immediately after the education session, found some evidence of lower frustration levels in the intervention group ( $p = 0.10$ ,  $n = 33$ ).

### 3.6. Parental mental health

One RCT (Bishe et al., 2020) comparing a home education package to standard care reported both ‘state anxiety’ (current anxiety when answering questionnaire) and ‘trait anxiety’ (general anxiety level) were lower at follow-up in the intervention group ( $p < 0.001$ ,  $n = 70$ ). One cluster RCT (Doi, Fujiwara, Isumi, & Mitsuda, 2020; Fujiwara et al., 2020a) assessed depression using the Edinburgh Postnatal Depression Scale, and found no difference between groups (13.7 % intervention, 16.0 % control; OR 0.85, 95 % CI 0.64 to 1.12,  $n = 2601$ ).

### 3.7. Frequency or duration of infant crying

This outcome was measured in two studies (Barr et al., 2009b; McRury & Zolotor, 2010). One RCT (Barr et al., 2009b) evaluating effectiveness of PURPLE crying material reported a small increase in average minutes of crying and inconsolable crying per day in the intervention group compared to controls (MD 5.5 min, 95 % CI 2.7 to 8.4 min,  $n = 1857$ , and MD 1.9 min, 95 % CI 0.4 to 3.3 min,  $n = 1857$ , respectively). A second RCT (McRury & Zolotor, 2010) comparing “Happiest Baby” with a control intervention found no difference in mean daily hours of crying between groups at 4 weeks ( $p = 0.3$ ,  $n = 33$ ), 6 weeks ( $p = 0.4$ ,  $n = 33$ ) or 12 weeks ( $p = 0.8$ ,  $n = 26$ ), but found frequency of crying was higher in the intervention group at 8 weeks ( $p = 0.04$ ,  $n = 34$ ).

### 3.8. Infant sleep patterns

One RCT (McRury & Zolotor, 2010) comparing “Happiest baby” with a control intervention measured mean daily hours of sleeping, and found no difference between groups at 4, 6, 8 or 12 weeks ( $p = 0.2$  [ $n = 33$ ],  $p = 0.8$  [ $n = 33$ ],  $p = 0.7$  [ $n = 34$ ] and  $p = 1.0$  [ $n = 26$ ], respectively).

None of the included RCTs reported outcomes on confidence/self-efficacy, frequency of seeking support, other infant abuse, or infant mortality.

### 3.9. Certainty of evidence

Based on GRADE assessments, there is low certainty evidence from two case-control studies and two CBA studies that educational interventions have no effect on AHT, due to serious bias concerns (downgraded 2 levels for bias). Evidence for self-reported shaking was of very low certainty due to serious bias concerns (downgraded 2 levels for bias) and imprecision. Evidence for parental responses to crying, some parental behaviours (e.g. walking away from infant, picking-up infant and others) and parental frustration ranged from very low to moderate certainty. GRADE assessments are presented in the summary of findings table (Table 5).

## 4. Discussion

### 4.1. Summary of findings

This systematic review found low certainty evidence (from two case-control studies and two controlled before-after studies) of no effect of educational interventions on the incidence of AHT. Further, we found very low certainty evidence, from a cohort study and a cluster-RCT, of reduced incidence of infant shaking; this self-reported outcome had high potential for bias as parents in the intervention group may underreport its occurrence.

There was moderate certainty evidence of negligible improvements in parental response to inconsolable crying, and low certainty evidence of possible increase in the ‘walking away’ behaviour in intervention groups, although this latter result was imprecise. There was no evidence for three other measures of parental responses to infant crying. In the one study that assessed anxiety there was an improvement in the intervention group, but the study was small. There was no difference between intervention and control in infant picking up behaviours and parental frustration with crying, and also for emotional regulation and postnatal depression. There was some indication that some evidence was potentially missing for parental mental health outcomes (depression, anxiety and stress).

**Table 5**

Summary of findings and certainty of evidence (based on GRADE rating) for abusive head trauma, self-reported shaking, parental responses to crying and parental frustrations syntheses.

Certainty assessment							No. of patients		Effect		Certainty of evidence
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Comparison	Relative (95 % CI)	Absolute (95 % CI)	
Abusive head trauma (incidence)											
4	Observational studies (2 case-control + 2 CBA)	Very serious <sup>a</sup>	Not serious	Not serious	Not serious <sup>b</sup>	None	Case control studies: 86 cases, 644 controls CBA studies: >1.5 million	Unavailable	OR 0.95 (0.81 to 1.13)	0 fewer per 1000 (from 0 fewer to 0 fewer) Narrative synthesis: educational interventions appear to have no effect on the incidence of AHT	⊕⊕○○ Low
Self-reported shaking of the baby (incidence)											
3	2RCTs + 1 NRS	Very serious <sup>c</sup>	Not serious	Not serious	Serious <sup>d</sup>	None	-/2692	-/5924	Not pooled. Narrative synthesis: educational interventions appear to reduce frequency of shaking		⊕○○○ Very low
Parental responses to crying: active coping (scale from: 0 to 100)											
1	Randomised trials	Serious <sup>e</sup>	Not serious	Not serious	Serious <sup>f</sup>	None	1058	1597	-	MD 0.59 higher (0.73 lower to 1.91 higher)	⊕⊕○○ Low
Parental responses to crying: response to general crying (scale from: 0 to 100)											
3	Randomised trials	Not serious	Not serious	Not serious	Serious <sup>g</sup>	None	1734	2060	-	MD 0.08 higher (0.84 lower to 1 higher)	⊕⊕⊕○ Moderate
Parental responses to crying: response to inconsolable crying (scale from: 0 to 100)											
3	Randomised trials	Not serious	Not serious	Not serious	Serious <sup>h</sup>	None	1773	1724	-	MD 1.58 higher (0.11 higher to 3.06 higher)	⊕⊕⊕○ Moderate
Parental responses to crying: Self-talk (Scale from: 0 to 100)											
4	Randomised trials	Serious <sup>i</sup>	Serious <sup>j</sup>	Not serious	Serious <sup>k</sup>	None	2830	3316	-	MD 1.38 higher (1.27 lower to 4.02 higher)	⊕○○○ Very low
Parental responses to crying: walking away from crying baby (times per day)											
3	Randomised trials	Not serious	Serious <sup>l</sup>	Not serious	Serious <sup>m</sup>	None	-/1527	-/1522	Rate ratio 1.52 (0.94 to 2.49)	-	⊕⊕○○ Low

(continued on next page)

Table 5 (continued)

Certainty assessment							No. of patients		Effect		Certainty of evidence
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Comparison	Relative (95 % CI)	Absolute (95 % CI)	
3	Randomised trials	Not serious	Not serious	Not serious	Serious <sup>a</sup>	None	-/1527	-/1522	Rate ratio 1.02 (0.96 to 1.07)	-	⊕⊕⊕○ Moderate
3	Randomised trials	Not serious	Not serious	Not serious	Serious <sup>o</sup>	None	1502	1497	-	MD 0.01 lower (0.08 lower to 0.05 higher)	⊕⊕⊕○ Moderate

CI: confidence interval; OR: odds ratio; MD: mean difference. RCT: randomised trial; NRS: non-randomised study.

<sup>a</sup> Serious risk of bias due to confounding and selection bias in case-controlled studies. Serious risk of confounding in CBA studies. Downgraded by 2 levels.

<sup>b</sup> Very wide confidence interval from two pooled case-control studies, and a very small number of cases (77 + 9). Summary estimate from only two CBA studies has narrow CI around the null. The overall estimate including all 4 studies has a narrow CI around the null. No downgrades made for precision.

<sup>c</sup> One cluster RCT at high risk of bias and one NRS at serious risk of bias (self-reported shaking - high risk of bias in the measurement of outcome). Studies not pooled due to different study design. Third RCT was inestimable due to zero events in both arms.

<sup>d</sup> Studies not pooled. Confidence intervals were somewhat wide for one of the studies and the third study was non-estimable because of no events.

<sup>e</sup> High risk of bias for deviations from intended interventions and missing data.

<sup>f</sup> Single study. Although the confidence interval is not wide, it is around a very small difference in measurement scale.

<sup>g</sup> CI relatively wide and consistent with the direction of both benefit and harm.

<sup>h</sup> Only 3 included studies.

<sup>i</sup> Two of the four included results had risk of bias issues: one was at high risk of bias (36.67 % weight in MA) and the other was rated some concerns (7.67 % weight).

<sup>j</sup> I-sq = 61 %, study estimates vary in opposite directions.

<sup>k</sup> CI wide across both directions of effect.

<sup>l</sup> I-sq = 61 %, estimates vary between studies (but they are in the same direction).

<sup>m</sup> Only 3 included studies and wide CI consistent with both benefit and harm.

<sup>n</sup> Only 3 included studies and CI consistent with both benefit and harm.

<sup>o</sup> Only 3 included studies and CI consistent with both benefit and harm.

The mixed evidence from our review is comparable with the findings from a recent review of interventions for managing colic (Lynøe & Eriksson, 2021), which concluded that preventive programs showed little or no effect on incidence of AHT. An older review (Lopes, Eisenstein, & Williams, 2013) reported that the eight studies they identified all reported positive effects of the intervention, and another review by the same author (Lopes & Williams, 2018) found weak evidence of effectiveness of interventions for reducing infant crying and raising awareness about AHT. However, neither of these reviews considered study design specific issues when assessing bias and quality of the included studies and overall certainty of evidence.

#### 4.2. Strengths and limitations

Our review brings a comprehensive synthesis of effectiveness of educational interventions for AHT prevention. Few other reviews have addressed this topic (Iqbal O'Meara, Sequeira, & Miller, 2020; Lopes et al., 2013; Lopes & Williams, 2018; Lynøe & Eriksson, 2021), most of which were not systematic. Our comprehensive search strategy, developed by an experienced information specialist (SD) with input from clinical co-authors (ML, JM) and public health experts (JM, JW) imparts assurance that we identified all relevant studies. Our search and inclusion criteria did not impose any limitations by date or language. Cochrane guidance for conducting systematic reviews was rigorously followed.

There were several limitations. Our initial intention to include studies in which the intervention aim was to prevent AHT was challenging to operationalise in practice due to variations in how this was reported. Instead, we opted to examine the content of intervention packages for messaging regarding AHT to determine eligibility, and were sometimes required to contact authors to determine this.

No RCTs measured our primary outcome of AHT, and self-reported infant shaking was reported in three RCTs. Whilst other behaviour changes are proxies for intervention success, AHT reduction is the ultimate focus. We addressed this by including non-randomised studies that did measure AHT reduction. Most meta-analyses included the same three or four studies from two research groups, and several evaluated the same intervention (PURPLE Crying). Most studies assessed knowledge-based outcomes, which were not of interest for this review as they are process outcomes, early in the pathway to behaviour change. Such process or surrogate outcomes may be misleading as they may not accurately predict clinically important outcomes (AHT in this case) (McKenzie et al., 2022). Several studies included in this review concluded their intervention was effective based solely on these knowledge outcomes, a finding which is largely not supported based on the behaviour change outcomes. Further work is required to understand how to turn the gains made in knowledge acquisition into behaviour change.

We identified important gaps in the evidence. Most studies did not include fathers or male partners who are more frequent perpetrators of AHT (Schnitzer & Ewigman, 2005; Starling et al., 1995). Most included studies were from North America and Japan, with only one from Europe (France), and none reported cost-effectiveness outcomes. Only one study evaluated training for healthcare professionals delivering prevention programmes.

Issues with risk of bias contributed to the GRADE judgment of low certainty evidence for AHT, and risk of bias and imprecision led to the judgment of very low certainty evidence for incidence of infant shaking. Certainty of evidence for secondary outcomes varied from very low to moderate. Not all results from completed studies were publicly available, and some studies remain unpublished or inaccessible.

#### 4.3. Implications for research and policy

Our review highlights large gaps in the evidence for effectiveness of educational and behavioural interventions which aim to reduce AHT. Such interventions are unlikely to be harmful (Fujiwara et al., 2020a), but there is very little robust evidence on whether they are effective.

Development of robust evidence to support or refute the role of educational interventions to prevent AHT is therefore needed, but any such evaluations are challenging for several reasons. Whilst a cluster RCT which linked patients to hospital records to accurately assess AHT rates may be possible, this would be difficult to conduct due to the rarity of the outcome, the large number of participants required, and challenges with linking safeguarding outcomes across health and social care agencies. Alternatively, large-scale, well-designed and conducted comparative NRSs utilising routinely recorded AHT outcome data could be used to assess effectiveness of preventative programmes. Future studies should consider in their designs the opportunity to address areas of limited evidence. Specifically, the ability of the intervention to reach and impact male carers and ensuring that study samples are representative of the population targeted by the intervention.

In summary, we found low certainty evidence that preventative interventions focused on educating parents on how to cope with infant crying do not reduce the incidence of AHT. Very low certainty evidence suggests that prevention programmes might reduce the incidence of infant shaking. There is very low to moderate certainty evidence that some of these interventions might marginally increase some intended parental behaviours (e.g. walking away from a crying infant, picking up a child). As RCTs are often not feasible to assess rare outcomes like AHT, more robust, large-scale, comparative NRSs that make use of routinely collected data and include assessment of cost-effectiveness should be conducted to inform decisions on preventative interventions.

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### CRedit authorship contribution statement

Conception: MDL, JM, MTR, JS.  
 Protocol development: LJS, PD, MDL, JM, SI, MTR, JGW, JS.  
 Data searches: SD.  
 Study selection: LJS, RW, PD, SD, SI, JS.  
 Data extraction: LJS, RW, JS.  
 Risk of bias assessments: LJS, RW, JS.  
 Meta-analysis: LJS, RW, JS.  
 Interpretation: all.  
 Drafting paper: LJS, RW, JS.  
 Reviewing and revising paper: all.

### Declaration of competing interest

LJS, RW, PD, SI, MTR, SD and JS report grant funding from NIHR (NIHR ARC West) during the conduct of the study. JS reports personal fees from Core Models Limited, UK (for teaching introductory systematic review methods at an online course), unrelated to the submitted work. Other authors have no competing interests to declare.

### Data availability

The data is already publicly available

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### Appendix A. Supplementary data

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