Systematic Review and Meta-Analysis

of Fuss/Cry Durations and Colic Prevalence in Infants across Countries

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Short Title: Meta- Analysis of Fuss/Cry Duration

Abbreviations: CMA – Comprehensive Meta-Analysis; SD – Standard Deviation; CI - Confidence Interval

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Contributor's Statements:

Dieter Wolke: Prof. Wolke conceptualized and designed the study, drafted the manuscript, supervised the study, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Ayten Bilgin: Miss Bilgin conducted the data collection, carried out the analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted.

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Abstract

Objective: To determine the mean duration of fussing and crying and prevalence of colic using modified Wessel criteria in infants in the first 3 months of life. Is there a universal 6 week crying peak and what is the prevalence of colic according to age and country?

Study Design: A systematic literature search was performed using the databases Medline, PsycINFO and Embase. The major outcome measure was mean total fuss/cry duration during 24 hours at 1-2 weeks (11 samples), 3-4 weeks (6 samples); 5-6 weeks (28 samples), 8-9 weeks (9 samples) and 10-12 weeks (12 samples).

Results: Of 5687 articles reviewed, 28 diary studies (33 samples) were suitable for inclusion in meta-analysis. The studies included 8690 infants. No statistical evidence for a universal crying peak at 6 weeks across studies was found. Rather, the mean fuss/cry duration across studies was stable at around 117-133 minutes (SDs: 66-70) in the first 6 weeks and dropped to a mean of around 68 minutes (SD: 46.2) by 10-12 weeks. Colic was much more frequent in the first 6 weeks (17-25%) than thereafter (11% by 8-9 weeks and 0.6% by 10-12 weeks) according to modified Wessel criteria and lowest in Denmark and Japan.

Conclusions: Fuss/cry duration drops significantly after 8-9 weeks of age with colic as defined by modified Wessel criteria being rare in infants older than 9 weeks. Colic or excessive fuss/cry may be more accurately identified by defining fuss/cry above the 90^{th} percentile in the chart provided based on the review.

Introduction

Colic is a common source of concern for parents, a frequent reason for seeking help and advice from health care professionals [1,2] and a trigger for abusive head trauma (previously shaken baby syndrome).[3] However, definitions for colic vary widely ranging from gastrointestinal symptoms [4,5] to inconsolable crying,[6] which has resulted in variations of the prevalence rate from 1.5% to 11.9%.[7] Increasingly colic is defined in terms of total daily duration of fussing and crying. [8-11] The most widely used definition for colic is the "Rule of Three's"[12]: an infant is considered to have colic if the infant fusses or cries for >3 hours, >3 days per week, for >3 weeks. However, it is impracticable for parents to assess and document fuss/cry duration for a 3-week period using detailed diaries. [13] Thus, "modified Wessel criteria" are most often used, requiring the infant to have fussed/cried for more than three hours a day, on at least three days in any one week. [12,14,15]

Although the modified Wessel criteria are widely used, firstly, normative studies in the general infant population are lacking. [15] Secondly, considerable changes in infant care have occurred over the last 60 years since the Wessel criteria were published,[16,17] thus prevalence may be quite different than in the 1950s. Thirdly, while modified Wessel criteria have been used in different countries, the impact of cultural variations such as caregiving styles [18-23] and maternal soothing techniques [23,24] on the duration of infant fussing and crying may need to be taken into consideration. Furthermore, the cry/fuss duration may depend on the patterns of feeding (breast vs. bottle).[25] Finally, several studies have documented a developmental pattern of fuss/cry duration in the first three months of life, [1,26-29] indicating a gradual increase that peaks at 5-6 weeks of age with a decrease to half the amount by 3-4 months of age.

[18,22,27,28,30,31] This "normal crying curve" has been interpreted as universal across cultures [18] although some have not found evidence for it. [20,32,33]

We conducted a systematic review and meta-analysis of fuss/cry durations reported in diary studies from around the world. Twenty-four hour behavior diaries are considered to be the international gold standard for measurement. [14,34-36] We investigated, firstly, what is the change in fuss/cry duration over the first 12 weeks of life and is there a universal "crying curve" (5-6 week fuss/cry duration peak)? Secondly, do mean fuss/cry duration vary across studies in different countries, according to feeding type or study quality? Thirdly, what is the prevalence of colic according to the modified Wessel criteria at different ages in the first 12 weeks?

Methods

The current meta-analysis was conducted in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[37]

We searched the databases Medline (1964 - December 2015), PsycINFO (1964 - December 2015) and Embase (1964 - December 2015) using the search headings "infant and crying" OR "crying and amount" OR "crying and duration" OR "fussing and infant". In addition, infant cry researchers who had participated in the International Cry Research Workshops were approached concerning unpublished data. Finally, we conducted a separate bibliography search and included all new relevant research.

Criteria for inclusion of articles in the analysis were as follows: 1) at least one 24-hour behavior diary to measure fuss/cry duration; 2) unselected sample, i.e. no infants had been excluded according to fuss/cry duration (e.g. only colic infants or all non-colic infants); 3) observation study (i.e. no intervention trial); 4) infant age between 1 and 13 weeks; and 5) the authors reported (or provided after request) mean

fuss/cry duration as well as distribution indices (i.e. standard deviation (SD). For the colic prevalence analysis, only the studies which reported at least three 24-hour behavior diaries were included in order to meet the modified Wessel criteria. Abstracts were screened according to the selection and inclusion criteria explained above by two authors, each screening half of the abstracts (AB, MS). Study selection and data extraction were performed independently by two authors (AB, DW).

The quality of studies was evaluated according to 8 criteria: a) subject selection (whole vs. convenience population); b) recruitment rate ($\geq$ 50% vs. < 50%), c) participation rate ($\geq$ 75% vs. < 75%), d) sample size ($\geq$ 101 vs. <101), e) whether the following four sample characteristics were reported: socioeconomic status, parity, infant sex, and maternal age (3 of 4 reported vs. <3 reported), f) feeding type (reported vs. not reported), g) resolution time for the diary (5 min. vs. 15 min.), h) number of days requested for diary ($\geq$ 4 vs. < 4 days), and, i) whether modified Wessel criteria were employed. Each sample, at each measurement age, received a score of 0 or 1 for each of the criteria. A score of 0 was also given in cases where the information for the criterion was not reported. The individual scores were summed to give a total quality score that could range from 0 to 8 (Table 1).

The major outcome measure was mean total fuss/cry duration during 24 hours. The studies were grouped according to assessment age: 1-2 weeks (11 samples), 3-4 weeks (6 samples); 5-6 weeks (28 samples), 8-9 weeks (9 samples) and 10-12 weeks (12 samples). Furthermore, information regarding the sample size and feeding type (bottle-fed, breastfed, mixed) was extracted from the articles.

To test question 1 (fuss/cry peak duration), we calculated a weighted mean and the pooled weighted standard deviation (SD) for each period. To test for mean differences, ANOVA was performed between individual weighted means. To evaluate

the prevalence of colic, 3 samples which used the diaries for less than 3 days were removed from the 8-9 weeks analysis. The prevalence of colic for each study at each assessment point was computed according to the modified-Wessel criteria and overall prevalence rates are reported as weighted mean and pooled weighted standard deviation.

Meta-analysis was conducted with the Comprehensive Meta-Analysis (CMA) software. [38] Effect sizes are reported as standardized mean difference with 95% confidence intervals for each study. The mean difference (Cohen's *d*) compares the individual study's mean to the overall weighted mean across studies at each assessment time. A *d* of .20 is a small, .50 medium and .80 or more a large effect.[39] Effect sizes were analyzed using the random effects model, in which the error term is composed of variation originating from both within-study variability and between-study differences.[40,41]

The distribution of effect sizes was examined using tests of heterogeneity. Significant heterogeneity indicates that differences across effect sizes are likely due to sources other than sampling error, such as different study characteristics. Categorical moderator tests were applied to test for within groups Q (Q_w) and between groups Q (Q_b). A significant value for Q_w indicates that the effect sizes within a category of the moderator variable are heterogeneous, whereas a significant value for Q_b indicates that the effect sizes are significantly different across different categories of the moderator variable. Meta-regression analyses were performed to test quality assessment as a continuous moderator.

We examined the potential for publication bias by using two methods suggested for observational studies. First, biases according to study size were assessed

with use of the Begg and Mazumdar[42] rank correlation test (Kendall's tau b). Second, the Duval and Tweedie[43,44] 'Trim and Fill' method was applied.

Results

The online search yielded 5680 articles. An additional seven potential studies were identified through searches of bibliographies and from the Infant Cry Research Workshops (Figure 1; online only). After removing the duplicates, the overall systematic literature search included 4109 articles. We reviewed the titles and abstracts of all articles found (N: 4109), resulting in 227 abstracts for joint review (AB, MS). After excluding 138 articles based on their abstract, a total of 89 full-text articles were independently reviewed by two authors (AB, DW). Based on the inclusion criteria, 43 articles were further excluded. Among the remaining forty-six articles, there were 18 studies with missing data which required their authors to be contacted to obtain further information about the fuss/cry duration or moderator variables. However, some authors were not able to provide missing data (e.g., means, SD etc.) [8,14,15,22,45-49] or could not be reached; [50-54] and some studies did not meet the inclusion criteria (e.g. selected population, no fuss/cry duration data etc.). [55-58] These studies were therefore not included in the meta-analysis. Five study reports [20,21,59-61] reported on more than one sample, resulting in a total of twenty-eight articles with 33 samples being included in the meta-analysis (Table 1). The majority of the studies used at least 3 days diary except 3 samples from 2 study reports.[60,62] The studies included in the analysis with their quality rating scores and descriptions of each study are shown in Table 1.

The overall agreement in the selection of articles according to the predefined criteria was Cohen's k= 0.89 at the full-text retrieval stage. The discrepancies in articles were discussed and mutually resolved by the coders.

Fuss/cry duration across 1-12 weeks

Mean fuss/cry duration

The weighted mean average for each period was computed (see Figure 2, A). As shown, mean fuss/cry durations were around 117-133 minutes (SDs: 66-70) in the first 6 weeks and then dropped to around 68 minutes (SD: 46) by 10-12 weeks. Post-hoc comparisons showed that fuss/cry duration did not significantly differ from each other across the first 6 weeks. However, the fuss/cry duration at 10-12 weeks (M: 68.03, SD: 46.2) was significantly lower than at 1-2 weeks (M: 117.3, SD: 66.8; $p < .001$); 3-4 weeks (M: 118.2, SD: 69.3; $p <. 01$); and 5-6 weeks (M: 133.3, SD: 70.1; $p < .001$).

Potential Moderator Variables

Country

Random effects meta-analyses (Figure 3; online only) showed that the standardized fuss/cry duration means in Germany at 1-2 (M: 69, SD: 60) weeks and 3-4 weeks of age (M: 80.8, SD: 67.4) and in Japan at 5-6 weeks age (M: 107, SD: 36) were significantly lower than the overall weighted average mean (Figure 3; online only). Similarly, the standardized fuss/cry duration means in Denmark were significantly lower than the overall weighted average mean across the first 12 weeks except 8-9 weeks of age. On the other hand, the standardized fuss/cry duration mean in Canada at 3-4 weeks of age (M: 149.8, SD: 73.5) and in The Netherlands at 5-6 weeks of age (M: 150.4, SD: 66.3) was significantly higher than the overall weighted fuss/cry duration mean (Table 2). The Q test for heterogeneity was significant at each age ($p < 0.001$).

Feeding Type

Feeding type was found to be a significant moderator at 1-2 weeks (Q_b=22.91; p < 0.001), 5-6 weeks (Q_b=12.28; p < 0.01), and at 10-12 weeks (Q_b=21.01; p < 0.001). Samples which included babies who were bottle-fed (z = -3.461; p<0.01) or mixed-fed (breast and bottle) (z = -3.656; p<0.01) had significantly lower fuss/cry durations than the overall weighted fuss/cry mean at 5-6 weeks. In contrast, samples which included babies who were breastfed had significantly higher fuss/cry durations at 3-4 weeks (z = 3.500; p<0.01). Furthermore, samples that did not report on the type of feeding (1-2 weeks and at 10-12 weeks of age) reported significantly higher fuss/cry durations than the overall weighted fuss/cry.

Quality Assessment

Univariate meta-regression analyses indicated a positive significant moderating influence of study quality at 8-9 weeks of age (the slope: point estimate= 0.15; z= 4.09; SE= 0.04; p < 0.001; Q_b= 16.79; df: 1; p <0.001): As study quality increased, fuss/cry duration also increased.

Prevalence of colic

We calculated the overall mean weighted colic prevalence of all studies at each assessment point (Figure 2, B). Mean colic prevalence at 10-12 weeks (0.6%) was significantly lower than the mean colic prevalence at 1-2 weeks (17.4%, z=2.95; p < 0.01), 3-4 weeks (18.4%, z=3.40; p < 0.001), 5-6 weeks (25.1%, z=3.64; p < 0.001) and 8-9 weeks (10.8%, z=2.93, p<0.01). Furthermore, it was found that colic prevalence at 5-6 weeks was significantly higher than colic prevalence at 8-9 weeks (z=2.01; p<0.05).

Potential Moderator Variables

Significant moderating effects were observed for country at 1-2 weeks (Q_b=16.24; $p < 0.01$), 3-4 weeks (Q_b=22.91; $p < 0.001$), and 8-9 weeks (Q_b=9.44; $p < 0.05$). The average standardized difference (*d)* in mean colic prevalence of the UK studies at 1-2 weeks (28%), Canada at 3-4 weeks (34.1%), and Italy at 8-9 weeks (20.9%) was significantly higher than the overall weighted colic prevalence. In contrast, Denmark (5.5%) and Germany (6.7%) had lower colic rates at 3-4 weeks of age (Table 2).

Although country was not a significant moderator at 5-6 weeks, fewer infants with colic were reported across all Danish studies (6.7%), the Japanese study (2.1%) and the UK studies (18.1%) compared to the overall prevalence.

Feeding type was found to be a significant moderator at 5-6 weeks (Q_b=14.23; $p < 0.01$) and 10-12 weeks of age (Q_b=4.55; $p < 0.05$). At 5-6 weeks, studies that reported infants who were bottle-fed ($z = -3.87$; $p < 0.001$) and mixed fed ($z = -3.54$; $p < 0.001$) had lower prevalence of colic. On the other hand, at 10-12 weeks studies that did not report the feeding type (6 studies) had significantly higher colic prevalence ($z = 2.62$; $p < 0.05$) compared to overall weighted colic prevalence.

The homogeneity analysis was significant at the following ages: 1-2 weeks: Q=29.42; $p < 0.01$; 3-4 weeks: Q=24.87; $p< 0.001$; 5-6 weeks: Q=74.57; $p<0.001$.

Quality Assessment

Univariate meta-regression analyses showed that study quality had a positive significant moderating influence at 8-9 weeks of age (the slope: point estimate= 0.53; z= 2.57; SE= 0.21; $p < 0.05$; Q_b= 6.61; df: 1; $p <0.5$). Increased quality of study was associated with increased prevalence of colic.

Publication Bias

The Begg and Mazumdar Rank Correlation Test (correlation between study size and effect size) suggest that there was little evidence for publication bias.

We assessed the possibility of publication bias by using a funnel plot to assess for asymmetry. The Duval and Tweedie's Trim and Fill method indicates that two studies are missing left to the mean at 1-2 weeks (combined studies: 0.01; 95% CI: -0.23 – 0.26; using trim and fill the imputed point estimate: -0.08; 95% CI: -0.32 - 0.16), three studies are missing left to the mean at 3-4 weeks (combined studies: -0.02; 95% CI: -0.38 to 0.34; using trim and fill the imputed point estimate: 0.29; 95% CI: -0.67 to 0.09) and three studies are missing left to the mean at 10-12 weeks (combined studies: 0.14; 95% CI: -0.09 to 0.38; using trim and fill the imputed point estimate: -0.01; 95% CI: -0.26 to 0.24).

Discussion

This review and meta-analysis investigated mean fuss/cry duration and prevalence of colic in diary studies from around the world. Firstly, no statistical evidence was found for a "universal" increase of fuss/cry duration over the first 6 weeks of life culminating in a "crying peak" at 5-6 weeks as proposed previously,[28,29] although visual inspection shows a slight increase. [63] Overall, fuss/cry durations were high across the first 6 weeks of life, then reduced significantly over the following 6 weeks. All studies found a "universal" reduction in fuss/cry duration between 6 and 12 weeks of age. The average fuss/cry durations were around 117-133 minutes in the first 6 weeks and then dropped to a mean of around 68 minutes by 10-12 weeks.

Secondly, the significant differences in mean fuss/cry durations between studies were moderated by country of origin. The most consistent finding was the

lower fuss/cry durations reported in Denmark at several age points. [32] On the other hand, with the exception of Denmark, no consistent pattern for significantly higher fuss/cry duration between other countries was found. At different assessment ages, studies from the Netherlands [64] and Canada [65,66] had significantly higher fuss/cry durations compared to the overall mean weighted fuss/cry duration.

The findings regarding the country differences appear robust according to publication bias results. However, we can only speculate on the reasons why there are country differences, in particular between Denmark and the rest of Europe and North America. These could range from economic conditions, such as less social inequality, to caretaking patterns such as responsiveness, carrying behavior and management in Denmark that have been shown to differ from the UK. [20] However, there may also be population genetic differences, and the infants both inherit their parents' genes and are reared by them (gene-environment correlation). [67] Nevertheless, further analysis of caretaking patterns may prove to provide clues for effective preventative strategies.

Feeding type was a further moderator of fuss/cry duration. Bottle or mixed feeding was associated with reduced duration of fussing and crying or colic from 3-4 weeks onwards. Switch in feeding type is one frequently adopted method by parents dealing with a crying baby [68] and has been found to reduce crying regardless of what formula change is instituted, suggesting a placebo effect.[69] Feeding type has also been previously reported to be associated with more night waking in infants. [70,71] Night waking is often signaled by fussing or crying and thus may have increased the total fuss/cry duration in diary reports in those breast feeding. Alternatively, cultural differences might have influenced the accuracy of diary keeping. Furthermore, mothers' perception of the frequency of their infants' crying might be enhanced by cultural variations in support for shouldering the burden in caring for their infant.

Thirdly, the prevalence of colic according to Wessel's modified criteria ranged from 17-25% in the first 6 weeks, then reduced to less than 11% by 8-9 weeks and finally, to only 0.6% by 10-12 weeks. Notably, the lowest colic prevalence rate was found for Danish infants (around 6%) and Japanese (2%) infants during the first 6 weeks. In contrast, the highest mean prevalence rate was found for the UK studies at 1-2 weeks (ranged from 17% to 47%). If colic is considered the extreme of a normal distribution of fuss/cry duration, then it is not surprising that fewer infants with colic were found in Denmark where the mean fuss/cry duration was lower than in other countries. However, if alternatively, colic is considered to be qualitatively different from normal fussing and crying [8] then a similar prevalence should have been found across countries. Our findings are consistent with the first interpretation that colic reflects the extreme of normal fuss/cry distribution. Further, but less consistent, moderation of colic prevalence was found by feeding type. There was a weak trend for infants who were bottle or mixed-fed to have lower prevalence of colic at 5-6 weeks.

There are strengths and limitations that require comment. This is the first review that has quantitatively evaluated changes in mean fuss/cry durations and colic prevalence across studies from different countries. The study only included those with diary measures: all but 3[60,72] used 5-minute resolution and most samples had 3 or more days of diaries. On the other hand, there were unequal numbers of studies from different countries. Although we identified empirical studies in Australia, Iran and Korea, despite contacting the authors, the required distribution measures were not available. Thus, this is a review of studies in North America and parts of Europe with only one study from Japan. No studies from threshold or developing countries were available, but these would be needed to provide adequate feedback to parents on other

continents. Feeding type information was also not available for some studies. Abstracts were screened by two of the authors. If there was any doubt, full texts were retrieved. We consider it unlikely that relevant studies with diary data were missed, but it cannot be excluded. Moreover, there might be a loss of studies in the title and abstract screening procedure, which was conducted by one author. Furthermore, multiple statistical comparisons were not Bonferroni adjusted and need to be interpreted cautiously. Finally, the lack of a significant peak at 5-6 weeks of age should be interpreted cautiously, since our study might be underpowered to detect a small peak amounting to 15 minutes.

Conclusion

There are several implications for research on colic and clinical practice. Firstly, colic is best defined as the extreme of the distribution of fuss/cry duration. Secondly, the cut-off points need to take into account the rapid developmental changes occurring in fuss/cry durations during the first 3 months. The modified Wessel criteria may have served researchers or clinicians well for more than sixty years but may be inaccurate when applied at any time across the first 3 months. As shown here, fuss/cry duration is highest in the first 6 weeks and reduces rapidly during the next 6 weeks. Thus cut-off points need to be determined for the first 6 weeks, at 8-9 weeks and 10-12 weeks. Figure 4 provides a percentile chart for "average" and "excessive" fussing and crying on basis of this meta-analysis across countries, allowing clinicians an approximation of whether the infant is excessively fussing or crying according to age or within the normal range. This feedback to parents is a first step of psycho education on fussing or crying and whether their infant's fuss/cry is within the normal range. Those above the 90^{th} percentile may be identified as excessive criers or infants with colic. Thirdly, as the mean fuss/cry

duration was found to vary between countries, future normative country specific studies may be required on representative samples. Nevertheless, the provided percentile chart (Figure 4) provides a more accurate estimate of normal to excessive fuss/cry duration of infants in industrialized countries than previously provided by individual studies. Fourthly, the rapid developmental change in fuss/cry duration has implications for treatment and interpretation of treatment studies. Consistent with recent advice, [29] colic is the extreme of normal fuss/cry behavior, self-limiting and thus the vast majority will spontaneously remit. Adequate management of fussing and crying in the first 3 months rather than treatment may be required.[73] However, if excessive fuss/cry persists beyond the first 3 months, there is increasing evidence that this may indicate regulatory problems with adverse consequences for future development and may require treatment.[74]

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Figure Legends

Figure 1 (online only). Search strategy for the systematic review

Figure 2. A) Weighted mean fuss/cry duration (in mins) across countries [1-2 wks vs. 10-12 wks ($p<0.001$); 3-4 wks vs.10-12 wks ($p<0.01$); 5-6 wks vs.10-12 wks ($p<0.001$)] and **B)** overall colic percentages (95% Confidence Interval) for all studies combined in each period **[**1-2 wks- vs.10-12 wks ($p<0.01$); 3-4 wks vs.10-12 wks ($p<0.001$); 5-6 wks vs.10-12 wks ($p<0.001$); 8-9 wks vs.10-12 weeks ($p<0.05$); 5-6 wks vs.8-9 wks ($p<0.05$)].

Figure 3 (a-e; online only). Random effect meta-analysis comparing crying amounts across countries at 1-2 weeks, 3-4 weeks, 5-6 weeks, 8-9 weeks and 10-12 weeks.

Figure 3a. Random effect meta-analysis comparing crying amounts across countries at 1-2 weeks

Figure 3b. Random effect meta-analysis comparing crying amounts across countries at 3-4 weeks

Figure 3c. Random effect meta-analysis comparing crying amounts across countries at 5-6 weeks

Figure 3d. Random effect meta-analysis comparing crying amounts across countries at 8-9 weeks

Figure 3e. Random effect meta-analysis comparing crying amounts across countries at 10-12 weeks

Figure 4. Percentile chart of above average fuss/cry at the age 1-2, 3-4, 5-6, 8-9 and 10-12 weeks of age in infants

Table 2

Table 2. Countries with statistically significant deviations from mean fuss/cry duration and colic percentages compared to the overall mean across all countries (all studies)

	Fuss/Cry Duration					
	Number of Studies	Overall Mean (SD) in minutes	Mean (SD) in minutes	Higher or Lower than Overall	Z score	p
1-2 Weeks						
Denmark	1	117.3 (66.8)	80 (44)	Lower	-3.86	<0.001
Germany	1	117.3 (66.8)	69 (60)	Lower	-4.55	<0.001
3-4 Weeks						
Canada	1	118.2 (69.3)	149.8 (73.5)	Higher	3.50	<0.001
Denmark	1	118.2 (69.3)	90 (58)	Lower	-3.24	<0.001
Germany	1	118.2 (69.3)	80.8 (67.4)	Lower	-3.78	<0.001
5-6 Weeks						
Denmark	3	133.3 (70.1)	85.6 (64.7)	Lower	-11.27	<0.001
Japan	1	133.3 (70.1)	107 (36)	Lower	-2.04	<0.05
The Netherlands	1	133.3 (70.1)	150.4 (66.3)	Higher	2.05	<0.05
10-12 Weeks						
Denmark	1	68 (46.2)	48 (44)	Lower	-3.01	<0.01
	Colic Percentage					
	Number of Studies	Overall Colic Percentage	Colic Percentage	Higher or Lower than Overall	Z score	p
1-2 weeks						
United Kingdom	7	17.4%	28%	Higher	2.73	<0.01
3-4 weeks						
Canada	1	18.4%	34.1%	Higher	2.76	<0.01
Denmark	1	18.4%	5.5%	Lower	-2.84	<0.001
Germany	1	18.4%	6.7%	Lower	-2.36	<0.001
5-6 weeks*						
Denmark	3	25.1%	6.7%	Lower	-7.22	<0.001

Japan	1	25.1%	2.1%	Lower	-2.16	<0.05
United Kingdom	7	25.1%	18.1%	Lower	-2.56	<0.05
8-9 weeks						
Italy	2	11.5%	20.9%	Higher	1.98	<0.05

Please note that this table only illustrates the findings for countries which were significantly different from overall. *Country overall was not a significant moderator.

Table1

Table 1. Summary table of all samples included in the meta-analysis with quality ratings

	Sample Code	Study	Weeks	Sample size	Mean (SD) of Cry/Fuss Duration in mins	Recruitment rate	Participation rate at each age	Characteristic of sample	Subject selection (whole vs. defined population)	Feeding type	Diary duration	Resolution time for the diary (5 min. vs. 15 min.)	Modified-Wessel definition	Quality rating scores
1	UK1*	Darlington & Wright, (2006)[52]	8	24	105 (47.7)	Not reported	20%	Yes	Whole	Breastfed	2 days	15 min	No	3
2	UK2*	Darlington & Wright, (2006) [52]	8	51	58 (45.8)	Not reported	42%	Yes	Whole	Bottlefed	2 days	15 min.	No	3
3	UK3	St. James-Roberts & Plewis (1996)[33]	2 6 12	128 94 69	133 (77) 128 (70) 97(44)	74%	64% 47% 35%	No	Whole	Not reported	3 days	5 min	No	4 3 3
4	UK4	St. James-Roberts et al. (2001)[73]	1 3 6 12	191 181 173 152	107 (77) 122 (72) 102 (66) 60 (42)	35%	94% 89% 85% 75%	Yes	Whole	Mixed	3 days	5 min.	No	5 6 6 6
5	UK5	St. James-Roberts et al. (2006)[20]	1 5	111 81	120 (63) 126 (58)	81%	64% 47%	Yes	Whole	Breastfed	4 days	5 min	Yes	8 7
6	UK6	St. James-Roberts &	1	14	170 (133.9)	Not reported	56%	No	Whole	Not reported	3 days	5 min.	No	2

	Sample Code	Study	Weeks	Sample size	Mean (SD) of Cry/Fuss Duration in mins	Recruitment rate	Participation rate at each age	Characteristic of sample	Subject selection (whole vs. defined population)	Feeding type	Diary duration	Resolution time for the diary (5 min. vs. 15 min.)	Modified-Wessel definition	Quality rating scores
		Menon-Johnson (1999)[74]	6 12	20 20	129 (65.1) 82 (45.4)		80% 80%							3 3
7	UK7	Lucas & St. James-Roberts (1998) [21]	2 6	43 36	128 (79) 149 (66)	Not reported	96% 80%	Yes	Whole	Breastfed	3 days	5 min.	Yes	5 5
8	UK8	Lucas & St. James-Roberts (1998) [21]	2 6	49 41	144 (98) 110 (51)	Not reported	94% 79%	Yes	?	Bottlefed	3 days	5 min.	Yes	5 5
9	UK9	St. James-Roberts et al. (2003)[75]	1	93	126.8 (75.3)	Not reported	68%	Yes	Selected	Mixed	3 days	Not reported	Yes	4
10	UK10	St. James-Roberts & Peachey (2011)[76]	5-6 12	352 316	104.7 (63.2) 63 (42.1)	Not reported	Not reported	Yes	Whole	Mixed	3 days	5 min	No	3
11	Canada1	Barr et al., (1988)[77]	6	10	125 (48.1)	Not reported	Not reported	Yes	Defined	Mixed	7 days	5 min.	No	4
12	Canada2	Barr et al., (1989)[51]	6	283	93 (61.1)	84%	69%	No	Whole	Breastfed	8 days	5 min	No	6
13	Canada3	Barr et al., (1989)[51]	6	91	88.7 (65.7)	84%	22%	No	Whole	Bottlefed	8 days	5 min.	No	5

	Sample Code	Study	Weeks	Sample size	Mean (SD) of Cry/Fuss Duration in mins	Recruitment rate	Participation rate at each age	Characteristic of sample	Subject selection (whole vs. defined population)	Feeding type	Diary duration	Resolution time for the diary (5 min. vs. 15 min.)	Modified-Wessel definition	Quality rating scores
14	Canada4	Kramer et al. (2001)[63]	4 6 9	183 156 148	149.8 (73.5) 131.6 (72.5) 107.6 (64.6)	Not reported	71% 61% 57%	Yes	Defined	Breastfed	3 days	5 min	No	3 3 3
15	Canada5	Miller et al. (1993) [64]	5	88	136.8 (66)	Not reported	78%	No	Defined	Breastfed	7 days	5 min.	Yes	6
16	Canada 6	Fujiwara et al. (2011)[53]	5	1065	163.4 (75)	78.6%	58.3%	Yes	Whole	Not reported	4 days	5 min	No	6
17	USA1	Blum et al. (2002)[78]	5 6 8	60 59 58	140.9 (75.1) 127.1 (69.9) 97.9 (46.9)	Not reported	53% 52% 51%	Yes	Defined	Not reported	4 days	5 min.	No	3 3 3
18	USA2	Stifter & Spinard (2002)[79]	6	116	116.2 (58.2)	Not reported	74%	Yes	Whole	Not reported	4 days	5 min.	No	6
19	USA3	Stifter et al. (2003)[80]	6	128	120.6 (64.1)	Not reported	89%	Yes	Whole	Not reported	4 days	5 min.	Yes	7
20	USA4	Fujiwara et al. (2011)[53]	5	1857	152 (71.8)	54.2%	68.4%	Yes	Whole	Not reported	4 days	5 min.	No	6
21	USA5	McRury & Zolotor, (2010)[81]	4 6 8	16 16 17	126 (72) 114 (66) 90 (72)	1408 fliers distributed, 51 responses to fliers	69%	Yes	Whole	Not reported	3 days	5min	No	2

	Sample Code	Study	Weeks	Sample size	Mean (SD) of Cry/Fuss Duration in mins	Recruitment rate	Participation rate at each age	Characteristic of sample	Subject selection (whole vs. defined population)	Feeding type	Diary duration	Resolution time for the diary (5 min. vs. 15 min.)	Modified-Wessel definition	Quality rating scores
			12	14	72 (48)									
22	Italy1	Bonichini et al. (2008)[82]	2	70	147.6 (90.2)	Not reported	77%	Yes	Whole	Not reported	3 days	5 min.	Yes	5
			5	70	150.6 (100.1)		77%							5
			8	70	118.5 (78.5)		77%							5
23	Italy2**	Mazzotti et al. (2003)[83]	2	12	106.8 (46)	Not reported	79%	No (2/4)	Whole	Not reported	3 days	5 min.	Yes	4
			4	12	145.4 (77.1)									
			6	12	119.9 (53.9)									
			8	12	105.7 (88.8)									
			10	12	86.7 (34.5)									
24	The Netherlands1	de Weerth & Buitelaar (2007)[62]	6	103	150.4 (66.3)	Not reported	89%	Yes	Whole	Mixed	4 days	5 min.	No	7
25	Germany1	Keller et al. (1998)[84]	12	62	84.6 (54)	70%	82%	Yes	Whole	Not reported	3 days	5 min.	No	5
26	Germany2	Lohaus et al. (2001)[85]	12	20	78.8 (59.9)	Not reported	100%	Yes	Defined	Not reported	3 days	5 min.	No	3
27	Germany3	Bensel (2003)[70]	2	96	69 (60)	Not reported	72%	Yes	Defined	Mixed	2-3 times weekly	15 min.	No	2
			3	97	80.8 (67.4)		72%							2
			6	99	85 (78)		74%							2

	Sample Code	Study	Weeks	Sample size	Mean (SD) of Cry/Fuss Duration in mins	Recruitment rate	Participation rate at each age	Characteristic of sample	Subject selection (whole vs. defined population)	Feeding type	Diary duration	Resolution time for the diary (5 min. vs. 15 min.)	Modified-Wessel definition	Quality rating scores
			9	101	66.3 (69)		75%							2
			12	91	51 (51)		68%							2
28	Germany4	Wurmser et al. (2006)[86]	6	64	145.6 (84.4)	Not reported	68	Yes	Whole	Not reported	5 days	5 min.	No	4
			12	63	107.9 (58.2)		67							
29	Australia1*	Wake et al. (2006)[54]	8	446	113.5 (64.1)	Not reported	92%	Yes	Whole	Mixed	1 day	5 min.	No	6
30	Denmark1	St. James-Roberts et al. (2006)[20]	1	70	80 (44)	88%	80%	Yes	Whole	Breastfed	4 days	5 min.	Yes	8
			5	64	81 (60)		79%							8
31	Denmark2	Sondergaard (2000)[87]	6	432	88 (67)	Not reported	Not reported	Yes	Defined	Mixed	4 days	5 min.	Yes	6
32	Denmark3	Alvarez (2004)[88]	3	118	90 (58)	55%	79%	Yes	Defined	Mixed	3 days	5 min.	Yes	7
			6	111	79 (67)		74%							6
			12	110	48 (44)		73%							6
33	Japan1	Shinohara & Kodama, (2012)[89]	4-6	31	107 (36)	50%	Not reported	Yes	Whole	Mixed	3 days	5 min.	No	4
			8-10		80 (36)									

*Excluded from the colic prevalence analysis; **Cross-sectional study. Please note that the following samples were reported in the same study: 1) UK1 and UK2; 2) UK5 and Denmark1; 3) UK7 and UK8; 4) Canada2 and Canada3; 5) Canada6 and USA4

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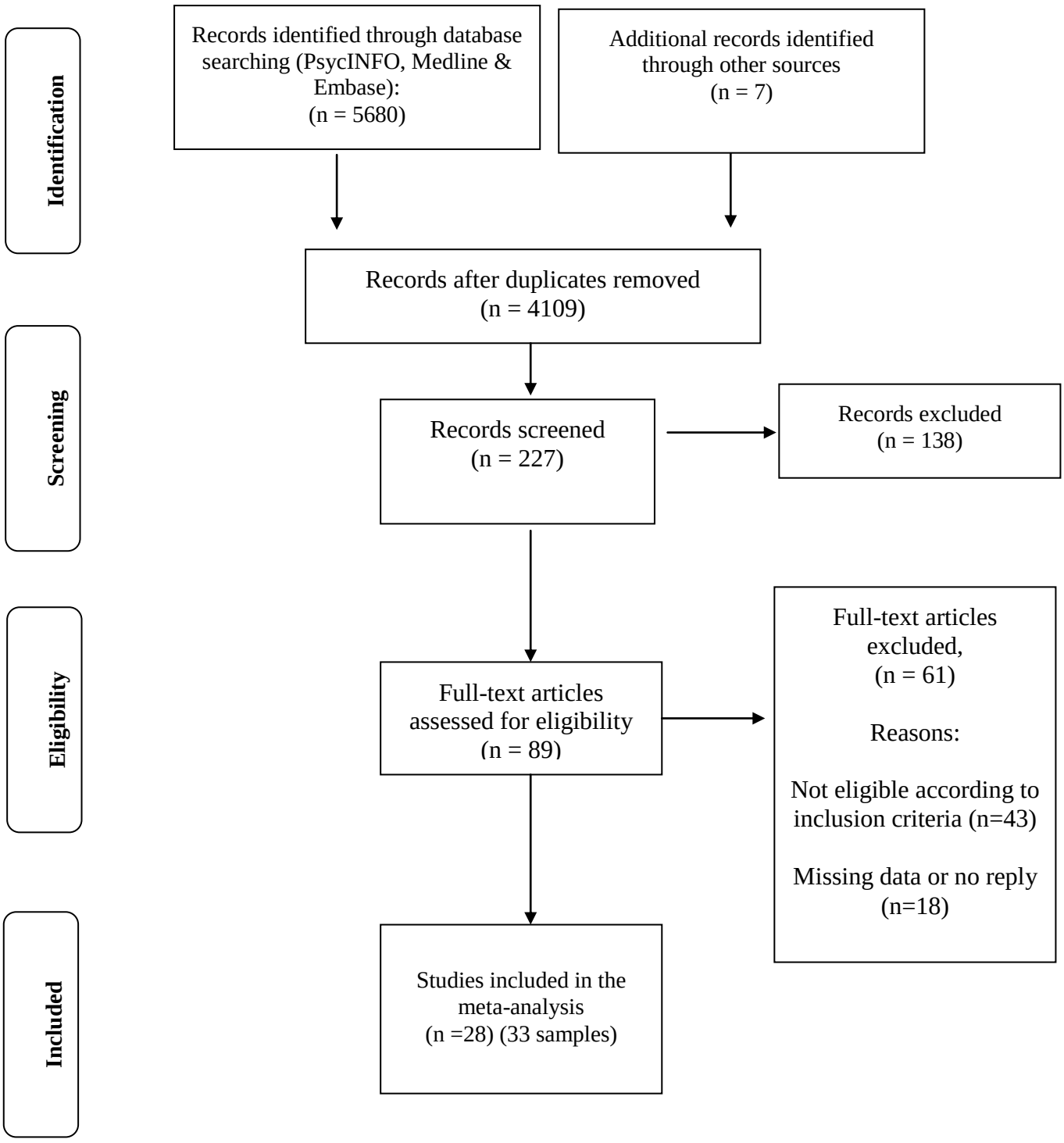

Figure 2

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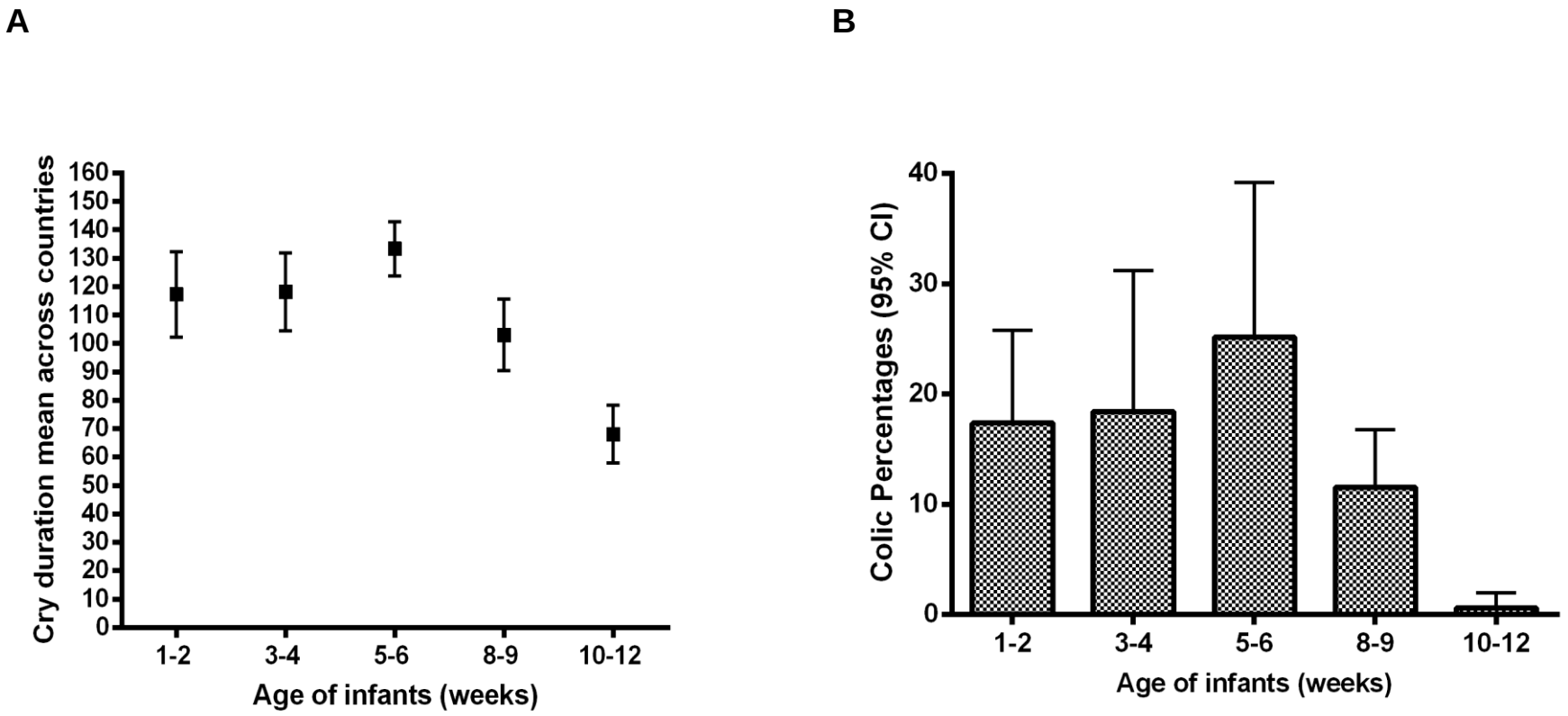

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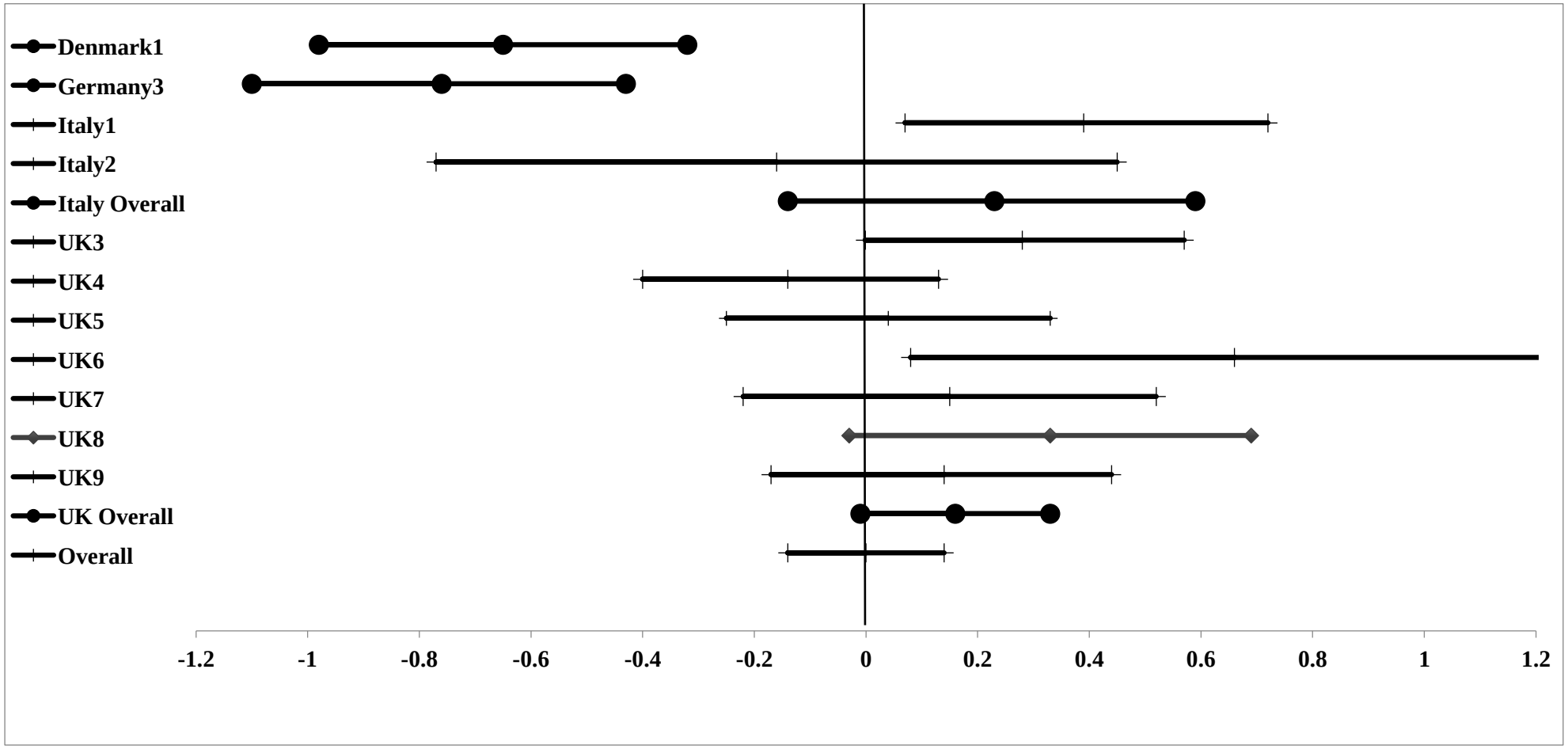

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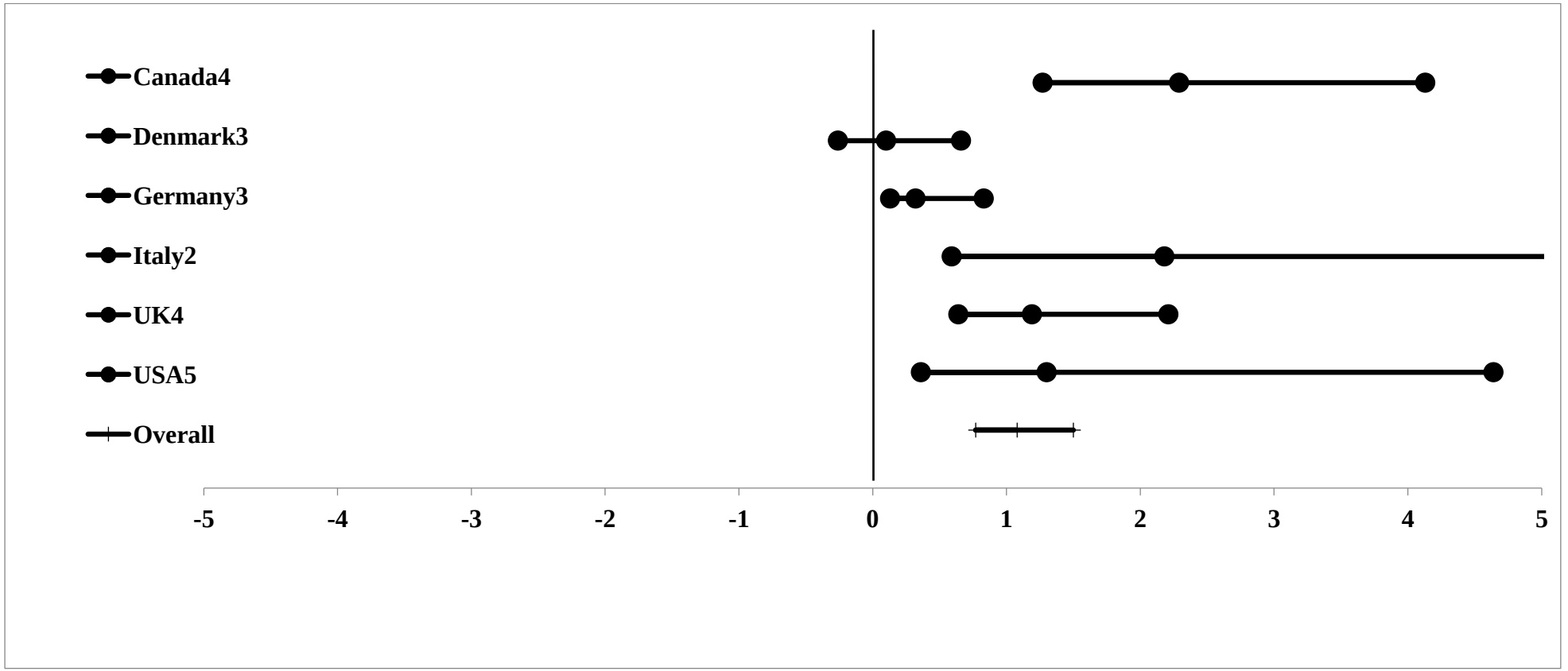
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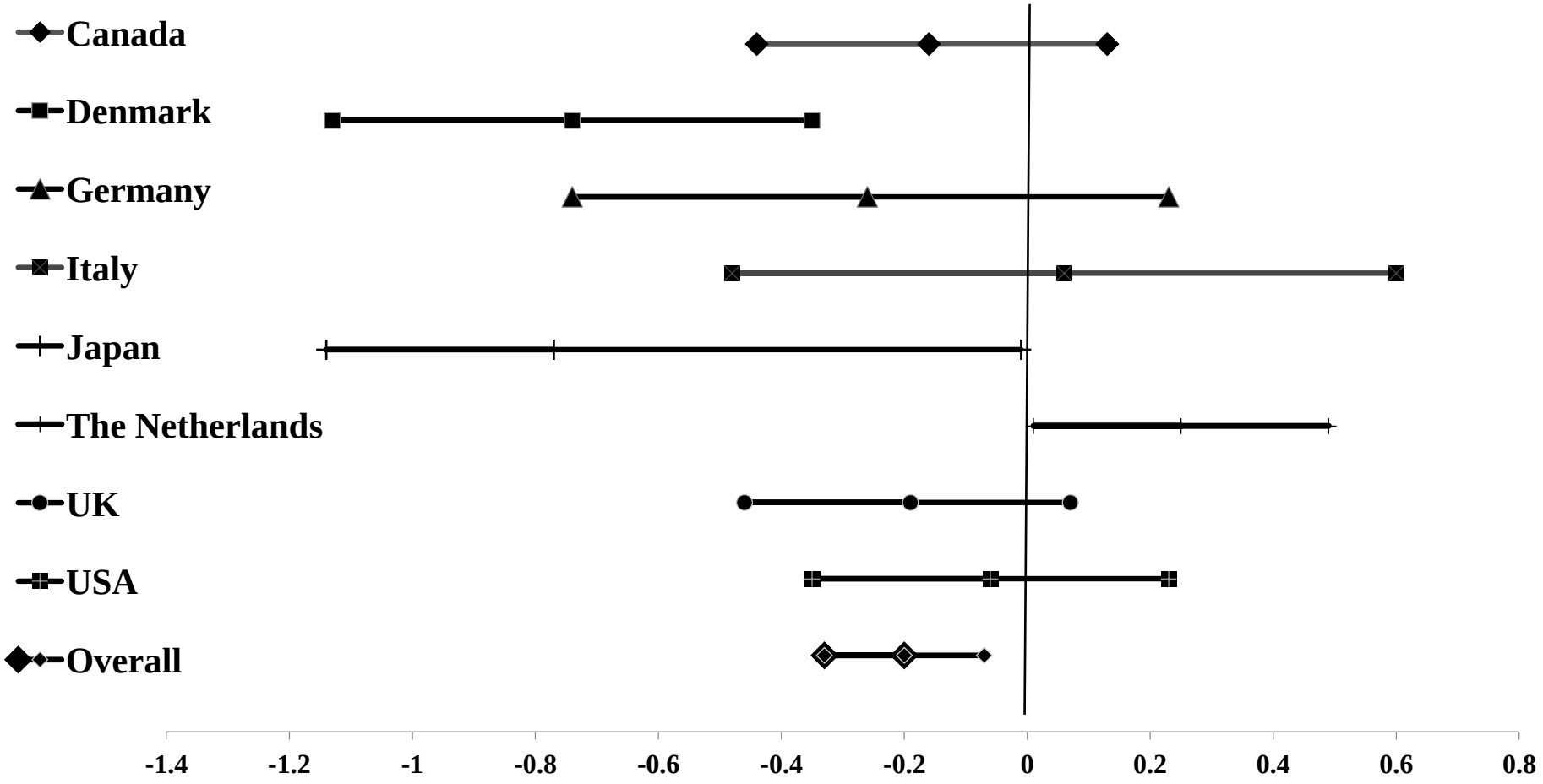

Please note that only the overall country effect sizes are shown for each country. The overall effect size at the bottom indicates the finding of the moderator analysis, revealing that the effect size was related to the country where the studies were conducted. Therefore, it does not cross 0.

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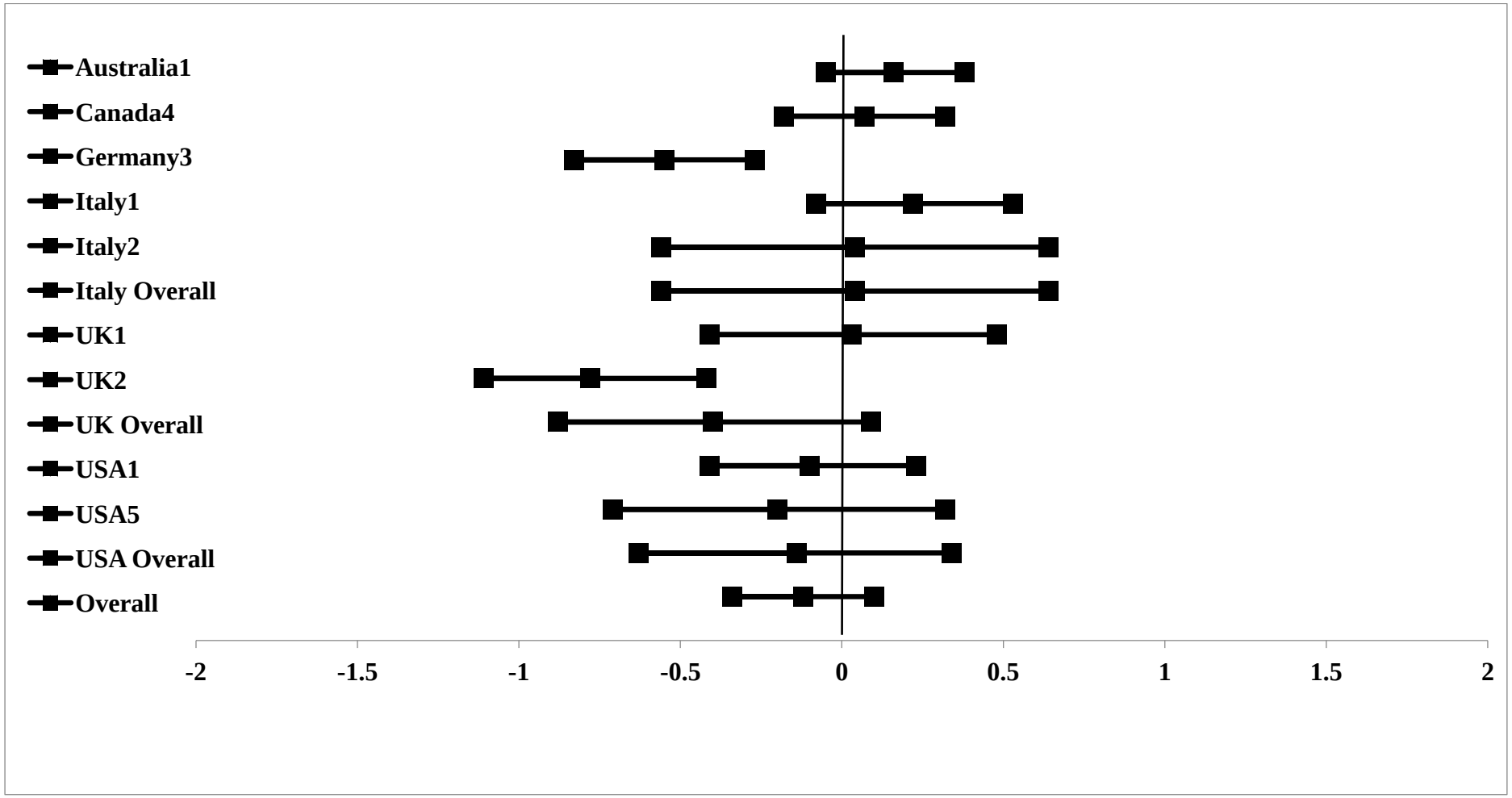
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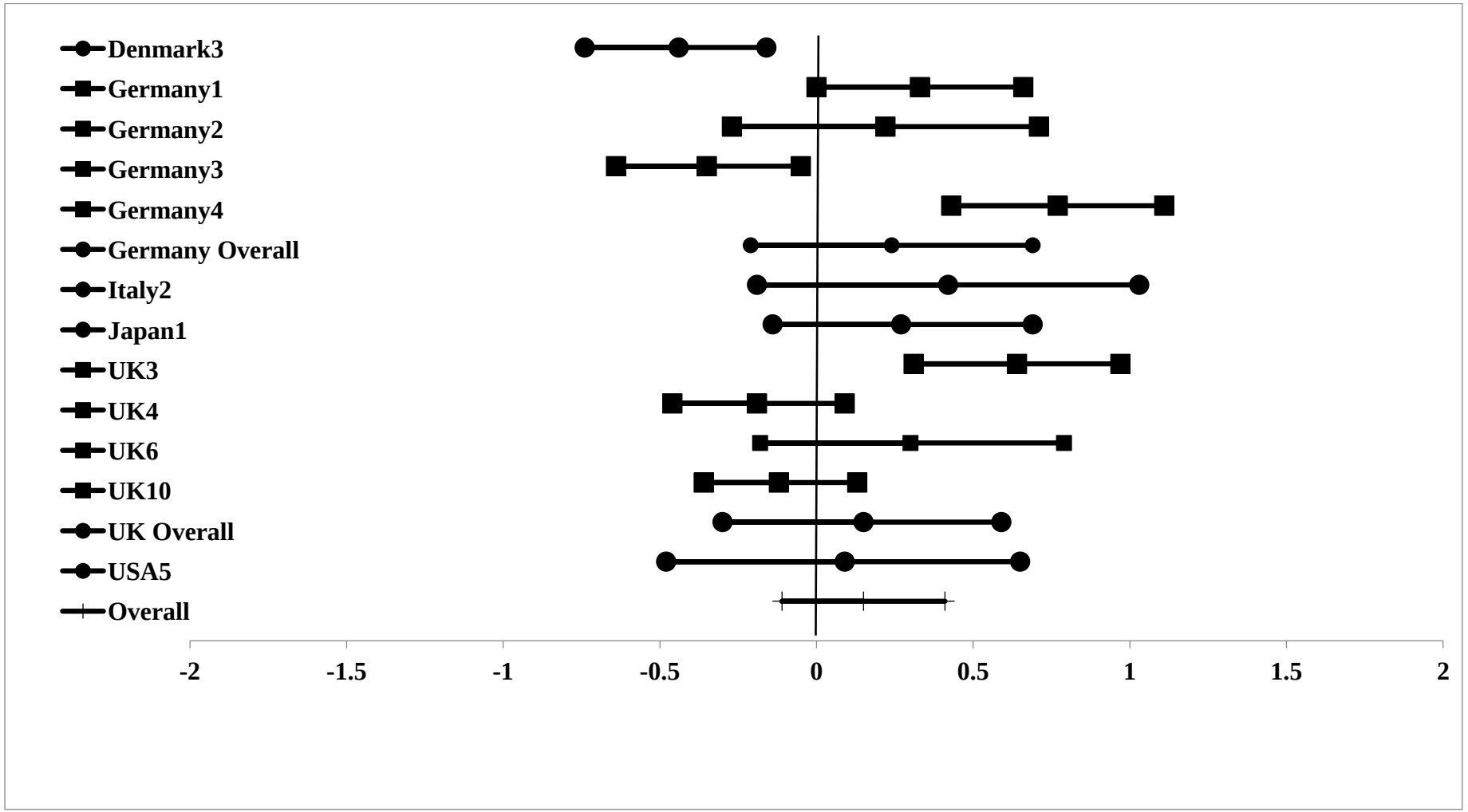
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Figure4

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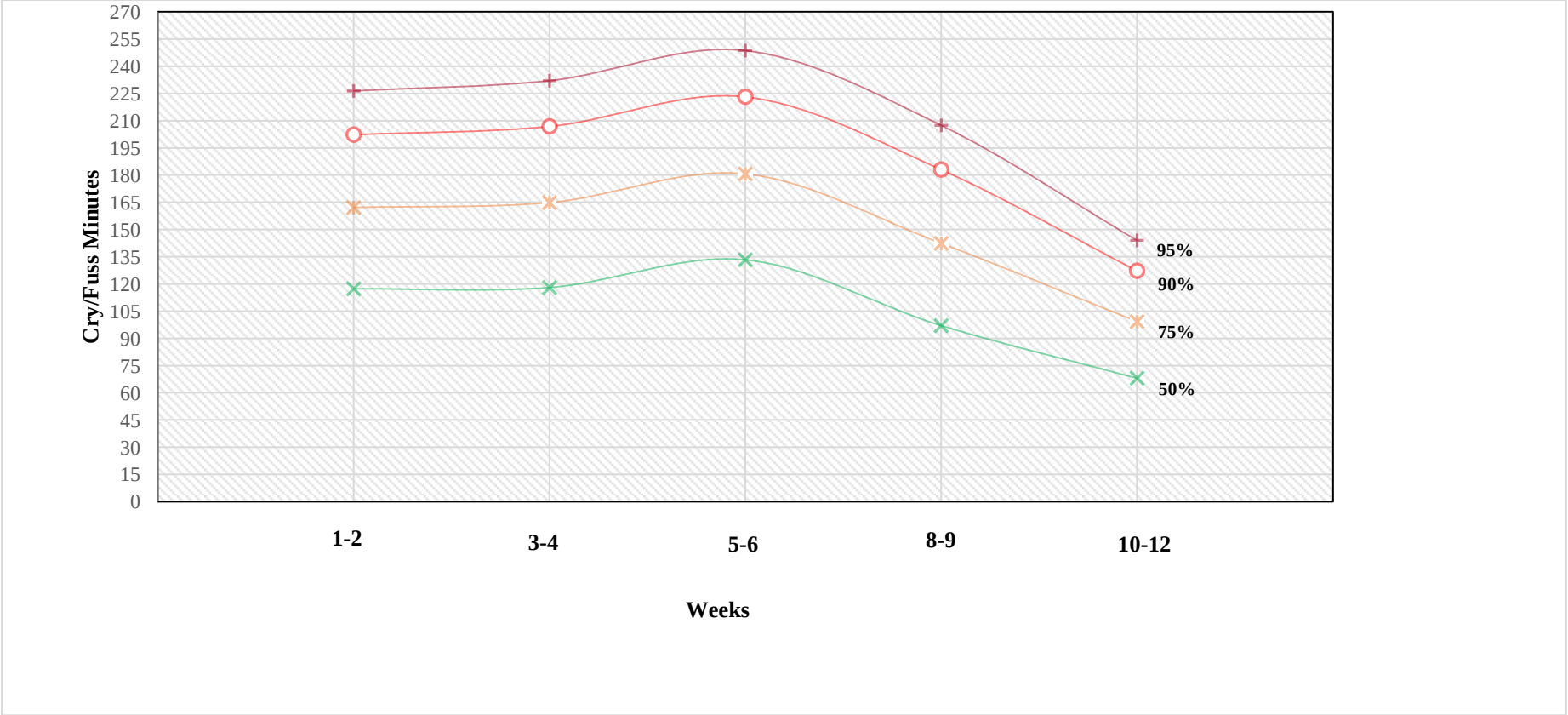

Please note that this is an approximation of average to high fuss/cry amount percentiles based on the samples included in the meta-analysis. It should only be used as a rough guide to identify excessively crying infants according to age.