

Introduction and Objective

- Migraine is a common complaint in the paediatric population.¹
- 10% of children aged 5-15 years have migraine and it also accounts for 75% of headaches in young children.¹
- The lack of studies regarding its treatment in this paediatric population makes it harder to select from a broad range of treatment choices or regimens.¹
- The objective of the current study is to compare the efficacy and safety of melatonin in paediatric migraine.

Methodology

- PubMed®, Embase®, and Cochrane via Ovid platform were searched until 17th of May 2022 and reviewed for studies reporting safety and efficacy of melatonin in paediatric patients with migraine and extracted data.
- No restriction regarding year of publication was applied.
- Two reviewers independently searched for articles, reviewed, and extracted data, with differences resolved through consensus.
- The Downs and Black Checklist and Cochrane risk of bias V 2.0 (ROB 2) were used to assess study quality of observational and RCTs, respectively.
- A meta-analysis using fixed effects model was conducted to calculate pooled effect estimates with 95% confidence intervals (CI).

Table 1: Study eligibility criteria

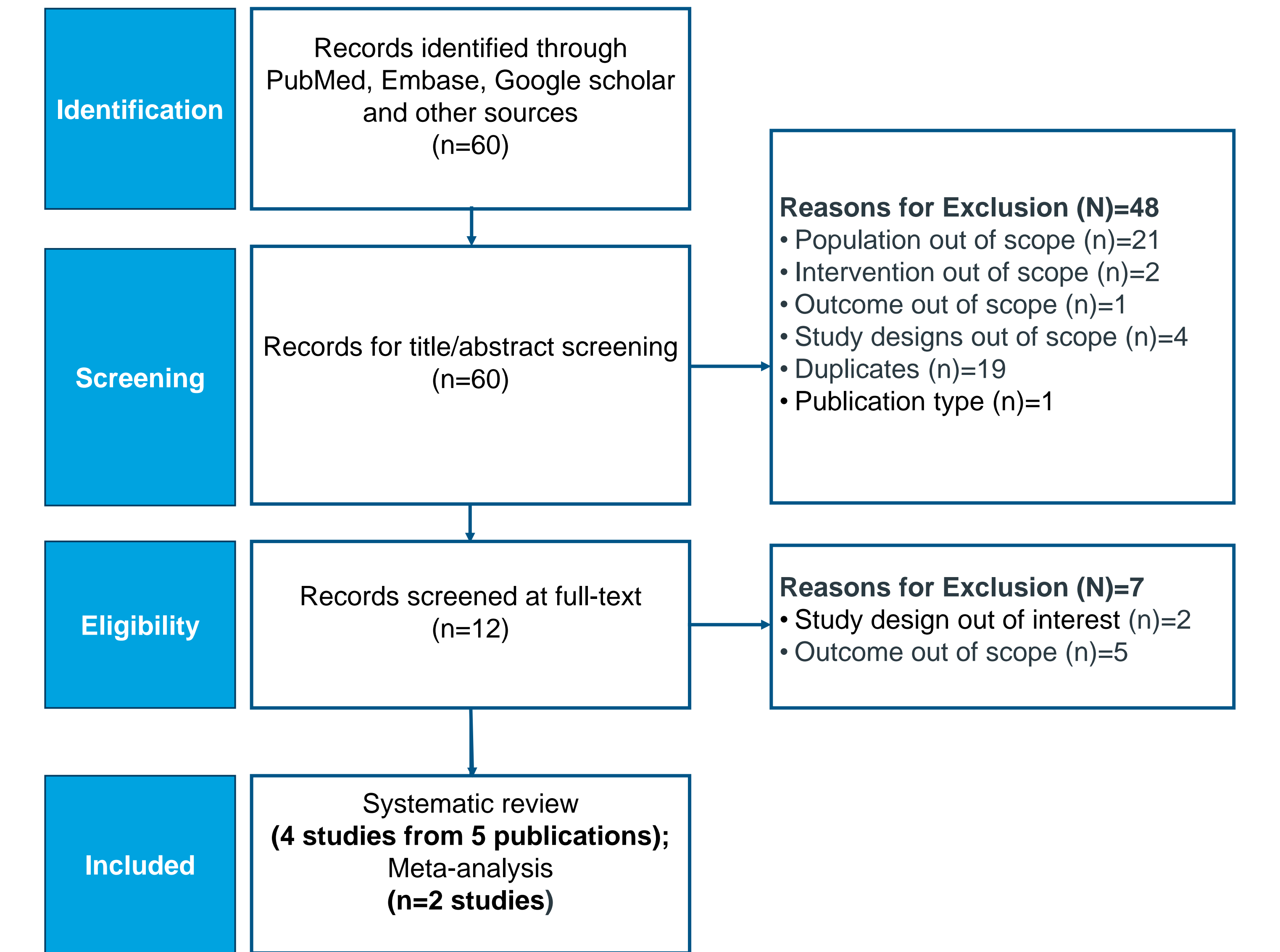
PICOS	Inclusion criteria
Populations	Paediatrics with migraine
Interventions/Comparators	Melatonin Other than melatonin
Outcomes	Response rate, monthly headache frequency, severity of headache, headache duration
Study designs	Clinical trials, observational study (retrospective or prospective)

Results

Study Selection:

- Out of the 60 articles screened, 5 publications (4 studies, N=224) were included for the systematic review.²⁻⁶ (Figure 1)
- Two RCTs^{3,4} (N=170) comparing melatonin with amitriptyline were included for meta-analyses.

Figure 1: PRISMA chart of included studies



- One retrospective² (N=32) and one open-label single arm trial⁶ (N=22) showed that headache attacks had decreased by more than 50% with melatonin use.

- The pooled analysis of two studies^{3,4} demonstrated that amitriptyline showed better response rate (risk ratio [RR] 1.31; 95% CI 1.10 to 1.56) in comparison to melatonin in paediatric patients having migraine as presented in Figure 2.
- Amitriptyline showed better efficacy in terms of reduction in monthly headache frequency (mean difference [MD] -2.71, 95% CI -3.95 to -1.48), severity of headache (MD -1.97, 95% CI -2.31 to -1.62) and duration of headache (MD -0.88, 95% CI -1.12 to -0.63) versus melatonin as presented in Figure 3.

Figure 2: Forest plot of pooled response rate

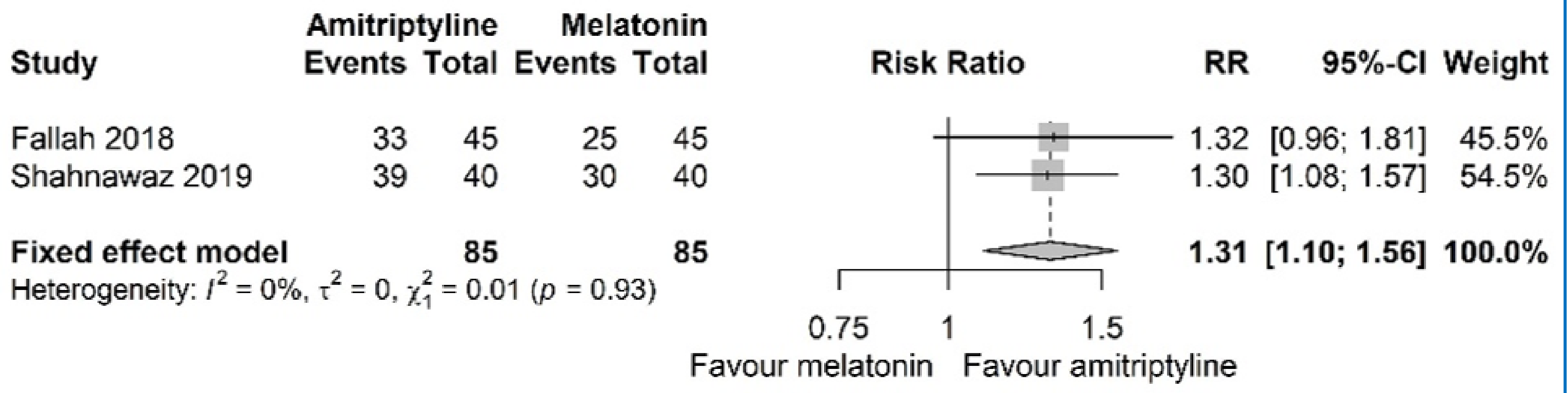
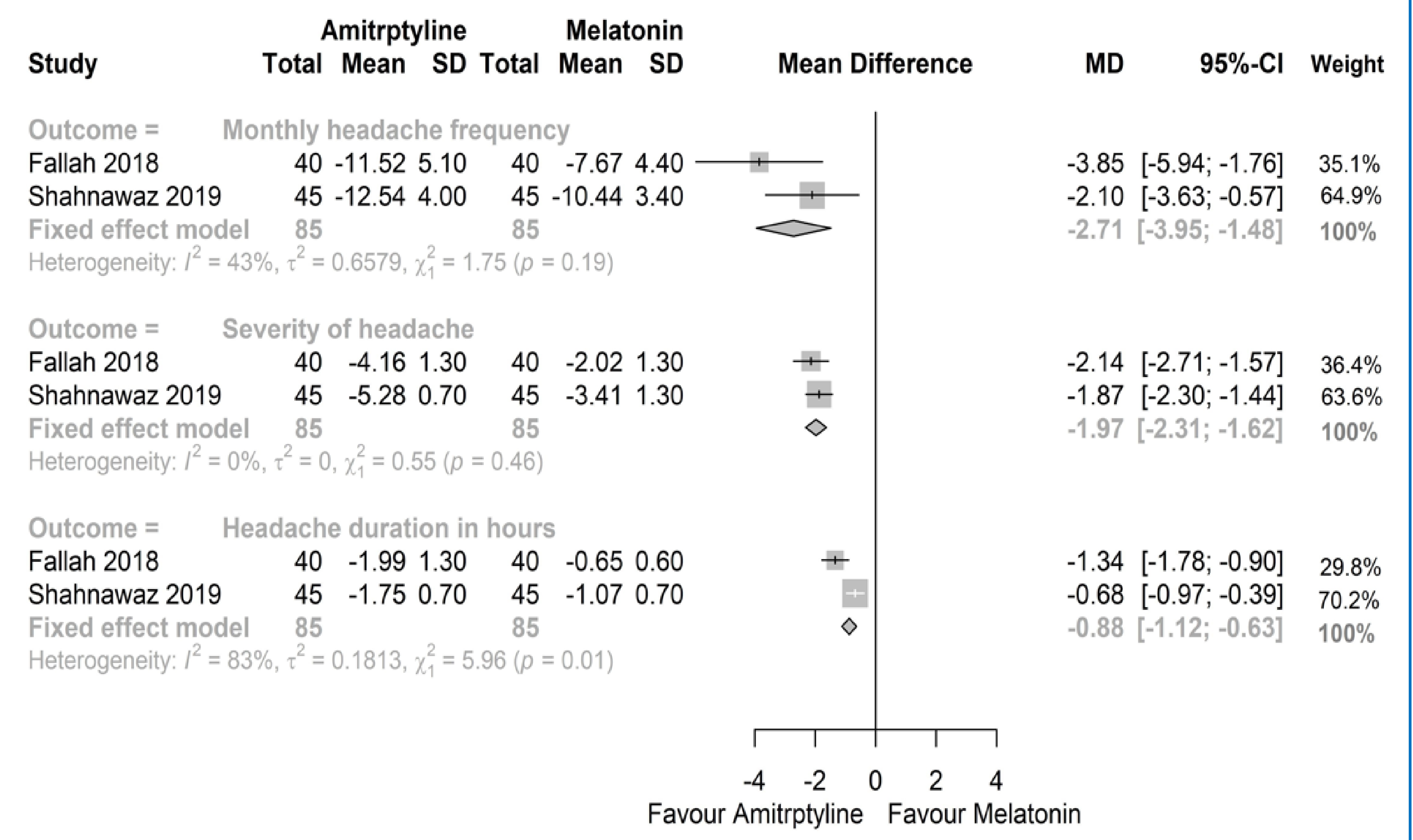


Figure 3: Forest plot of pooled response rate



Reference	Randomisation process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall
Shahnawaz K 2019	+	+	+	+	+	+
Fallah R 2018	+	+	+	+	+	+
Fallah R 2015	+	+	+	+	+	+

Legend: + Low risk, + Some concerns, + High risk

Conclusions

- Melatonin might be considered as an effective drug without life-threatening side effects in prophylaxis of migraine in children.
- Melatonin and amitriptyline both are effective and safe, but amitriptyline can be considered as a more effective drug.
- Further high-quality RCTs and systematic reviews are required for conclusive determination of its effectiveness and tolerability compared to active comparators.

References

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