Supplementary material

Figure S1. Search strategy

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The search strategy applied was as follows: ("asthma"[MeSH Terms] OR "asthma"[Text Word] OR “Rhinitis”[MeSH Terms] OR “Rhinitis"[Text Word] OR "Rhinitis, Allergic"[MeSH Terms] OR "Allergic Rhinitis"[Text Word]) AND ("leukotriene antagonists"[MeSH Terms] OR "leukotrien"[Text Word] OR "leukotriene antagonists"[Text Word] OR Antileukotrien*[Text Word] OR Antileucotrien*[Text Word] OR Anti-leukotrien*[Text Word] OR Antileucotrien*[Text Word] OR "leukotrienes"[MeSH Terms] OR "leukotrienes"[Text Word] OR "leukotriene"[Text Word] OR "leukotriens"[Text Word] OR "montelukast"[Text Word] OR "singulair"[Text Word]) AND ("therapeutics"[MeSH Terms] OR Therap*[Text Word] OR "treatment*"[Text Word] OR "cortico*"[Text Word]) AND ("quality of life"[MeSH Terms] OR "quality of life"[Text Word] OR "health related quality of life"[Text Word] OR "patient reported outcome measures"[MeSH Terms] OR "patient reported outcome measures"[Text Word] OR "patient reported outcome"[Text Word] OR "asthma control"[Text Word] OR "symptoms control"[Text Word] OR "symptoms score"[Text Word]).

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1. asthma/ or asthma.mp.
2. rhinitis/ or allergic rhinitis/ or rhinitis.mp. or allergic rhinitis.mp. or rhinitis, allergic.mp.
3. 1 or 2
4. (leukotriene antagonists or antileukotrien* or antileucotrien* or anti-leukotrien* or anti-leucotrien* or leukotriene or leukotrien or leukotrienes or leukotriens).mp. or leukotriene receptor blocking agent/ or leukotriene/
5. montelukast.mp. or montelukast/
6. singulair.mp.
7. 4 or 5 or 6
8. (therapeutics or treatment* or therap*).mp. or therapy/
9. cortico*.mp. or corticosteroid/
10. 8 or 9
11. (health related quality of life or quality of life).mp. or "quality of life"/
12. (patient reported outcome or patient reported outcome measures).mp. or exp Patient Reported Outcome Measures/
13. asthma control.mp.
14. symptoms control.mp.
15. symptoms score.mp.
16. 11 or 12 or 13 or 14 or 15
17. 3 and 7 and 10 and 16
18. remove duplicates from 17

Supplementary Material. Table A. Characteristics of the studies that data could not be extracted for meta-analysis

First author; publication year	Study design; follow-up period	Sample size; age range (mean)	Diagnosis	Intervention (I) or control (C) group	PROM administered	PROM as primary, secondary, or tertiary outcome	PROM score	Adverse events reported	Study PROMs findings
LRA vs ICs									
Maspero [58], 2001	RCT 6 months	Total n= 124 6-11 yrs (9.5)	Stable asthma	**(I):** Montelukast (5 mg) **(C):** Beclomethasone (300 µg)	Patients and parent satisfaction questionnaires	Not specified	+	No	Parents showed significantly higher satisfaction and numerically higher satisfaction scores in all categories with montelukast at 6 months than with inhaled beclomethasone. Asthmatic children receiving montelukast reported significantly greater overall satisfaction and had a significantly greater satisfaction score than children receiving beclomethasone.
Meltzer [59], 2002	RCT 24 weeks	Total n= 522 (395 completed the study) >15-77 yrs (36)	Persistent asthma	**(I):** Montelukast (10 mg) **(C):** Fluticasone (176 µg)	AQLQ (emotional function) Symptoms score (0-5) Satisfaction with medicine	Not specified	-	Yes	A low dose of fluticasone was more effective in improving asthma control. This was demonstrated by a significantly greater improvement in symptoms control, subject satisfaction, and asthma-related quality of life.
Zeiger [60], 2005	RCT 12 weeks	Total n= 400 15-85 yrs (35)	Mild persistent Asthma	**(I):** Montelukast (10 mg) **(C):** Fluticasone (176 µg)	Asthma Symptom Questionnaire ATAQ AQLQ	Primary	=	No	Patient-reported asthma outcome measures, including scores for asthma symptoms, asthma control, and asthma-specific quality of life, significantly improved for both montelukast and fluticasone groups compared with baseline. Fluticasone treatment was associated with a significant decrease in night-time symptom frequency (P= 0.04).
Zeiger [61], 2006	RCT 16 weeks	Total n= 144 6-17 yrs	Mild-to-moderate persistent asthma	**(I):** Montelukast (5 or 10 mg) **(C):** Fluticasone (200 µg)	ACQ	Not specified	-		The validated Asthma Control Questionnaire improved significantly more with fluticasone than with montelukast treatment.
Kumar [62], 2007	RCT 12 weeks	Total n= 62 5-15 yrs	Mild persistent asthma	**(I):** Montelukast (5 mg) **(C):** Budesonide (800 µg)	Symptom score	Secondary	=	No	No statistically significant difference in the average symptom score and symptom-free days for cough, wheezing and sneezing.
Knuffman [63], 2009	RCT 48 weeks	Total n= 191 6-14 yrs	Mild moderate persistent asthma	**(I):** Montelukast (5 mg) **(C):** Fluticasone (200 µg)	ACQ Night-time awakenings	Primary	-	No	Poorer asthma control was found in the montelukast group.
LRA vs other treatment combinations									
°Laviolette [64], 1999	RCT 16 weeks	Total n= 642 (39)	Intermittent or persistent asthma	**(I):** Montelukast (10 mg) **(C):** Beclomethasone (400 µg) **(C):** Montelukast (10 mg) + Beclomethasone (400 µg) **(C):** Placebo	AQLQ Daytime symptom score Global evaluation question	Primary	-	Yes	Montelukast provided significant (p= 0.05) clinical benefit in addition to inhaled beclomethasone in terms of daytime asthma symptom scores, and nocturnal awakenings. Blind removal of beclomethasone in the presence of placebo tablets caused worsening of asthma control, and in the presence of montelukast resulted in less asthma control but not to the level of the placebo group.
Nelson [76], 2000	RCT 12 weeks	Total n= 447 >15 yrs (42)	Asthma	**(I):** Montelukast (10 mg) + fluticasone (200 µg) **(C):** Fluticasone / salmeterol (200/ 100 µg)	Daytime symptom score (0-5)	Secondary	-	Yes	Fluticasone/salmeterol provided clinically important and statistically significant improvement in overall asthma control compared with fluticasone + montelukast. **AE:** for both groups were oral candidiasis, sore throat, hoarseness, and headache.

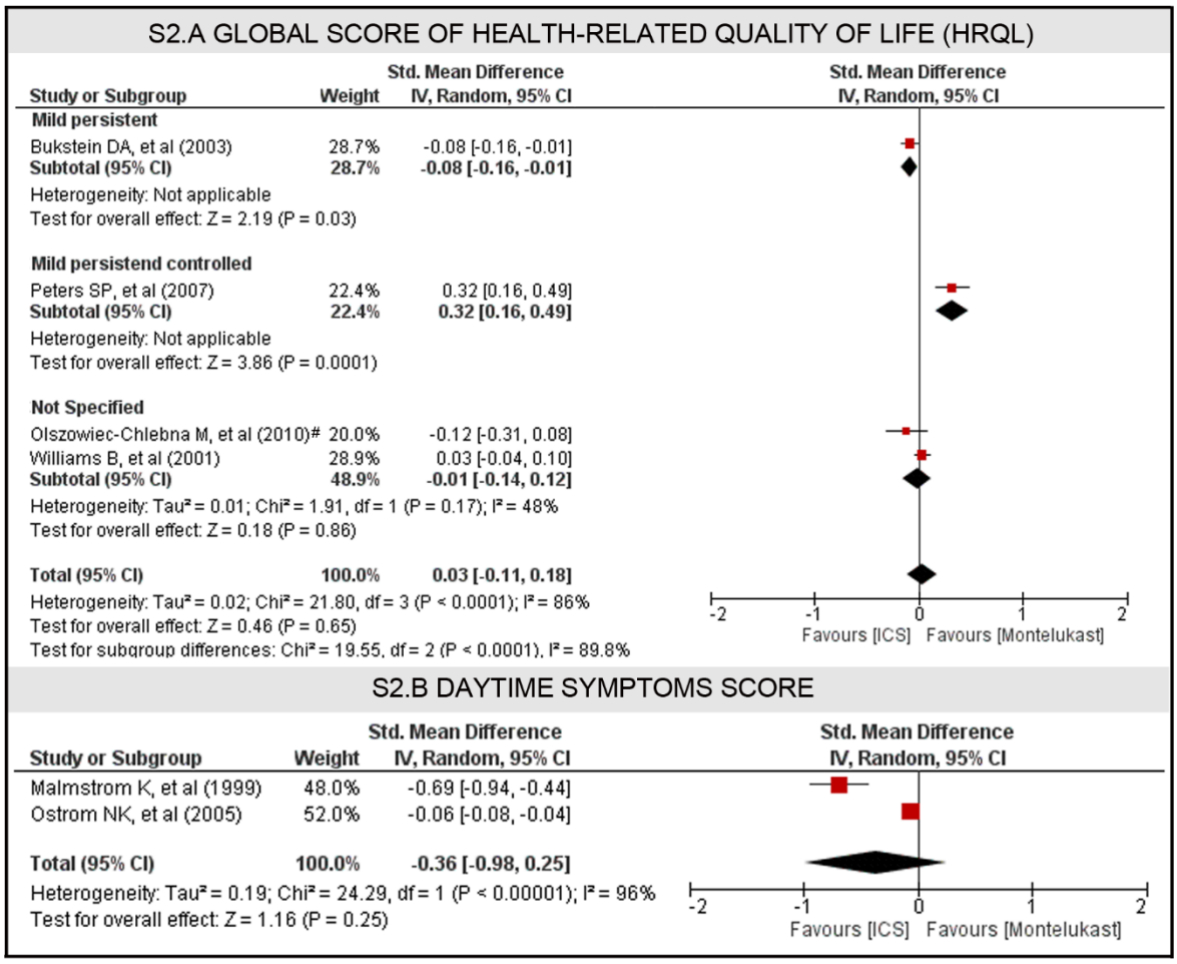
°Narayanan [83], 2002	Observational-prospective 4 weeks	Total n= 175 6-14 yrs (9.6)	Persistent asthma	**(I):** Montelukast **(C):** Montelukast / another controller medication	ACI Satisfaction with medication (0-6)	Primary	-	No	The results for the individual ACI items indicate that there were improvements in all four items. A fivefold reduction in loss of activity due to asthma was reported among patients for whom montelukast was prescribed alone, while a twofold reduction from baseline was observed among patients using montelukast in combination with another long-term controller. Patient satisfaction with montelukast at 1 month was markedly greater than with the asthma control medication used at baseline.
Pearlman [77], 2002	RCT 12 weeks	Total n= 432 >15 yrs (36)	Persistent asthma	**(I):** Montelukast (10 mg) **(C):** Fluticasone / salmeterol (200/ 100 µg)	AQLQ Symptom scores (0-5) Satisfaction with medicine	Secondary	-	No	The mean AQLQ increase (improvement) from baseline at endpoint in global and individual domain AQLQ scores was significantly greater for patients treated with Fluticasone compared with montelukast (P=0.001). Initial maintenance therapy with FSC provides greater improvement in asthma control and patient satisfaction than montelukast.
Price [78], 2003	RCT 12 weeks	Total n= 889 15-75 yrs (43)	Optimally controlled Asthma	**(I):** Montelukast (10 mg) + budesonide (800 µg) **(C):** Budesonide (1600 µg)	AQLQ Daytime symptom score	Secondary	=	No	Both groups showed similar improvements with respect to 'as needed' B agonist use, mean daytime symptom score, nocturnal awakenings, exacerbations, asthma-free days, peripheral eosinophil counts, and asthma-specific quality of life.
°Bjermer [79], 2003	RCT 52 weeks	Total n= 1490 15-72 yrs (41)	Chronic asthma	**(I):** Montelukast (10 mg)/ fluticasone **(C):** Salmeterol/ fluticasone	AQLQ Daytime symptom score	Secondary	=	No	Both treatments significantly decreased nocturnal awakenings compared with baseline ($P \leq 0.001$). The asthma-specific quality of life score significantly improved from baseline for both treatments ($P \leq 0.001$) with no significant difference between the two groups.
Karaman Ö [65], 2004	RCT 12 weeks	Total n= 63 8-14 yrs (120 months)	Mild persistent asthma	**(I):** Montelukast (5 mg) **(C):** Budesonide (800 µg) **(C):** Montelukast (5 mg) + budesonide (800 µg)	Symptoms score (0-5)	Not specified	=	Yes	The beneficial effects of Montelukast were similar to those produced by inhaled corticosteroids. **AE**: There were no significant adverse effects requiring treatment discontinuation.
Ilowite [80], 2004	RCT 48 weeks	Total n= 1059 14-73 yrs (38.5)	Moderate-to severe persistent asthma	**(I):** Montelukast (10 mg) + fluticasone (220 µg) **(C):** Salmeterol (84 µg) + fluticasone (220 µg)	AQLQ	Secondary	-	No	Salmeterol significantly increased asthma-specific quality of life, morning peak expiratory flow rate, and decreased nocturnal awakenings compared with montelukast. Differences between treatments were small, and both treatments were generally well tolerated.
Hsieh [68], 2004	RCT 12 weeks	Total n= 65 6-12 yrs (8)	Moderate to severe perennial allergic rhinitis	**(I):** Montelukast (5 mg) **(C):** Placebo **(C):** Cetirizine (10 mg)	PRQLQ Nasal symptom score (0-3)	Not specified	=C +P	Yes	Cetirizine has been shown to be more efficacious than montelukast as regards controlling the total symptom score after week 8. Compared with the placebo, cetirizine and montelukast significantly improved the quality of life of children suffering perennial allergic rhinitis. There appears to be no significant difference between cetirizine and montelukast in the scores of the PRQLQ.
O'Connor [84], 2006	Observational prospective 12 months	Total n= 1270 15-18 yrs Total n: 107 (>15 yrs)	Asthma	**(I):** Montelukast (10 mg) **(C):** Fluticasone / salmeterol (100/ 50 µg)	ACQ AQLQ Satisfaction with medication	Not specified	-	No	Fluticasone patients on average reported inferior asthma control and lower assessment of quality of life, compared to montelukast patients. Despite their poorer baseline status, patients treated with fluticasone demonstrated greater improvement in asthma control and asthma-related quality of life, higher satisfaction with treatment, and went to work or school with asthma symptoms less often, compared to patients treated with montelukast, 12 months after initiating therapy.

American Lung Association Asthma Clinical Research Centers [69], 2007	RCT 24 weeks	Total n= 489 >15 yrs (40)	Poorly controlled asthma	**(I)**: Montelukast (10 mg)● **(C):** Theophylline (300 mg)● **(C):** Placebo●	ASUI ACQ AQLQ	Secondary	-	No	For patients not using inhaled corticosteroids, low-dose theophylline improved asthma symptom control more than montelukast or placebo, and provides a safe and low-cost alternative asthma treatment.
Moeller [85], 2008	Observational-prospective 8 weeks	Total n= 31 2-5 yrs (4)	Mild to moderate asthma	**(I):** Montelukast (4 mg) **(C):** Montelukast (4 mg) ● baseline treatment	Symptom score (1-5)	Not specified	+	No	First-line or add-on treatment of oral montelukast in children with asthma improved symptom scores. The symptom scores were generally low in both groups and ranged between 1 and 5, with no differences between the two groups at visit 1 (P=0.26). Symptom scores in group 1 were reduced at visit 2 compared to visit 1 (P=0.034), whereas no change was observed for group 2.
Koenig [81], 2008	RCT 16 weeks	Total n= 647 >15 yrs (41)	Well controlled asthma	**(I):** Montelukast (10 mg) **(C):** Fluticasone / salmeterol (200/100 µg) **(C):** Fluticasone (200 µg) **(C):** Salmeterol (100 µg)	Daily asthma symptom scores (0-5) Satisfaction with medication	Secondary	-	No	Satisfaction with treatment was rated highest in the fluticasone treatment group, with 76% of subjects reporting being satisfied or very satisfied with therapy. Asthma symptom scores at endpoint showed an improvement from baseline following fluticasone treatment and a worsening from baseline in the salmeterol and montelukast treatment groups.
°Lu [66], 2009	RCT 16 weeks	Total n= 406 15-65 yrs (34)	Asthma	**(I):** Montelukast (10 mg) **(C):** Loratadine (10 mg) **(C):** Beclomethasone (400 µg) **(C):** Montelukast (10 mg) + Loratadine (10 mg)	AQLQ domains Symptoms score Patient global evaluation question	Secondary	=	Yes	When compared to montelukast, montelukast + loratadine significantly improved the tertiary endpoints of nocturnal asthma symptom score (p = 0.006), nocturnal awakenings (p = 0.045), and asthma-specific quality of life (p =0.029). There is no benefit of adding loratadine to montelukast for the treatment of asthma.
Katial [82], 2010	RCT 4 weeks	Total n= 1081 >15 yrs (34.5)	Asthma with seasonal allergic rhinitis	**(I):** Montelukast (10 mg) **(C):** Fluticasone / salmeterol (200/100 µg) **(C):** Fluticasone / salmeterol (200/100 µg) + Montelukast (10 mg) **(C):** Fluticasone / salmeterol (200/100 µg) + Fluticasone nasal spray (50 µg)	Symptoms score (0-5)	Not specified	-	No	Treatment with fluticasone alone achieves similar asthma control to concurrent treatment with fluticasone and LTRA. Fluticasone nasal spray was statistically superior in controlling active seasonal allergic rhinitis symptoms compared with montelukast. Treatment with FSC produced significant (p <0.001) improvements in all clinical and patient-reported measures versus montelukast. FSC+ fluticasone nasal spray was superior to fluticasone + montelukast (p < 0.001) in improving daytime and night-time total nasal symptom scores.
Price [67], 2011	RCT 2 years	Total n= 650 12-80 yrs (47.5)	Uncontrolled Asthma	**(I):** Montelukast (10 mg) or Montelukast (10 mg) + Beclomethasone or budesonide or fluticasone **(C):** Beclomethasone or budesonide or fluticasone Beclomethasone or budesonide or fluticasone + Salmeterol or formoterol	EQ-5D utility scores MiniAQLQ ACQ	Secondary	-	Yes	No significant between-group differences were found in ACQ score at either 2 months [adjusted difference 0.01 (–0.20 to 0.22)] or 2 years [0.13 (–0.07 to 0.33)]. MiniAQLQ scores were marginally over the equivalence threshold, favouring long-acting β2-agonist as an add-on therapy.
LRA vs placebo									

Simons [70], 2001	RCT 4 weeks	Total n= 279 5-15 yrs (10.4)	Persistent asthma	**(I):** Montelukast (5 mg) **(C):** Placebo	PAQLQ	Secondary	=	No	The effects of montelukast and placebo did not differ significantly. There was no significant difference between treatment groups in global evaluations or asthma attacks.
Strauch [71], 2003	RCT 12 weeks	Total n= 36 6-14 yrs (11.9)	Moderate asthma	**(I):** Montelukast (5 or 10 mg) **(C):** Placebo	PAQLQ	Secondary	+	No	Patients receiving montelukast showed a significant elevation in the QOL scores within the domains 'emotions' and 'overall quality of life score.' This might suggest a clinical effect of the add-on treatment with montelukast, which is in agreement with earlier reports from randomized controlled trials on montelukast.
Patel [72], 2005	RCT 6 weeks	Total n= 1992 15-81 yrs (36.4)	Rhinitis	**(I):** Montelukast 10 mg **(C):** Placebo	RQLQ Daytime symptom score (0-3)	Primary	+	No	All domains of the RQLQ were statistically significantly improved with montelukast relative to placebo.
Wise [73], 2009	RCT 4 weeks	Total n= 601 >15 yrs (37)	Inadequately controlled asthma	**(I):** Montelukast (10 mg) **(C):** Placebo	ACQ KASE-AQ ASUI Asthma treatment perceptions	Secondary	-	Yes	The improvement in the ASUI was most evident in the patients receiving placebo. Participants assigned to the neutral placebo group had more symptom-free days and fewer nocturnal awakenings than those assigned to usual care. Participants at baseline thought that montelukast was an effective drug for the treatment of asthma. Four weeks later, this perception was significantly improved for participants assigned to the enhanced expectancy presentation compared with the neutral presentation but was not different for most perceptions in those assigned to montelukast versus placebo.
Goh [74], 2014	RCT 8 weeks	Total n= 128 13-51 yrs (24.5)	Rhinitis	**(I):** Montelukast (10 mg) **(C):** Placebo	RQLQ Daytime symptom score (0-3)	Primary and secondary	+	No	The mean improvement in overall quality of life score was significantly greater for the montelukast group than the placebo group.
Kim [75], 2020	RCT 5 weeks	Total n= 30 6-8 yrs (7.1)	Clinical asthma	**(I):** Montelukast (4 or 5 mg) **(C):** Placebo	C-ACT	Not specified	=	No	Compared to the montelukast group, the placebo group showed no significant changes in symptoms by the C-ACT.

(●) Added to existing medication; **(/)** Combo (fixed dose); **(+)** added treatment; **(‡)** PROM information not available. **RCT** Randomized controlled trial; PROM score: **(+)** favours montelukast, **(-)** against montelukast, **(=)** no differences between treatments; **I** Intervention group; **C** Control group; **G** Generic questionnaires; **S** Specific questionnaires; **LRA** Leukotriene receptor antagonists; **ICS** Inhaled corticosteroids; **AntiH1** Antihistamines against the H1 receptor; **LABA** Long-acting beta agonists; **AQLQ** Asthma Quality of Life Questionnaire; **PAQLQ** Pediatric Asthma Quality of Life Questionnaire; **ACI** Asthma Control Index; **ATAQ** Asthma Therapy Assessment Questionnaire; **TRACK** Test for Respiratory and Asthma Control in Kids; **KASE-AQ** Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire; **ASUI** Asthma Symptom Utility Index; **RQLQ** Rhinoconjunctivitis Quality-of-Life Questionnaire; **PRQLQ** The Pediatric Rhinoconjunctivitis Quality of Life Questionnaire; **ACT** Asthma Control Test; **C-ACT** Childhood Asthma Control Test; **ATAQ** The Asthma Therapy Assessment Questionnaire; **ACQ** Asthma Control Questionnaire.

Figure S2. Sensitivity analysis - forest plot of studies comparing patients with asthma treated with ICs vs Montelukast in terms of global Health-related Quality of Life and daytime symptoms scores.



Study evaluating more than one dose of ICs. 400 µg of budesonide was used.

Figure S3. Sensitivity analysis - forest plot of studies comparing patients with asthma treated with Placebo vs Montelukast in terms of symptoms

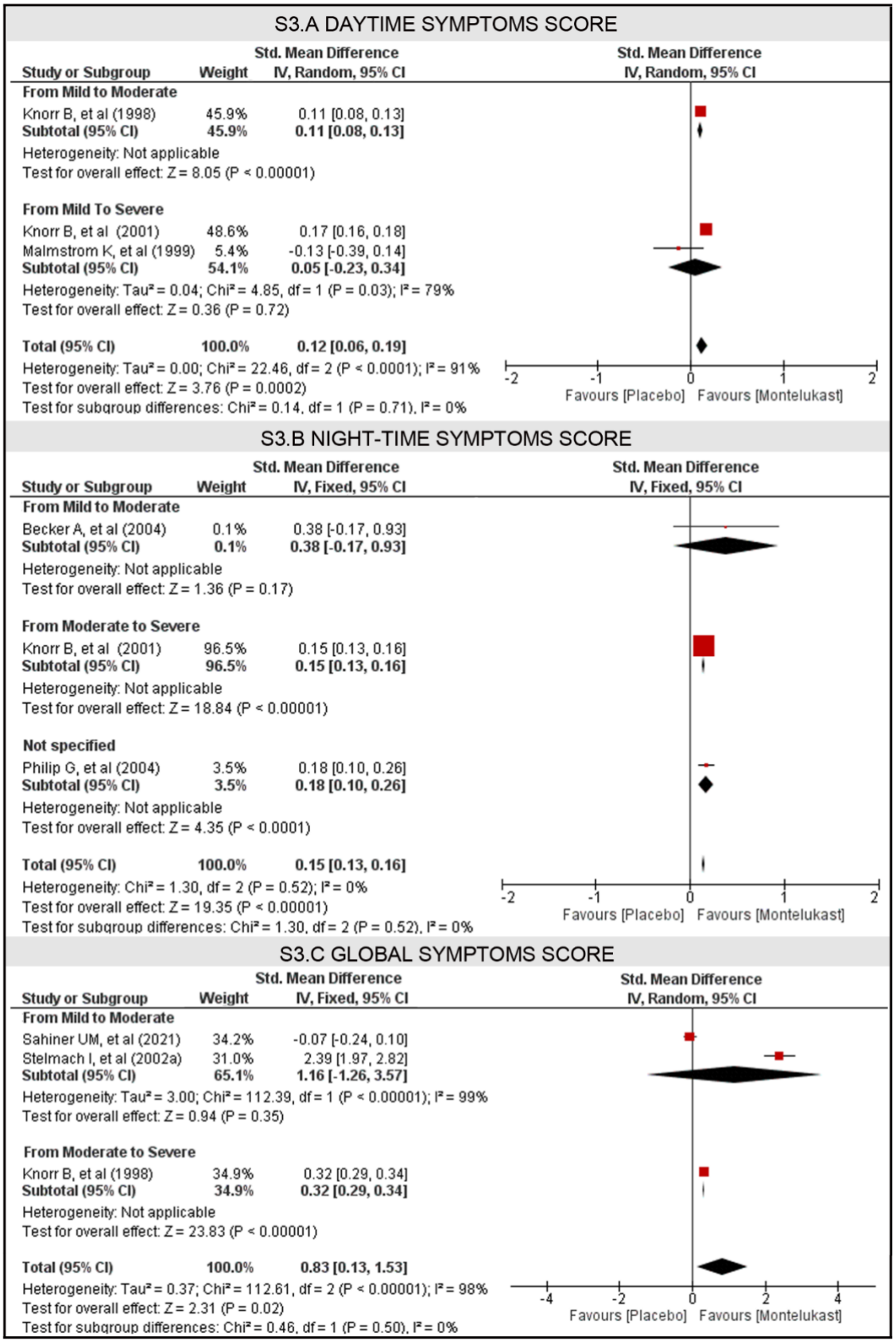


Table B. Adverse drug events

PMID	Description of Groups Study Withdrawals	Adverse drug events		
		Type of event	Intervention group	Control group
Knorr [48], 1998	**Description** **(I):** Montelukast (4 mg) (n=201) **(C):** Placebo (n=135) **Withdrawals** **(I):** 4% (8 of 201) **(C):** 2.2% (3 of 135)	Upper respiratory tract infection	23.9% (48 of 201)	29.6% (40 of 135)
		Headache	18.9% (38 of 201)	21.5% (29 of 135)
		Asthma	16.4% (33 of 201)	22.2% (30 of 135)
		Pharyngitis	13.9% (28 of 201)	12.6% (17 of 135)
		Abdominal pain	5.0% (10 of 201)	10.4% (14 of 135)
		Influenza	8.5% (17 of 201)	4.4% (6 of 135)
		Cough	6.0% (12 of 201)	7.4% (10 of 135)
		Fever	7.5% (15 of 201)	3.7% (5 of 135)
°Knorr [50], 2001	**Description** **(I):** Montelukast (5 mg) (n=461) **(C):** Placebo (n=228) **Withdrawals** **(I):** 9.8% (45 of 461) **(C):** 11.4% (26 of 228)	Asthma	29.7% (137 of 461)	37.7% (86 of 228)
		Fever	27.1% (125 of 461)	26.8% (61 of 228)
		Upper respiratory infection	26.7% (123 of 461)	27.6% (63 of 228)
		Vomiting	16.3% (75 of 461)	19.7% (45 of 228)
		Nervous System and Psychiatric Disorders	13.0% (60 of 461)	13.2% (30 of 288)
		Cough	12.6% (58 of 461	11.4% (26 of 228)
		Pharyngitis	11.7% (54 of 461)	15.4% (35 of 228)
		Abdominal pain	11.1% (51 of 461)	9.2% (21 of 228)
		Diarrhoea	9.76% (45 of 461)	7.5% (17 of 228)
		Headache	7.6% (35 of 461)	7.5% (17 of 288)
		Irritability	1.5% (7 of 461)	2.2% (5 of 288)
		Nervousness	0.9% (4 of 461)	0.9% (2 of 288)
		Behaviour disturbance	0.7% (3 of 461)	0.4% (1 of 288)
		Enuresis	0.7% (3 of 461)	0% (0 of 288)
		Insomnia	0.7% (3 of 461)	0.4% (1 of 288)
		Falling	0.4% (2 of 461)	0% (0 of 288)
		Gait abnormality	0.4% (2 of 461)	0% (0 of 288)
		Hyperkinesia	0.4% (2 of 461)	1.3% (3 of 288)
		Dream abnormality	0.2% (1 of 461)	0% (0 of 288)
		Excitement	0.2% (1 of 461)	0% (0 of 288)
		Aggressive behaviour	0.2% (1 of 461)	0.4% (1 of 288)
		Parasomnia	0.2% (1 of 461)	0% (0 of 288)
		Somnolence	0.2% (1 of 461)	0% (0 of 288)
		Anxiety	0% (0 of 461)	0.4% (1 of 288)
		Bipolar disorder	0% (0 of 461)	0.4% (1 of 288)
		Crying	0% (0 of 461)	0.4% (1 of 288)
		Dizziness	0% (0 of 461)	0.4% (1 of 288)
		Personality change	0% (0 of 461)	0.4% (1 of 288)
Garcia-Garcia [38], 2005	**Description** **(I):** Montelukast (5 mg) (n=263) **(C):** Fluticasone (200 µg) (n=278) **Withdrawals** **(I):** 7.3% (36 of 495) **(C):** 6.6% (33 of 499)	Headache	3.8% (10 of 263)	1.8% (5 of 278)
		Asthma	1.1% (3 of 263)	0.7% (2 of 278)
		Laboratory adverse Experian	0.8% (2 of 263)	0.0% (0 of 278)
Ostrom [39], 2005	**Description** **(I):** Montelukast (5 mg) (n=167) **(C):** Fluticasone (100 µg) (n=172) **Withdrawals** **(I):** 21.0% (35 of 167) **(C):** 13.0% (25 of 172	Asthma exacerbations	14.5% (25 of 167)	19.8% (33 of 172)
		Headache	11.9% (20 of 167)	12.2% (21 of 172)
		Sore throat	11.9% (20 of 167)	9.9% (17 of 172)
		Upper respiratory tract infection	10.8% (18 of 167)	11.6% (20 of 172)
		Fever	7.2% (12 of 167)	9.9% (17 of 172)
		Cough	6% (10 of 167)	10% (17 of 172)
*****Stelmach [37], 2005	**Description** **(I):** Montelukast (5 or 10 mg) (n=17) **(C):** Budesonide (400 or 800 µg) (n=16) **Withdrawals** **(I):** 5.8% (1 of 17)	**(AE):** Information not reported in the article.		

PMID	Description of Groups Study Withdrawals	Adverse drug events		
		Type of event	Intervention group	Control group
	(C): 6.3% (1 of 16)			
Spahn [55], 2006	**Description** **(I):** Montelukast (5 mg) (n=11) **(C):** Placebo (n=10) **Withdrawals** **(I):** 9.0% (1 of 11) **(C):** 10.0% (1 of 10)	**(AE):** Both treatments were well tolerated, with no serious adverse events noted.		
Szefler [40], 2007	**Description** **(I):** Montelukast (5 mg) (n=197) **(C):** Budesonide 500 µg (n=197) **Withdrawals** **(I):** 2.5% (5 of 197) **(C):** 1.0% (2 of 197)	Upper respiratory tract infection	28.9% (57 of 197)	26.9% (53 of 197)
		Pyrexia	23.4% (46 of 197)	17.8% (35 of 197)
		Otitis media	17.3% (34 of 197)	11.2% (22 of 197)
		Sinusitis	13.7% (27 of 197)	12.7% (25 of 197)
		Nasopharyngitis	11.7% (23 of 197)	11.7% (23 of 197)
		Headache	11.2% (22 of 197)	9.6% (19 of 197)
		Pharyngitis	10.2% (20 of 197)	6.1% (12 of 197)
Máspero [46], 2008	**Description** **(I):** Montelukast (5 mg) (n=267) **(C):** Salmeterol / Fluticasone (100/200µg) (n=281) **Withdrawals** **(I):** 11.2% (30 of 267) **(C):** 6.4% (18 of 281)	**(AE):** Information not reported in the article.		
Bérubé [47], 2014	**Description** **(I):** Montelukast (4 or 5 mg) (n=73) **(C):** Montelukast (4 or 5 mg) + ICs (different doses) (n=252) **Withdrawals** There were 40 (12.2%) patients who were discontinued from the study	A total of 3 serious adverse events were experienced by 3 patients: asthma episode (1), bronchitis (1) and pneumonia (1), none related to the study medication. There were 25 (13.7%) non-serious adverse events, probably related to montelukast. The most frequent non-serious adverse events related to montelukast were: Nightmares and sleep terror (n = 6), abdominal pain (n = 5), insomnia (n = 2), and headache (n = 2).		

(*) Citations identified from other reviews; **(º)** Data obtained after contacting sponsor; (I) Intervention group; (C) Control group.