Appendix 4C: Characteristics of randomized, placebo-controlled trials involving patients with fibromyalgia or mixed neuropathic and nociceptive pain and an *N*-of-1 trial that were included in the meta-analysis

Study report	Study population, *n* (withdrawals)	Intervention and dosage	End points and outcomes
Fibromyalgia*			
Russell 2000, USA Parallel groups Quality: 5	Fibromyalgia 69 (1)	Tramadol 50-400 mg/d for 6 wk	Primary: No. of patients exiting because of inadequate pain relief Secondary: pain intensity* (10-cm VAS), pain relief, tender-point count, myalgic score, FMIQ* (0-100) Results: see Appendixes 5 and 8
Bennett 2003, USA Parallel groups Quality: 5	Fibromyalgia 315 (177)	Tramadol 37.5-300 mg/d + acetaminophen 325-2600 mg/d for 11.5 wk	Primary: cumulative time of discontinuation due to lack of efficacy Secondary: pain intensity* (100-mm VAS), pain relief, tender-point count, myalgic score, FMIQ,* SF-36,12-SQ Results: see Appendixes 5 and 8
Mixed pain			
Maier 2002, Germany Crossover design Quality: 4	67% neuropathic, 32% nociceptive 49 (13)	SR morphine 10-180 (mean 114) mg/d for 1 wk	Primary: pain intensity* (0-10 NRS) Secondary: tolerability of pain, sleep quality, physical fitness, mental state and mood, PDI,* complaints about symptoms Results: see Appendixes 5 and 8
***N*-of-1 randomized trial**			
Sheather-Reid 1998, Australia Quality: 3	Regional cervico-brachial pain 8 (3)	For 4 wk: A) Codeine 120 mg/d B) Ibuprofen 800 mg/d Placebo group	Primary: pain intensity (VAS) Secondary: change in pain, uptime and hours of sleep Results: analgesic efficacy with either drug was inadequate in the 5 subjects who completed the 12-week trial

Note: VAS = visual analog scale, FMIQ = Fibromyalgia Impact Questionnaire, SF-36 = Short Form 36 Health Survey, 12-SQ = 12-item sleep questionnaire, SR = sustained release, NRS = numeric rating scale, PDI = Pain Disability Index.
*Data used in the meta-analysis.

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