

NKR16_PICO11_TCA for Fibromyalgi

Characteristics of studies

Characteristics of included studies

Braz 2013

Methods	
Participants	
Interventions	
Outcomes	
Notes	Data obtained from: Moore RA, Derry S, Aldington D, Cole P, Wiffen PJ. Amitriptyline for fibromyalgia in adults. Cochrane Database of Systematic Reviews 2015, Issue 7, Art. No.: CD011824. doi: 10.1002/14651858.CD011824

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Reference: Moore et al., 2015
Allocation concealment (selection bias)	Unclear risk	Reference: Moore et al., 2015
Blinding of participants and personnel (performance bias)	Low risk	Reference: Moore et al., 2015
Blinding of outcome assessment (detection bias)	Low risk	Reference: Moore et al., 2015
Incomplete outcome data (attrition bias)	High risk	Reference: Moore et al., 2015
Selective reporting (reporting bias)	Unclear risk	Not addressed in Moore et al., 2015
Other bias	High risk	Moore et al., 2015 (Size)

Carette 1986

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Caruso 1987

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de Zanette 2014

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Ginsberg 1996

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Goldenberg 1986

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Hannonen 1998

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Heymann 2001_amt

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Heymann 2001_ntl

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Kempnaers 1994

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Scudds 1989

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Interventions	
Outcomes	
Notes	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Allocation concealment (selection bias)	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Blinding of participants and personnel (performance bias)	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Blinding of outcome assessment (detection bias)	Low risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Incomplete outcome data (attrition bias)	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Selective reporting (reporting bias)	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.
Other bias	Unclear risk	Data obtained from: Sommer C, Häuser W, Alten B, Petzke F, Späth M, Tölle T, Uçeyler N, Winkelmann A, Winter E, Bär KJ; Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften . [Drug therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline]. [Article in German]. Schmerz . 2012 Jun;26(3):297-310. doi: 10.1007/s00482-012-1172-2.

Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables**Additional tables****References to studies****Included studies*****Braz 2013***

[Empty]

Carette 1986

[Empty]

Carette 1994

[Empty]

Carette 1995

[Empty]

Caruso 1987

[Empty]

de Zanette 2014

[Empty]

Ginsberg 1996

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Goldenberg 1986

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Goldenberg 1996

[Empty]

Hannonen 1998

[Empty]

Heymann 2001_amt

[Empty]

Heymann 2001_ntl

[Empty]

Kempenaers 1994

[Empty]

Scudds 1989

[Empty]

Excluded studies**Studies awaiting classification****Ongoing studies****Other references****Additional references****Other published versions of this review****Classification pending references****Data and analyses****2 TCAs versus placebo**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Function (funktionsevne), EoT	1	82	Mean Difference (IV, Random, 95% CI)	Not estimable

2.2 Quality of Life (livskvalitet)	7	390	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.42, -0.00]
2.3 Pain at final treatment	11	546	Std. Mean Difference (IV, Random, 95% CI)	-0.48 [-0.74, -0.23]
2.4 Pain_change	1	42	Mean Difference (IV, Random, 95% CI)	-0.50 [-1.33, 0.33]
2.5 Fatigue at final treatment	8	369	Std. Mean Difference (IV, Random, 95% CI)	-0.49 [-0.84, -0.15]
2.6 All-cause withdrawal	14	774	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.56, 1.06]
2.7 Adverse event withdrawal	5	340	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.51, 2.04]
2.8 Severe adverse events	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
2.9 Ventricular arrhythmia	2	118	Risk Ratio (M-H, Random, 95% CI)	0.17 [0.01, 4.01]
2.12 Hypertension	1	60	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.13, 70.83]
2.13 Addiction	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
2.14 Dry mouth	5	304	Risk Ratio (M-H, Random, 95% CI)	4.95 [1.72, 14.24]
2.15 Constipation	2	106	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.10, 17.14]
2.16 Vomiting	1	60	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.13, 70.83]
2.17 Drowsiness	1	60	Risk Ratio (M-H, Fixed, 95% CI)	25.00 [1.55, 403.99]
2.18 Nausea	3	228	Risk Ratio (M-H, Random, 95% CI)	0.50 [0.11, 2.17]
2.19 Dizziness	2	158	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.28, 2.19]
2.20 Weight gain	2	158	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.13, 71.51]

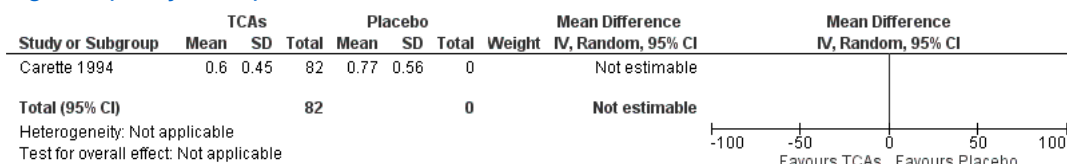
Figures

Figure 1

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Braz 2013	?	?	+	+	-	?	-
Carette 1986	?	?	+	+	-	?	-
Carette 1994	+	?	+	+	?	?	-
Carette 1995	+	?	+	+	+	?	-
Caruso 1987	?	+	?	?	?	?	?
de Zanette 2014	?	+	?	?	?	?	-
Ginsberg 1996	?	?	+	+	+	?	-
Goldenberg 1986	?	?	?	?	?	?	-
Goldenberg 1996	+	?	+	+	-	?	-
Hannonen 1998	+	?	+	+	?	?	-
Heymann 2001_amt	+	+	?	?	?	?	?
Heymann 2001_ntf	+	+	?	?	?	?	?
Kempnaers 1994	?	?	?	?	?	?	?
Scudds 1989	?	?	?	+	?	?	?

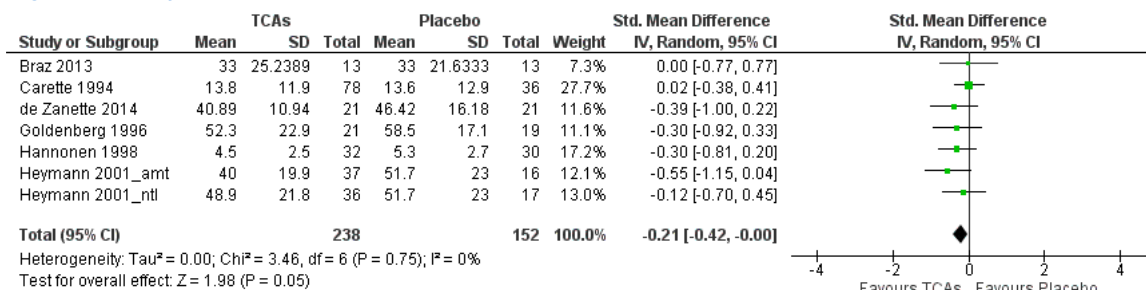
Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 2 (Analysis 2.1)



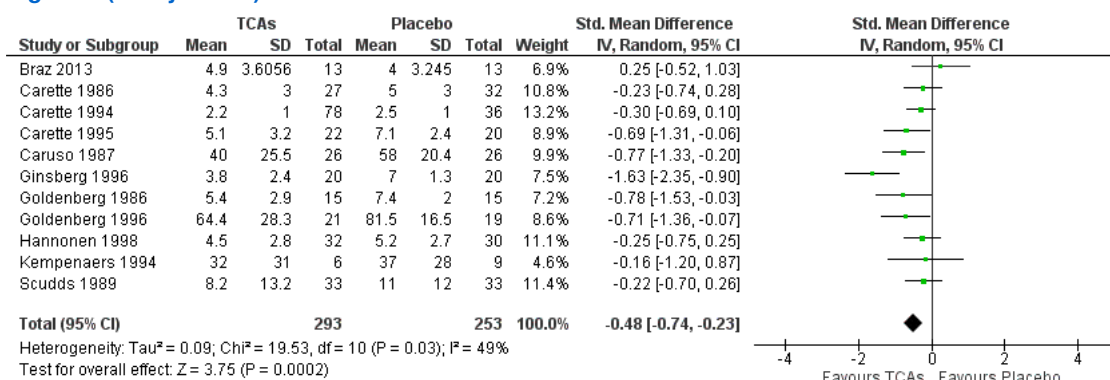
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.1 Function (funktionsevne), EoT.

Figure 3 (Analysis 2.2)



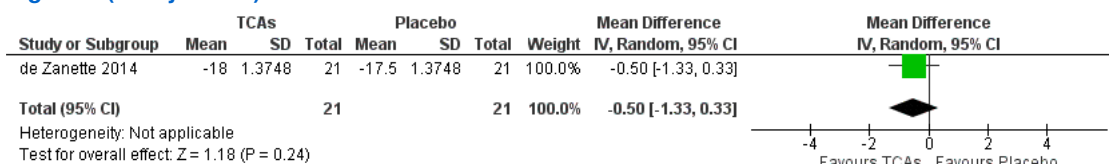
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.2 Quality of Life (livskvalitet).

Figure 4 (Analysis 2.3)



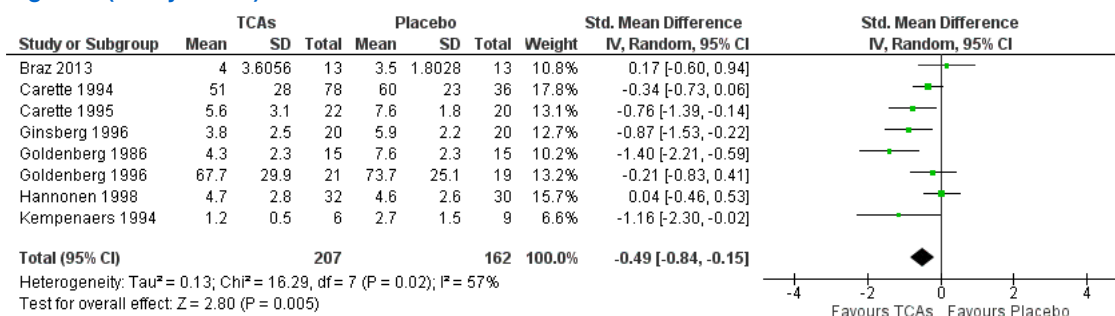
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.3 Pain at final treatment.

Figure 5 (Analysis 2.4)



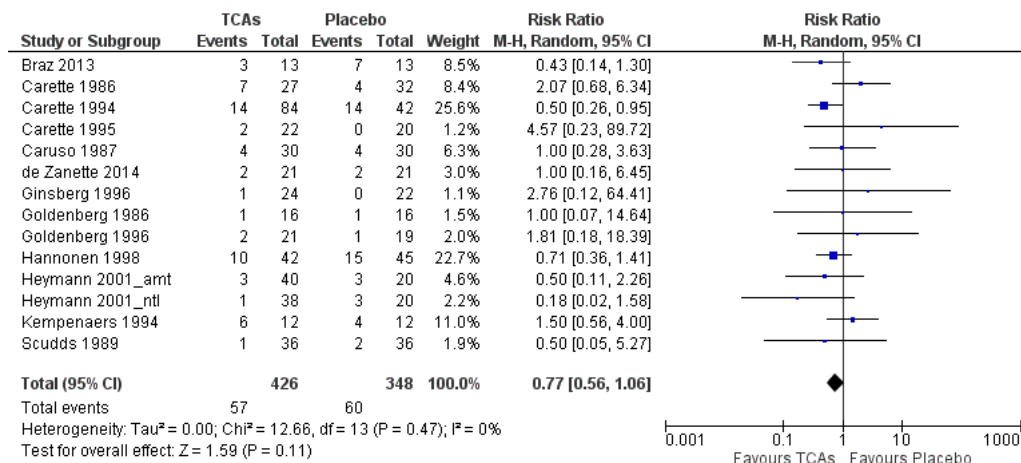
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.4 Pain_change.

Figure 6 (Analysis 2.5)



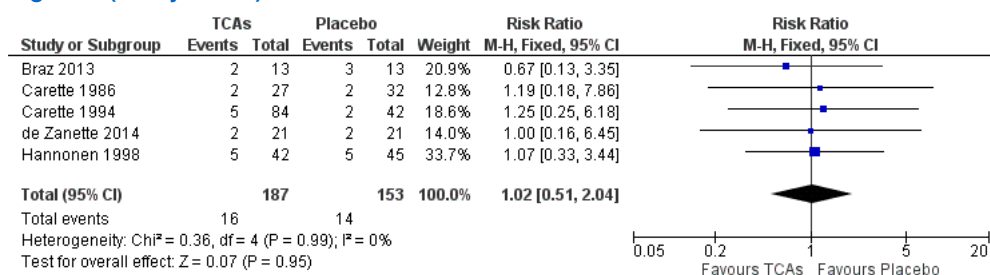
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.5 Fatigue at final treatment.

Figure 7 (Analysis 2.6)



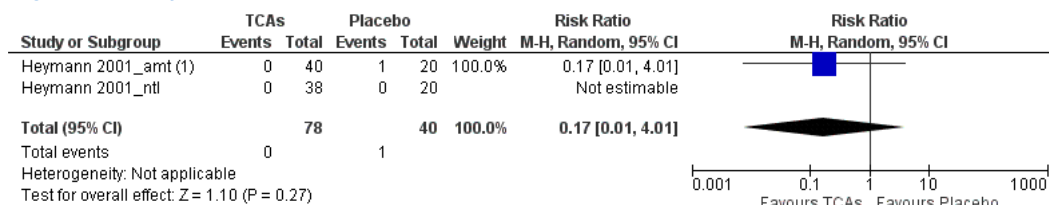
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.6 All-cause withdrawal.

Figure 8 (Analysis 2.7)



Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.7 Adverse event withdrawal.

Figure 9 (Analysis 2.9)

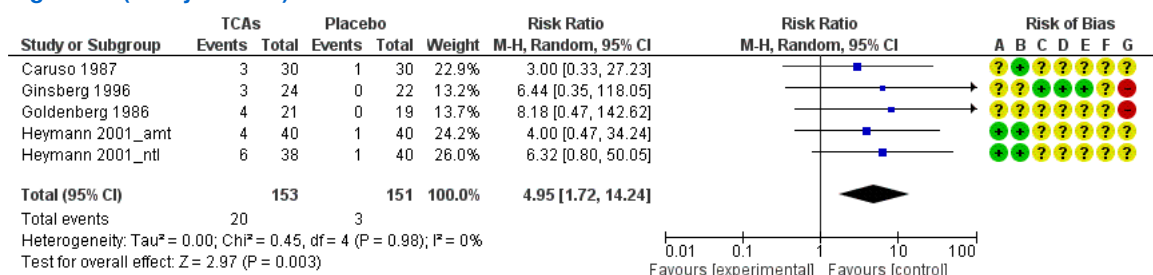


Footnotes

(1) Placebogruppen er delt ud på 2 referencer (da Sommer 2012 har gjort dette i øvrige analyser)

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.9 Ventricular arrhythmia.

Figure 10 (Analysis 2.14)

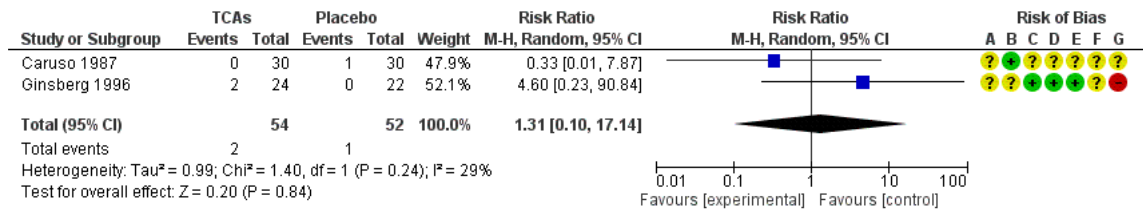


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.14 Dry mouth.

Figure 11 (Analysis 2.15)

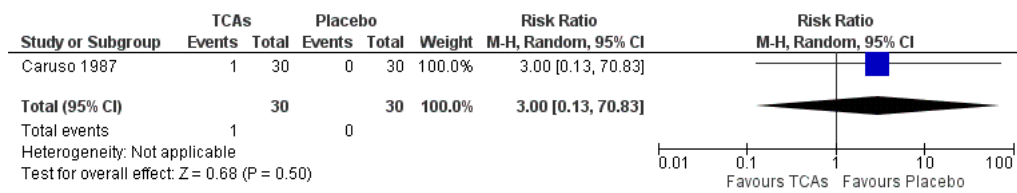


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

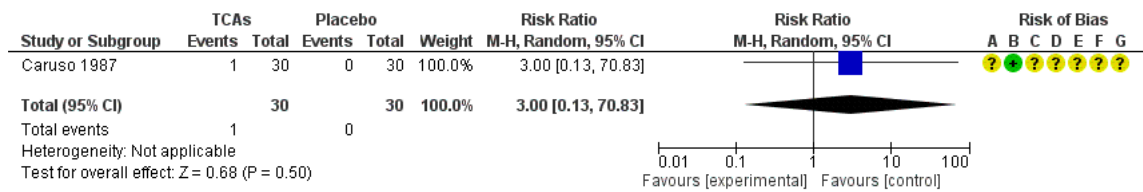
Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.15 Constipation.

Figure 12 (Analysis 2.12)



Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.12 Hypertension.

Figure 13 (Analysis 2.16)

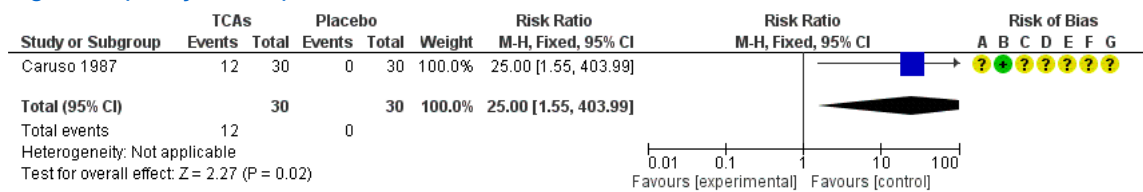


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.16 Vomiting.

Figure 14 (Analysis 2.17)

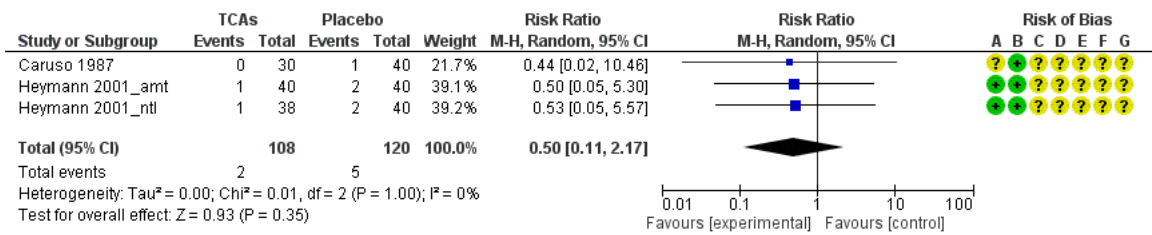


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.17 Drowsiness.

Figure 15 (Analysis 2.18)

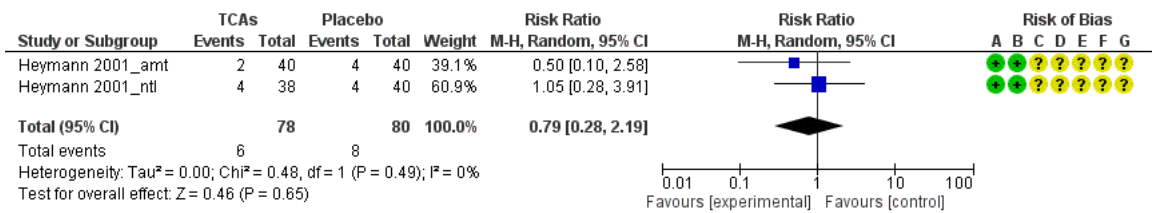


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.18 Nausea.

Figure 16 (Analysis 2.19)

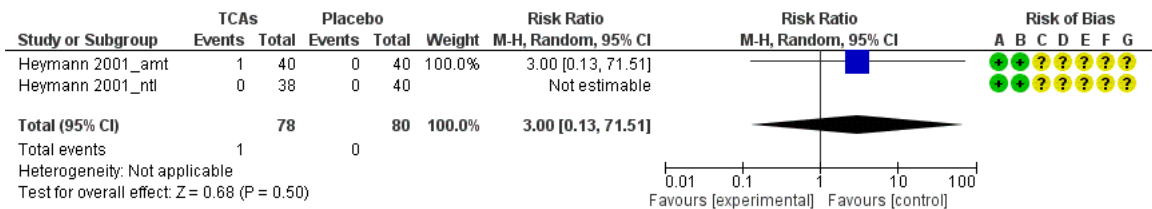


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.19 Dizziness.

Figure 17 (Analysis 2.20)



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 2 TCAs versus placebo, outcome: 2.20 Weight gain.