

Table 34: Clinical evidence profile: Galantamine hydrobromide versus placebo

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Galantamine hydrobromide versus placebo	Control	Relative (95% CI)	Absolute		
Fatigue: fatigue on VAS (follow-up 2 weeks; Better indicated by lower values)												
1	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	25	24	-	MD 0.14 higher (0.84 lower to 1.12 higher)	⊕000 VERY LOW	CRITICAL
Cognitive function: memory on VAS (follow-up 2 weeks; Better indicated by higher values)												
1	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	25	24	-	MD 0.91 higher (0.67 lower to 2.49 higher)		CRITICAL
Pain: myalgia on VAS (follow-up 2 weeks; Better indicated by lower values)												
1	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	25	24	-	MD 0.47 lower (1.39 lower to 0.45 higher)	⊕000 VERY LOW	CRITICAL
Sleep quality: sleep disturbance on VAS (follow-up 2 weeks; Better indicated by lower values)												

1	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	25	24	-	MD 0.34 higher (1.02 lower to 1.7 higher)	⊕000 VERY LOW	CRITICAL
Adverse events: AEs dizziness on VAS (follow-up 2 weeks; Better indicated by lower values)												
1	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	25	24	-	MD 0.72 higher (0.93 lower to 2.37 higher)	⊕000 VERY LOW	CRITICAL
Return to work: work capacity/satisfaction on VAS (follow-up 2 weeks; Better indicated by higher values)												
1	randomised trials	serious ¹	no serious inconsistency	serious ²	very serious ³	none	25	14	-	MD 0.17 lower (1.38 lower to 1.04 higher)	⊕000 VERY LOW	CRITICAL
Symptom scales: clinical global impression score, no change or worse (follow-up 20 weeks)												
1	randomised trials	very serious ³	no serious inconsistency	serious ²	serious ³	none	169/280 (60.4%)	47/67 (70.1%)	RR 0.86 (0.72 to 1.03)	98 fewer per 1000 (from 196 fewer to 21 more)	⊕000 VERY LOW	CRITICAL

¹ Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

² The majority of the evidence included an indirect population (downgraded by one increment) or a very indirect population (downgraded by two increments). Populations were downgraded if the ME/CFS diagnostic criteria used did not include PEM as a compulsory feature

³ Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs