

# Effect of Homotaurine on functional abilities in patients with mild-to-moderate Alzheimer's disease treated with a cholinesterase inhibitor therapy

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**Objective:** The study was designed to assess the effect on functional abilities of homotaurine, a patented variant of the aminoacid taurine, as add-on therapy to cholinesterase inhibitors (ChEIs) in patients with mild-to-moderate Alzheimer's disease (AD).

**Methods:** This was a prospective, randomized, 12 month, parallel-group study comparing ChEIs vs ChEIs + Homotaurine (100 mg/die). Drug effects on IADL and ADL were evaluated cross-sectionally at baseline, 6 and 12 months.

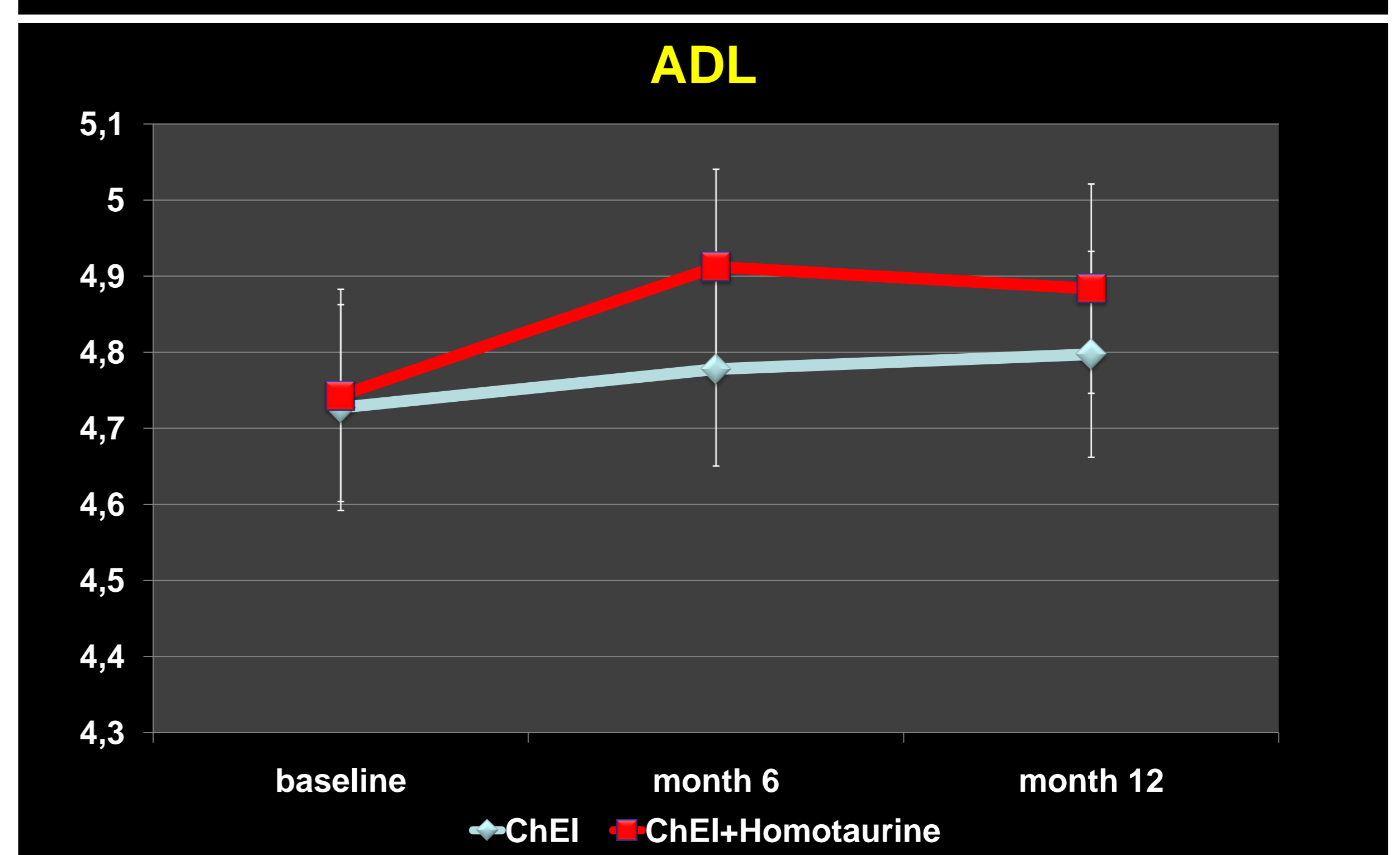
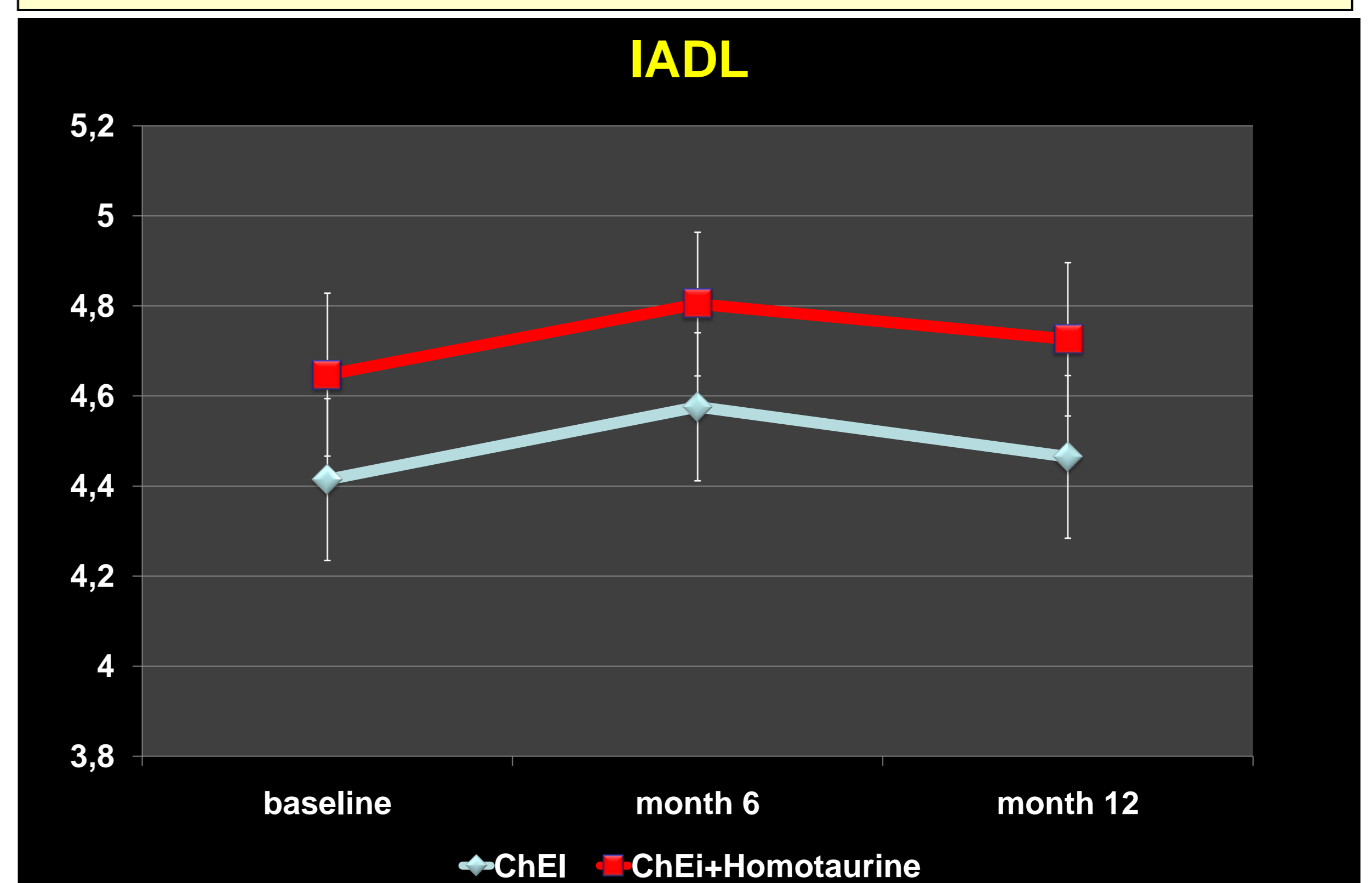
**Results:** 132 (80.4%) of 164 patients completed the study. 90 (54.8%) were female and 74 (45.2%) were male. 32 (19.6%) patients discontinued treatment prematurely. The most frequent reason for premature discontinuation was multiple failed appointments or non compliance. Analysis of IADL total scores revealed that monotherapy had a baseline mean score of  $4.41 \pm 1.79$  and a final score of  $4.46 \pm 1.80$ . IADL baseline score for combination therapy was  $4.64 \pm 1.63$ , and  $4.72 \pm 1.72$  at the study end. The IADL score for combination therapy showed a mean improvement versus baseline of +0.08 points compared with monotherapy that showed a mean improvement of +0.05 points. The IADL scores for both treatment groups did not differ significantly from baseline. The between-group difference in IADL change showed a trend for superiority of combination therapy, but did not reach statistical significance ( $p \leq 0.1$ ). ADL total mean score for monotherapy was  $4.72 \pm 1.35$  at baseline, and  $4.79 \pm 1.38$  at the study end. Combination therapy had a baseline score of  $4.74 \pm 1.83$  and a final score of  $4.88 \pm 1.39$ . The ADL score for combination therapy showed a mean improvement versus baseline of +0.14 points compared with monotherapy that showed a mean improvement of +0.07 points. The ADL scores for both treatment groups did not differ significantly from baseline. The between-group difference in ADL reached statistical significance ( $p = 0.05$ ) in favour of combination therapy. Adverse events occurred in 36.2% and in 42.5% of patients on combination and monotherapy groups respectively. The most common was nausea, followed by vomiting and anorexia.

**Discussion:** Homotaurine has been shown, in both in vitro and in vivo models, to provide a relevant neuroprotective effect by its specific anti-amyloid activity and by its GABA A receptor affinity. The addition of homotaurine to ChEIs resulted in better outcomes than ChEIs monotherapy on measures of functional abilities without major side effects.

**Conclusions:** The results of our study suggest a positive effect of homotaurine on functional abilities among patients suffering from AD.

Baseline characteristics of the patient population (n=164)

	ChEIs + homotaurine (n=84)	ChEIs (n=80)
MALES (n, %)	38 (42.72)	36 (44.85)
FEMALES (n, %)	46 (57.27)	44 (55.14)
MEAN AGE (yr $\pm$ SD)	$76.4 \pm 8.1$	$75.6 \pm 8.2$
MEAN EDUCATION (yr $\pm$ SD)	$5.1 \pm 2.9$	$5.3 \pm 2.8$
MEAN AD DURATION (yr $\pm$ SD)	$5.6 \pm 1.2$	$5.3 \pm 1.4$
MMSE (total mean score $\pm$ SD)	$17.7 \pm 2.8$	$17.6 \pm 2.4$
ADAS Cog (total mean score $\pm$ SD)	$36.3 \pm 1.5$	$37.1 \pm 1.5$
HIS (total mean score $\pm$ SD)	$3.5 \pm 2.9$	$3.8 \pm 2.1$
GDS (total mean score $\pm$ SD)	$4.7 \pm 0.5$	$4.8 \pm 0.6$



## References

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