

Ginkgo biloba did not prevent dementia or Alzheimer disease in elderly people

QUESTION

Does *Ginkgo biloba* reduce incident dementia and Alzheimer disease in elderly people with normal cognition or mild cognitive impairment?

METHODS

Design: randomised placebo controlled trial (*Ginkgo Evaluation of Memory [GEM] study*). ClinicalTrials.gov NCT00010803.

Allocation: unclear allocation concealment.*

Blinding: blinded (patients, clinicians, and outcome assessors).*

Follow-up period: median 6.1 years.

Setting: 5 academic medical centres in the USA.

Participants: 3069 participants >75 years of age (mean age 79 y, 54% men) who had normal cognition or mild cognitive impairment (impaired at $\leq 10^{\text{th}}$ percentile of Cardiovascular Health Study normative data on 2 of 10 neuropsychological tests and Clinical Dementia Rating global score of 0.5). Exclusion criteria included dementia; bleeding disorders; Parkinson disease; receipt of warfarin, cholinesterase inhibitors, antidepressants, or antipsychotics; abnormal thyroid tests, serum creatinine concentration >2 mg/dl (>176.8 $\mu\text{mol/l}$), or liver function test result >2 times the upper limit of normal; or allergy to *Ginkgo biloba*.

Intervention: *Ginkgo biloba*, 120 mg twice daily (n = 1545), or matching placebo (n = 1524).

Outcomes: diagnosis of dementia and Alzheimer disease.

Patient follow-up: 94% (intention-to-treat analysis).

MAIN RESULTS

Ginkgo biloba and placebo did not differ for incident dementia or Alzheimer disease (table).

CONCLUSION

Ginkgo biloba did not prevent incident dementia or Alzheimer disease in elderly people with normal cognition or mild cognitive impairment.

ABSTRACTED FROM

Dekosky ST, Williamson JD, Fitzpatrick AL, *et al* for the Ginkgo Evaluation of Memory (GEM) Study Investigators. *Ginkgo biloba* for prevention of dementia: a randomized controlled trial. *JAMA* 2008;**300**:2253–62.

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► **Clinical impact ratings:** Elderly care 6/7; Family/general practice 6/7; Psychiatry 6/7

Ginkgo biloba v placebo for preventing dementia in elderly people*

Outcomes	<i>Ginkgo biloba</i>	Placebo	At a median 6.1 years	
			RRI (95% CI)	NNH
Dementia	18%	16%	11% (–6 to 29)	Not significant
Alzheimer disease	17%	14%	15% (–3 to 35)	Not significant

*Abbreviations defined in glossary. RRI, NNH, and CI calculated from control event rates and hazard ratios in article.

Ginkgo biloba is a popular herbal supplement that is widely used in Europe and the USA for both treating and preventing dementia. However, good quality evidence supporting its effectiveness is lacking. In 2007, a Cochrane review of 35 clinical trials (n = 4247) suggested that *Ginkgo biloba* was ineffective for dementia.¹ The study by DeKosky *et al* shows that *Ginkgo biloba* is no more effective than placebo for preventing dementia. It addresses many weaknesses identified in previous studies by virtue of its large size (n = 3069) and relatively lengthy duration (≥ 6 y exposure to *Ginkgo biloba* or placebo).

People often consider herbal therapies to be safe, even if they are not effective, and although I have

previously suggested that financial harm occurs if people spend money on ineffectual remedies,² this study suggests that physical harm may also occur. There was a non-significant increase in haemorrhagic strokes in the intervention group, and although this may be due to chance alone, it raises the question of "how safe is *Ginkgo biloba*?" This is an important question as the perception exists that herbal remedies are intrinsically safer than pharmaceutical preparations.³ The clinical bottom line is that no evidence exists to support use of this supplement to prevent dementia. This fits into the broader picture that *Ginkgo biloba* has no effect on slowing down progression of dementia in the early stages of disease.

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