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A randomised controlled trial of B-vitamin supplementation on neuropsychiatric performance: results from the BrainHOP trial

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Globally populations are ageing and mental health disorders, including dementia and depression, are reported as the leading cause of disability and ill health in older people⁽¹⁾. Epidemiological and randomised trial evidence supports potential roles for folate and the metabolically related B-vitamins in preventing cognitive dysfunction and depression in ageing, but the evidence is inconsistent⁽²⁾. The aim of this study was to investigate the effect of supplementation with folate and related B-vitamins, over a 2 year period, on cognitive function (primary outcome) and depression (secondary outcome) in older adults.

The B-vitamins and Brain Health in Older People (BrainHOP) randomised controlled trial was conducted in adults aged 70 years and older. Participants were randomised to receive a supplement containing folic acid (400 µg), vitamin B12 (10 µg), vitamin B6 (10 mg) and riboflavin (10 mg) or placebo daily. Cognitive function was assessed before and after the 2-year intervention using the Frontal Assessment Battery (FAB) and the Repeatable Battery of the Assessment of Neuropsychological Status (RBANS). Depression was assessed using the Centre for Epidemiological Studies Depression (CES-D) scale.

Of the 328 participants initially recruited, 249 (74%) participants completed the intervention. Results showed that B-vitamin intervention appeared to have no significant effect on either frontal lobe or global cognitive function (as measured by FAB and RBANS, respectively). However, when specific domains within global cognition (i.e. RBANS index scores) were examined separately, B-vitamin intervention was found to protect against visuospatial cognitive decline over the two year period (Table).

	Placebo (n 125)		B-vitamin (n 124)		P*
	Mean	SD	Mean	SD	
Age (at baseline)	78.2	4.7	77.9	4.2	0.607
Gender (male) n %	80	48.5	67	41.1	0.218
Cognitive Scores	Adjusted mean	SEM	Adjusted mean	SEM	
FAB					
Pre-intervention	14.7	0.2	15.1	0.2	
Post-intervention	14.4	0.2	14.7	0.2	0.485
RBANS					
Total Score					
Pre-intervention	93.3	1.3	93.4	1.3	
Post-intervention	95.5	1.4	97.8	1.4	0.117
Index II (Visuospatial Cognition)					
Pre-intervention	98.8	1.6	95.0	1.7	
Post-intervention	95.8	1.7	99.2	1.7	0.001

*Time × treatment interaction (repeated measures ANCOVA, comparing the effect of treatment vs placebo over time, controlling for age, education, depression, anxiety, hyperlipidaemia, hypertension and smoking status.
FAB, frontal Assessment Battery; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status.

In the case of depression, although the effect of B-vitamin intervention on depression (i.e. CES-D score) did not reach statistical significance, rates of depression (i.e. % with CES-D score > 16) doubled over the 2-year period in the placebo group (from 4.0% to 8.0%) compared with a minimal increase in the B-vitamin group (from 4.0% to 4.8%) (Data not shown).

The BrainHOP trial is the first randomised trial to investigate the potential benefits of combined folic acid, vitamin B12, vitamin B6 and riboflavin supplementation on cognitive function and depression in generally healthy older adults. Intervention with low dose B-vitamins (i.e. within the dietary range) resulted in beneficial effects on both visuospatial cognition and depression. Optimising B-vitamin status in older populations (through fortification or supplementation programs) may have important impacts on brain health and in turn would help to preserve better quality of life in ageing.

1. Prince M, Wu F, Guo Y *et al.* (2015) *The Lancet* **385**, 549–562.
2. Smith AD & Refsum H (2016) *Annual Review of Nutrition* **36**, 211–239.