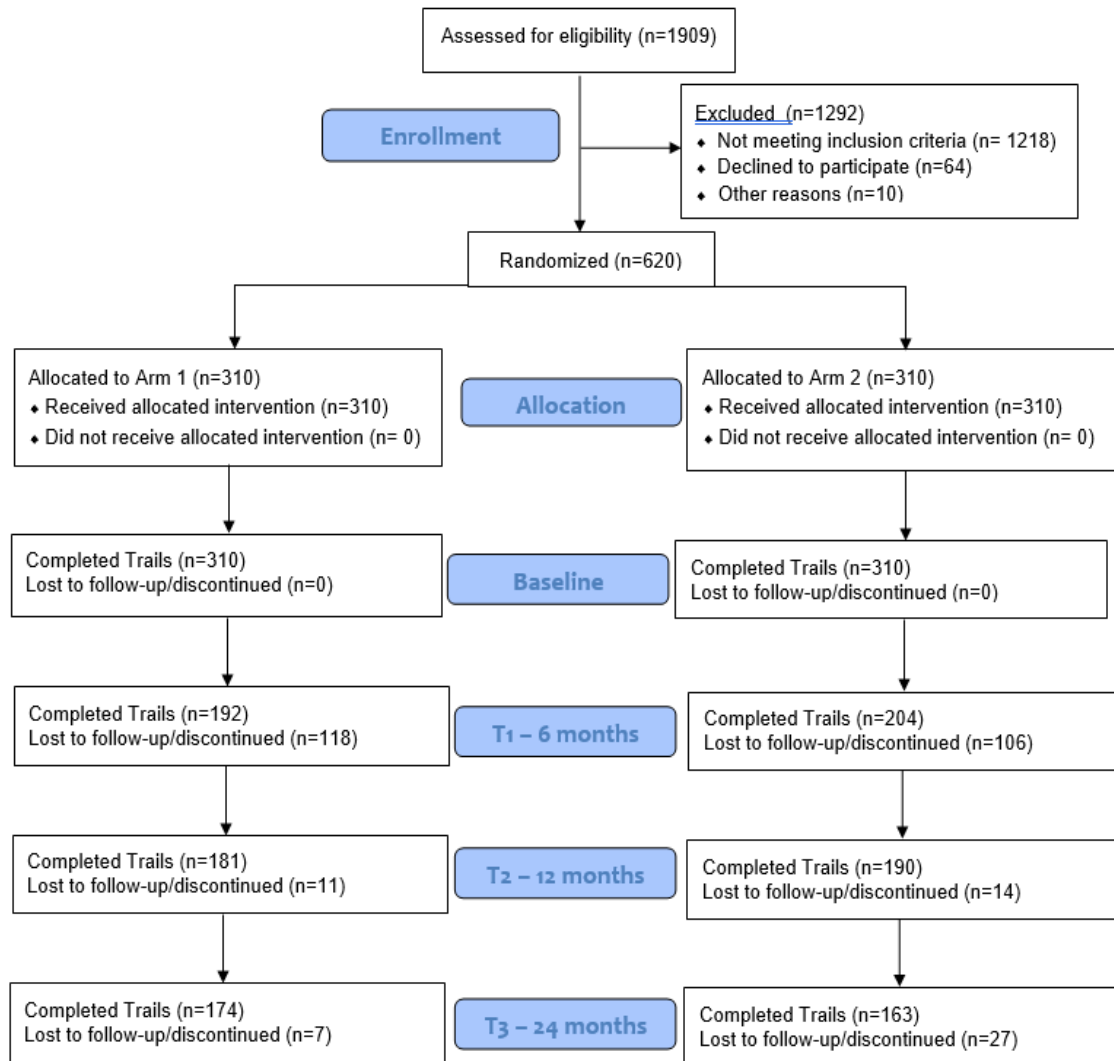


A randomised clinical trial of vitamin D to improve cognition in people at risk of dementia

(VitaMIND): Report of Outcomes

CONSORT chart showing the flow of participants through the VitaMIND trial



Baseline characteristics for the VitaMIND trial

Characteristic		Full cohort n = 620	VitaMIND group n = 310	Control group n = 310
Age	Range	50 – 80	50 – 80	50 – 80
	Mean (SD)	60.7 (6.58)	60.3 (6.27)	60.8 (6.73)
Sex	Male n (%)	154 (25%)	75 (25%)	79 (25%)
	Female n (%)	466 (75%)	235 (75%)	231 (75%)
Educational attainment	Mean (SD)	3.17 (1.38)	3.19 (1.35)	3.14 (1.41)
Ethnicity	White n (%)	608 (98)	301 (97)	303 (98)
	Mixed n (%)	4 (<1)	3 (<1)	1 (<1)
	Asian n (%)	7 (<1)	3 (<1)	4 (<1)
	Black n (%)	1 (<1)	1 (<0.5)	0 (0)

Impact of Vitamin D supplementation on executive function (primary outcome), cognition (Secondary outcomes), function, behaviour and wellbeing at 24 months

	Vitamin D Group		Control Group		Between group difference*		Effect size
	Baseline	2-years	Baseline	2-years	Mean (95% CI),	P-value	
	N mean (SD)	N mean (SD)	N mean SD	N mean SD			
Primary outcome							
Trail making B	310 61869 (27299)	174 61388 (22976)	310 61421 (31949)	163 55954 (49506)	5770 (-2189 to 13730)	0.16	0.116552
Secondary cognitive outcomes							
Baddeley Grammatical Reasoning	310 36.0 (11.7)	169 37.8 (11.4)	310 36.7 (11.8)	150 37.7 (10.8)	0.1 (-1.4 to 1.5)	0.92	0.009259
Switching Stroop	310 40.2 (17.6)	174 44.5 (17.2)	310 41.5 (17.0)	163 43.2 (18.6)	0.7 (-2.2 to 3.7)	0.63	0.037634
Paired Associate Learning	310 3.98 (1.02)	170 4.11 (0.92)	310 4.04 (1.18)	155 4.17 (0.95)	-0.02 (-0.21 to 0.17)	0.84	0.021053
Digit Span	310 7.32 (1.64)	166 7.51 (1.55)	310 7.23 (2.00)	149 7.39 (1.39)	0.11 (-0.14 to 0.38)	0.38	0.079137
Self-Ordered Search Task	310 7.54 (1.98)	172 7.62 (1.80)	310 7.59 (2.13)	157 7.59 (1.91)	0.09 (-0.28 to 0.45)	0.64	0.04712
Secondary non-cognitive outcomes							
Instrumental Activities of Daily Living Scale	302 0.44 (1.55)	177 0.38 (1.50)	302 0.45 (1.35)	177 0.42 (1.33)	0.02 (-0.18 to -0.22)	0.86	0.015038
Mild Behaviour Impairment Scale	302 7.31 (15.31)	176 4.98 (13.61)	303 6.92 (11.70)	175 4.16 (7.11)	0.52 (-1.71 to 2.75)	0.65	0.073136

EQ-5D-5L scale	302 0.84 (0.16)	174 0.84 (0.18)	303 0.83 (0.16)	175 0.85 (0.13)	0.00 (-0.03 to 0.03)	0.92	0
EQ-5D-5L VAS	302 76.1 (19.8)	180 77.5 (18.1)	303 76.4 (19.4)	180 77.7 (18.1)	-0.7 (-3.7 to 2.4)	0.69	0.04

Secondary Analysis: Impact of vitamin D supplementation in sub-groups of age, sex and vitamin D deficiency severity (mild/moderate or severe)

Subgroups	Age 50-59 vs. 60-69 vs. 70-79 vs. 80+ yrs	Sex male vs. female	Vitamin D deficiency Mild/moderate<50nmol/l vs. severe <25 nmol
Primary Outcome			
Trail making B	P=0.69	P=0.79	P=0.97
Secondary Cognitive Outcomes			
Verbal reasoning	P=0.13	P=0.35	P=0.95
Paired Associate Learning	P=0.02	P=0.48	P=0.84
Digit span	P=0.21	P=0.83	P=0.15
Self-ordered search	P=0.13	P=0.73	Not estimable
Switching Stroop	P=0.42	P=0.58	Not estimable
Secondary Non-Cognitive Outcomes			
IADL helplessness	P=0.21	P=0.40	Not estimable
IADL difficulty	P=0.52	P=0.87	Not estimable
MBI	P=0.08	P=0.65	P=0.65
EQ-5D VAS	P=0.70	P=0.14	P=0.67
EQ-5D utility score	P=0.37	P=0.88	P=0.92

Adverse Events

There were no adverse events associated with this study