

Cognitive results after a FINGER-like one year randomized controlled multidomain intervention.

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Background

GOIZ ZAINDU (“caring early” in Basque language) is a pilot study to adapt FINGER methodology^{1,2} in Southern Europe with the aim to evaluate the feasibility of a lifestyle intervention program in this cultural and social context. An additional exploratory aim is to assess the efficacy of the intervention on cognition.

Methods

Study design	1 year controlled, randomized, multidomain intervention for cognitive decline prevention to be carried out in the municipality of Beasain, in the Basque Country
Number of subjects	125 (randomized 1:1 to each group)
Inclusion criteria	≥60 y. and CAIDE ≥ 6. Non demented. Below-expected performance in at least one of the cognitive tests (T@M ³ and Fototest ⁴) or a score ≥ 2 in the AD8 informant's questionnaire of cognitive symptoms.
Intervention	Intensive Multidomain Intervention (MI) on cognition, physical activity, nutrition and vascular risk factors.
Control	Regular Health Advice (RHA)
Cognitive outcomes	Neuropsychological test battery (NTB) ⁵ : global, memory, executive function and processing speed z scores decline: - Z scores were standardized to the baseline mean and SD. - Z score decline was defined as any decrease between pre-intervention and post-intervention assessment.

References

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- This project has been partially financed by the Health Department of the Basque Government (File No. 2017111120).



Results

125 participants were recruited. 64 people were assigned to MI and 61 to RHA. The study started in June 2018, last patient first visit was in March 2019. Up to March 2020, 93 participants (89%) completed the study and 14 discontinued. Due to COVID-19 situation, between March and May, post-intervention assessments were paused, nowadays, 18 post-intervention assessments are being finished.

Table 1. Characteristics at pre-intervention visit.

Characteristics	MI n = 64	RHA* n = 61
Age	76.07 (6.68)	75.22
Sex: women, n (%)	36 (59%)	37 (58%)
Education: years	7.72 (2.92)	8.48 (4.11)
Anxiety (HADS)	4 (2 - 8)	6 (3 - 8)
Depression (HADS)	2 (1 - 5)	3 (1 - 6)
MMSE score	27 (25 - 29)	26 (24 - 28)
Cognitive domain (NTB: z score)		
Global	-0.07 (0.72)	0.02 (0.67)
Memory global	-0.04 (0.84)	0.04 (0.74)
Executive Function	-0.10 (0.72)	0.04 (0.67)
Processing speed	-0.05 (0.92)	0.03 (0.84)

Mean (standard deviation) or median (Pc25 – Pc75).

*No differences between groups, p > .05

Figure 1. Percentage of cognitive decline from pre-intervention to post-intervention.

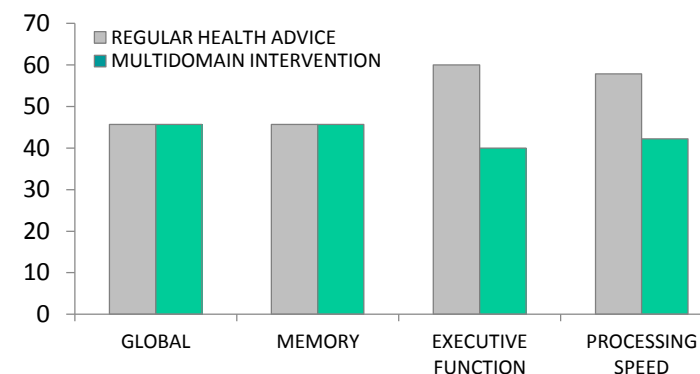


Table 2. Risk of cognitive decline from pre-intervention to post-intervention.

	Odds ratio (CI: 95%)		p
	MI (n = 46)	RHA (n = 46)	
Overall Cognitive decline			
NTB total	1 (reference)	1.000 (0.440 – 2.272)	1.000
Cognitive decline per domain			
NTB memory global	1 (reference)	1.000 (0.400 – 2.272)	1.000
NTB executive functioning	1 (reference)	2.250 (0.968 – 5.230)	.060
NTB processing speed	1 (reference)	2.053 (0.558 - 4.755)	.093

Cognitive decline was defined as decreased in NTB scores between the assessments at pre-intervention and post-intervention. Binary logistic analyses were carried out to assess risk of cognitive decline in the Regular Health Advice Group compared to Multidomain Intervention Group.

Conclusion

The GOIZ-ZAINDU study has proved that the FINGER methodology is adaptable and feasible in a different socio-cultural environment. Exploratory efficacy results show that in the Multidomain Intervention group, there is a trend to present a lower risk to decline in Executive Function and Processing Speed than in the Regular Health Advice group. These results support the design of the large-scale efficacy FINGER-like trial in the Basque Country.