Title of the study: A Randomized Controlled Trial to Address a Multimodal Intervention in the Elderly

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Study protocol

At the beginning of the intervention, an initial evaluation was carried out using the different tests for all the participants (baseline). During the intervention, the users received weekly sessions (individual and group) via videoconference from a social worker, a psychologist, a sociocultural activities technician, and a physiotherapist. Appointments were previously arranged according to the availability of each user. Participants were classified according to the following therapeutic profiles: active aging, emotional disorders, unwanted loneliness, residential care center users, cognitive impairment, physical limitations and social exclusion. Table 1 shows a typical schedule for one of the participants. Nevertheless, the number of sessions may vary depending on the therapeutic profile of the participants. For example, the unwanted loneliness and social exclusion profiles have 5 weekly sessions, the physical or cognitive limitation profiles have 3 to 3.5 weekly sessions, while the active aging profile has 2 to 2.5 weekly sessions. Individual sessions were held on a fortnightly basis.

Table 1. Schedule of a typical weekly intervention for one of the participants.

Time	Monday	Tuesday	Wednesday	Thursday	Friday
12:00-13:00	Recreational group session		Cognitive group session with psychologist		Individual follow-up session with social worker/ psychologist
17:00-18:00				Gym group session with physiotherapist	

Approximately halfway through the intervention, the same instruments were applied again and right at the end of the intervention, in order to verify our hypothesis. Therefore, in addition to the baseline measures, we obtained two more measures (an intermediate data collection at the middle of the intervention and another one at the end).

The following inventories were used as instruments to measure the effectiveness of the intervention. To cognitively assess the participants, the MMSE (Folstein et al., 1975) was used. The FUMAT scale (Gómez et al., 2008) was used to assess quality of life by means of 8 different dimensions. The abbreviated version of the Yesavage Geriatric Depression Scale (Martínez de la Iglesia et al., 2002) was used to assess depression. Loneliness was assessed using the revised ESTE scale (ESTE-R) (Rubio & Aleixandre, 1999). The Barthel's scale (F.I. Mahoney & Barthel, 1965) was used to measure the subjects' functional capacity to perform basic activities and tasks of daily living (ADL) whereas the Lawton and Brody's test (Lawton & Brody, 1970) was used to measure the ability to perform instrumental activities of daily living (IADL). Finally, Tineti's scale (Tinetti, 1986) was used to assess the balance and gait of older adults and determine the risk of falls.

Statistical analysis plan

Initially, the Kolmogorov-Smirnov test was applied to assess the normality of the variables. Only the Fumat test values showed a normal distribution, so parametric statistics were used for the analysis of this particular case. The remaining variables showed a non-normal distribution, so nonparametric tests were used. Data were reported as mean ± SD. The demographic and clinical variables of the groups at baseline were compared using the chi-square test for categorical variables and the independent-samples t test for quantitative data.

This research also performed Wilcoxon signed rank tests to examine whether there was a statistically significant difference in a group of participants between time intervals (t0: baseline, t1:mid intervention, t2: end of intervention). In addition, a 2-way repeated measure analysis of Variance (ANOVA) was performed to study the interaction effects of time (at baseline, mid intervention and end of intervention) in the two intervention groups (experimental and control) in the Fumat scale, together with the plot of the estimated marginal means. Partial eta-squared (η_p^2) was used to categorize effect sizes when the distribution was normal. In this case, $\eta_p^2 = 0.01$ for a small effect, 0.06 for a medium effect, and 0.14 for a large effect, respectively. When the data did not follow a normal distribution, Cohen's r ratio (r = Z/sqrt(N)) was used. This ratio indicates that a large effect corresponds to r = 0.50, a medium effect to r = 0.30, and a small effect to r = 0.10, respectively. The size of the effect will indicate us the practical relevance. Version 26 SPSS software was used to perform all the statistical analyses. The level of significance was set at 0.05.