EFFECTIVENESS OF A BRIEF INFORMATION ABOUT ADVANCE DIRECTIVES IN PRIMARY CARE: A RANDOMIZED CLINICAL TRIAL

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Statistical Analysis Plan (SAP)

Intention-to-treat analysis. No intermediate analysis is planned. A bilateral significance level of 5%, 95% CI and 80% power will be used. The SPSS V21 program will be used. Analysis of efficacy of unadjusted parallel clinical trials. Data will be analyzed according to the CONSORT guidance and comparisons between groups will be based on the intention-to-treat principle. First: analysis of the baseline comparability of the study groups in relation to the variables studied. Descriptive statistics of all variables collected. The Student's t test or the Mann-Whitney U test (according to the frequency distribution of the variables studied) will be used to compare continuous variables, and Chi-square or Fisher's exact test for comparison of categorical variables.

In the case of finding a very different distribution of the independent baseline variables (1st visit) between the two groups, which would indicate an obvious selection bias despite randomization, the possibility of analyzing as a cohort study by means of propensity score techniques .

• Main objective "To assess the effect of brief oral and written information on the Advance Directives (ADs) given by primary care physicians, compared to usual clinical practice, on the proportion of persons interested in or performing VAD in 3 months in a heterogeneous group of patients (different ages and ethnicities) who go to a previous appointment ": inferential analysis of effectiveness, analysis of proportions of two samples. A multivariate logistic regression analysis with the variables of interest or realization of the yes / no VAS as the dependent variable will be performed and the group assigned as an independent variable, adjusting for the potential confounding factors.

• Secondary objectives: demographic and clinical characteristics that are considered likely to be associated with the completion of a priori VAD or that differ between study groups will be included in the logistic regression model for the dichotomous dependent variable.

1 · "Evaluate the baseline characteristics of those who perform or are interested in the VAD of both the control group and the intervention group": descriptive analysis for independent quantitative variables (age, number of children) and for qualitative variables , studies, comorbidity, religion, testament, marital status), frequency tables. Bivariate analysis using as a dependent variable the answer yes or no to the realization of the DVA or interest by DVA and as independent variables the basal characteristics. The Student's t test or the Mann-Whitney U test (according to the frequency distribution of the variables studied) will be used to compare continuous variables, and Chi-square or Fisher's exact test for comparison of categorical variables.

2 · "Evaluate the baseline characteristics of those who perform the VAD and those who are not in the intervention group": descriptive analysis for independent quantitative variables (age, number of children) and for qualitative variables

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(gender, race, comorbidity, religion, testament, marital status), frequency tables. Bivariate analysis using as a dependent variable the answer yes or no to the realization of the VAD within the intervention group and as independent variables the basal characteristics. The Student's t test or the Mann-Whitney U test (according to the frequency distribution of the variables studied) will be used to compare continuous variables, and Chi-square or Fisher's exact test for comparison of categorical variables.

3 · "Evaluate the reasons why the document is formalized by open question": it will be categorized if there is a limited number of categories of responses and a descriptive univariate analysis will be done (frequency tables). In case of multiple answers the reasons will be described qualitatively.

4 · "Evaluate the average time to perform the DVA from the day of recruitment of the patient.": Univariate descriptive analysis.

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