

Cover Page

Official Title: Effectiveness of a telephone-delivered psycho-behavioural intervention on depression in elderly with chronic heart failure

NCT Number: NCT03233451

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Statistical Plan

For the demographic and other baseline characteristics of the subjects, summary statistics will be conducted, including mean (standard deviation) or median (25th -75th percentile) for continuous variables and frequency (percentage) for categorical variables. The patient characteristics will be compared using Chi-square test for categorical variables and Student's t test for continuous variables, as appropriate.

For the primary outcome, Logistic regression model adjusting for clinical sites will be used to examine the difference in the response rate of depression at the end of intensive phase between the two arms. For the secondary outcomes, mixed-effects linear regression models will be used to test the change of the difference in cardiac function, quality of life and severity of depressive symptoms over the intensive phase and the maintenance phase, respectively, with the fixed effect of treatment, time, clinical sites, the interaction of treatment and time, as well as the random effect of patient.

The primary analysis of the study will be conducted based on the intention-to-treat principle (ITT), using data for all subjects who are randomized. A per-protocol analysis will also be performed on the difference of the response rate of depression at the end of acute phase between the two arms, using data for those participants who completed 12 weeks of treatment and QIDS-SR16 both at baseline and the end of intensive phase.

All statistical analyses will be performed using statistical package for the social sciences (SPSS) software version 23.0. All P values will be two-sided. A P value of less than 0.05 will be considered to be statistically significant