STATISTICAL ANALYSIS PLAN

Before starting the statistical analysis, the databases will be cleaned, correcting any errors and identifying missing values that can be recovered. Variables will also be transformed and/or categorised.
Next, a univariate descriptive analysis will be carried out in which all the variables in the study will be described. For this purpose, the mean and standard deviation will be calculated for quantitative variables with a normal distribution, and the median and interquartile range for quantitative variables that do not follow a normal distribution. Qualitative variables will be described by frequency and percentage.
Next, in order to answer the main objective and to be able to evaluate the therapeutic effect of CPAP therapy on BP control, a descriptive bivariate analysis will be performed for paired data, since this is a prepost study, in which the variable SBP pre-treatment CPAP vs post-treatment CPAP in the same patients will be compared. By treating the data as paired, we will be considering the possible correlation that may exist between the SBP measurements of the same patient. The same analysis will be performed by OSA severity subgroups and by CPAP adherence subgroups.

A bivariate analysis for paired data will also be performed to answer each of the secondary objectives.
The pre and post of the different measures (other BP parameters; recovery of the normal circadian profile pattern; echocardiographic parameters; sleepiness by Epworth scale and quality of life) will be compared.
To answer the secondary objective of usability and experience with the AKTIIA handheld, a descriptive univariate analysis of each of the questions in the questionnaire will be carried out.
Finally, a multivariate analysis will also be performed to control for independent variables that may be influencing the change between pre- and post-CPAP treatment BP values.
All statistical analysis will be performed with Stata v16 and for all tests the confidence intervals will be 95%.

SAMPLE SELECTION
Accepting an alpha risk of 0.05 and a beta risk of 0.20 in a bilateral contrast, 90 patients with moderate-severe OSA with indication for CPAP therapy, diagnosis of HBP in AKTIIA test and effective titration of CPAP therapy are required to start Aktiia monitoring, to detect a difference equal to or greater than 5 mmHg in SBP in these patients before and after therapeutic treatment with CPAP. A standard deviation of 16 is assumed (Bazzano 2007). A loss-to-follow-up rate of 10% is estimated between before and after treatment.