Statistical Analysis Plan

STUDY NAME: '**Tilburg Health Outcomes Registry of Emotional Stress in Coronary Intervention**'

STUDY ACRONYM: THORESCI

IRB REGISTRATION NUMBER: NL46259.028.13 / M534

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Statistical analysis plan THORESCI

THORESCI is an observational cohort study, and therefor there is no blinding of conditions or treatments. Our statistical approach is as follows:

Each 6 months an extraction from the data is made, and psychological data is then merged with medical and outcome data. The dataset will show cumulative growth and only after 2 years of follow-up will include the final psychological follow-up assessment for the first set of patients. This means that there is a natural order of analysis.

First, studies on baseline data will be analyzed, examining the validity of the ESC screener and psychological profiles at baseline. Whenever a paper has a prospective research question (for validity purposes for examine it is important to analyze predictive validity as well) we will use the 6-month follow-up data.

> Statistical techniques that will be used are:
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> Factor analysis and crosstabs for validity analysis
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> Latent class analysis for the discovery of profiles
>
> Logistic regression

Second, when sufficient patients are included to answer the short-term (1-year) medical outcome questions, these outcome data will be added to the dataset and will be included in the analysis as well.

> Statistical techniques that will be used:
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> 3-step latent class analysis, in which profiles predict outcome
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> Logistic regression analysis for dichotomous outcomes (complications, events)
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> Linear regression analysis in case of continuous outcomes (SAQ angina symptoms, MOS adherence to treatment scores)

Third, to use mortality as an outcome, we need to wait until 10 year of follow up has passed for 3000 patients. We will analyze these data at that time.

One special line of inquiry will focus on the characterization of study refusers. A special informed consent has been drafted for this purpose.

> Multinomial regression analysis for categorical outcomes.
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> We will predict research participation status (refused+consent vs. participant vs. dropout) using demographic and medical (including psychological screening instruments administered during cardiac rehabilitation) variables.