Correction

Johansen PP, Zwisler A-D, HastrupSvendsen J, *et al.* The CopenHeartSF trial—comprehensive sexual rehabilitation programme for male patients with implantable cardioverter defibrillator or ischaemic heart disease and impaired sexual function: protocol of a randomised clinical trial. *BMJ Open* 2013;3:e003967.

There has been an update to the Statistical Analyses Plan. The new Statistical Analysis section should read:

Statistical analysis

The analysis will follow the intention-to-treat principle with two-sided significance test at the 5% level. Continuous outcomes will follow the same procedure as described in the following for the primary outcome. The primary outcome is the International Index of Erectile Function overall score. The five domains of the questionnaire are all exploratory outcome, but particular attention is given the Erectile Function domain. The secondary outcome is PAIS-SR sexual relationship domain.

The explorative physical outcomes are pelvic floor strength and endurance (one categorical and two continuous variables), peak VO₂, heart rate (beats per minute), blood pressure, Watt Max, Anaerobic Threshold, and VE/VCO₂ slope. The questionnaire-based exploratory outcomes are SF-36 (the two component scores: physical (SF36-PCS) and mental (SF36-MCS)), Hospital Anxiety and Depression Scale (HADS) anxiety and depression (binary variable: score of 8+) and EQ-5D-5L converted to index score. Sex after ICD-questionnaires (reported as categorical variables) are evaluated for ICD patients.

The primary model for assessing the effect of intervention is the univariate general linear model. This model assesses (1) whether there is an effect of the intervention 16 weeks after randomization, between the intervention group and the control group. If there is a statistically significant effect we will perform subgroup analysis and test (2) whether there is a difference between the two patient groups regarding the size of the effect.

Model 2 includes the follow-up data (month six) using a mixed model because of repeated outcome measures. In this model the baseline value of the outcome, intervention indicator (I), patients indicator (G), the interaction between I and G and stratification variable (aged above and below 60 years) are included.

Subgroup analysis of the primary outcome and all analyses of the secondary and exploratory outcomes are considered hypothesis generating if the effects are statistically significant ($P < 0.05$).

If missing values of the primary outcome is above 15% or the P-value of Little's test is below 0.05 multiple imputation techniques will be used. If the intervention effect of the primary analysis in the univariate general linear model is significant, the analysis is supplemented with a worst/best case analysis. The results of the multiple imputed dataset are considered the primary analysis.

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