Interim power-analysis by Karolinska Trial Alliance

Supplement material to "Study protocol for a single-blind, randomized controlled, non- inferiority trial of Internet-based versus face-to-face cognitive behaviour therapy for obsessive-compulsive disorder"

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To make sure that the study would be informative, without looking at the outcome data ourselves, we requested an interim power-analysis by the *Karolinska Trial Alliance* (KTA). KTA is an independent body that monitors clinical trials and makes sure that researchers follow good clinical practice.

Because our power calculation used variances of regressions coefficients rather than estimates of the coefficients themselves [1], we were able to request estimates on our collected data (80 out of 120 individuals) without including the grouping variable in the data and inadvertently revealing the results. The interim power-analysis would inform us whether the initial power calculation, using data from [2], was accurate or not.

We extracted data needed for the analysis (ID-number and Y-BOCS ratings for all time-points except the 12-month follow-up) and sent to KTA with instructions for how to fit the correct mixed-effects model and obtain variance estimates. We received their report with the following variance estimates:

- Random intercept variance of 12.77
- Random slope variance of 10.02
- Residual variance of 14.10

We then used these estimates in an updated power calculation and concluded that our planned sample size of 120 participants would be sufficient for the study to be informative with a non-inferiority margin of 3 points on the clinician-rated Y-BOCS [3].

Supplement references

1 Yi Q, Panzarella T. Estimating sample size for tests on trends across repeated measurements with missing data based on the interaction term in a mixed model. *Control Clin Trials* 2002;**23**:481–496. doi: doi.org/10.1016/S0197-2456(02)00223-4

2 Andersson E, Hedman E, Enander J *et al.* D-Cycloserine vs Placebo as Adjunct to Cognitive Behavioral Therapy for Obsessive-Compulsive Disorder and Interaction With Antidepressants. *JAMA Psychiatry* 2015;**72**:659.

3 Goodman WK, Price LH, Rasmussen SA *et al.* The Yale-Brown Obsessive Compulsive Scale. I. Development, Use, and Reliability. *Arch Gen Psychiatry* 1989;**46**:1012–6. doi:10.1001/archpsyc.1989.01810110048007