Sample size calculation

Sample size calculation is based on a two-step procedure due to the hierarchical data structure. In the first step, the sample size for an individual randomized study is calculated. Since SATT is a dichotomous outcome recorded in every patient, the sample size calculation is done by the chi-square test (two-sided, alpha = 5 %, power = 90 %). Assuming SATT of 40 % in the SAU condition [11,33,34]and a SATT of 60 % in the TFS condition, a sample size of 130 patients in each group would be needed in an individually randomized study (in total 260 patients). The second step in sample size calculation accounts for the cluster-structure of the trial. Clusters are the therapists. The design effect (DE) is needed for the inflation of the group sample size (see first step above): DE=1+(m-1)\*ICC with the fixed cluster size m and the intra-cluster correlation coefficient (ICC). For the fixed cluster size, a value of m = 5 was set. For the ICC, a liberal value of 0.10 is assumed to control for the correlation of the outcome of patients treated by the same therapist. Thereby, the DE is 1+(5-1)\*0.1 = 1.4 which gives a group size of 130 x 1.4 = 182, i.e. 2 x 182 = 364 patients in the whole trial. A dropout rate of 20 % of patients is assumed. To compensate this, an oversampling of 91 patients is needed resulting in a sample size of 455 patients. As every therapist is supposed to treat 5 patients, 91 therapists are needed for the whole trial. As there is also assumed a dropout rate of 20% for therapists, an oversampling of 23 therapists is needed, resulting in 114 therapists. So, the overall sample is estimated as 114 x 5 = 570 patients. This is higher than the dropout rates reported in existing studies, but mirrors the extensive experience of the consortium members in supervising therapists treating PTSD and working with CYWA residents, where the high turnover makes high dropout rates likely. To allow equal subgroup sizes by therapist qualification level (PIT, LPT) and supervision condition (TFS, SAU) we aim to recruit 116 therapists with altogether 580 patient treatments.