

## **Appendix 1 (as supplied by the authors)**

Supplemental File 1: Further information about randomization

The randomization sequence was generated as follows:

Number of treatment groups: 2

Balance between treatment groups: Yes

Allocation ratio used to achieve balance: 1:1

There were two two-level stratification variables [gender (female, male), site (Clinic 1, Clinic 2)] yielding four strata: 1) female/Clinic 1, 2) female/Clinic 2, 3) male/Clinic 1, 4) male/Clinic 2.

Blocks of size 4 and 6 were used to build the sequence within each stratum. These sequences were produced by randomly and repeatedly selecting blocks from all available blocks until the required number of 80 was attained.

The total number of entries in the randomization sequence for the trial was 320 (80 x 4).