**p.135**

**6.1.4.3 Block, Cluster and Stratified Randomization**

A popular method is block randomization. This requires that subjects are divided into M blocks of size 2*n*/*M* each where *n* is the stipulated size of each group. The block size must be a multiple of number of groups. For two groups, the block size can be 4 or 6 or 8 but not 5 or 7. If you have enrolled a total of 80 subjects, you can make 20 blocks of 4 subjects each. Within each block, allocate two subjects at random to group-1 and the other two to group-2. Thus you can have one of the following allocations.

 (1,1,2,2), (1,2,1,2), (1,2,2,1), (2,2,1,1), (2,1,1,2), (2,1,2,1),

When you allocate randomly, one of these six is randomly chosen. This method is called block randomization**.**

An advantage of block randomization is that the possibility of one group becoming full before the other is ruled out. But the difficulty is that you know that the fourth subject after first three going to groups 1,1,2 must go to group-2. Thus masking is difficult. For this, several random block sizes are advocated that are concealed from the investigators. Just as simple randomization, this method too does not eliminate the possibility of one group getting subjects with different baseline covariates than the other.

 For a large trial, particularly in a community, such as for evaluating the impact of special education on sexual behavior in school adolescents, you can randomly allocate 5 schools out of participating 10 to receive the education and the other 5 to serve as control. This is called cluster randomization**.** Schools serve as cluster.

 Another method, though rarely used, is stratified randomization**.** This ensures that the subjects with important covariates are equally distributed to the groups. If your study is on wonder dose that controls blood sugar level for one month, and if you know that the effect could be different in males of age <50 years than females of age ≥50 years, you may want to divide the enrolled subjects as <50M, ≥50M, <50F and ≥50F so that each of these strata are adequately represented, and then divide them equally to group-1 and group-2.