Randomized Designs

Design 1 – COMPLETELY RANDOMIZED DESIGN

Assign 30 patients to treatments A, B, and C, according to a completely randomized design with equal allocation.

Every patient is assigned to one treatment, but the sample sizes are not equal.

Prepare the treatment schedule:

```
> Treatment = numeric(N);
> K = length(proportions);  # Number of treatments
> TreatmentNames = c("TreatmentA", "TreatmentB", "Placebo");
> Patient = paste0("Patient",1:N);  # Patients' names or ID
> for (k in 1:K){ Treatment[Schedule[k,]==1] = TreatmentNames[k]; }
> data.frame(Patient, Treatment)
```

Patient Treatment Patient Treatment Patient1 TreatmentB 16 Patient16 TreatmentA 1 17 Patient17 Patient2 Placebo Placebo 18 Patient18 TreatmentA 3 Patient3 Placebo Patient4 TreatmentA 19 Patient19 TreatmentB 4 5 Patient5 TreatmentA 20 Patient20 Placebo Patient6 Placebo 21 Patient21 6 Placebo 7 Patient7 TreatmentB 22 Patient22 TreatmentA Patient8 TreatmentB 23 Patient23 TreatmentB Patient9 TreatmentB 24 Patient24 TreatmentA 10 Patient10 TreatmentB 25 Patient25 11 Patient11 TreatmentB 26 Patient26 TreatmentB 12 Patient12 TreatmentA 27 Patient27 TreatmentA 13 Patient13 Placebo 28 Patient28 TreatmentA 14 Patient14 Placebo 29 Patient29 Placebo 15 Patient15 Placebo 30 Patient30 Placebo

Design 2 – BLOCK RANDOMIZATION

Create a block randomization with 30 patients, 3 treatments, and equal allocation.

```
> N = 30; K = 3;
> TreatmentGroup = sample( rep(1:K, N/K) );
rep creates a non-random vector 1,2,3,1,2,3,... with equal group sizes
sample shuffles it randomly
> Treatment = TreatmentNames[TreatmentGroup];
> data.frame(Patient, Treatment)
      Patient Treatment
                                        Patient Treatment
 1
     Patient1 TreatmentB
                                        16 Patient16 TreatmentA
     Patient2 TreatmentB
                                        17 Patient17
                                                      Placebo
     Patient3
                Placebo
                                        18 Patient18
                                                      Placebo
 4
     Patient4 TreatmentB
                                        19 Patient19
                                                      Placebo
 5
     Patient5 TreatmentA
                                        20 Patient20
                                                      Placebo
 6
     Patient6
                Placebo
                                        21 Patient21 TreatmentA
 7
     Patient7 TreatmentA
                                        22 Patient22
                                                       Placebo
 8
     Patient8
                Placebo
                                        23 Patient23 TreatmentB
     Patient9 TreatmentA
                                        24 Patient24 TreatmentA
 10 Patient10 TreatmentA
                                        25 Patient25 TreatmentB
 11 Patient11 TreatmentB
                                        26 Patient26
                                                       Placebo
 12 Patient12 TreatmentB
                                        27 Patient27 TreatmentA
 13 Patient13 TreatmentB
                                        28 Patient28 TreatmentB
                                        29 Patient29 TreatmentA
 14 Patient14 TreatmentB
 15 Patient15
                Placebo
                                        30 Patient30 TreatmentA
 > table(Treatment)
 Treatment
    Placebo TreatmentA TreatmentB
          10
                      10
                                  10
```

Equal group sizes!

<u>Design 3 - STRATIFICATION</u>

There are 18 female and 12 male patients.
Randomize them to 3 treatments equally within each sex group.

```
> N = 30; K = 3;
> Sex = sample( c(rep("Female",12), rep("Male",18)) );
> Data = data.frame(ID = 1:N, Patient, Sex)
> Data
```

```
ID
        Patient
                                                Patient
                                                          Sex
                   Sex
                                           ID
 1
                                        16 16 Patient16
                                                         Male
     1 Patient1
                  Male
 2
     2 Patient2 Female
                                        17 17 Patient17
                                                         Male
 3
     3 Patient3 Female
                                        18 18 Patient18
                                                         Male
 4
     4 Patient4 Female
                                        19 19 Patient19
                                                         Male
 5
     5 Patient5 Female
                                        20 20 Patient20
                                                         Male
 6
     6 Patient6 Female
                                        21 21 Patient21 Female
 7
       Patient7
                  Male
                                        22 22 Patient22
                                                         Male
 8
     8
       Patient8
                  Male
                                        23 23 Patient23
                                                         Male
 9
     9 Patient9
                  Male
                                        24 24 Patient24
                                                         Male
 10 10 Patient10
                                        25 25 Patient25
                  Male
                                                         Male
 11 11 Patient11
                  Male
                                        26 26 Patient26 Female
 12 12 Patient12 Female
                                        27 27 Patient27 Female
 13 13 Patient13 Female
                                        28 28 Patient28 Female
 14 14 Patient14
                  Male
                                        29 29 Patient29
                                                         Male
15 15 Patient15 Female
                                        30 30 Patient30
                                                         Male
> table(Sex)
 Sex
 Female
           Male
     12
             18
> GroupNames = names(table(Sex))
> Ngroups = length(GroupNames)
Prepare a randomized schedule stratified by sex
> Schedule = data.frame()
> for (j in 1:Ngroups){
     Group = Data[Sex==GroupNames[j],]
+
     n = nrow(Group);
     Treatment = TreatmentNames[sample( rep(1:K, n/K ) )];
     Schedule = rbind(Schedule,
+
                 data.frame(Group, Treatment));
+
     }
+
We can return to the original order, sorting by ID
> Schedule = Schedule[order(Schedule$ID),]
 > table(Schedule$Sex,Schedule$Treatment)
           Placebo TreatmentA TreatmentB
   Female
                 4
                             4
                                          4
                 6
                             6
                                         6
   Male
```

Equal allocation within each sex group

> Schedule

	ID	Patient	Sex	Treatment
1	1	Patient1	Male	TreatmentA
2	2	Patient2	Female	TreatmentA
3	3	Patient3	Female	TreatmentA
4	4	Patient4	Female	Placebo
5	5	Patient5	Female	Placebo
6	6	Patient6	Female	TreatmentB
7	7	Patient7	Male	Placebo
8	8	Patient8	Male	TreatmentB
9	9	Patient9	Male	Placebo
10	10	Patient10	Male	TreatmentA
11	11	Patient11	Male	TreatmentA
12	12	Patient12	Female	${\tt TreatmentB}$
13	13	Patient13	Female	${\tt TreatmentB}$
14	14	Patient14	Male	TreatmentB
15	15	Patient15	Female	TreatmentA
16	16	Patient16	Male	${\tt TreatmentB}$
17	17	Patient17	Male	Placebo
18	18	Patient18	Male	TreatmentB
19	19	Patient19	Male	TreatmentA
20	20	Patient20	Male	Placebo
21	21	Patient21	Female	TreatmentB
22	22	Patient22	Male	Placebo
23	23	Patient23	Male	Placebo
24	24	Patient24	Male	TreatmentB
25	25	Patient25	Male	TreatmentA
26	26	Patient26	Female	Placebo
27	27	Patient27	Female	TreatmentA
28	28	Patient28	Female	Placebo
29	29	Patient29	Male	TreatmentB
30	30	Patient30	Male	TreatmentA