

# Clinical Trials & Survival Analysis

## Micro Session 1, Friday 20 April, 10-12, Computer room 72

This session is an opportunity to try some of the practical exercises contained on the task sheets and more substantial exercises. Some of the data sets are on the course web page at <http://nickfieller.staff.shef.ac.uk/tampere12/index.html> and you can download them (recommended) or open them directly in **R**. In particular you should check that you know how to perform t-tests and Mann-Whitney-Wilcoxon tests (the non-parametric equivalent) and what the differences are between separate and pooled variance versions of the two-sample t-test (see Clinical Trials Exercises Q2). It is assumed that you know how to do these basic tests. In **R** the commands are `t.test()` and `wilcox.test()` and `help(t.test)` etc will give you information on their uses together with examples.

To get started in Windows it is suggested you do the following:

- On the course web page go down to Download Datasets and right-click on Hours Sleep. Choose Save target as.... and save the file in a convenient directory on your hard disk (or USB stick).
- Using Windows Explorer navigate to the file, it will be called `hourssleep.Rdata` and *double click* on it. This will open **R** and change the working directory to your convenient directory or USB stick.
- Type `hourssleep` and this will list the entire datafile. Note the names of the variables (`period1`, `period2`, ..., `treat.diffs`)
- Type `attach(hourssleep)` and this will allow you to refer to the variables by name.
- Type `t.test(period1,period2)`
- `etc, etc, etc`

## Randomization lists

If you are an SPSS user then you can investigate how to construct randomization lists in SPSS (certainly not the best package to use however but maybe a useful exercise). Some suggestions are that you can generate random numbers by Transform > Compute > Random Numbers (*under Function Group*) > Rv.Uniform(?,?) and you can then use these 'by hand' as indicated in the lecture notes. Better is to use a column of random numbers to sort a column of treatment labels (see Data > Sort ). Can you find better ways?

Next, look at Martin Bland's guide to randomization software and see what is available and what descriptions there are available. He also has guides to many other sources for software of use in Medical Statistics.

Next, look at the lecture slides 92-93 and course notes §3.5.1 (p58-59) & in particular the **R** code for handling the construction of various randomization lists. Try typing the commands yourself and then try the following questions:

1. Construct a randomization list for 24 subjects so that six subjects receive each of four treatments A, B, C and D, not necessarily using blocks of size 4 (perhaps look at lecture slide 93).
2. Construct a list for the situation in Q1 so that the imbalance between replication of treatments is as small as possible if the trial stops early before reaching subject 24 (i.e. use blocks of size 4)
3. Construct a list for 36 subjects so that half receive a placebo and a quarter each receive one of treatments A and B
4. Try some or all of Exercises 9 to 12. Try the remaining ones and Q13 later.

## Sample Size calculations (in all cases take the significance level as 0.05)

The commands in **R** for calculation of power, sample size etc are `power.t.test()` and `power.prop.test()`.

1. Type `help(power.t.test)` and `help(power.prop.test)` to find out how they work
2. Try some or all of Q14 to Q27 (and the rest later).

## Cross-over trials

The `hourssleep` data set is available from the course web page (see above) and you can use either **R** to perform the various tests of carry over, period and treatment effects asked for in Exercises Q29. Also, Question 33 in the Exercises provides a similar opportunity.