

## Clinical Trials: Task Sheet 3 for Week 3

(Released 16/10/11, see §5.1–§5.7)

- 1) A trial for the relief of pain in patients with osteoarthritis of the knee is being planned on the basis of a pilot survey which gave a 25% placebo response rate against a 45% active treatment response rate.
  - a) How many patients will be needed to be recruited to a trial which in a two-sided 5% level test will detect a difference of this order of magnitude with 90% power? (Calculate this first 'by hand' and then using a computer package and compare the answers).
  - b) With equal numbers in placebo and active groups, what active rates would be detected with power in the range 50% to 95% and group sizes 60 to 140? (Calculate for power in steps of 15% and group sizes in steps of 20).
  
- 2) Woollard & Cooper (1983) *Clinical Trials Journal*, 20, 89-97, report a clinical trial comparing Moducren and Propranolol as initial therapies in essential hypertension. These authors propose to compare the change in initial blood pressure under the two drugs.
  - a) Given that they can recruit only 100 patients in total to the study, calculate the approximate power of the two-sided 5% level t-test which will detect a difference in mean values of  $0.5\sigma$ , where  $\sigma$  is the common standard deviation.
  - b) How big a sample would be needed in each group if they required a power of 95%? (Calculate this first 'by hand' and then using a computer package and compare the answers).
  
- 3) What evidence is there that taking fish oil helps schoolchildren concentrate?

