CRITICAL APPRAISAL 1 (MATH38071 - MEDICAL STATISTICS)

Read through the clinical trial report Quist-Paulsen P, Gallefoss F. Randomised controlled trial of smoking cessation intervention after admission for coronary heart disease *BMJ* 2003;327:1254. PDF and HTML version of the paper can be found at bmj.com/cgi/content/full/327/7426/1254.

Find answers to the following questions from the paper.

- 1. What was the objective of the trial?
- 2. What was the intervention being tested?
- 3. What was the control group?
- 4. What were the inclusion and exclusion criteria?
- 5. What method was used to randomise patients?
- 6. Was there any concealment of allocation in the trial?
- 7. Where the characteristics of the two intervention groups similar at the start of treatment?
- 8. What was planned sample size in this study?
 - a. What statistical method was used to calculate sample size?
 - b. What rate of dropout was assumed?
- 9. What were the outcome measures in the trial?
- 10. What methods of statistical analyses were used to assess the effect of the intervention?
- 11. Some outcome data was missing at 12 months.
 - a. Calculate the dropout rate for each treatment.
 - b. What is the implication of this?
 - c. What analysis were carried out to investigate this?
- 12. What conclusions did the researchers make from the trial?
- 13. Do you agree or disagree with the conclusions?
- 14. Do you think the researchers have satisfactorily answered their question?