Homework 4, CPH 675 Clinical Trials Spring 2015, Dr Melanie Bell

Due: 1 May 2015

Include only relevant code and output!

Use the Share data. Project SHARE was a CRT carried out in Scotland to measure the impact of a school-based sexual health education program. In this trial, 25 secondary schools were allocated to intervention and control arms. The intervention consisted of a teacher delivered program of 20 sessions on sexual health. The control group continued with their existing sex ed programs. A total of 8430 students were enrolled in the cohort and 5854 were successfully followed up 2 years later.

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| storage display value  variable name type format label variable label  ----------------------------------------------------------------------------------------------------------  school byte %8.0g school number: 1-25  sex byte %8.0g sex: 1=male, 2=female  arm byte %8.0g treatment arm: 0=control, 1=intervention  scpar byte %8.0g social class:  10=I,20=II,31=IIInon-manual,32=IIImanual,40=IV,50=V,99=not coded  debut byte %8.0g onset of sexual activity during follow-up: 0=no, 1=yes  regret byte %8.0g regret of first sex with last partner (in those with >1 partner):  0=no, 1=yes  kscore byte %8.0g knowledge of sexual health at follow-up: score from -8 to +8  idno float %9.0g individual number |

1. [10pts] Is there a difference in knowledge between the two arms following the intervention? Use an unadjusted mixed model on *the individual level* data to determine this, while accounting for the clustering design. Show relevant code and output. Write your answer in a few sentences appropriate for a journal. Include both your statistical methods (briefly) and the results.

2. [4pts] Using your model from 1, what is the intracluster correlation?

3. [4pts] What is the design effect for this study? What does this mean?

4. [10pts] Analyze this study at the *cluster level* as outlined in the Wears paper. Show relevant code and output. Write your answer in a few sentences appropriate for a journal. Include both your statistical methods (briefly) and the results. Compare your answer to the results you found by analyzing at the individual level. SAS users should use the ods output statement in a proc means. Stata users should use the collapse command.

5.[5pts] Your research team is designing a study to investigate a new pain regimen, as compared to usual care, in a two arm RCT. Calculate the required sample size to detect a standardized effect size of 0.2 (a small effect) with 80% power, using a 2:1 allocation to intervention and control respectively.

6. [5pts] Replicate the sample size calculation in the SUPPORT trial. You may not be able to get the exact number, but you should be close.

7. [8 pts] Replicate the original sample size calculations in Livingstone et al (2011). You may not be able to get the exact number, but you should be close.

8. [5 pts] You are writing an NIH R21 grant, which is a pilot and feasibility study mechanism. The feasibility outcomes are the percentage of participants that are screened and found to be eligible, and the percentage of enrolled participants that remain in the study for the entire follow-up time. If the researchers would like their estimates of these two percentages to be within 10% of the “true” values, with 95% confidence, what should the sample size be? Write a few sentences that would be appropriate for the grant proposal.

9. [6pts] The following formulae are for three alpha spending functions. Assuming theta = 1 and using each of the alpha spending functions below, find the alpha for early stopping when:

a) one quarter of the information in the trial has been obtained.

b) one half of the information in the trial has been obtained.

c) three quarters of the information in the trial has been obtained.

