**Acupuncture for Chronic Headache RCT Data**

**Resource 01 - Exercises   
*8-3-2015***

**This data set contains data obtained from "Acupuncture for chronic headache in primary care: large, pragmatic, randomized trial", Andrew J Vickers, Rebecca W Rees, Catherine E Zollman, Rob McCarney, Claire M Smith, Nadia Ellis, Peter Fisher and Robbert Van Haselen, 2004 Mar 27;328(7442):744.**

**Introduction to Exercises**

The goal of this in-class activity is to familiarize you with interpreting confidence intervals within the general context of the clinical research setting.

**Concepts covered in this assignment include:**

1. Providing a proper statistical interpretation of a calculated confidence interval
2. Providing a clinical interpretation of a confidence interval appropriate to the context of specific clinical studies.

**Resources/Files needed for this assignment:**

* R Script (acupunctureCI\_RScript.R)

We will be working with the acupuncture trial data set (acupunc\_data\_reduced.RData).

This data set contains data obtained from "Acupuncture for chronic headache in primary care: large, pragmatic, randomized trial", Andrew J Vickers, Rebecca W Rees, Catherine E Zollman, Rob McCarney, Claire M Smith, Nadia Ellis, Peter Fisher and Robbert Van Haselen, 2004 Mar 27;328(7442):744. The trial aimed to determine the effect of acupuncture therapy vs. no acupuncture therapy on headache, health status, days off sick, and resource use in patients with chronic headaches. These measures were assessed at randomization, 3 months post-randomization, and 1 year post-randomization. 401 patients were enrolled in the trial at 36 sites.

Note: In this assignment we are using all observations from the full set of data from the Acupuncture trial. However, have only included a limited number of variables for the sake of simplicity.

An abbreviated data dictionary describing the variables we will be working with is provided below:

|  |  |
| --- | --- |
| Variable name | Variable description |
| id | patient ID code |
| age | Age |
| sex | sex; female (1) vs. male (0) |
| migraine | diagnosis ; migraine (1) vs. tension-type (0) |
| chronicity | number of years of headache disorder |
| acupuncturist | acupuncturist id code |
| practice\_id | gp practice id |
| group | treatment group; acupuncture (1) vs. control (0) |
| pk1 | headache severity score baseline |
| pk2 | headache severity score 3 month |
| pk5 | headache severity score 1 year |
| f1 | headache frequency baseline |
| f2 | headache frequency 3 month |
| f5 | headache frequency 1 year |

**Exercise**

Recall, the goal of this trial was to compare the effectiveness of acupuncture therapy vs. standard of care on headache related measures among patients with chronic headaches. In this exercise, we will focus on one outcome measure – headache severity. To examine the relationship between the randomized treatment and this outcome, suppose the researchers decided to construct a confidence interval for the mean headache severity score at 1 year in each treatment arm separately. They would like to use the findings of this analysis to create an abstract for an upcoming conference.

In order to construct a confidence interval for the mean headache severity score in each treatment arm, you need to read the trial data into R and use R commands to create the interval estimates. We have provided R code that will do this in the script file, **acupunctureCI\_RScript.R**. You should not need to do any coding on your own. The goal is to give you the experience of ‘doing one’ to get practice with running code and interpreting the resulting output. There are a few key points to keep in mind when answering the following questions:

* To construct a confidence interval for the mean headache severity score at 1 year in each treatment group, we need to create subsets of the data for each treatment group.
* Some patients are missing their 1 year headache severity score (see the output of the summary() function), so t.test() will remove these values before constructing the confidence interval (i.e. it performs a “complete case” analysis).

**Parts (a) – (e) walk you through the process of collecting the information needed to draft the different sections (Introduction, Methods, Results, and Discussion) of an abstract:**

* 1. Report the point estimate and associated 95% confidence interval for the mean headache severity score at 1 years (*variable name is pk5*), for the acupuncture group.
  2. Report the point estimate and associated 95% confidence interval for the mean headache severity score at 1 years (*variable name is pk5*), for the control group.
  3. Write a statement that provides a statistical interpretation of the confidence intervals in (a) and (b).
  4. There are underlying statistical assumptions that should be met when constructing confidence intervals. If these assumptions are not met, the interval estimate may be biased and conclusions based on the interval invalid. When calculating a confidence interval for a population mean, the underlying assumptions are the observations are independent, the sample is unbiased, and the sample size is sufficiently large. Do you think these assumptions are reasonable for the cohort used in that analysis?
  5. In the trial protocol, researchers describe the primary outcome as follows:

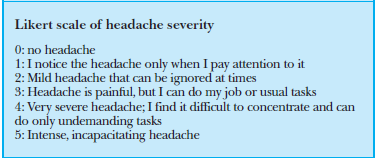
***Outcome assessment***

*Patients completed a daily diary of headache and medication use for four weeks at baseline and then three months and one year after randomisation. Severity of headache was recorded four times a day on a six point Likert scale (box) and the total summed to give a headache score.*

***Statistical considerations***

*The primary outcome measure was headache score at the one year follow up.*

*Likert Scale:*



Based on this information, it appears that the data set contains the sum of the daily headache severity scores. If this were the case, the scores in the data set should range from 0 to 20, but the mean outcome in the control arm is 22.3. It appears the authors reported the average weekly headache severity score. That is, the 28 daily scores from a given week were summed and then averaged over the 4 weeks of journaling to create the score reported in the data set. This means that the scores in the data set could range from 0 to 140. Using this information, can you make a clinical assessment about the confidence intervals in (a) and (b)? That is, do the confidence intervals contain clinically relevant values of mean headache severity? If so, provide a clinical interpretation of the findings. If not, explain why and explain what additional information might be needed in order to provide a clinical interpretation of the findings.

**In parts (f) – (i) you should use the information collected in parts (a) – (e) to draft the different sections of an abstract that could be used to describe the findings of the analysis:**

* 1. Based on your responses in parts (a) – (e), what would you report in the Methods section of a manuscript describing the findings of this analysis? Give a brief 1 to 2 sentence example.
* Recall, in this section you should state which statistical approach was used to obtain the results that will be described in the abstract.
  1. Based on your responses in parts (a) – (e), what would you report in the Results section of a manuscript describing the findings of this analysis? Give a brief 1 to 2 sentence example.
* Recall, in this section you should state the *statistical* findings of the analysis. That is, report the findings of the analysis and the “answer” to the research question.
  1. Based on your responses in parts (a) – (e), what would you report in the Discussion section of a manuscript describing the findings of this analysis? Give a brief 1 to 2 sentence example.
* Recall, in this section you should discuss the *clinical relevance* of the findings and any *limitations* that may influence the validity and generalizability of the findings.
  1. The previous questions have ignored the justification of the analysis that is usually given in the Introduction section of a manuscript. Recall, the goal of the trial was to determine whether adding acupuncture to standard care improved outcomes for patients suffering chronic headaches. Do you think that the analysis performed here addresses the researchers’ goal? Why or why not?