## Homework #3

#### BSTA 519 - Fall 2021

## Applied Longitudinal Data Analysis Due - Monday 10/25/2021 by Midnight

## The Toenail Data

A randomized, double-blinded parallel group study was conducted for the comparison of two oral treatments (group A: Lamisil; group B: Itraconazol) for toenail dermatophyte onychomycosis (TDO). TDO is a common toenail infection and difficult to treat. The aim of the present study was to compare the efficacy and safety of 3 months of continuous therapy for the two treatments.

In total,  $2 \times 189$  patients were randomized and subjects were followed up to a total of 12 months. Measurements were taken at baseline, every month during treatment, and every 3 months afterward, resulting in a maximum of seven measurements per subject. For the purpose of this homework, we will consider one of the secondary outcomes, unaffected nail length as our outcome variable of interest.

You have obtained the dataset from Homework 1. Using the same dataset, do the following:

#### Parametric and Semi-parametric curves

- a) Fit a linear trend model to test whether the linear trends differ between the two groups. Write down the overall linear trend model and the null hypothesis for this test. Will you reject the null hypothesis? Is there a difference in linear trends among the two groups?
  - Write out the fitted linear equation for each group and interpret the slope coefficient. Do you think the linear trend model provides a good fit for the data?
- b) Fit a quadratic trend model to test whether the time trends differ between the two groups. Write down the overall quadratic trend model and the null hypothesis for this test. Will you reject the null hypothesis?
  - Write out the fitted equation for each group. Test whether the quadratic trend model provides a better fit for the data than the linear trend model.
- c) For the purpose of exercise, use t\* = 6 months and fit a linear spline model to evaluate the difference in time trends between the two groups. Write down the overall model, specify the null hypothesis for this test and interpret your test results.

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Write out the fitted linear equation for each group within each time segment, and test the significance of and interpret the slope for each line. Is there evidence that the slope of the line changes after 6 months for each group? Is there evidence that the time trends are different between the two groups within each time segment?

d) If you need to decide a best model that fits the data and evaluate the differences between the two groups, which model would you choose among a), b) and c)?

**Note:** for the interpretation of beta coefficients, describe what the estimates mean in plain language and don't forget your 95% CI!

from Margaret Munroe to everyone: 4:12 PM Rochelle, for the final question on the homework assignment about which of the models we made we would use, I was wondering - what kind of answer is the assignment looking for? Should we be doing some sort of statistical testing of the models between the three groups, or is it more a narrative about the pros and cons of the different models?

from Rochelle Fu to everyone: 4:15 PM
For the last question, it is fne to do some comparisons using AIC, BIC measures and the statistical tests you have done. It is also fine that you made some general comments about the pros and cons informal by looking at the shape of the mean response over time and the interpretation.

Code for displaying output: grp.a <- c(0,0,1,1) e <- esticon(lt.model, grp.a, beta0 = 0, conf.int = TRUE) e\$estimate e\$lwr e\$upr