

Toenail RCT: profiles of unaffected nail length according to treatment (with some individual profiles highlighted). The straight (dashed) lines are the average evolutions in the treatment groups obtained from the fixed effects.

Load the attached "toenail.rda" file (load(toenail.rda)).

Study description: In this double-blinded multicentric RCT (36 centers) sportsmen and elderly people were treated for toenail dermatophyte onychomycosis with either of two oral medications: Itraconazol 250 mg daily (treat = 0) or Lamisil 250 mg daily (treat = 1). The patients received treatment for 12 weeks and were evaluated at 0, 1, 2, 3, 6, 9 and 12 months (De Backer et al. 1996). As response, we have taken the unaffected nail length for the big toenail of a subgroup of 298 patients. Figure 9.11 shows the individual profiles of the unaffected nail length split up according to treatment. Looking at the profiles the treatments seem to work on average.

This analysis is based on the "toenailconti" data matrix (View(toenailconti)).

Let the variables in the dataset be $y_{i,j}$ =unaffected nail length for the big toenail on j-th visit for i-th subject, $t_{i,j}$ =time, τ_i =treatment type 0 or 1, and i everywhere stands for the subject id (thus the same subject id is repeated for the corresponding time points).

What will be a possible linear-mixed effect model?

Fixed effects we want to estimate: 1) Effect of time, the effect of treatment with time.

For random effect: note that there is an increase of SD (from about 2.5 to 5 mm) over time.