Analysis of parallel groups designs

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17 oktober 2018

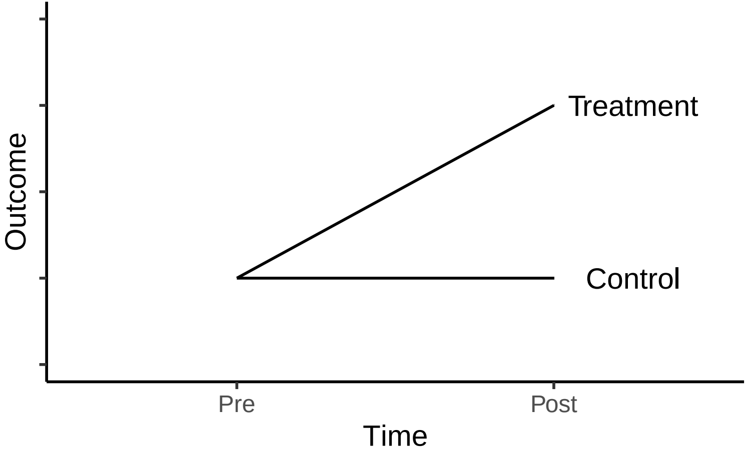
Background

- In sport science (and e.g. medical-, nutritional-, psychological-sciences), intervention-studies are common. We are interested in the effect of e.g. a training method, nutritional supplement or drug.
- The outcome in these studies could be physical performance, degree of symptoms, muscle size or some other measure that we are interested in studying.
- These studies are often called *Randomized Controlled Trials* (RCT)

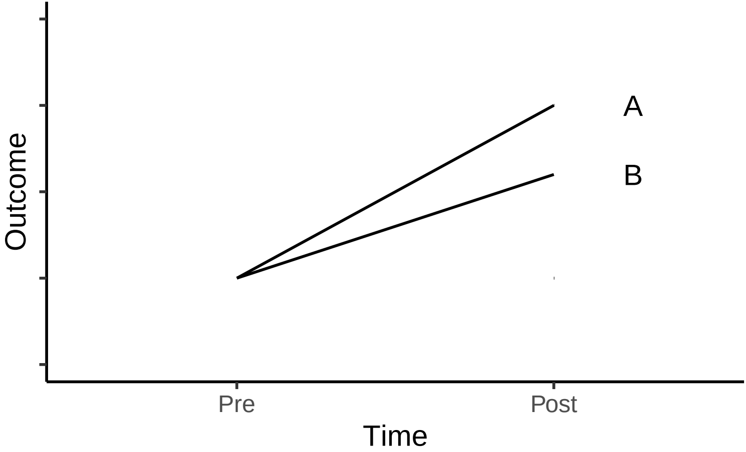
Different study design

- The choice of study design relates to the research-question and dictates what statistical methods can be applied.
- The study design affects the ability of the study to detect an effect (the power)
- A common case of a RCT is the parallel-groups design
- Participants are **allocated** to two or more "treatment groups", **at random**, one group gets a treatment, the other group acts as the control.
- Usually, a measurement is made prior to the intervention (Baseline) and after the intervention.
- This is a common design **when wash-out is not possible** and thus, the two treatment can not be compared within the same individual.

A pre-post parallel-groups design



A pre-post parallel-groups design



What is the question

- Here we are interested in the **treatment effect** (or the difference in effect of two different treatments)
- This means that we want to establish if

$$\Delta Y_A - \Delta Y_B \neq 0$$

... meaning that the **null hypothesis** is that the **change** (Δ) in group A is not different to the **change** in group B

Different statistical solutions (1)

- We could do a *t-test* on the change score between groups. This is equivalent to a regression model where we model change as a function of groups

$$outcome = \beta_0 + \beta_1 Group_B$$

```
# t.test example
with(data, t.test(outcome_A, outcome_B, paired = FALSE))

# The same in regression
lm(change ~ group, data = data)
```

Problems with the simple solution

- Baseline values can affect the interpretation of a pre- to post-intervention study through **regression to the mean**
- If we analyse change scores (*post* − *pre*), regression to the mean will give an overestimation of the effect, if there is, by chance, a difference in baseline values between groups (lower values in treatment group) (Vickers and Altman 2001).
- If we analyse follow up scores, the pattern will be reversed.

A solution to this problem

- Instead of only analyzing change-scores, we can also control for the relationship between baseline values and the change scores.
- This technique is called Analysis of Co-Variance (ANCOVA), where the baseline is considered the adding the covariance.
- This is an extension of the simple linear regression

```
# Extending the linear regression equation
lm(change ~ baseline + group, data = data)
```

Why ANCOVA

- The ANCOVA model has better power (Senn 2006)
- The ANCOVA model gives **unbiased** estimates of differences between groups (Vickers and Altman 2001)

When can we use the ANCOVA model?

- When the allocation of participants have been done at random (e.g. RCTs), differences at baseline should be due to random variation

Presentation of 10 vs 30RM-study

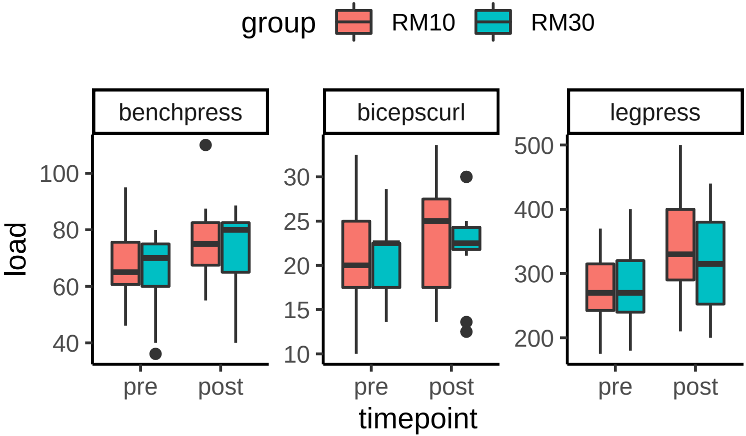
- 31 participants were assigned to one of two groups training with either 10RM or 30RM, 27 participants completed the trials (24 participants completed to full time).
- The main interest in the study was development of strength and muscle hypertrophy (we are interested in strength)
- The variables in the file are:

a. `subject`: ID of participant
b. `timepoint`: prior to *pre* or after the intervention *post*
c. `group`: The intervention group
d. `exercise`: The exercise that was tested, *legpress*, *benchpress* or *bicepscurl*
e. `load`: The load lifted in 1RM test (kg)

Reading the data set and exploratory analysis

```
library(tidyverse); library()
read_excel("./data/ten_vs_thirty.xlsx", na = "NA") %>%
        mutate(timepoint = factor(timepoint,
                                  levels = c("pre", "post"))) %>%
        ggplot(aes(timepoint, load, fill = group)) +
        geom_boxplot() +
        facet_wrap(~ exercise, scales = "free")
```

Exploratory analysis



The main purpose of your analysis:

What training method would you, based on your analysis recommend for improvning maximal strength?

How to answer the question

- Choose the most appropriate 1RM test or use all
- Choose the most appropriate statistical model/test, compare different models (`lm` on the change-score, `lm` with baseline as covariate, `lm` on post-values with baseline as a covariate)
- Write a full report (Background, methods (with emphasis on statistics), results and discussion)

References

Senn, S. 2006. "Change from Baseline and Analysis of Covariance Revisited." Journal Article. *Stat Med* 25 (24): 4334–44. https://doi.org/10.1002/sim.2682.

Vickers, Andrew J., and Douglas G. Altman. 2001. "Analysing Controlled Trials with Baseline and Follow up Measurements." Journal Article. *BMJ : British Medical Journal* 323 (7321): 1123–4. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1121605/%0Ahttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC1121605/pdf/1123.pdf.