



For all hypothesis tests you should state the null and alternative hypotheses, test statistic, distribution of the test statistic under  $H_0$ , p-value and conclusion.

You should submit your assignment via the Turnitin tool on iLearn.

Zhang et al (2015) report a randomised controlled trial of a device (oscillating positive expiratory pressure, PEP) used on patients who had just undergone thoracic or upper abdominal surgery. The aim was to reduce postoperative complications. Patients were randomised to the treatment group ( $n = 99$ ) or control group ( $n = 104$ ). The research question was:

“In patients who have undergone thoracic or upper abdominal surgery, what is the effect of regular postoperative use of an oscillating PEP device on fever, white cell count, length of hospital stay, mortality, treatment costs and the need for antibiotics?”

We will focus on the two outcomes *length of hospital stay* and *white cell count*. The data are in PEP.sav. Variables are:

	Variable	Description
Demographic and baseline variables	Group	Con = control; Exp = treatment
	Gender	M; F
	Age	
	BodyMassIndex	
	Siteofsurgery	thor; abdo
	Durationofsurgery	in hours
	MaxtempDay1	maximum temperature
Outcome variables	WhitecellcountDay1	white cell count
	Antibiotictherapy	yes; no
	Abnormalchestxray	yes; no
	Fever	yes; no
	Hospitalstay	length of stay in hospital (days)
	Daysofantibiotictherapy	days of antibiotic therapy
	Whitecellcount	white cell count

### 1. Length of hospital stay

Table 3 of Zhang et al (2015) gives the analysis for length of hospital stay as

Characteristics	Exp (n=99) Mean (SD)	Con (n=104) Mean (SD)	Exp - Con Mean difference (95% CI)
Length of hospital stay (d)	10.7 (7.1)	13.3 (8.7)	-2.6 (-4.8 to -0.4)

- a. What statistical test has been used?
- b. Reproduce this result in SPSS (show the output).
- c. What are the assumption(s) underlying this test? Do you think they are satisfied? (It is not necessary to perform a formal hypothesis test.)
- d. Develop an appropriate linear model for evaluating whether there has been a treatment effect on length of hospital stay. You should only use demographic and baseline variables for prediction (i.e. do not use outcome variables to predict another outcome). Note that in order to evaluate whether there has been a treatment effect, treatment (**Group**) must be in the model, whether or not it is significant. Perform usual diagnostic model checking. Write down your final model.
- e. In the clinical trials world, there is debate on whether treatment effects should be presented as *unadjusted* or *adjusted*. Unadjusted treatment effects do not include any covariates besides treatment in the model, whereas adjusted treatment effects include baseline covariates that are found to be significant. Compute a similar regression model as in (d) for the *unadjusted* evaluation of treatment effect. (Just present the SPSS output.)
- f. Does the PEP treatment have an effect on hospital stay? Compare your conclusions with that obtained by Zhang et al (2015), and discuss.

## 2. White cell count

White cell count has been measured at baseline (day 1) and as an outcome (day 5).

- a. Is there evidence of baseline imbalance? (Examine graphical as well as numerical evidence.)
- b. Develop an appropriate statistical model for determining the treatment effect on white cell count.
  - i. Perform diagnostic checking for your final model (examine residuals only);
  - ii. write down your final model;
  - iii. Is the treatment effective in reducing white cell count?
- c. From Table 3, is there a treatment effect on White cell count on Day 5? Explain.
- d. Comment on the difference between your method of analysis and that used by Zhang et al (2015) to arrive at the result given in Table 3.

## Reference

Zhang, X. Y., Wang, Q., Zhang, S., Tan, W., Wang, Z., and Li, J. (2015). The use of a modified, oscillating positive expiratory pressure device reduced fever and length of hospital stay in patients after thoracic and upper abdominal surgery: a randomised trial. *Journal of Physiotherapy*, 61(1), 16-20.