Chapter 4
Unpaired Continuous Data (Unpaired T-Test, Mann-Whitney, 20 Patients)

1 General Purpose

Double-blind placebo-controlled studies often include two parallel groups receiving different treatment modalities. Unlike crossover studies (Chap. 3), they involve independent treatment effects, i.e., with a zero correlation between the treatments. The two samples t-test, otherwise called the independent samples t-test or unpaired samples t-test, is appropriate for analysis.

2 Schematic Overview of Type of Data File

Outcome	binary predictor
.	.
.	.
.	.
.	.
.	.
.	.
.	.
.	.
.	.

Unpaired t-tests are for comparing two parallel-groups and use a binary predictor, for the purpose, for example an active treatment and a placebo. They can only include a single predictor variable. Gaussian frequency distributions of the outcome data of each parallel-group are assumed.

3 Primary Scientific Question

Is one treatment significantly more efficaceous than the other.

T.J. Cleophas, A.H. Zwinderman, *SPSS for Starters and 2nd Levelers*,
DOI 10.1007/978-3-319-20600-4_4

4 Data Example

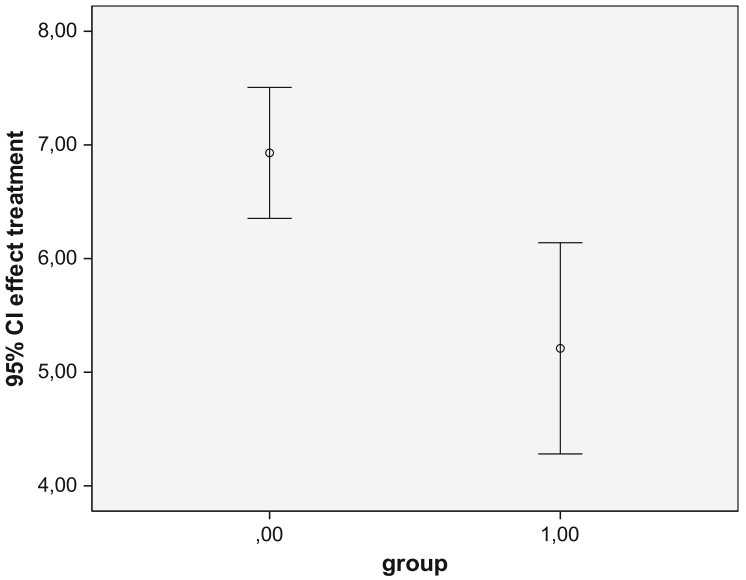
In a parallel-group study of 20 patients 10 of them are treated with a sleeping pill, 10 with a placebo. The first 11 patients of the 20 patient data file is given underneath.

Outcome	group
6,00	,00
7,10	,00
8,10	,00
7,50	,00
6,40	,00
7,90	,00
6,80	,00
6,60	,00
7,30	,00
5,60	,00
5,10	1,00

the group variable has 0 for placebo group, 1 for sleeping pill group
outcome variable = hours of sleep after treatment

We will start with a graph of the data. The data file is entitled "chapter4unpairedcontinuous", and is in extras.springer.com. Start by opening the data file in SPSS.

Command:
Graphs....Legacy Dialogs....Error Bar....click Simple....mark Summaries for groups of cases....click Define....Variable: enter "effect treatment"....Category Axis: enter "group"....Bars Represent: choose "Confidence interval for means".... Level: choose 95%....click OK.



The above graph shows that one group (the placebo group!!) performs much better than the other. The difference must be statistically significant, because the 95 % confidence intervals do not overlap. In order to determine the appropriate level of significance formal statistical testing will be performed next.

5 Analysis: Unpaired T-Test

For analysis the module Compare Means is required. It consists of the following statistical models:

Means,
One-Sample T-Test,
Independent-Samples T-Test,
Paired-Samples T-Test, and
One Way ANOVA.

Command:
Analyze....Compare Means....Independent Samples T-test....in dialog box Grouping Variable: Define Groups....Group 1: enter 0,00....Group 2: enter 1,00....click Continue....click OK.

In the output sheet the underneath table is given.

Independent sample test

		Levene's test for equality of variances		t-test for equality of means						
									95% confidence interval of the difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean difference	Std. Error difference	Lower	Upper
Effect treatment	Equal variances assumed	1,060	,317	3,558	18	,002	1,72000	,48339	,70443	2,73557
	Equal variances not assumed			3,558	15,030	,003	1,72000	,48339	,88986	2,75014

It shows that a significant difference exists between the sleeping pill and the placebo with a p-value of 0.002 and 0.003. Generally, it is better to use the largest of the p-values given, because the smallest p-value makes assumptions that are not always warranted, like, for example in the above table, the presence of equal variances of the two sets of outcome values.

6 Alternative Analysis: Mann-Whitney Test

Just like with the Wilcoxon's test (Chap. 3) used for paired data, instead of the paired t-test, the Mann-Whitney test is a nonparametric alternative for the unpaired t-test. If the data have a Gaussian distribution, then it is appropriate to use this test even so. More explanations about Gaussian or parametric distributions are given in Statistics applied to clinical studies 5th edition, 2009, Chap. 2, Springer Heidelberg Germany, 2012, from the same authors. For analysis Two-Independent-Samples Tests in the module Nonparametric Tests is required.

Command:
Analyze....Nonparametric....Two-Independent-Samples Tests....Test Variable List: enter ëffect treatment"....Group Variable: enter "group"....click group(??)....click Define Groups....Group 1: enter 0,00....Group 2: enter 1,00....mark Mann-Whitney U....click Continue....click OK.

Test Statistics[b]

	effect treatment
Mann-Whitney U	12,500
Wilcoxon W	67,500
Z	-2,836
Asymp. Sig. (2-tailed)	,005
Exact Sig. [2*(1-tailed Sig.)]	,003[a]

a. Not corrected for ties.

b. Grouping Variable: group

The nonparametric Mann-Whitney test produces approximately the same result as the unpaired t-test. The p-value equals 0,005 corrected for multiple identical values and even 0,003 uncorrected. The former result is slightly larger, because it takes into account more, namely, that all tests are 2-tailed (not a single but two sides of the Gaussian distribution is accounted). Which of the two results is in your final report, will not make too much of a difference. Ties are rank numbers with multiple values.

7 Conclusion

Statistical tests for assessing parallel-groups studies are given, both those that assume normality, and those that account nonnormality. It may be prudent to use the latter tests if your data are small, and, if nonnormality can not be ruled out. Normality of your outcome data can be statistically tested by goodness of fit tests, and can be graphically assessed with quantile-quantile plots (see Sect. 8).

8 Note

More explanations about Gaussian or parametric distributions are given in Statistics applied to clinical studies 5th edition, 2012, Chaps. 1 and 2, Springer Heidelberg Germany, from the same authors.

Normality of your outcome data can be statistically tested by goodness of fit tests (Statistics applied to clinical studies 5th edition, 2012, Chap. 42, Springer Heidelberg Germany, from the same authors), and can be graphically assessed with quantile-quantile plots (Machine Learning in Medicine a Complete Overview, 2015, Chap. 42, pp 253–260, Springer Heidelberg Germany, from the same authors).