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A randomised controlled trial of chemotherapy agent “A” as a treatment for advanced gastrointestinal cancer

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Aim

- To determine the effect of chemotherapy agent “A” on survival and quality of life of advanced GI cancer patients.
  - Does chemotherapy agent "A" have an effect on the **survival-time** of advanced GI cancer patients?
  - Does chemotherapy agent "A" have an effect on the **wellbeing** of advanced GI cancer patients?

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Survival

"Overall survival was significantly longer in the chemotherapy group, median 8 vs. 4.5 months, p<0.01."

Measuring Wellbeing:
The EORTC Quality of life questionnaire

Global health status	Functional scales	Symptoms scales
Global health score	Physical	Fatigue
	Role	Pain
	Cognitive	Nausea
	Emotional	Dyspnoea
	Social	Appetite loss
		Insomnia
		Constipation
		Diarrhoea

Raw score

Calculate the raw score

$$RawScore = RS = (I_1 + I_2 + ... + I_n)/n$$

Linear transformation

Apply the linear transformation to 0-100 to obtain the score S,

Functional scales: $$S = \left\{1 - \frac{(RS - 1)}{range}\right\} \times 100$$

Symptom scales / items: $$S = \{(RS - 1)/range\} \times 100$$

Global health status / QoL: $$S = \{(RS - 1)/range\} \times 100$$

Aaronson, Neil K., et al. "The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology." *JNCI: Journal of the National Cancer Institute* 85.5 (1993): 365-376.

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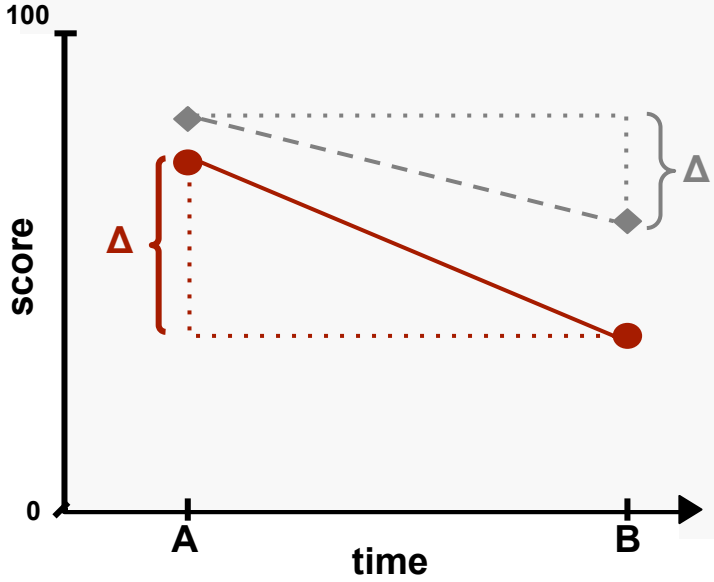
Aim(2): Constructing a testable hypothesis



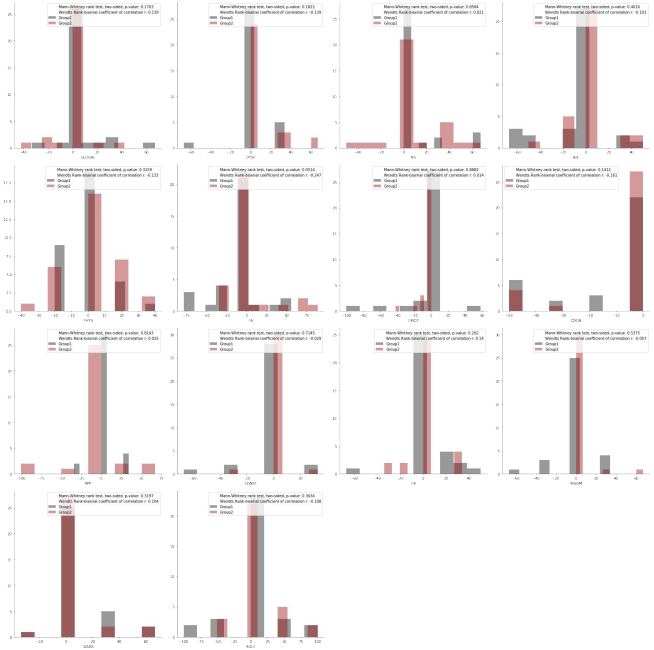
treatment, n=34
control, n=32

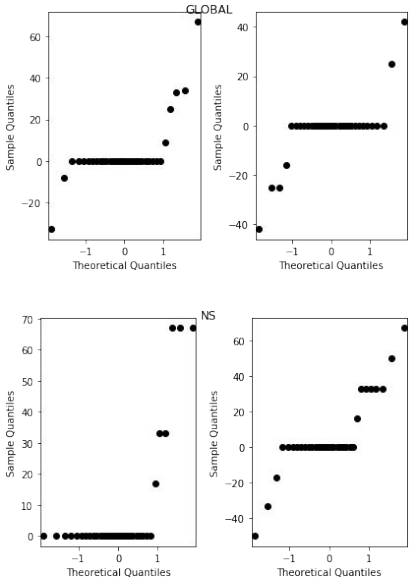
Aim: Does chemotherapy agent "A" have an effect on the wellbeing of advanced GI cancer patients, as measured in EORTC quality of life scores ?

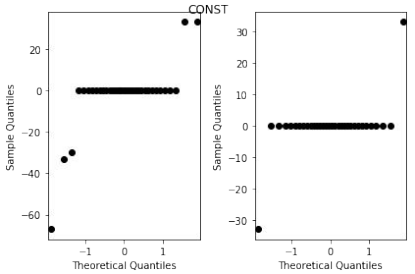
H_0 : The distributions of changes in quality score are the same between treatment and control.
H_1 : The distributions of changes in quality score are **not** the same between treatment and control

Are the data normally distributed?

Visual inspection via histogram and qq-plot



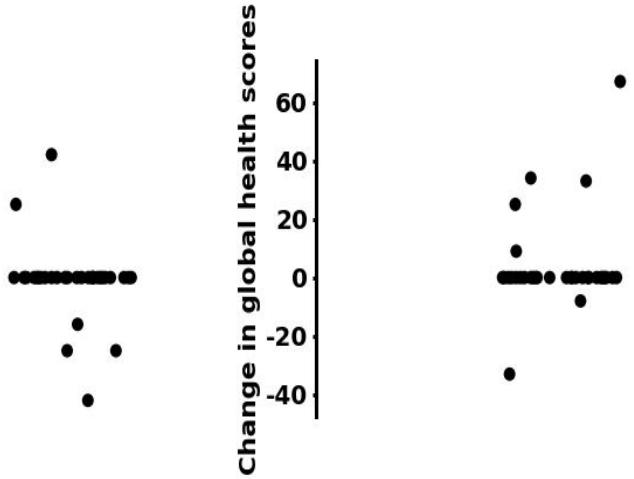




two-sided Mann-Whitney U test (as implemented in scipy.stats.mannwhitneyu)

rank-biserial correlation coefficient r

No significant difference in the change of quality of life (p=0.139)



	p-value	r
Global Health Status/QoL	0,170	0,139
Functional Scales		
Physical functioning (PHYS)	0,316	-0,133
Role functioning (ROLE)	0,363	-0,108
Emotional functioning (EMOT)	0,888	0,014
Cognitive functioning (COGN)	0,141	-0,161
Social functioning (SOC)	0,402	-0,101
Symptom Scales		
Fatigue (FA)	0,051	-0,247
Nausea (NS)	0,858	0,021
Pain (PA)	0,202	0,140
Dyspnoea (DYSP)	0,182	-0,139
Insomnia (INSOM)	0,537	-0,057
Appetite loss (APP)	0,814	0,025
Constipation (CONST)	0,714	-0,029
Diarrhoea (DIARR)	0,320	0,104

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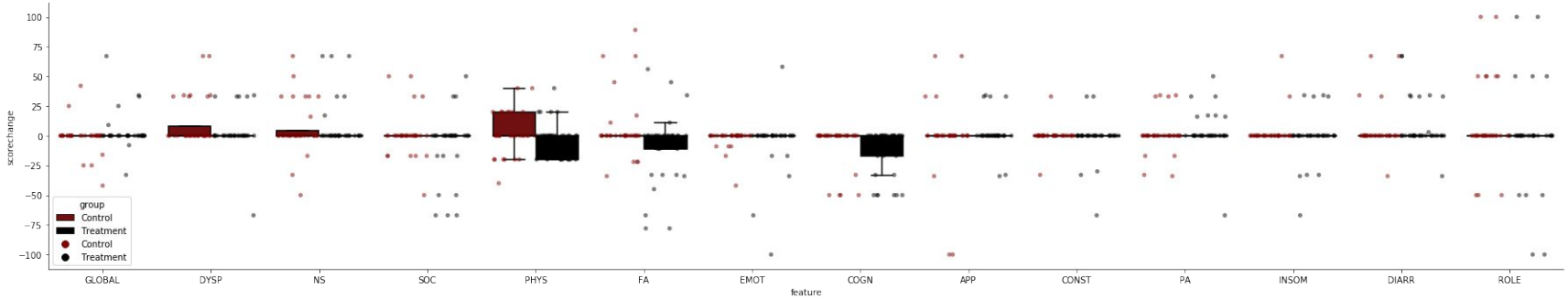
Results



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Conclusion

Chemotherapy agent "A" prolonged survival time for advanced GI cancer patients while not significantly affecting their quality of life.

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Discussion

- n=66
- Lack of significance due to lack of power? (use std. of control for power calc.)

- Higher power or transformation of data might also improve normality of the data, allowing for more powerful tests.

- Alternative methods (linear model?)

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more visualisations