

Statistical report for TECTO trial

Using simulated data

10 maj 2021

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Table 1 - Baseline characteristics

		B (n=64)	A (n=64)	Total (n=128)
Age	mean (sd)	15.9 (0.6)	16 (0.6)	16 (0.6)
Gender	Female	20 (31.2)	16 (25.0)	36 (28.1)
	Male	20 (31.2)	18 (28.1)	38 (29.7)
	Other	12 (18.8)	13 (20.3)	25 (19.5)
	Transgender	12 (18.8)	17 (26.6)	29 (22.7)
Nationality	Other	32 (50.0)	28 (43.8)	60 (46.9)
	Danish	32 (50.0)	36 (56.2)	68 (53.1)
Parental education level	2-year grad-school	14 (21.9)	14 (21.9)	28 (21.9)
	3-year grad-school	15 (23.4)	15 (23.4)	30 (23.4)
	5-year grad-school	12 (18.8)	9 (14.1)	21 (16.4)
	High-school (finished)	13 (20.3)	14 (21.9)	27 (21.1)
	Ph.d. or equal level	10 (15.6)	12 (18.8)	22 (17.2)
Parental nationality	Danish and other	23 (35.9)	21 (32.8)	44 (34.4)
	Other	20 (31.2)	23 (35.9)	43 (33.6)
	Danish	21 (32.8)	20 (31.2)	41 (32.0)
Parental stress scale (PSS)	mean (sd)	200.4 (115.5)	216.1 (126.5)	208.3 (120.9)
Family Environment Scale (FES)	mean (sd)	214 (116.6)	205 (112.6)	209.5 (114.2)
Social responsiveness scale (SRS)	mean (sd)	218.7 (123.7)	202.6 (111.4)	210.6 (117.5)
Intelligence (WISC-V/WAIS-IV)	mean (sd)	192.3 (124.8)	186.6 (107.9)	189.4 (116.2)

The education-level from the parent with the highest education is presented. For PSS, FES, and SRS the average of the parents who responded is presented

Table 2 - Diagnostic status and comorbidities at baseline

		B (n=64)	A (n=64)	Total (n=128)
CY-BOCS	mean (sd)	18.4 (11.2)	19.8 (12.3)	19.1 (11.7)
COIS-R	mean (sd)	15.5 (9.7)	15.3 (9.5)	15.4 (9.6)
CGI-S	mean (sd)	15.2 (9.2)	15.9 (10.1)	15.5 (9.6)
CGAS	mean (sd)	22.6 (13.3)	25.7 (13)	24.2 (13.2)
TOCS	mean (sd)	22.3 (13.2)	25.8 (12.2)	24.1 (12.8)
TAFQ-A	mean (sd)	20.5 (12.5)	23.6 (13.7)	22 (13.1)
FAS	mean (sd)	21.9 (12.8)	23.8 (14)	22.9 (13.4)
Depression		34 (53.1)	29 (45.3)	63 (49.2)
Agoraphobia		34 (53.1)	33 (51.6)	67 (52.3)
Social phobias		25 (39.1)	26 (40.6)	51 (39.8)
Specific phobias		37 (57.8)	28 (43.8)	65 (50.8)
Separation anxiety disorder		29 (45.3)	26 (40.6)	55 (43.0)
Generalized anxiety disorders		30 (46.9)	35 (54.7)	65 (50.8)
Anorexia nervosa		25 (39.1)	29 (45.3)	54 (42.2)
Anxious personality disorder		29 (45.3)	32 (50.0)	61 (47.7)
Adjustment disorders		31 (48.4)	30 (46.9)	61 (47.7)
Asperger syndrome		29 (45.3)	30 (46.9)	59 (46.1)
ADHD		29 (45.3)	28 (43.8)	57 (44.5)
Oppositional defiant disorder		36 (56.2)	27 (42.2)	63 (49.2)
Transient tics		33 (51.6)	32 (50.0)	65 (50.8)
Nonorganic enuresis		32 (50.0)	33 (51.6)	65 (50.8)
Nonorganic encopresis		28 (43.8)	35 (54.7)	63 (49.2)

Figure 1 - Psychopathological scores

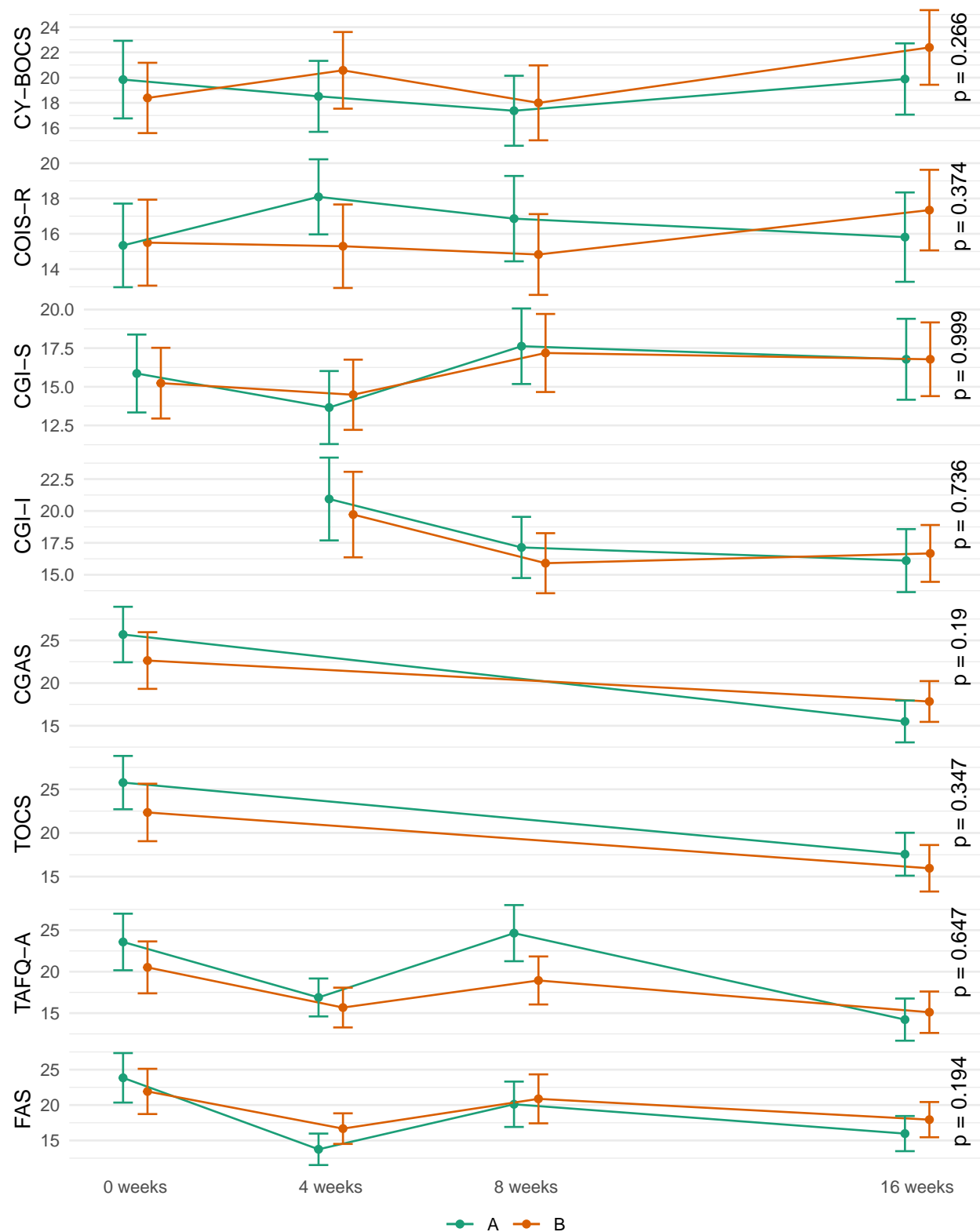


Figure 2 - Response Status at 16 weeks

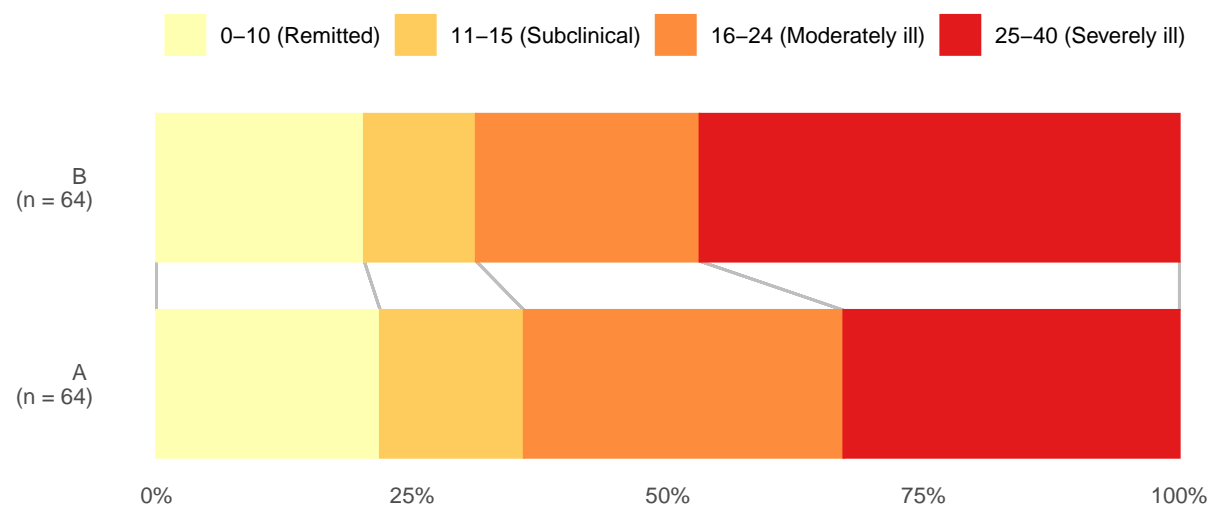
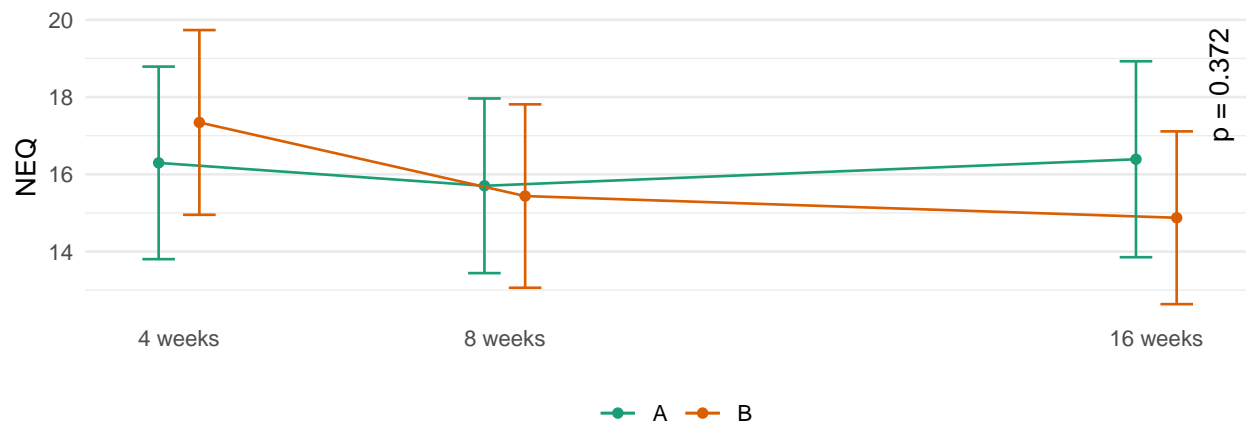


Figure 3 - Negative Effects Questionnaire



Supplemental Table 1 - Diagnostic scores

Tabellerne som ovenstående figur 1 bygger på.

Supplemental Timeline

This timeline will, together with the commits to the version control system, function as a log of the statistical process

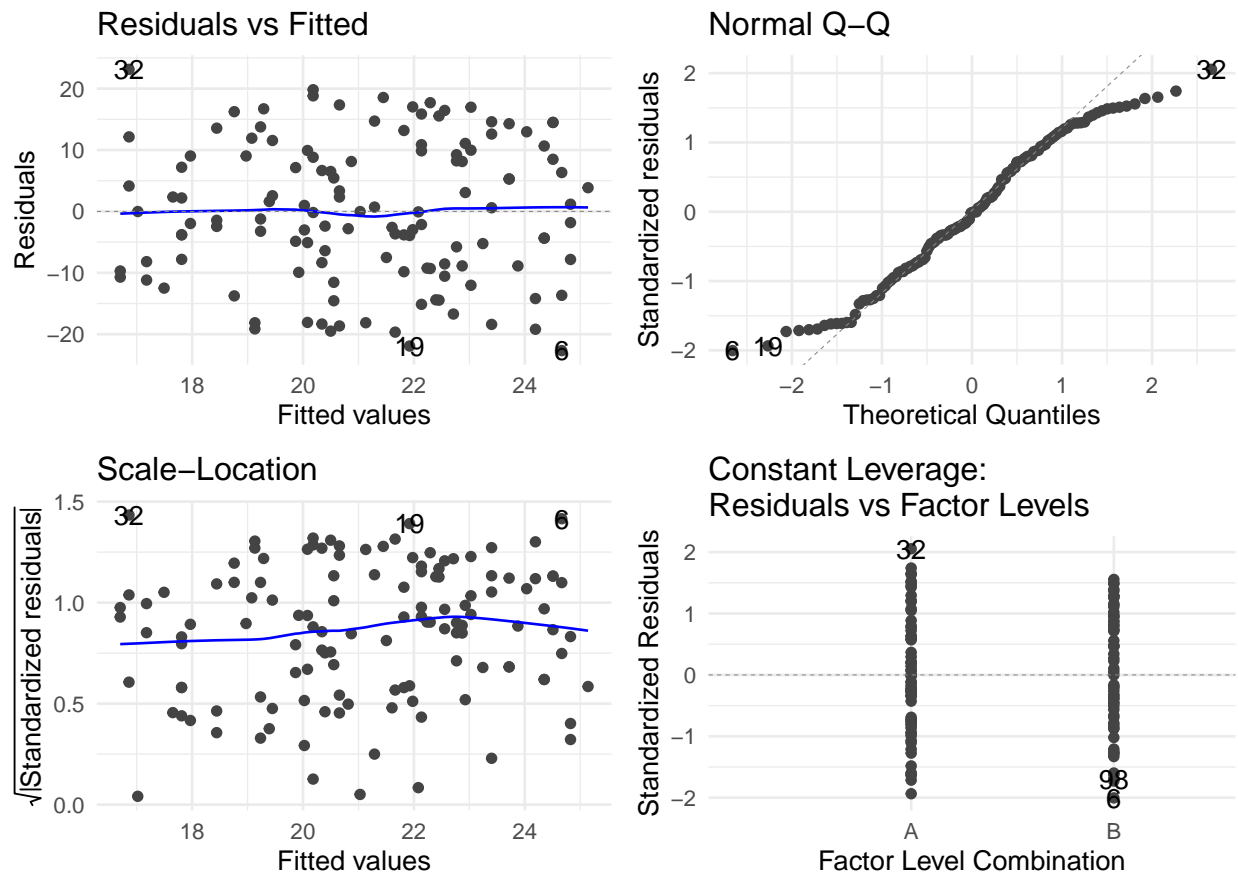
- 14.04.2021 - The work on the statistical report with simulated data has been initiated.
- 30.04.2021 - First evaluation of presentation of data using simulated tools.
- 03.05.2021 - Second evaluation of the statistical report.
- 11.05.2021 - Third evaluation of the statistical report.

Supplemental Assumptions

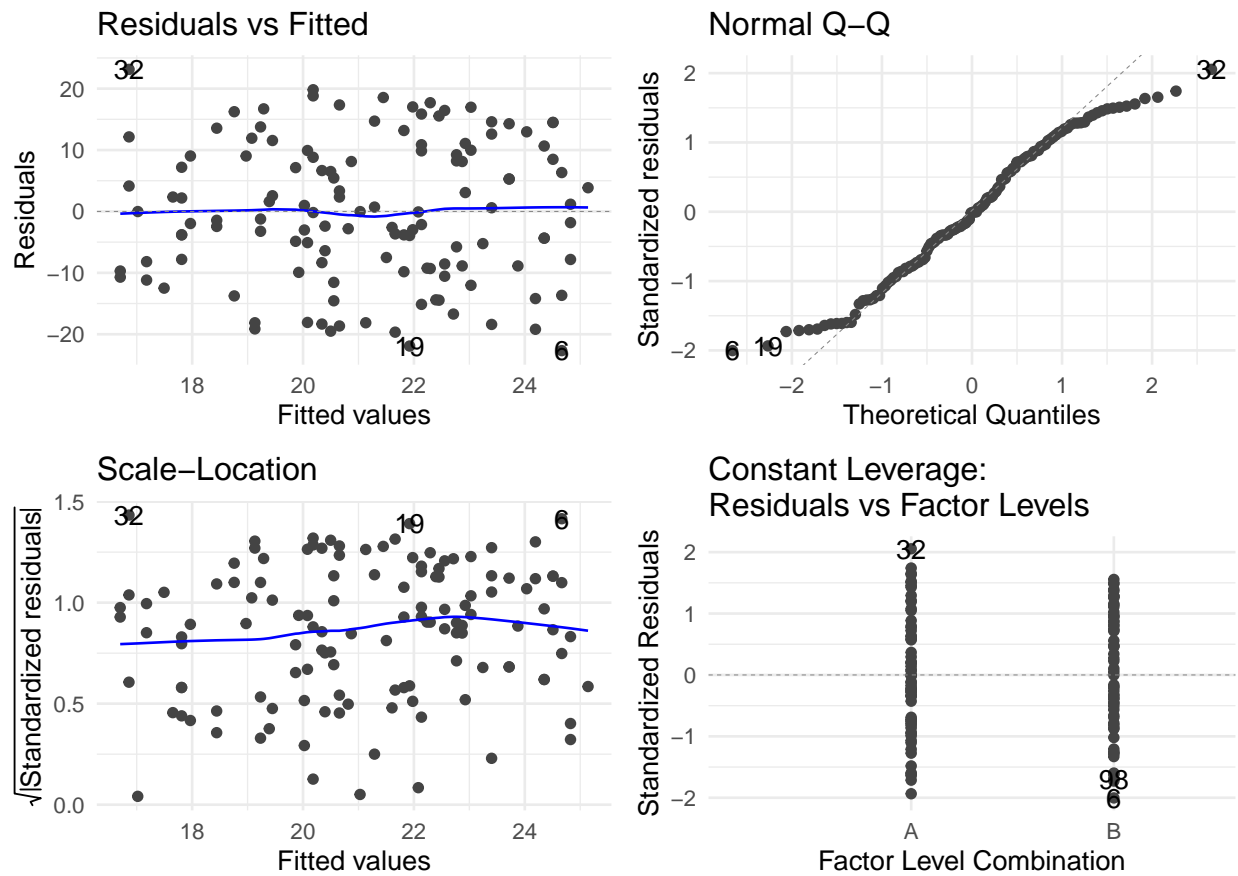
The assumptions for regression models will be assessed using four figures, for each variable.

1. *Residuals vs Fitted*. Used to check the linear relationship assumptions. A horizontal line, without distinct patterns is an indication for a linear relationship, what is good.
2. *Normal Q-Q*. Used to examine whether the residuals are normally distributed. It's good if residuals points follow the straight dashed line.
3. *Scale-Location* (or Spread-Location). Used to check the homogeneity of variance of the residuals (homoscedasticity). Horizontal line with equally spread points is a good indication of homoscedasticity.
4. *Residuals vs Leverage*. Used to identify influential cases, that is extreme values that might influence the regression results when included or excluded from the analysis.

CY-BOCS (primary)



KIDSCREEN-10 (secondary)



NEQ (secondary)

32 ITEMS

COIS (exploratory)

COIS

CGI-S (exploratory)

COIS

CGI-I (exploratory)

COIS

TAFQ-A (exploratory)

COIS

CGAS (exploratory)

COIS

TOCS (exploratory)

COIS

Clinical state (CY-BOCS, KIDSCREEN, COIS**, CGI-S, CGI-I (not at week 0), TAFQ-A*) C-GAS Self-report OCD rating (TOCS) Diagnostics (K-SADS-PL) Intelligence (WISC-V/WAIS-IV) Social competences (SRS) Negative effects of psychotherapy (NEQ) PSS, Family accomodation (FAS) Family Environment (FES)** Treatment compliance Experience of service questionnaire