

Statistical report for TECTO trial

Using simulated data

15 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)
Social responsiveness scale (SRS)	mean (sd)	214 (116.6)	205 (112.6)	209.5 (114.2)
Intelligence (WISC-V/WAIS-IV)	mean (sd)	218.7 (123.7)	202.6 (111.4)	210.6 (117.5)

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 - Family Environment Scale (FES)

Relationship Dimensions		B (n=64)	A (n=64)	Total (n=128)
Cohesion	mean (sd)	45 (26.3)	45.6 (29.8)	45.3 (28)
Expressiveness	mean (sd)	45.9 (28.9)	46.2 (29.4)	46.1 (29)
Conflict	mean (sd)	55.1 (26.1)	50.7 (24.9)	52.9 (25.5)

Personal Growth Dimensions		B (n=64)	A (n=64)	Total (n=128)
Achievement Orientation	mean (sd)	49.4 (27.9)	48.2 (27.8)	48.8 (27.8)
Intellectual-Cultural Orientation	mean (sd)	51.3 (29)	51.8 (26.9)	51.5 (27.9)
Active-Recreational Orientation	mean (sd)	49.1 (31)	49.7 (30.4)	49.4 (30.6)
Moral-Religious Emphasis	mean (sd)	45.5 (28.9)	51.6 (33.2)	48.5 (31.1)

System Maintenance Dimensions		B (n=64)	A (n=64)	Total (n=128)
Oranization	mean (sd)	51.8 (29.3)	50 (29.5)	50.9 (29.3)
Control	mean (sd)	55.5 (30.3)	59.6 (28.6)	57.6 (29.4)

Table 3 - Diagnostic status and comorbidities at baseline

		B (n=64)	A (n=64)	Total (n=128)
CY-BOCS	mean (sd)	17.9 (12.4)	18.1 (11.5)	18 (11.9)
COIS-R	mean (sd)	17.3 (9.3)	14.9 (9.8)	16.1 (9.6)
CGI-S	mean (sd)	15.4 (10.1)	16.8 (9.7)	16.1 (9.9)
CGAS	mean (sd)	22.9 (13.5)	23.3 (14.9)	23.1 (14.1)
TOCS	mean (sd)	23.7 (12.4)	22.3 (13.6)	23 (13)
TAFQ-A	mean (sd)	23.3 (14)	24.2 (12.3)	23.7 (13.1)
FAS	mean (sd)	20.8 (13.3)	22.8 (12.4)	21.8 (12.9)
Depression		38 (59.4)	26 (40.6)	64 (50.0)
Agoraphobia		35 (54.7)	30 (46.9)	65 (50.8)
Social phobias		30 (46.9)	38 (59.4)	68 (53.1)
Specific phobias		31 (48.4)	24 (37.5)	55 (43.0)
Separation anxiety disorder		30 (46.9)	31 (48.4)	61 (47.7)
Generalized anxiety disorders		29 (45.3)	31 (48.4)	60 (46.9)
Anorexia nervosa		34 (53.1)	34 (53.1)	68 (53.1)
Anxious personality disorder		35 (54.7)	29 (45.3)	64 (50.0)
Adjustment disorders		35 (54.7)	31 (48.4)	66 (51.6)
Asperger syndrome		29 (45.3)	29 (45.3)	58 (45.3)
ADHD		35 (54.7)	23 (35.9)	58 (45.3)
Oppositional defiant disorder		35 (54.7)	38 (59.4)	73 (57.0)
Transient tics		29 (45.3)	33 (51.6)	62 (48.4)
Nonorganic enuresis		34 (53.1)	24 (37.5)	58 (45.3)
Nonorganic encopresis		38 (59.4)	36 (56.2)	74 (57.8)

Figure 1 - Psychopathological scores

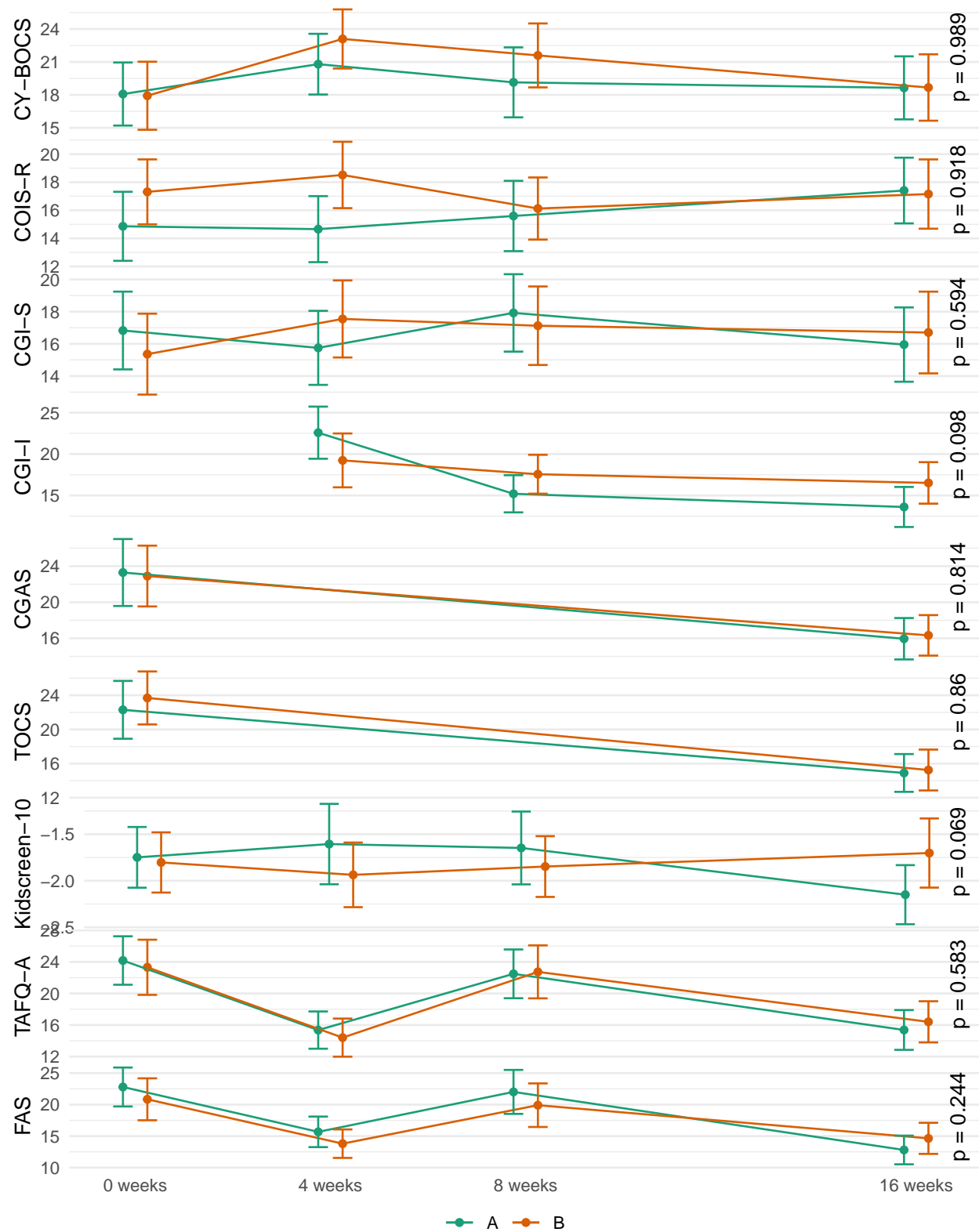


Figure 2 - Response Status at 16 weeks

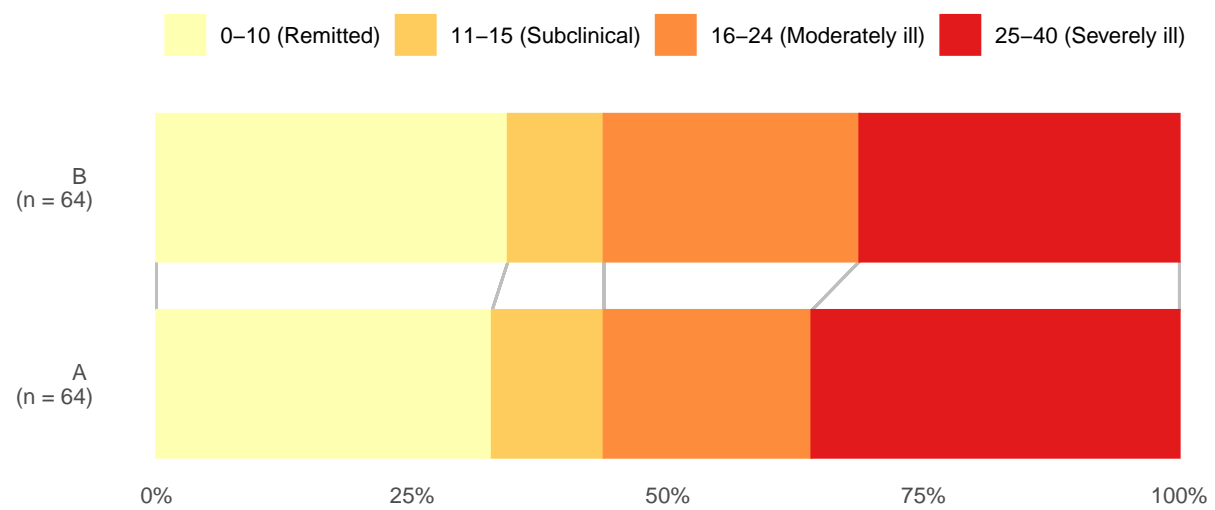
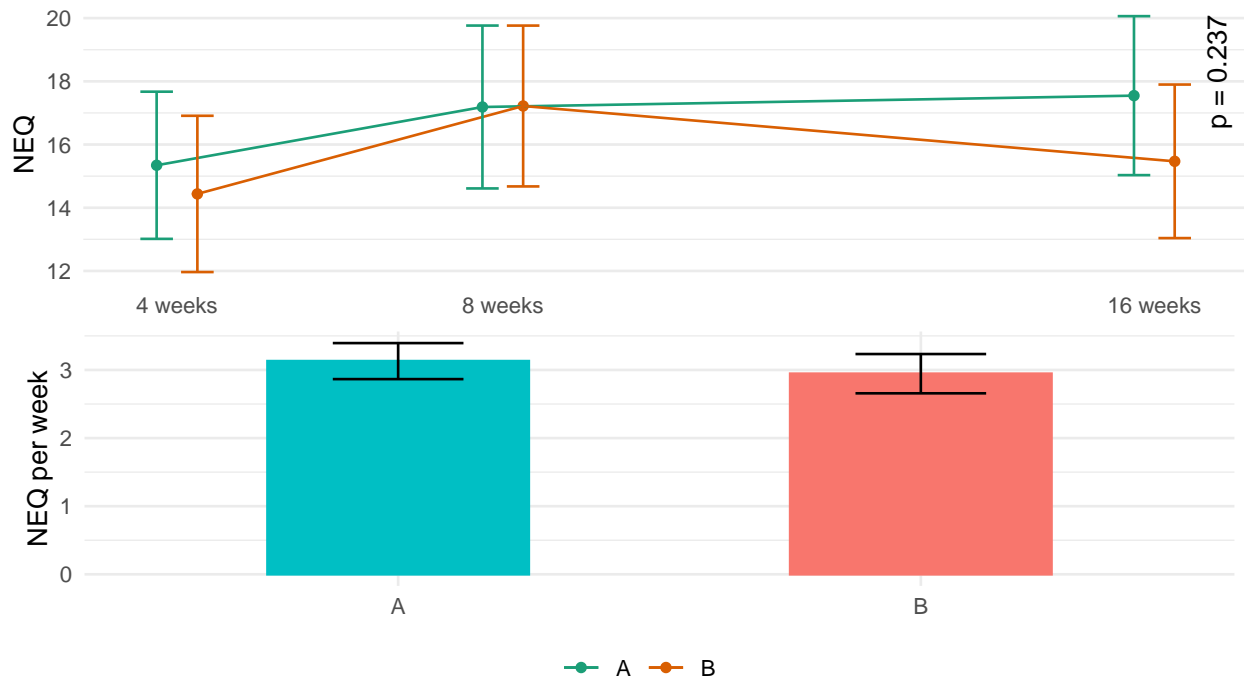


Figure 3 - Negative Effects Questionnaire



Supplemental Table 1 - Psychopathological scores

Refers to Figure 1

Supplemental Table 2 - Kidscreen-52

Tabellerne som ovenstående figur 1 bygger på.

- Physical well-being
- Psychological well-being
- Moods and emotions
- Self-perception
- Autonomy
- Parent relation and home life
- Peers and social support
- School environment
- Social acceptance (bullying)
- Financial resources

Supplemental Timeline

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

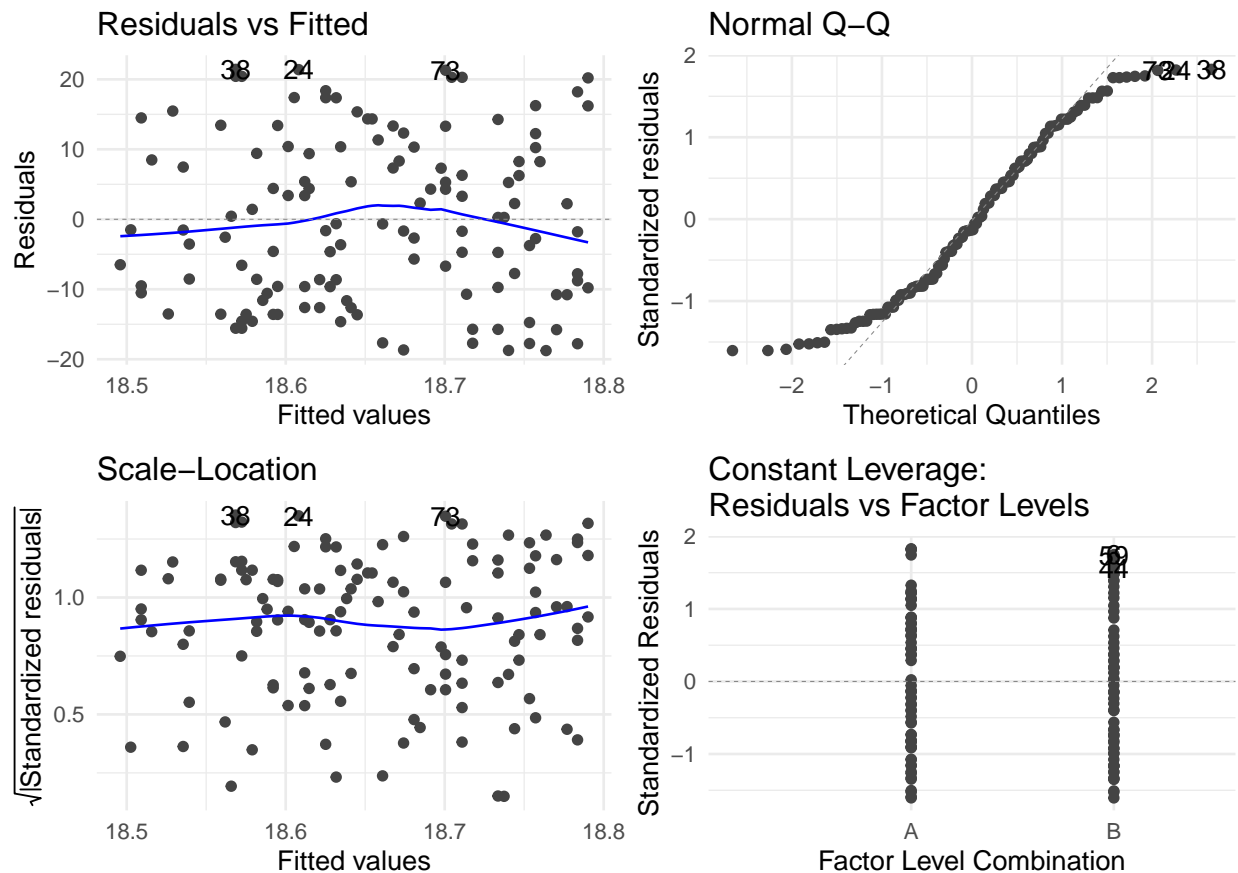
- 14.04.2021 - The work on the statistical report with simulated data has been initiated.
- 30.04.2021 - First evaluation of presentation of data using simulated tools.
- 03.05.2021 - Second evaluation of the statistical report.
- 11.05.2021 - Third evaluation of the statistical report.
- 14.05.2021 - Fourth evaluation of the statistical report.

Supplemental Assumptions

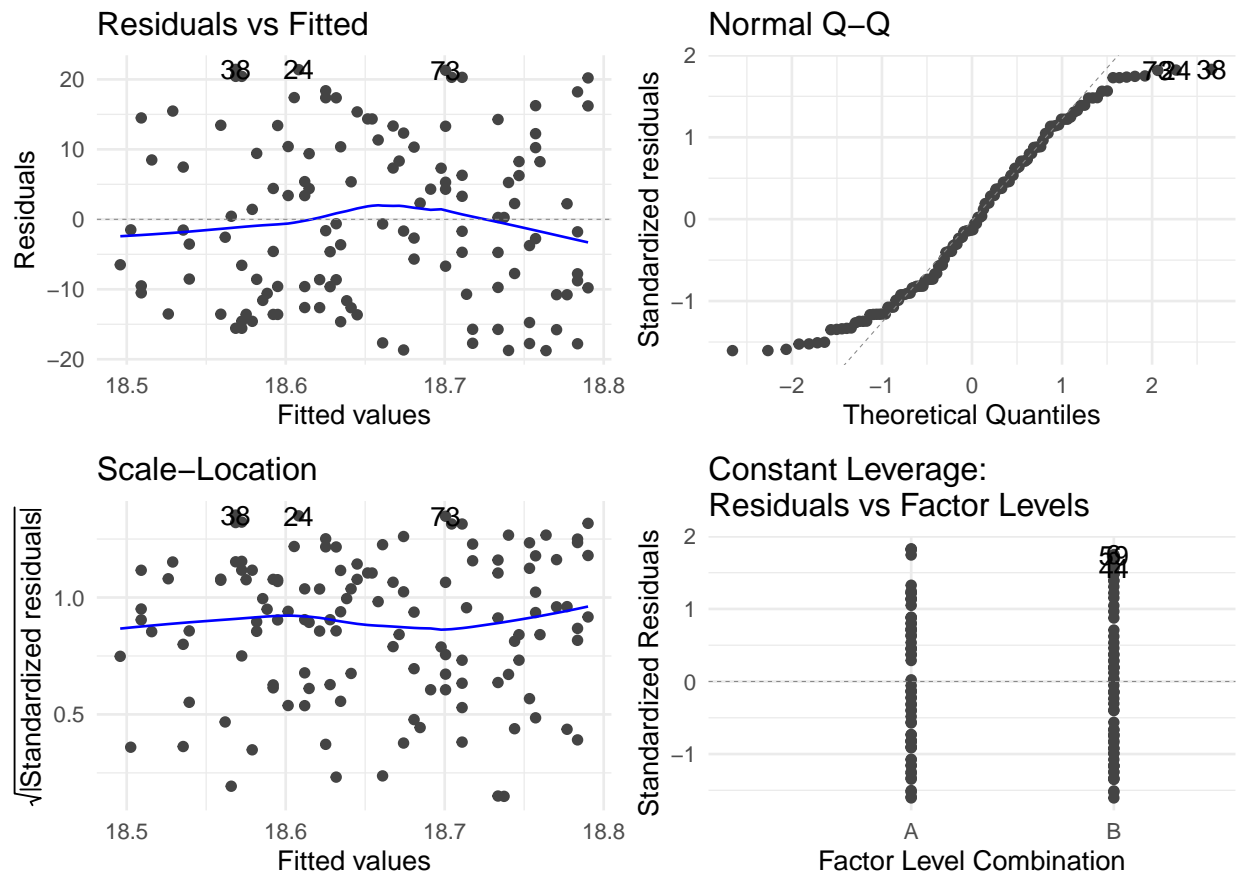
The assumptions for regression models will be assessed using four figures, for each variable.

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