

Statistical report for TEENS feasibility trial

Using simulated data

29 marts 2021

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Baseline characteristics

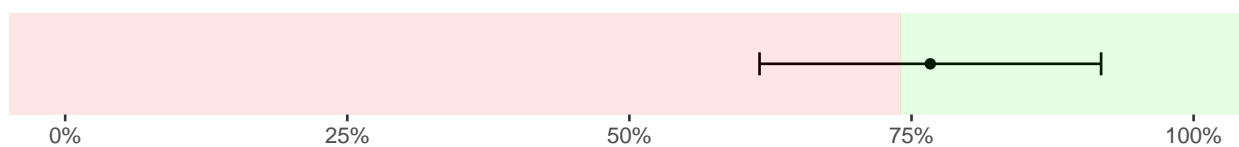
Baseline characteristics

	A	B	Overall
n	15	15	30
Age (mean (SD))	16.13 (0.83)	15.64 (0.50)	15.90 (0.72)
Gender (%)			
Female	6 (40.0)	5 (33.3)	11 (36.7)
Male	3 (20.0)	2 (13.3)	5 (16.7)
Other	3 (20.0)	3 (20.0)	6 (20.0)
Transgender	3 (20.0)	5 (33.3)	8 (26.7)
Nationality (%)			
Danish	4 (26.7)	6 (40.0)	10 (33.3)
European/North American	3 (20.0)	2 (13.3)	5 (16.7)
Middle Eastern	3 (20.0)	6 (40.0)	9 (30.0)
Other	5 (33.3)	1 (6.7)	6 (20.0)
School (%)			
Boarding school	1 (6.7)	4 (26.7)	5 (16.7)
High-school	3 (20.0)	3 (20.0)	6 (20.0)
Middle-school	6 (40.0)	3 (20.0)	9 (30.0)
No school	2 (13.3)	2 (13.3)	4 (13.3)
Other	3 (20.0)	3 (20.0)	6 (20.0)
Parental status (%)			
Cohabitant	3 (20.0)	3 (20.0)	6 (20.0)
Divorced	5 (33.3)	5 (33.3)	10 (33.3)
Married	4 (26.7)	2 (13.3)	6 (20.0)
Other	3 (20.0)	5 (33.3)	8 (26.7)

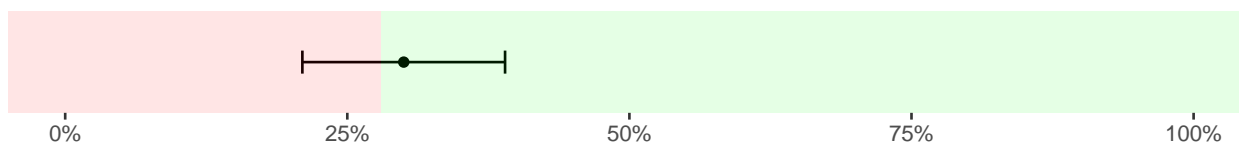
Missing data: Age: 3.3 %

Feasibility outcomes

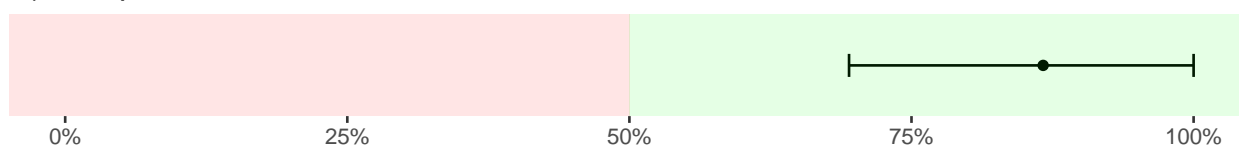
A) Completion of follow-up



B) Eligible participants who consent to inclusion and randomisation



C) Compliance



Outcome	Requirement	Fraction	LCL	UCL
A) Completion of follow-up	75%	77%	62%	92%
B) Eligible participants who consent to inclusion and randomisation	29%	30%	21%	39%
C) Compliance	51%	87%	69%	100%

Exploratory clinical outcomes

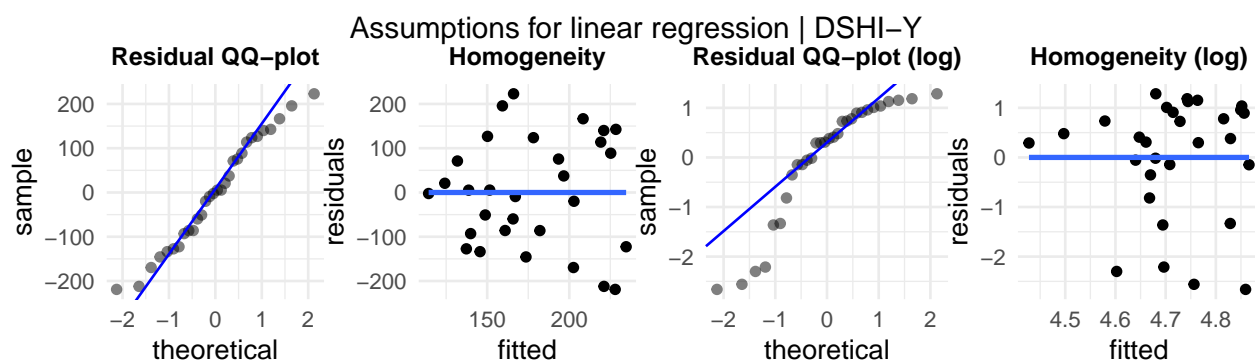
DSHI-Y (primary)

Data on non-suicidal self-injury (NSSI) as measured by DSHI-Y will be obtained in both groups at baseline and follow-up, and during the intervention for the interventional group. DSHI-Y reflects the number of NSSI events in the past month. The results will be presented as one sum score.

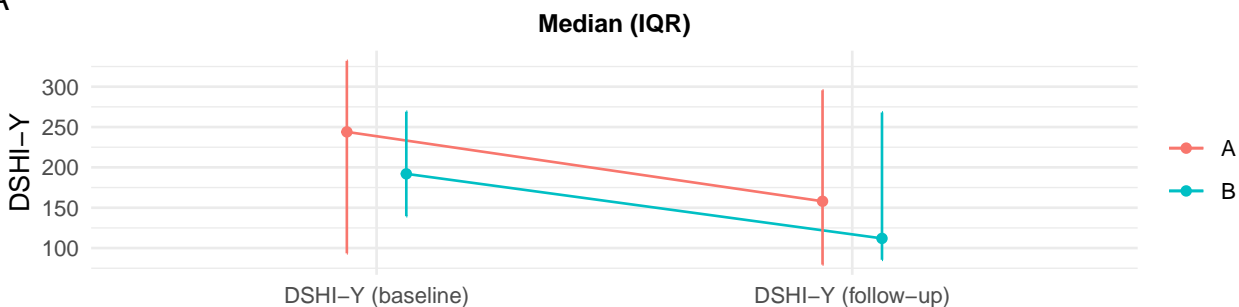
Results

Summarised results

	A	B	Overall
n	15	15	30
DSHI-Y (baseline) (mean (SD))	210.93 (126.99)	208.33 (107.99)	209.63 (115.83)
DSHI-Y (follow-up) (mean (SD))	183.47 (127.14)	171.00 (134.16)	177.23 (128.58)
Missing data: : %			



A



Linear regression

	p-value
DSHI-Y	0.80463

Kidscreen-10 (secondary)

Data on Kidscreen-10 will be obtained in both groups at baseline and follow-up. Kidscreen-10 has 10 items which each generates a score from 1 to 5. The sum of the raw scores will be processed using the algorithm below:

- $RASCH\ PP = (10 = -4.327) / (11 = -3.206) / (12 = -2.675) / (13 = -2.319) / (14 = -2.049) / (15 = -1.831) / (16 = -1.645) / (17 = -1.483) / (18 = -1.339) / (19 = -1.207) / (20 = -1.085) / (21 = -0.971) / (22 = -0.863) / (23 = -0.760) / (24 = -0.660) / (25 = -0.563) / (26 = -0.468) / (27 = -0.374) / (28 = -0.281) / (29 = -0.187) / (30 = -0.093) / (31 = 0.002) / (32 = 0.100) / (33 = 0.199) / (34 = 0.302) / (35 = 0.409) / (36 = 0.520) / (37 = 0.637) / (38 = 0.760) / (39 = 0.891) / (40 = 1.031) / (41 = 1.183) / (42 = 1.348) / (43 = 1.529) / (44 = 1.732) / (45 = 1.961) / (46 = 2.226) / (47 = 2.545) / (48 = 2.951) / (49 = 3.533) / (50 = 4.703)$

(points = sub-score)

The results are presented using two scales:

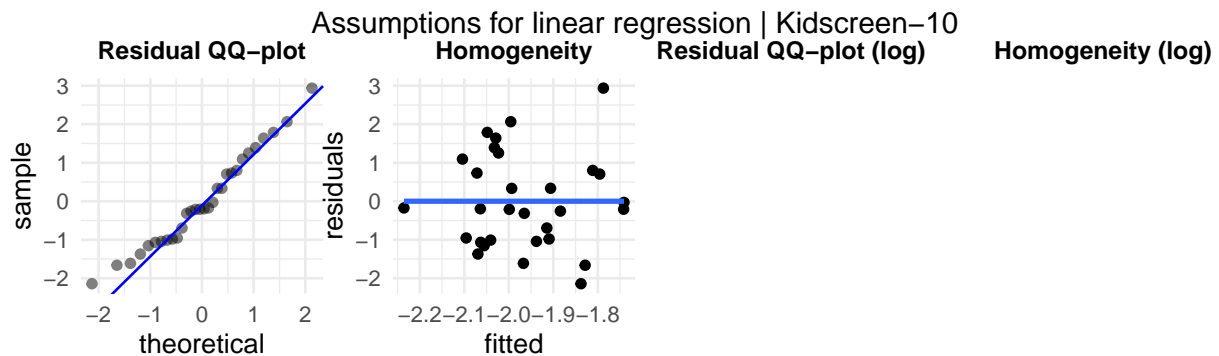
- General HRQoL index** = RASCH PP
- General HRQoL index European T-values** = (((RASCH PP - 1.2078) / 1.03377) * 10 + 50)

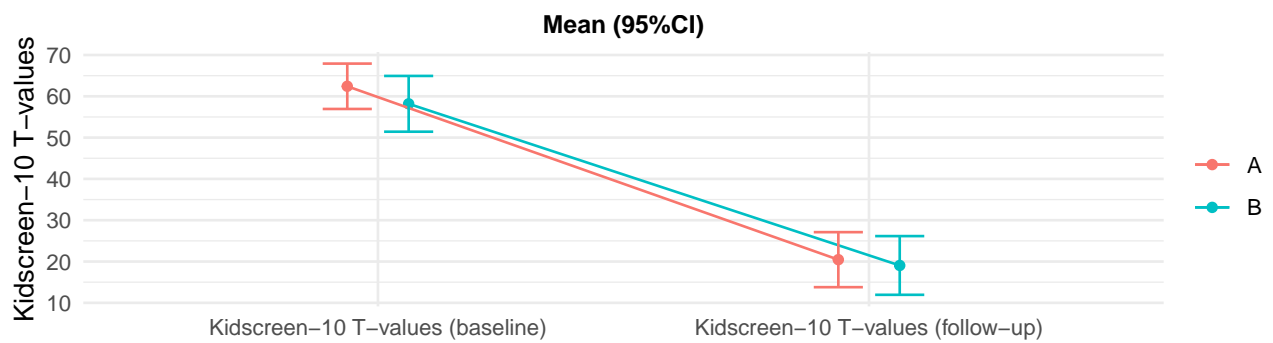
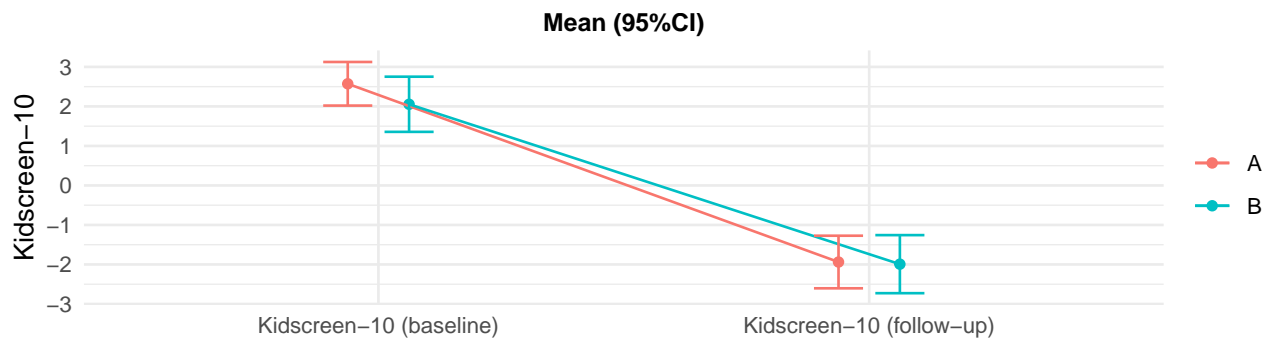
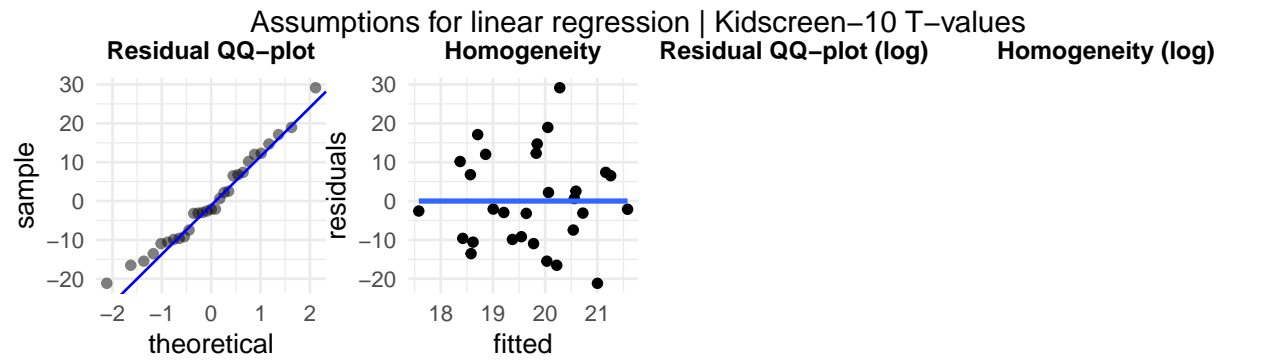
Results

Summarised results

	A	B	Overall
n	15	15	30
Kidscreen-10 (baseline) (mean (SD))	2.57 (1.00)	2.05 (1.26)	2.31 (1.15)
Kidscreen-10 (follow-up) (mean (SD))	-1.94 (1.20)	-1.99 (1.33)	-1.97 (1.24)
Kidscreen-10 T-values (baseline) (mean (SD))	62.43 (9.51)	58.19 (12.19)	60.23 (11.00)
Kidscreen-10 T-values (follow-up) (mean (SD))	20.45 (11.54)	19.05 (12.83)	19.72 (12.03)

Missing data: Kidscreen-10 T-values (baseline): 3.3 %; Kidscreen-10 T-values (follow-up): 3.3 %





Linear regression

	p-value
Kidscreen-10	0.82327
Kidscreen-10 T-values	0.72449

DASS-21 (secondary)

Data on DASS-21 will be obtained in both groups at baseline and follow-up. DASS-21 has 21 items which each generates a score from 0 to 3. The results will be presented as sum-score for the following three subscales:

- **Depression** = I3 + I5 + I10 + I13 + I16 + I17 + I21
- **Anxiety** = I2 + I4 + I7 + I9 + I15 + I19 + I20
- **Stress** = I1 + I6 + I8 + I11 + I12 + I14 + I18

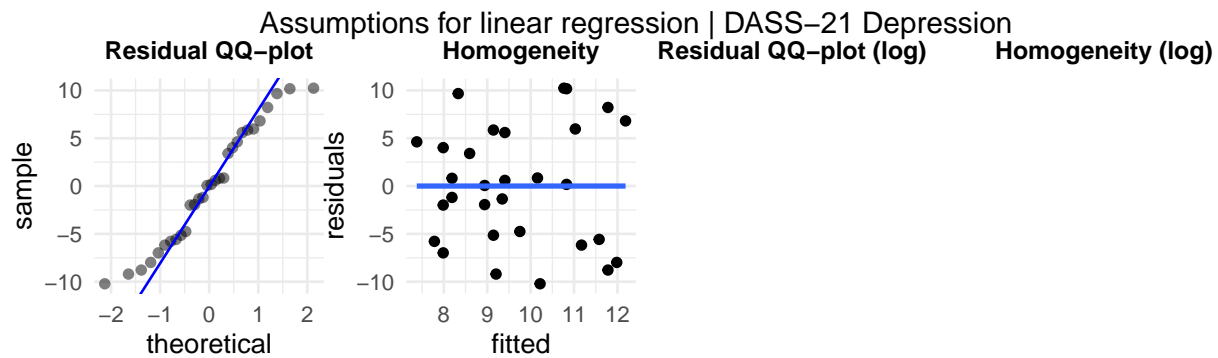
I: Items

Results

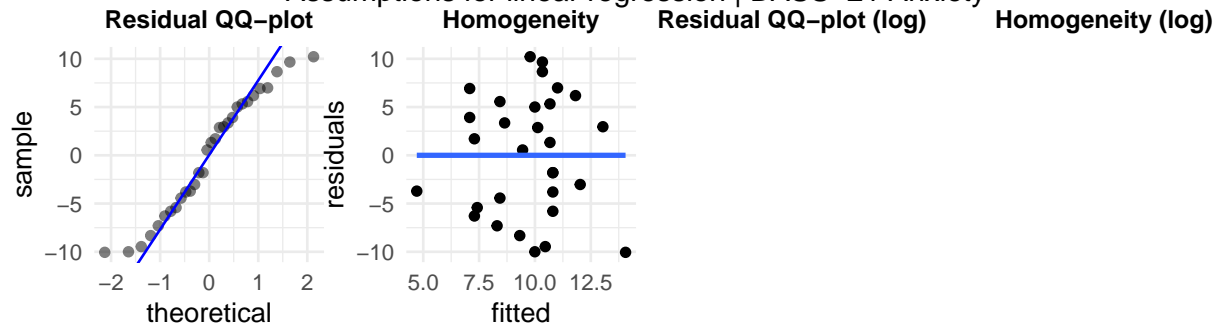
Summarised results

	A	B	Overall
n	15	15	30
DASS-21 Depression (baseline) (mean (SD))	10.00 (6.08)	11.13 (6.57)	10.57 (6.25)
DASS-21 Anxiety (baseline) (mean (SD))	8.60 (5.65)	13.27 (5.78)	10.93 (6.10)
DASS-21 Stress (baseline) (mean (SD))	11.07 (6.89)	10.87 (5.01)	10.97 (5.92)
DASS-21 Depression (follow-up) (mean (SD))	9.00 (6.35)	10.33 (6.50)	9.67 (6.35)
DASS-21 Anxiety (follow-up) (mean (SD))	10.20 (7.22)	9.20 (5.94)	9.70 (6.52)
DASS-21 Stress (follow-up) (mean (SD))	9.33 (7.83)	10.27 (7.05)	9.80 (7.33)

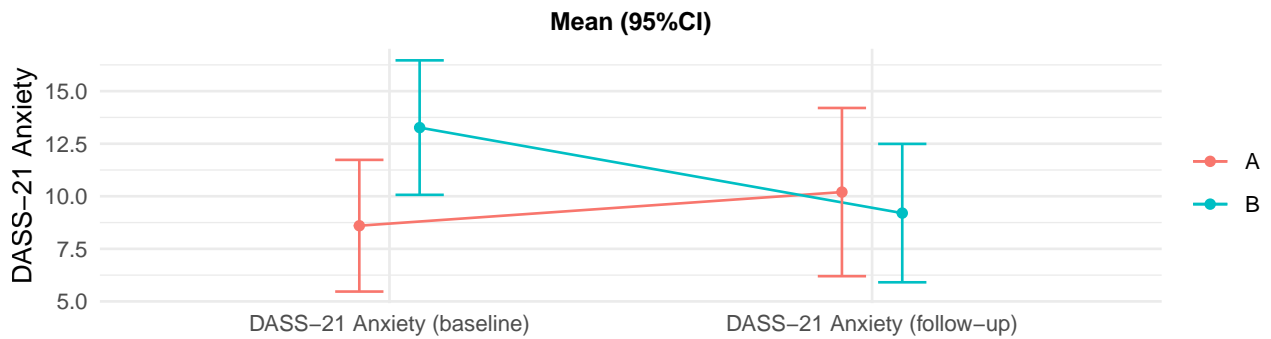
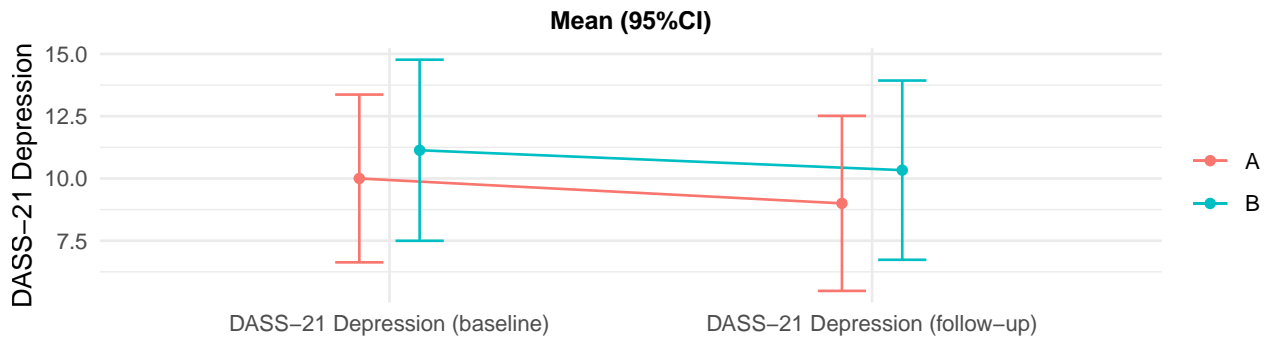
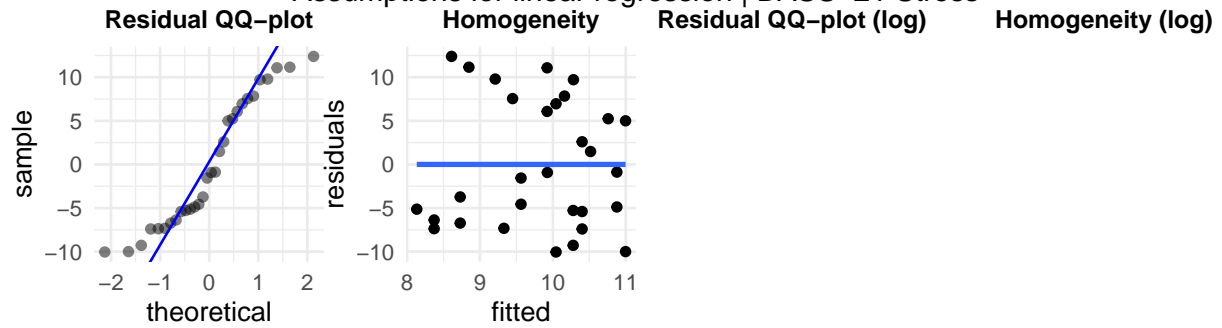
Missing data: : %

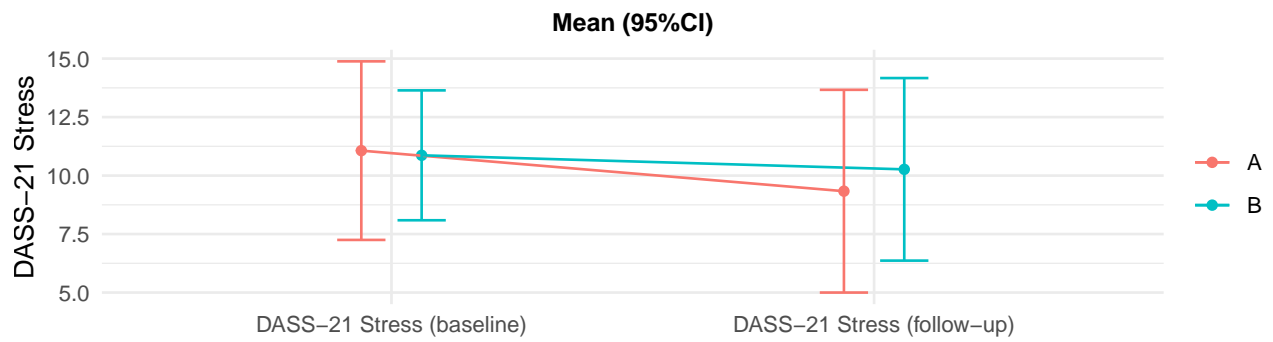


Assumptions for linear regression | DASS-21 Anxiety



Assumptions for linear regression | DASS-21 Stress





Linear regression

	p-value
DASS-21 Depression	0.51159
DASS-21 Anxiety	0.32147
DASS-21 Stress	0.73107

Self-injury (secondary)

Data on ‘Self-injury’ will be obtained in both groups only at follow-up. ‘Self-injury’ is answered as either ‘yes’ or ‘no’.

Summarised results

	A	B	Overall
n	15	15	30
Self-injury = Yes (%)	8 (53.3)	9 (60.0)	17 (56.7)
Missing data: : %			

var		R	lcl	ucl	p
Self-injury	OR	1.31	0.31	5.75	0.713
Self-injury	RR	1.12	0.60	2.11	

NB: Confidence intervals of RR are *Unconditional MLE & normal approximation (Wald) CI*, while the confidence intervals for RR will be obtained using marginal effects.

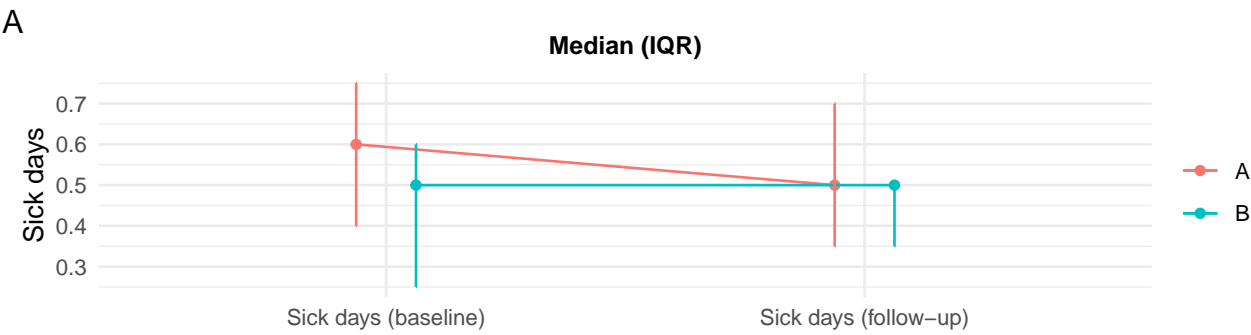
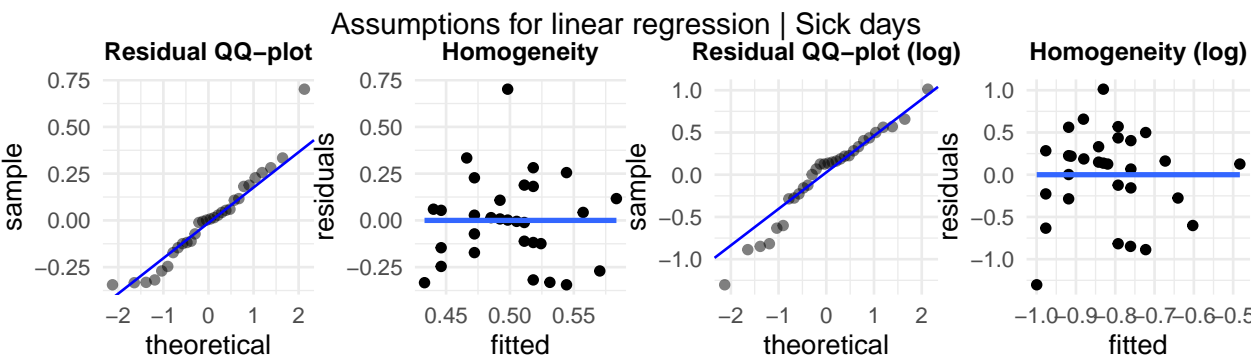
Sick days (secondary)

Data on ‘Sick days’ will be obtained in both groups at baseline and follow-up. ‘Sick days’ will be presented as a ratio, where 0 refers to full student capacity.

Summarised results

	A	B	Overall
n	15	15	30
Sick days (baseline) (mean (SD))	0.59 (0.29)	0.44 (0.22)	0.51 (0.26)
Sick days (follow-up) (mean (SD))	0.52 (0.22)	0.48 (0.26)	0.50 (0.24)

Missing data: : %



Linear regression

	p-value
Sick days	0.52578

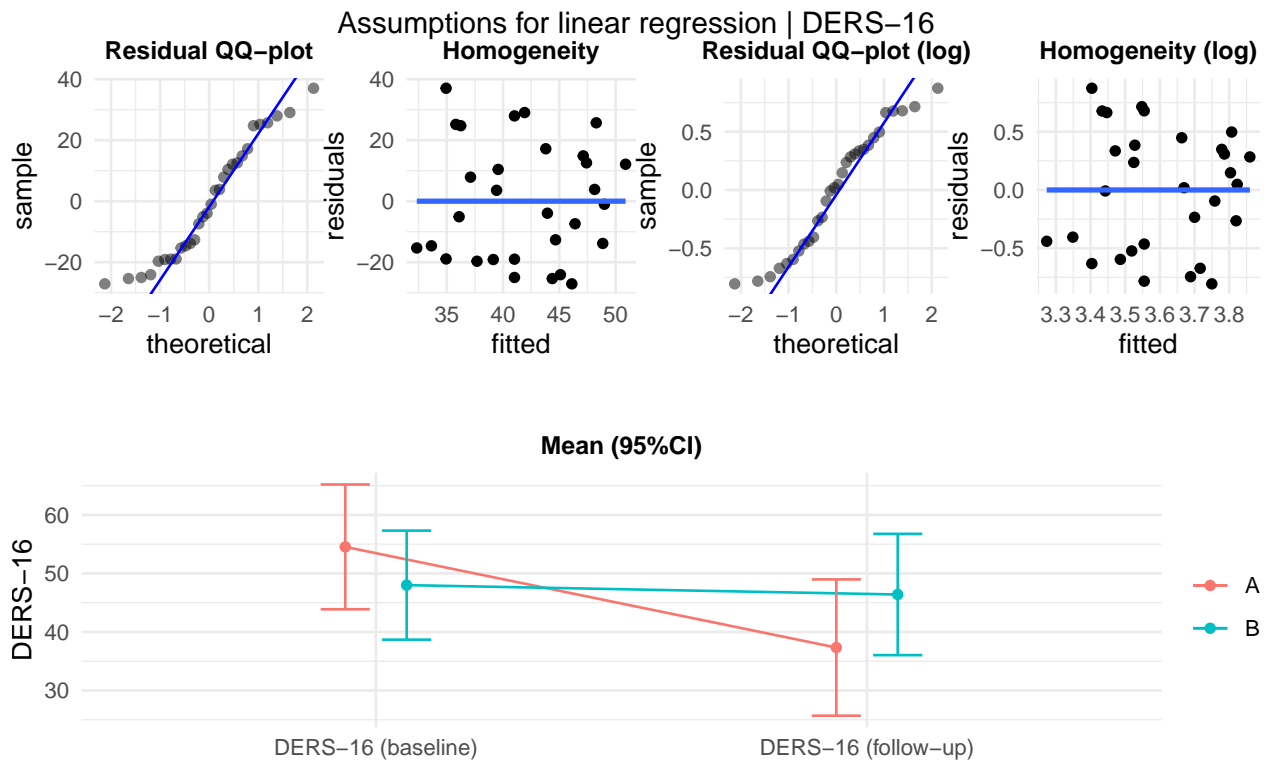
DERS-16 (further)

Data on DERS-16 will be obtained in both groups at baseline and follow-up, and during the intervention for the interventional group. DERS-16 has 16 items which each generates a score from 1 to 5. The results will be presented as one sum-score. The scores in this scale range from 16-80 with higher scores indicating greater emotion regulation difficulties.

Results

Summarised results

	A	B	Overall
n	15	15	30
DERS-16 (baseline) (mean (SD))	54.53 (19.25)	48.00 (16.82)	51.27 (18.07)
DERS-16 (follow-up) (mean (SD))	37.33 (21.02)	46.40 (18.70)	41.87 (20.09)
Missing data: : %			



Linear regression

	p-value
DERS-16	0.19082

BSL-supplement (further)

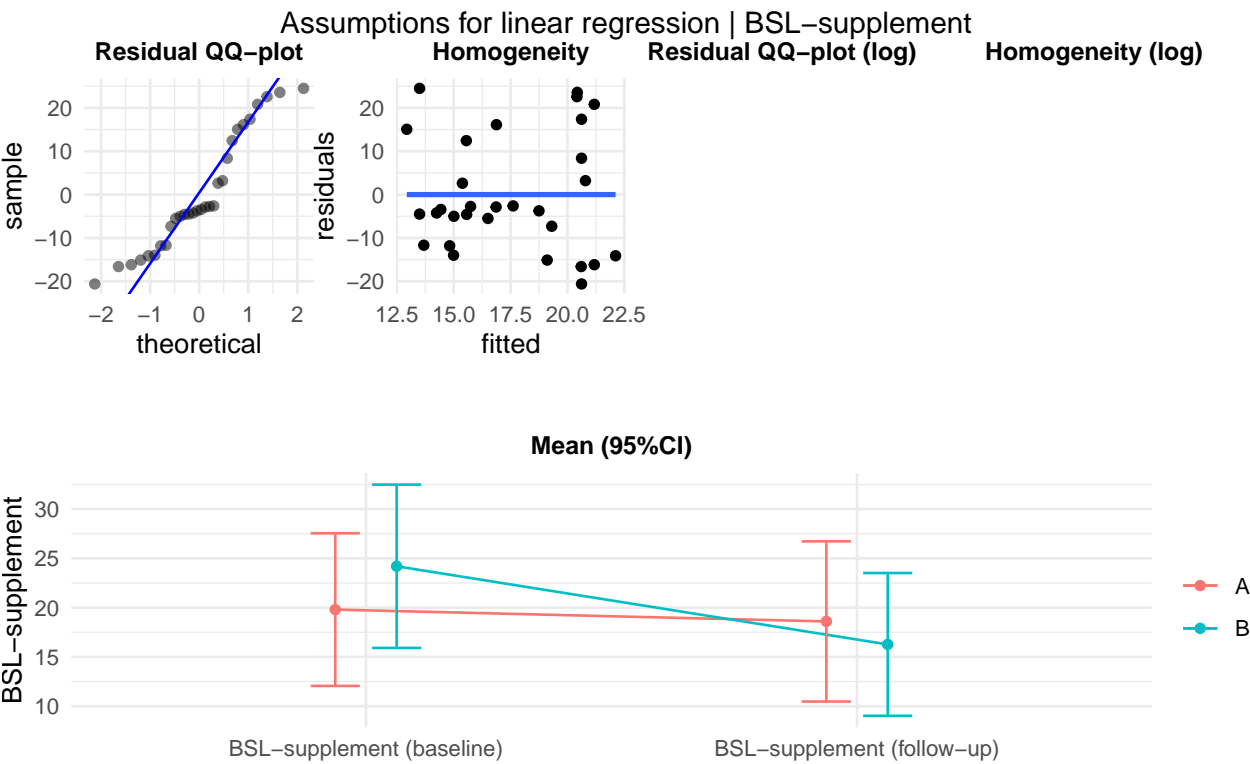
Data on BSL-supplement will be obtained in both groups at baseline and follow-up, and during the intervention for the interventional group. BSL-supplement has 11 items which each generates a score from 0 to 4. The results will be presented as one sum-score.

Results

Summarised results

	A	B	Overall
n	15	15	30
BSL-supplement (baseline) (mean (SD))	19.80 (13.99)	24.20 (14.97)	22.00 (14.41)
BSL-supplement (follow-up) (mean (SD))	18.60 (14.68)	16.27 (13.08)	17.43 (13.72)

Missing data: : %



Linear regression

	p-value
BSL-supplement	0.77085

CCNES-APP (further)

Data on CCNES-APP will be obtained from the participants in both groups only at follow-up. CCNES-APP has 9 main items with 6 sub items (a to f) for each. Each sub item generates a score from 1 to 7. The results will be presented as mean-scores for the following six subscales:

- **Distress reaction** = (I1a + I2d + I3f + I4d + I5a + I6b + I7f + I8a + I9d) / 9
- **Punitive reactions** = (I1e + I2f + I3b + I4c + I5e + I6c + I7b + I8e + I9c) / 9
- **Expressive encouragment** = (I1b + I2c + I3e + I4f + I5b + I6d + I7e + I8b + I9e) / 9
- **Emotion-focused reactions** = (I1c + I2b + I3c + I4a + I5c + I6f + I7d + I8c + I9a) / 9
- **Problem-focused reactions** = (I1f + I2e + I3a + I4b + I5f + I6e + I7a + I8f + I9b) / 9
- **Minimization reactions** = (I1d + I2a + I3d + I4e + I5d + I6a + I7c + I8d + I9f) / 9

I: Items

Results

Summarised results

	A	B	Overall
n	15	15	30
CCNES-APP Distress reaction (follow-up) (mean (SD))	3.39 (1.06)	3.33 (0.77)	3.36 (0.91)
CCNES-APP Punitive reactions (follow-up) (mean (SD))	3.79 (0.85)	4.23 (0.79)	4.01 (0.84)
CCNES-APP Expressive encouragment (follow-up) (mean (SD))	3.67 (1.25)	3.91 (1.08)	3.79 (1.16)
CCNES-APP Emotion-focused reactions (follow-up) (mean (SD))	3.52 (0.90)	3.87 (1.19)	3.69 (1.05)
CCNES-APP Problem-focused reactions (follow-up) (mean (SD))	3.86 (1.28)	3.78 (0.92)	3.82 (1.10)
CCNES-APP Minimization reactions (follow-up) (mean (SD))	3.41 (1.20)	3.56 (0.83)	3.49 (1.02)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Distress reaction	0.3 (-0.4-0.8)	0.3825
Punitive reactions	-0.5 (-1-0.2)	0.2124
Expressive encouragment	-0.2 (-1-0.6)	0.5192
Emotion-focused reactions	-0.3 (-1-0.5)	0.406
Problem-focused reactions	0.2 (-0.9-1.1)	0.7082
Minimization reactions	-0.2 (-0.9-0.6)	0.6629

CCNES-A (further)

Data on CCNES-A will be obtained from the parents in both groups at baseline and follow-up. CCNES-A has 9 main items with 6 sub items (a to f) for each. Each sub item generates a score from 1 to 7. The results will be presented as mean-scores for the following six subscales:

- **Distress reaction** = (I1a + I2d + I3f + I4d + I5a + I6b + I7f + I8a + I9d) / 9
- **Punitive reactions** = (I1e + I2f + I3b + I4c + I5e + I6c + I7b + I8e + I9c) / 9
- **Expressive encouragment** = (I1b + I2c + I3e + I4f + I5b + I6d + I7e + I8b + I9e) / 9
- **Emotion-focused reactions** = (I1c + I2b + I3c + I4a + I5c + I6f + I7d + I8c + I9a) / 9
- **Problem-focused reactions** = (I1f + I2e + I3a + I4b + I5f + I6e + I7a + I8f + I9b) / 9
- **Minimization reactions** = (I1d + I2a + I3d + I4e + I5d + I6a + I7c + I8d + I9f) / 9

I: Items

Results

Summarised results

	A	B	Overall
n	15	15	30
CCNES-A Distress reaction (follow-up) (mean (SD))	3.51 (0.76)	3.21 (1.11)	3.36 (0.94)
CCNES-A Punitive reactions (follow-up) (mean (SD))	3.83 (1.21)	3.35 (0.66)	3.59 (0.99)
CCNES-A Expressive encouragment (follow-up) (mean (SD))	3.56 (1.00)	3.37 (0.74)	3.47 (0.87)
CCNES-A Emotion-focused reactions (follow-up) (mean (SD))	3.67 (0.92)	4.07 (1.01)	3.87 (0.97)
CCNES-A Problem-focused reactions (follow-up) (mean (SD))	3.73 (0.81)	3.55 (0.91)	3.64 (0.85)
CCNES-A Minimization reactions (follow-up) (mean (SD))	3.87 (0.96)	3.51 (1.09)	3.69 (1.03)
Missing data: : %			

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Distress reaction	0.3 (-0.4-1.1)	0.2895
Punitive reactions	0.5 (-0.2-1.2)	0.1643
Expressive encouragment	0.1 (-0.4-0.7)	0.7553
Emotion-focused reactions	-0.4 (-1.2-0.3)	0.2284
Problem-focused reactions	0.2 (-0.5-0.9)	0.575
Minimization reactions	0.3 (-0.5-1.1)	0.2984

NEQ (further)

Data on NEQ will be obtained in both groups only at follow-up. NEQ has 20 items, with 5 sub-items The results will be presented as means and standard deviations:

- **Frequency negative effects** = I1a + I2a + I3a + I4a + I5a + I6a + I7a + I8a + I9a + I10a + I11a + I12a + I13a + I14a + I15a + I16a + I17a + I18a + I19a + I20a (*Score from 0 to 1*)
- **Frequency negative effects from treatment** = I1c + I2c + I3c + I4c + I5c + I6c + I7c + I8c + I9c + I10c + I11c + I12c + I13c + I14c + I15c + I16c + I17c + I18c + I19c + I20c (*Score from 0 to 1*)
- **Frequency negative effects from other circumstances** = Frequency negative effects - Frequency negative effects from treatment
- **Frequency Factor 1 (Symptoms) from treatment** = I1c + I2c + I3c + I4c + I6c + I7c + I8c + I10c (*Score from 0 to 1*)
- **Frequency Factor 2 (Quality) from treatment** = I15c + I16c + I17c + I18c + I19c + I20c (*Score from 0 to 1*)
- **Frequency Factor 3 (Dependency) from treatment** = I14c (*Score from 0 to 1*)
- **Frequency Factor 4 (Stigma) from treatment** = I9c + I11c (*Score from 0 to 1*)
- **Frequency Factor 5 (Hopelessness) from treatment** = I5c + I12c + I13c (*Score from 0 to 1*)
- **Negative impact from treatment** = I1d + I2d + I3d + I4d + I5d + I6d + I7d + I8d + I9d + I10d + I11d + I12d + I13d + I14d + I15d + I16d + I17d + I18d + I19d + I20d (*Score from 0 to 4*)
- **Negative impact Factor 1 (Symptoms) from treatment** = I1d + I2d + I3d + I4d + I6d + I7d + I8d + I10d (*Score from 0 to 4*)
- **Negative impact Factor 2 (Quality) from treatment** = I15d + I16d + I17d + I18d + I19d + I20d (*Score from 0 to 4*)
- **Negative impact Factor 3 (Dependency) from treatment** = I14d (*Score from 0 to 4*)
- **Negative impact Factor 4 (Stigma) from treatment** = I9d + I11d (*Score from 0 to 4*)
- **Negative impact Factor 5 (Hopelessness) from treatment** = I5d + I12d + I13d (*Score from 0 to 4*)

Summarised results

	A	B	Overall
n	15	15	30
NEQ Freq. negative effects (mean (SD))	10.40 (6.00)	9.67 (6.88)	10.03 (6.35)
NEQ Freq. negative effects from treatment (mean (SD))	12.13 (6.13)	11.60 (5.22)	11.87 (5.60)
NEQ Freq. negative effects from other circumstances (mean (SD))	-1.73 (7.72)	-1.93 (8.08)	-1.83 (7.77)
NEQ Freq. Fac. 1 (Symptoms) from treatment (mean (SD))	3.13 (2.42)	4.33 (2.44)	3.73 (2.46)
NEQ Freq. Fac. 2 (Quality) from treatment (mean (SD))	3.40 (1.92)	2.93 (2.12)	3.17 (2.00)
NEQ Freq. Fac. 3 (Dependency) from treatment (mean (SD))	0.60 (0.51)	0.60 (0.51)	0.60 (0.50)
NEQ Freq. Fac. 4 (Stigma) from treatment (mean (SD))	0.87 (0.74)	1.47 (0.74)	1.17 (0.79)
NEQ Freq. Fac. 5 (Hopelessness) from treatment (mean (SD))	1.20 (1.21)	1.87 (1.25)	1.53 (1.25)

Missing data: : %

Summarised results

	A	B	Overall
NEQ Neg. impact from treatment (mean (SD))	36.53 (25.82)	45.87 (28.82)	41.20 (27.30)
NEQ Neg. impact Fac. 1 (Symptoms) from treatment (mean (SD))	10.07 (8.37)	13.27 (8.27)	11.67 (8.33)
NEQ Neg. impact Fac. 2 (Quality) from treatment (mean (SD))	12.40 (7.35)	10.80 (5.17)	11.60 (6.30)
NEQ Neg. impact Fac. 3 (Dependency) from treatment (mean (SD))	2.73 (1.16)	2.20 (1.57)	2.47 (1.38)
NEQ Neg. impact Fac. 4 (Stigma) from treatment (mean (SD))	5.07 (2.49)	3.67 (2.77)	4.37 (2.68)
NEQ Neg. impact Fac. 5 (Hopelessness) from treatment (mean (SD))	6.27 (3.69)	7.00 (3.68)	6.63 (3.64)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
NEQ Freq. negative effects	1 (-4-6)	0.7711
NEQ Freq. negative effects from treatment	1 (-4-5)	0.7552
NEQ Freq. negative effects from other circumstances	1 (-6-7)	0.7085
NEQ Freq. Fac. 1 (Symptoms) from treatment	-1 (-3-1)	0.1944
NEQ Freq. Fac. 2 (Quality) from treatment	0 (-1-2)	0.598
NEQ Freq. Fac. 3 (Dependency) from treatment	0 (0-0)	1
NEQ Freq. Fac. 4 (Stigma) from treatment	-1 (-1-0)	0.0333
NEQ Freq. Fac. 5 (Hopelessness) from treatment	-1 (-2-0)	0.1366
NEQ Neg. impact from treatment	-8 (-34-7)	0.1836
NEQ Neg. impact Fac. 1 (Symptoms) from treatment	-3 (-10-3)	0.2797
NEQ Neg. impact Fac. 2 (Quality) from treatment	2 (-3-7)	0.4294
NEQ Neg. impact Fac. 3 (Dependency) from treatment	0 (0-2)	0.3452
NEQ Neg. impact Fac. 4 (Stigma) from treatment	2 (0-4)	0.1715
NEQ Neg. impact Fac. 5 (Hopelessness) from treatment	-1 (-3-2)	0.6617

WAI-SR (further)

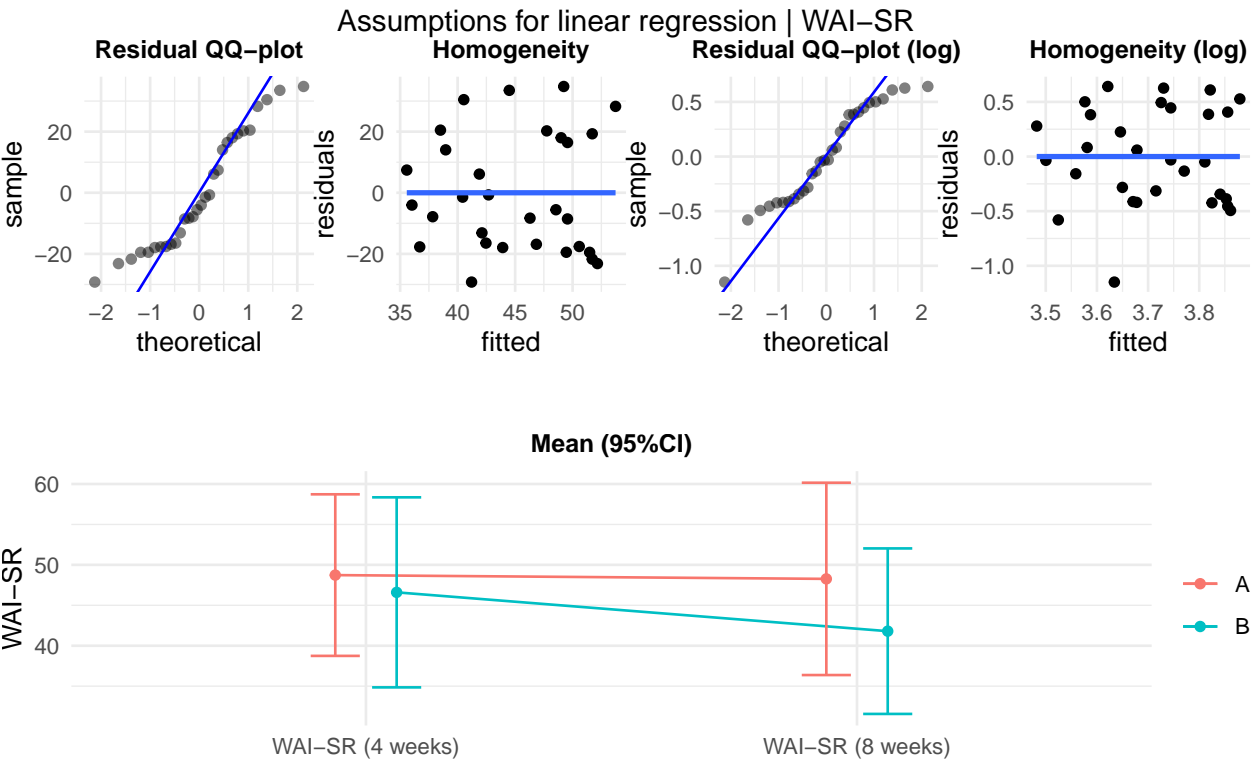
Data on WAI-SR will be obtained in both groups at 4 and 8 weeks. WAI-SR has 12 items which each generates a score from 1 to 7. The results will be presented as one sum-score.

Results

Summarised results

	A	B	Overall
n	15	15	30
WAI-SR (4 weeks) (mean (SD))	48.73 (18.04)	46.60 (21.22)	47.67 (19.38)
WAI-SR (8 weeks) (mean (SD))	48.27 (21.48)	41.80 (18.48)	45.03 (19.96)

Missing data: : %



Linear regression

	p-value
WAI-SR	0.41792

SDQ (further)

Data on SDQ will be obtained in both groups only at baseline. SDQ has 30 items where the first 25 will be included in the analyses. Each of these items generates a score from 0 to 2. The results will be presented as sum-scores for the 7 subscales, and a total sum-score:

- **Prosocial** = I1 + I4 + I9 + I17 + I20
- **Emotion** = I3 + I8 + I13 + I16 + I24
- **ADHD** = I2 + I10 + I15 + (2 - I21) + (2 - I25)
- **CD** = I5 + (2 - I7) + I12 + I18 + I22
- **Companion** = I6 + (2 - I11) + (2 - I14) + I19 + I23
- **Externalising** = CD + ADHD
- **Internalising** = Emotion + Companion
- **Sum** = Emotion + ADHD + Companion + CD

I: Items

Results

Summarised results

	A	B	Overall
n	15	15	30
SDQ Prosocial (baseline) (mean (SD))	4.13 (2.97)	5.00 (2.80)	4.57 (2.87)
SDQ Emotion (baseline) (mean (SD))	4.60 (2.61)	4.87 (3.09)	4.73 (2.82)
SDQ ADHD (baseline) (mean (SD))	4.47 (3.25)	4.87 (3.62)	4.67 (3.39)
SDQ CD (baseline) (mean (SD))	5.73 (3.45)	5.47 (4.02)	5.60 (3.68)
SDQ Companion (baseline) (mean (SD))	5.27 (3.10)	6.07 (2.96)	5.67 (3.01)
SDQ Externalising (baseline) (mean (SD))	10.20 (5.10)	10.33 (5.86)	10.27 (5.40)
SDQ Internalising (baseline) (mean (SD))	9.87 (3.91)	10.93 (4.93)	10.40 (4.41)
SDQ Sum (baseline) (mean (SD))	20.07 (4.62)	21.27 (9.15)	20.67 (7.15)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Prosocial	-1 (-3-1)	0.3662
Emotion	0 (-3-2)	0.7066
ADHD	0 (-3-2)	0.7854
CD	0 (-3-3)	0.8834
Companion	-1 (-3-2)	0.4145
Externalising	-1 (-5-4)	0.803
Internalising	-1 (-5-2)	0.5057

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Sum	-3 (-9-3)	0.406

ECR-RC (further)

Data on ECR-RC short version will be obtained in both groups only at baseline. ECR-RC has 12 items which each generates a score from 1 to 7. The results will be presented as sum-score for the following two subscales:

- **Anxiety items** = (I1 + I2 + I3 + I4 + I5 + I6) / 6
- **Avoidance items** = (I7 + I8 + I9 + (8 - I10) + (8 - I11) + (8 - I12)) / 6

I: Items

Results

Summarised results

	A	B	Overall
n	15	15	30
ECR-RC Anxiety (baseline) (mean (SD))	3.43 (0.75)	2.90 (1.04)	3.16 (0.93)
ECR-RC Avoidance (baseline) (mean (SD))	3.56 (1.01)	3.57 (1.32)	3.57 (1.16)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Anxiety items	0.6 (-0.1-1.2)	0.0884
Avoidance items	0 (-0.9-0.8)	0.9503