

Statistical report for TEENS feasibility trial

Using simulated data

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Baseline characteristics

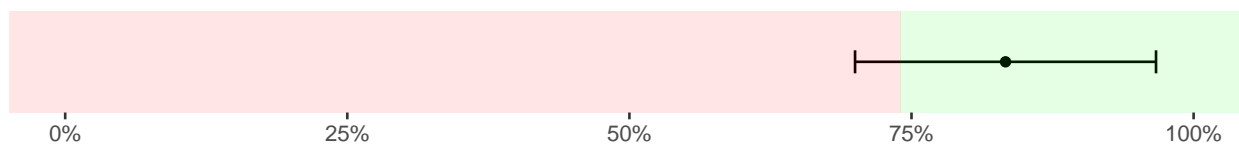
Baseline characteristics

	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/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 (%)			
Divorced	6 (40.0)	6 (40.0)	12 (40.0)
Married	4 (26.7)	5 (33.3)	9 (30.0)
Other	5 (33.3)	4 (26.7)	9 (30.0)

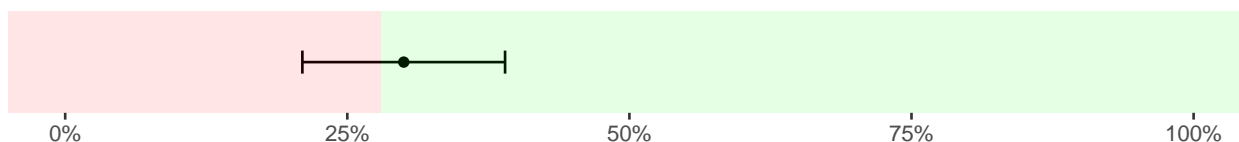
Missing data: Age: 3.3 %

Feasibility outcomes

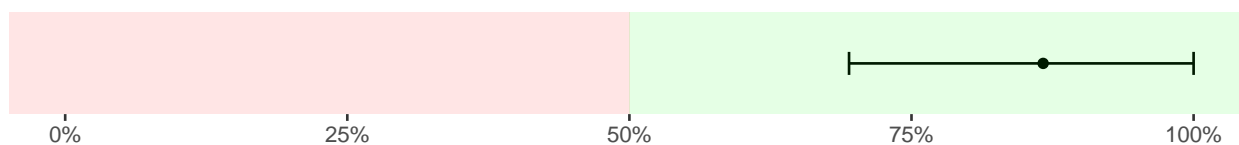
A) Completion of follow-up



B) Eligible participants who consent to inclusion and randomization



C) Compliance



Outcome	Requirement	Fraction	LCL	UCL
A) Completion of follow-up	75%	83%	70%	97%
B) Eligible participants who consent to inclusion and randomization	29%	30%	21%	39%
C) Compliance	51%	87%	69%	100%

Exploratory clinical outcomes

DSHI-Y (primary)

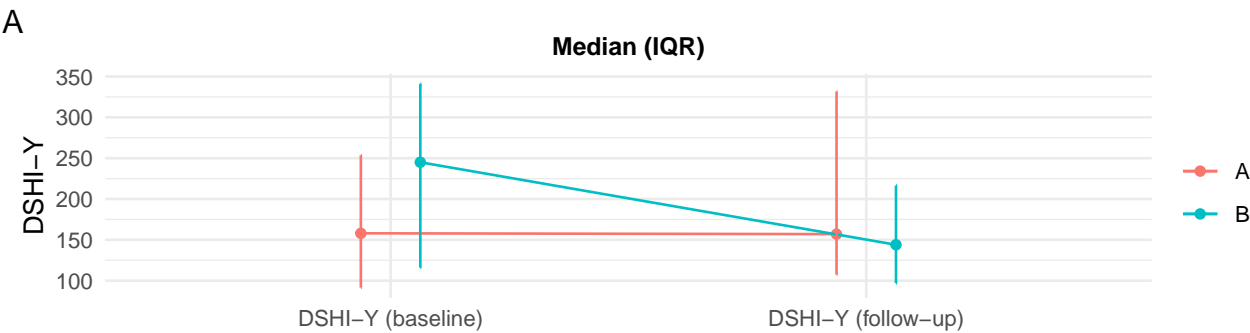
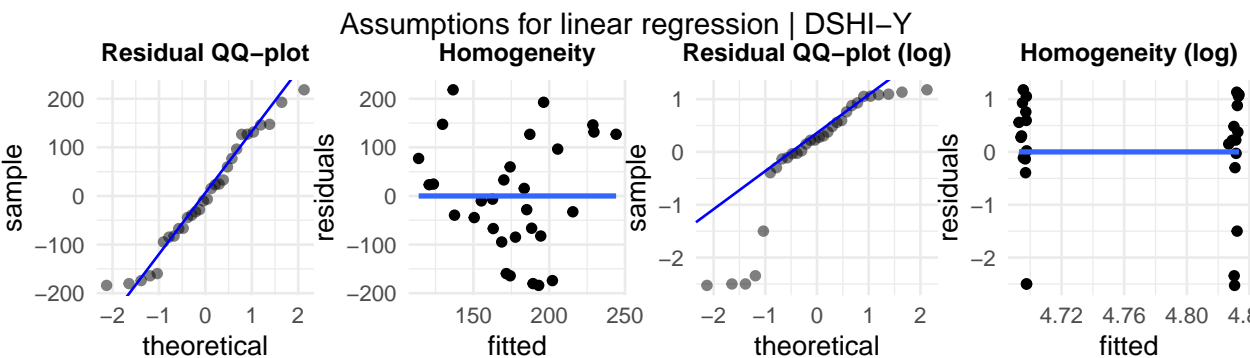
Data on non-suicidal self-injury (NSSI) as measured by DSHI-Y will be obtained in both groups at baseline and follow-up, and during the intervention for the interventional group. DSHI-Y reflects the number of NSSI events in the past month. The results will be presented as one sum score.

Results

Summarised results

	A	B	Overall
n	15	15	30
DSHI-Y (baseline) (mean (SD))	181.27 (114.99)	222.00 (124.46)	201.63 (119.54)
DSHI-Y (follow-up) (mean (SD))	193.80 (135.49)	157.73 (103.46)	175.77 (119.86)

Missing data: : %



Linear regression

	p-value
DSHI-Y	0.31309

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:

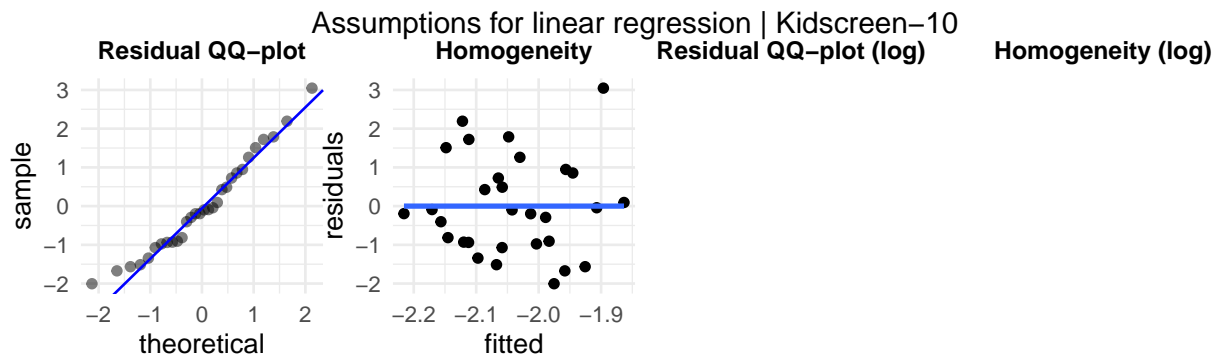
- General HRQoL index** = RASCH PP
- General HRQoL index European T-values** = (((RASCH PP - 1.2078) / 1.03377) * 10 + 50)

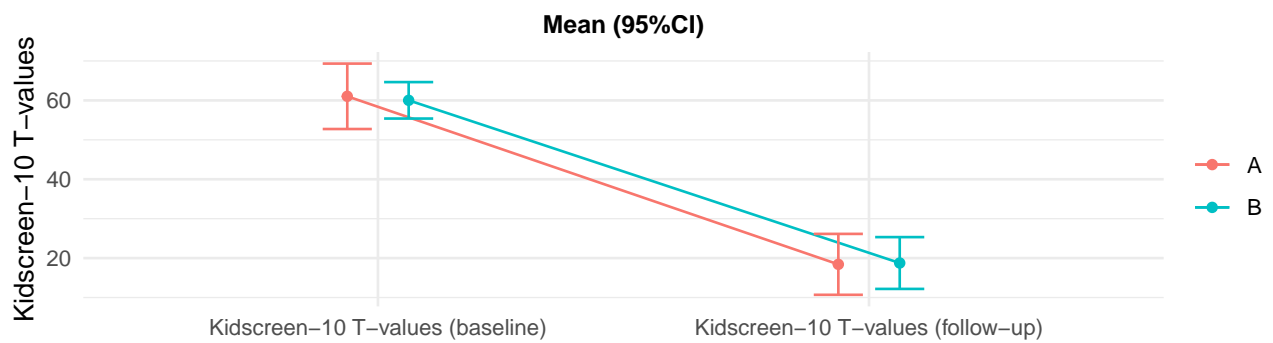
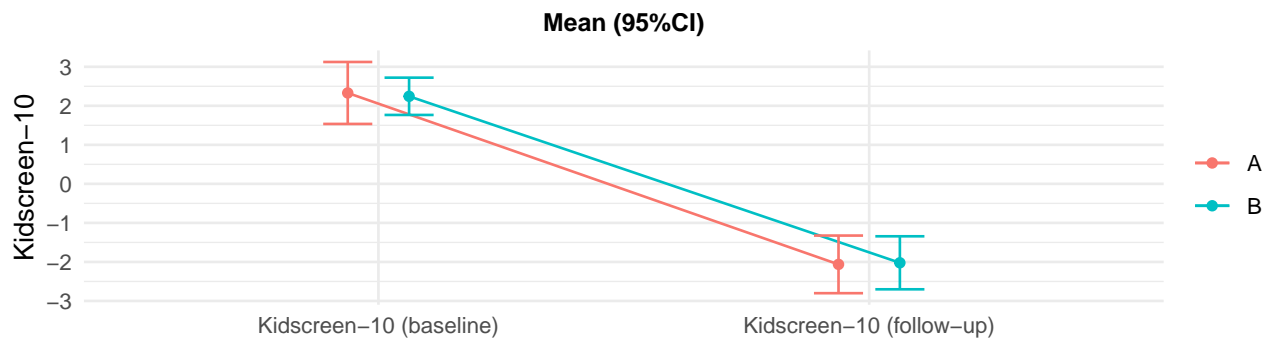
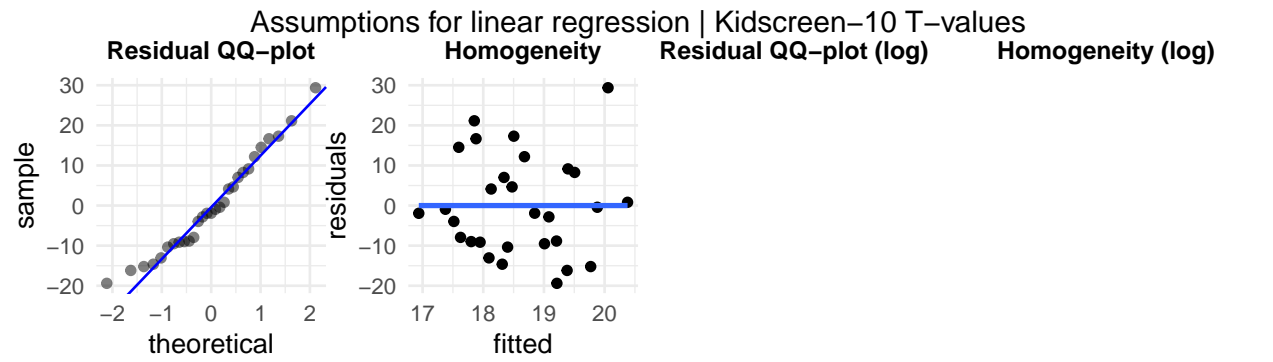
Results

Summarised results

	A	B	Overall
n	15	15	30
Kidscreen-10 (baseline) (mean (SD))	2.33 (1.43)	2.24 (0.86)	2.29 (1.16)
Kidscreen-10 (follow-up) (mean (SD))	-2.06 (1.33)	-2.02 (1.23)	-2.04 (1.26)
Kidscreen-10 T-values (baseline) (mean (SD))	61.04 (14.37)	60.02 (8.35)	60.51 (11.44)
Kidscreen-10 T-values (follow-up) (mean (SD))	18.42 (13.38)	18.76 (11.87)	18.59 (12.39)

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





Linear regression

	p-value
Kidscreen-10	0.94316
Kidscreen-10 T-values	0.95648

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

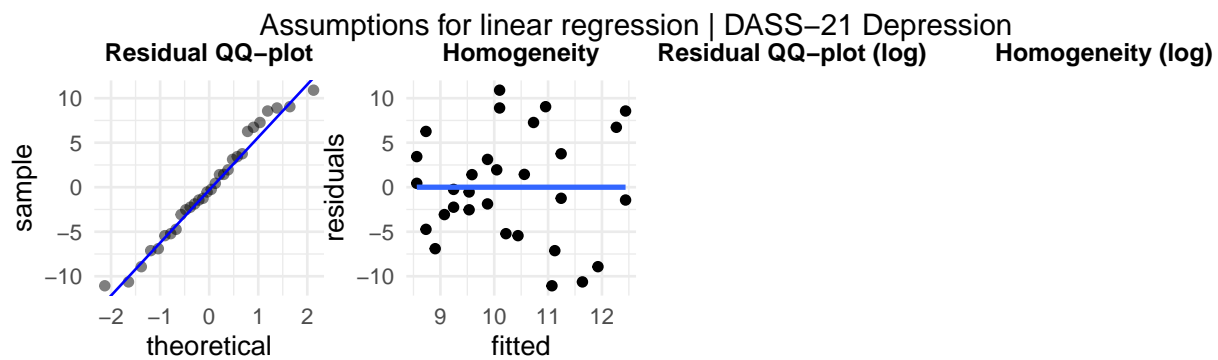
I: Items

Results

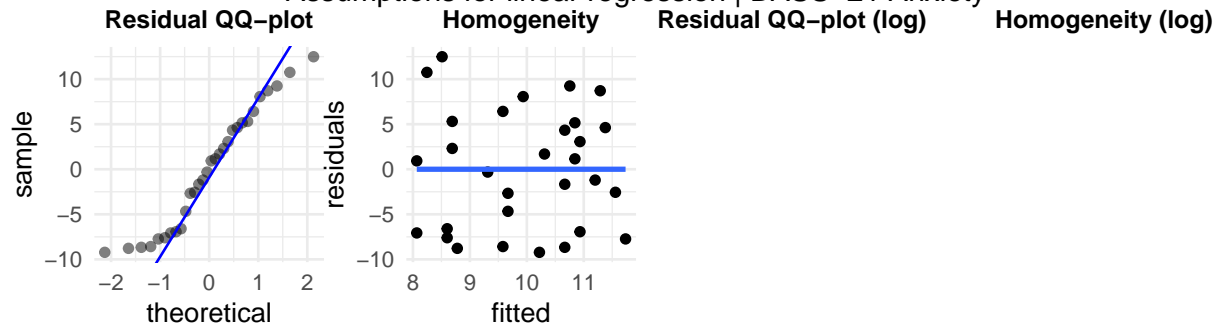
Summarised results

	A	B	Overall
n	15	15	30
DASS-21 Depression (baseline) (mean (SD))	11.53 (5.88)	10.20 (6.07)	10.87 (5.91)
DASS-21 Anxiety (baseline) (mean (SD))	9.73 (7.10)	11.00 (4.83)	10.37 (6.00)
DASS-21 Stress (baseline) (mean (SD))	9.87 (5.96)	12.40 (6.68)	11.13 (6.36)
DASS-21 Depression (follow-up) (mean (SD))	9.67 (6.54)	10.87 (5.89)	10.27 (6.15)
DASS-21 Anxiety (follow-up) (mean (SD))	8.93 (7.29)	10.93 (6.13)	9.93 (6.70)
DASS-21 Stress (follow-up) (mean (SD))	9.33 (6.52)	8.73 (7.68)	9.03 (7.00)

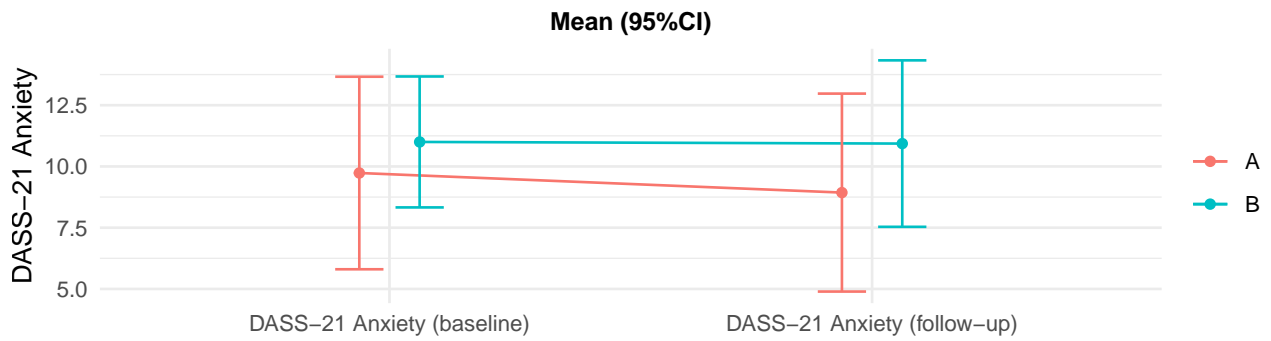
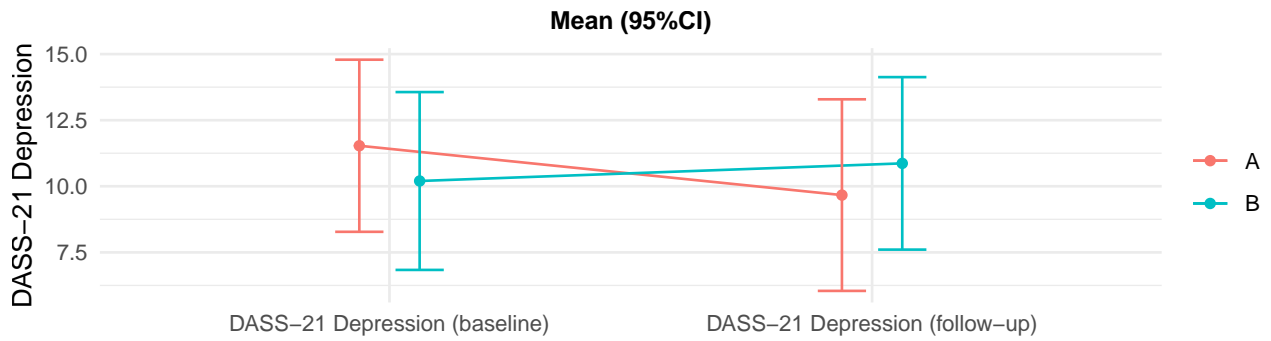
Missing data: : %

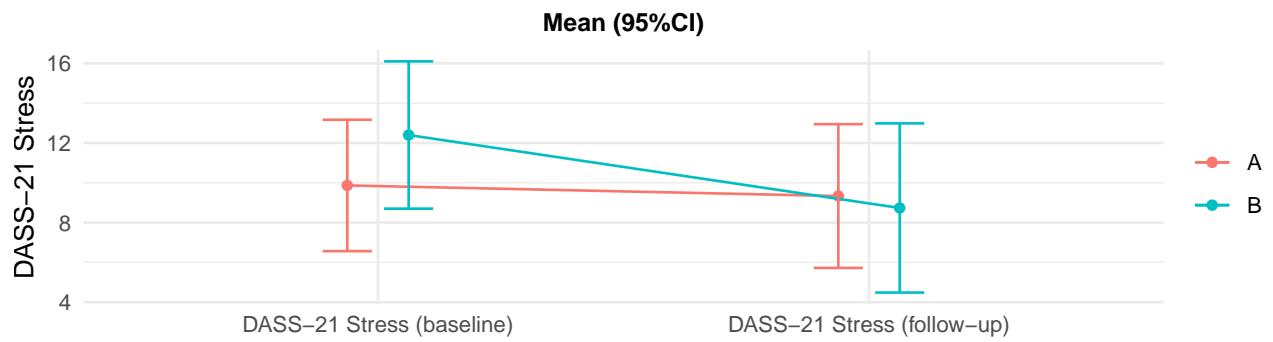


Assumptions for linear regression | DASS-21 Anxiety



Assumptions for linear regression | DASS-21 Stress





Linear regression

	p-value
DASS-21 Depression	0.67571
DASS-21 Anxiety	0.45908
DASS-21 Stress	0.60251

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 (%)	7 (46.7)	10 (66.7)	17 (56.7)
Missing data: : %			

var		R	lcl	ucl	p
Self-injury	OR	2.29	0.53	10.61	0.273
Self-injury	RR	1.43	0.75	2.73	

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

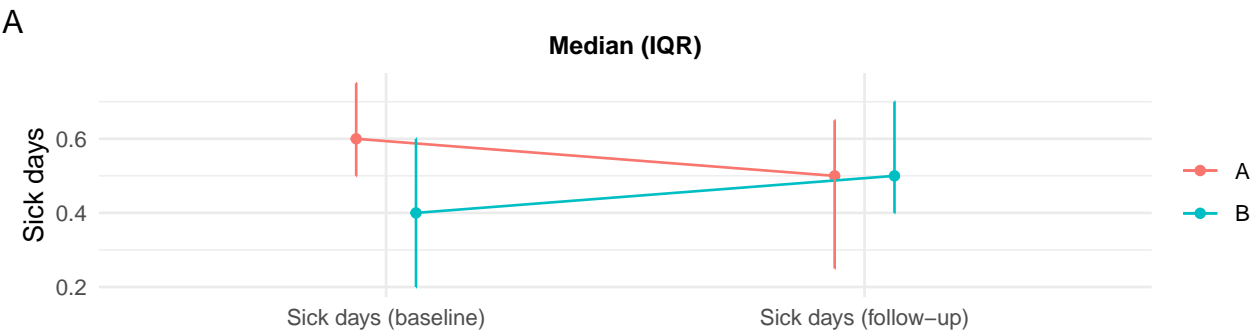
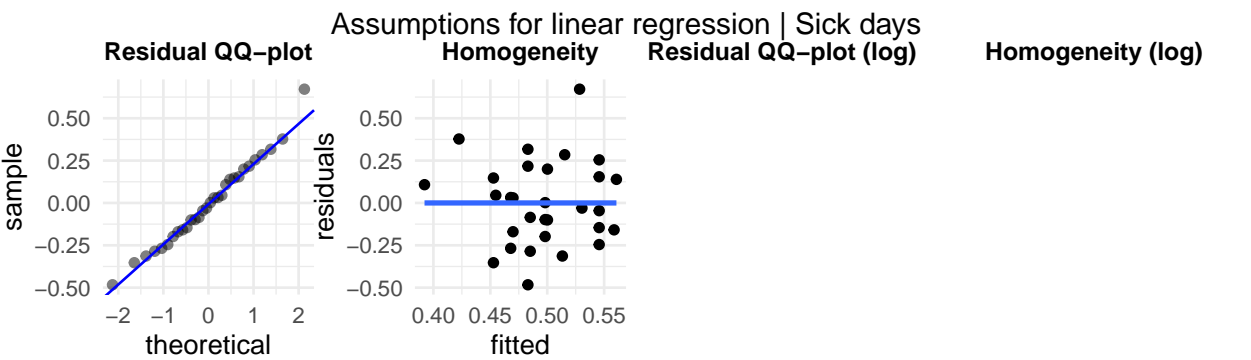
Sick days (secondary)

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))	0.62 (0.27)	0.41 (0.23)	0.52 (0.27)
Sick days (follow-up) (mean (SD))	0.48 (0.31)	0.51 (0.19)	0.50 (0.25)

Missing data: : %



Linear regression

	p-value
Sick days	0.98433

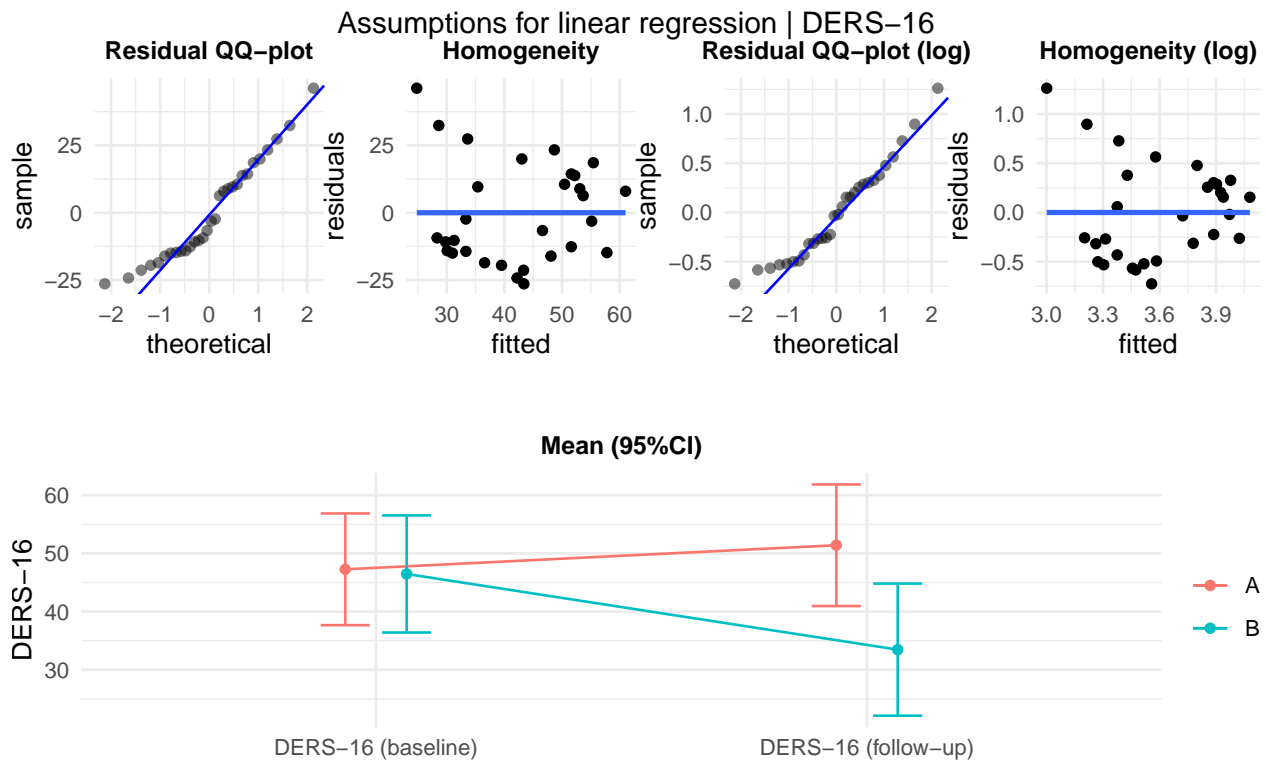
DERS-16 (further)

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))	47.27 (17.33)	46.47 (18.16)	46.87 (17.45)
DERS-16 (follow-up) (mean (SD))	51.40 (18.86)	33.47 (20.50)	42.43 (21.39)
Missing data: : %			



Linear regression

	p-value
DERS-16	0.01856

BSL-supplement (further)

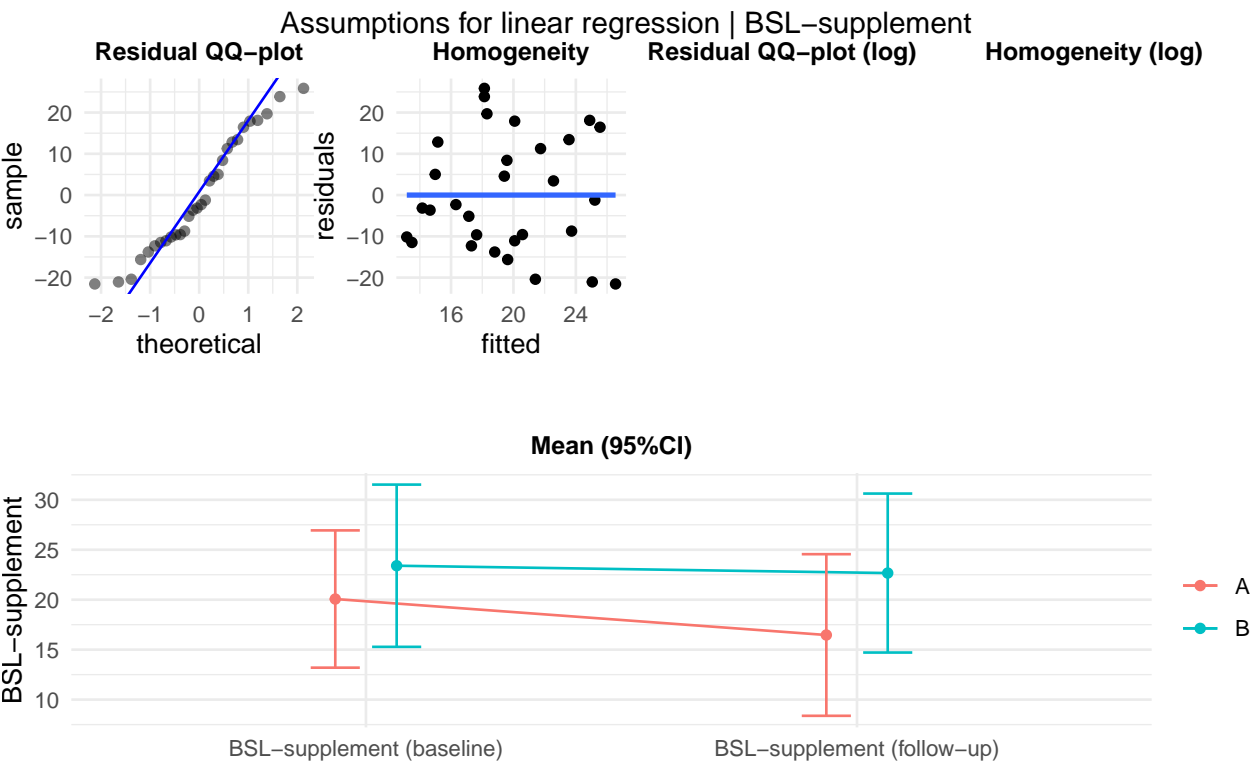
Data on BSL-supplement will be obtained in both groups at baseline and follow-up, and during the intervention for the interventional group. BSL-supplement has 11 items which each generates a score from 0 to 4. The results will be presented as one sum-score.

Results

Summarised results

	A	B	Overall
n	15	15	30
BSL-supplement (baseline) (mean (SD))	20.07 (12.41)	23.40 (14.66)	21.73 (13.45)
BSL-supplement (follow-up) (mean (SD))	16.47 (14.60)	22.67 (14.37)	19.57 (14.58)

Missing data: : %



Linear regression

	p-value
BSL-supplement	0.21881

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))	3.54 (1.17)	3.26 (1.13)	3.40 (1.14)
CCNES-APP Punitive reactions (follow-up) (mean (SD))	2.99 (0.92)	3.45 (1.21)	3.22 (1.08)
CCNES-APP Expressive encouragment (follow-up) (mean (SD))	3.27 (1.51)	3.36 (1.34)	3.31 (1.40)
CCNES-APP Emotion-focused reactions (follow-up) (mean (SD))	3.25 (0.89)	3.31 (0.91)	3.28 (0.88)
CCNES-APP Problem-focused reactions (follow-up) (mean (SD))	2.61 (1.26)	3.30 (0.94)	2.96 (1.15)
CCNES-APP Minimization reactions (follow-up) (mean (SD))	3.36 (1.20)	3.81 (1.01)	3.58 (1.11)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Distress reaction	0.2 (-0.7-1.1)	0.6479
Punitive reactions	-0.4 (-1.2-0.3)	0.3495
Expressive encouragment	-0.1 (-1.3-1.1)	0.9009
Emotion-focused reactions	-0.2 (-0.8-0.6)	0.6037
Problem-focused reactions	-0.7 (-1.5-0.2)	0.135
Minimization reactions	-0.5 (-1.4-0.4)	0.2713

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))	3.91 (0.65)	3.37 (0.92)	3.64 (0.83)
CCNES-A Punitive reactions (follow-up) (mean (SD))	3.16 (0.89)	2.77 (1.07)	2.97 (0.99)
CCNES-A Expressive encouragment (follow-up) (mean (SD))	3.31 (0.71)	3.27 (1.00)	3.29 (0.86)
CCNES-A Emotion-focused reactions (follow-up) (mean (SD))	3.43 (1.13)	3.97 (1.07)	3.70 (1.12)
CCNES-A Problem-focused reactions (follow-up) (mean (SD))	3.14 (1.23)	3.53 (1.22)	3.34 (1.22)
CCNES-A Minimization reactions (follow-up) (mean (SD))	3.54 (0.96)	3.81 (0.70)	3.68 (0.84)
Missing data: : %			

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Distress reaction	0.6 (0-1.2)	0.0483
Punitive reactions	0.5 (-0.2-1.1)	0.146
Expressive encouragment	0.1 (-0.4-0.7)	0.6466
Emotion-focused reactions	-0.4 (-1.5-0.3)	0.2049
Problem-focused reactions	-0.7 (-1.2-0.3)	0.1188
Minimization reactions	-0.4 (-1-0.4)	0.228

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))	10.07 (6.51)	11.07 (6.33)	10.57 (6.33)
NEQ Freq. negative effects from treatment (mean (SD))	11.27 (6.37)	10.67 (5.90)	10.97 (6.04)
NEQ Freq. negative effects from other circumstances (mean (SD))	-1.20 (9.05)	0.40 (8.30)	-0.40 (8.57)
NEQ Freq. Fac. 1 (Symptoms) from treatment (mean (SD))	3.40 (2.85)	3.07 (1.44)	3.23 (2.22)
NEQ Freq. Fac. 2 (Quality) from treatment (mean (SD))	1.93 (2.09)	3.00 (1.81)	2.47 (2.00)
NEQ Freq. Fac. 3 (Dependency) from treatment (mean (SD))	0.40 (0.51)	0.60 (0.51)	0.50 (0.51)
NEQ Freq. Fac. 4 (Stigma) from treatment (mean (SD))	0.87 (0.92)	0.93 (0.70)	0.90 (0.80)
NEQ Freq. Fac. 5 (Hopelessness) from treatment (mean (SD))	1.60 (1.24)	1.47 (1.19)	1.53 (1.20)

Missing data: : %

Summarised results

	A	B	Overall
NEQ Neg. impact from treatment (mean (SD))	50.27 (29.80)	52.93 (24.27)	51.60 (26.74)
NEQ Neg. impact Fac. 1 (Symptoms) from treatment (mean (SD))	8.53 (5.87)	15.13 (9.72)	11.83 (8.57)
NEQ Neg. impact Fac. 2 (Quality) from treatment (mean (SD))	12.67 (6.88)	11.13 (7.06)	11.90 (6.90)
NEQ Neg. impact Fac. 3 (Dependency) from treatment (mean (SD))	2.00 (1.56)	2.60 (1.35)	2.30 (1.47)
NEQ Neg. impact Fac. 4 (Stigma) from treatment (mean (SD))	3.73 (3.01)	4.47 (2.77)	4.10 (2.87)
NEQ Neg. impact Fac. 5 (Hopelessness) from treatment (mean (SD))	6.60 (4.22)	6.73 (3.56)	6.67 (3.84)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
NEQ Freq. negative effects	-2 (-6-4)	0.6927
NEQ Freq. negative effects from treatment	1 (-4-6)	0.7393
NEQ Freq. negative effects from other circumstances	-2 (-9-5)	0.5063
NEQ Freq. Fac. 1 (Symptoms) from treatment	0 (-2-2)	0.9832
NEQ Freq. Fac. 2 (Quality) from treatment	-1 (-3-0)	0.1033
NEQ Freq. Fac. 3 (Dependency) from treatment	0 (-1-0)	0.2815
NEQ Freq. Fac. 4 (Stigma) from treatment	0 (-1-1)	0.7574
NEQ Freq. Fac. 5 (Hopelessness) from treatment	0 (-1-1)	0.7639
NEQ Neg. impact from treatment	2 (-24-15)	0.8516
NEQ Neg. impact Fac. 1 (Symptoms) from treatment	-6 (-14-1)	0.0707
NEQ Neg. impact Fac. 2 (Quality) from treatment	1 (-4-7)	0.5191
NEQ Neg. impact Fac. 3 (Dependency) from treatment	-1 (-2-0)	0.2415
NEQ Neg. impact Fac. 4 (Stigma) from treatment	-1 (-3-1)	0.4882
NEQ Neg. impact Fac. 5 (Hopelessness) from treatment	0 (-3-3)	0.9834

WAI-SR (further)

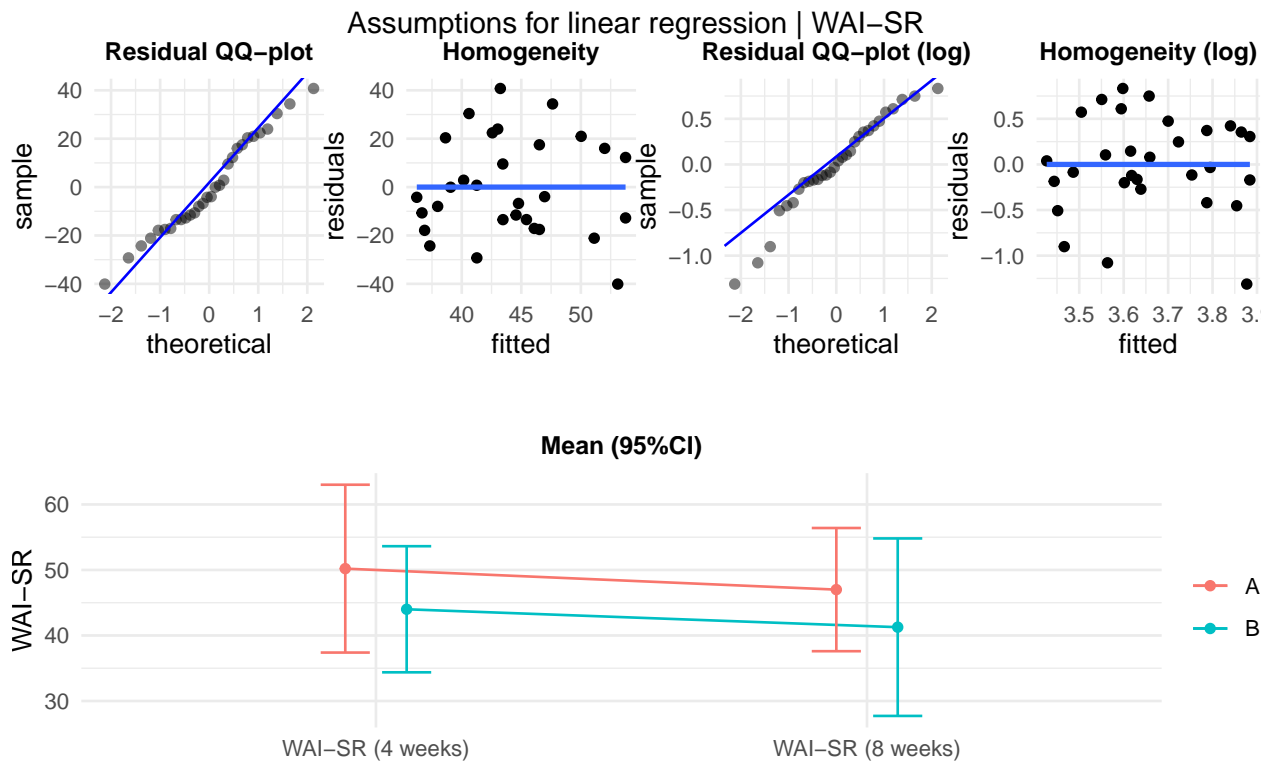
Data on WAI-SR will be obtained in both groups at 4 and 8 weeks. WAI-SR has 12 items which each generates a score from 1 to 7. The results will be presented as one sum-score.

Results

Summarised results

	A	B	Overall
n	15	15	30
WAI-SR (4 weeks) (mean (SD))	50.20 (23.13)	44.00 (17.38)	47.10 (20.35)
WAI-SR (8 weeks) (mean (SD))	47.00 (16.97)	41.27 (24.46)	44.13 (20.89)

Missing data: : %



Linear regression

	p-value
WAI-SR	0.57676

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))	6.27 (2.58)	3.53 (2.61)	4.90 (2.90)
SDQ Emotion (baseline) (mean (SD))	5.00 (2.73)	3.93 (2.76)	4.47 (2.75)
SDQ ADHD (baseline) (mean (SD))	5.93 (3.49)	5.33 (3.89)	5.63 (3.64)
SDQ CD (baseline) (mean (SD))	4.53 (3.80)	4.80 (3.19)	4.67 (3.45)
SDQ Companion (baseline) (mean (SD))	5.40 (2.87)	6.40 (2.75)	5.90 (2.81)
SDQ Externalising (baseline) (mean (SD))	10.47 (5.17)	10.13 (5.67)	10.30 (5.33)
SDQ Internalising (baseline) (mean (SD))	10.40 (4.58)	10.33 (4.10)	10.37 (4.27)
SDQ Sum (baseline) (mean (SD))	20.87 (7.78)	20.47 (6.66)	20.67 (7.12)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Prosocial	3 (1-4)	0.0132
Emotion	1 (-1-3)	0.3575
ADHD	0 (-2-4)	0.8015
CD	0 (-3-3)	0.8023
Companion	-1 (-3-1)	0.3578
Externalising	1 (-4-5)	0.7081
Internalising	1 (-3-3)	0.9171

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Sum	1 (-4-6)	0.7553

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))	3.97 (1.27)	3.60 (0.90)	3.79 (1.10)
ECR-RC Avoidance (baseline) (mean (SD))	3.27 (1.18)	3.31 (0.89)	3.29 (1.03)

Missing data: : %

Mann-Whitney U test

	Estimate (95% Confidence interval)	p-value
Anxiety items	0.4 (-0.4-1.2)	0.2533
Avoidance items	0 (-0.7-0.8)	0.9503