

## SnoreFree - Rhonchopathie & UARS Pilotstudie - Ergebnisbericht Update

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27.03.2024

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## 1. Statistische Einordnung der primären Ergebnisse | Statistical evaluation of the primary results

### 1.1 Deutschsprachige Verschriftlichung

Die nachfolgenden Analysen beziehen sich auf den Plan zur Systematischen Nutzerdatenauswertung Version 1.0 vom 28.12.2022 und den Nachforderungen des BfArM vom 02.02.2024. Der Vergleich der Interventionsgruppe mit der Kontrollgruppe zeigt keine auffälligen Gruppenunterschiede.

Dementsprechend war die Randomisierung bezogen auf die definierten Randomisierungs-Strata erfolgreich.

Die im Plan zur Systematischen Nutzerdatenauswertung unter 7.3 definierten Primäranalysen, werden im Kapitel 3 dieses Dokumentes angeführt. Die ITT-Analyse für den ESS mit Reference Based Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ( $p < 0,001$ ) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -3,324 in der Interventionsgruppe und -0,889 in der Kontrollgruppe.

Die ITT-Analyse für den ESS mit Normal Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ( $p = 0,004$ ) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -3,464 in der Interventionsgruppe und -0,846 in der Kontrollgruppe.

Die ITT-Analyse für den PSQI mit Reference Based Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ( $p < 0,001$ ) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -1,93 in der Interventionsgruppe und -0,23 in der Kontrollgruppe.

Die ITT-Analyse für den PSQI mit Normal Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ( $p = 0,005$ ) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -1,922 in der Interventionsgruppe und -0,150 in der Kontrollgruppe.

Die im Plan zur Systematischen Nutzerdatenauswertung unter 7.5 definierte Responderanalyse sind im nachfolgenden in Kapitel 5 dargestellt. Alle Responderanalysen sind bezogen auf die Gruppe signifikant (zum Signifikanzniveau 0,05), mit Ausnahme der univariaten Prüfung des PSQI ( $p = 0,054$ ). Die im Plan zur Systematischen Nutzerdatenauswertung unter 7.7 definierte Sensitivitätsanalysen sind im nachfolgenden in Kapitel 6 dargestellt. Da sich die Normalverteilungsannahmen bestätigten, wurden nur die Berechnung zu den Gemischten Linearen Modellen (LMM) durchgeführt. Beide LMM-Analysen für ESS und PSQI sind bezogen auf die Gruppe signifikant ( $p < 0,001$ ).

Die Auswertung der Sauerstoffmessungen ergab keine relevanten Ergebnisse im Gruppenvergleich. Dies ist zu erwarten, da die mittlere Sauerstoffsättigung zu  $t_0$  ( $\emptyset$ -durchschnittl..O2\_t0) in beiden Gruppen über 95% und damit im Normbereich von 95-99% liegt. Siehe Werte in Kapitel 7.3 " $\emptyset$ -

.durchschnittl..O2\_t0" in der Interventionsgruppe von 95,85 und in der Kontrollgruppe von 95,42. Die nachgeforderten Subgruppenanalysen nach Alter (65≤, >65) und Geschlecht zeigen in allen Subgruppen vergleichbare Effekte. Bei einigen Subgruppen lagen jedoch zu wenige Beobachtungen in den Merkmalsausprägungen vor, um die Stärke des Behandlungseffekts mit hinreichender Genauigkeit zu bestimmen.

## 1.2. English language transcription

The following analyses refer to the Systematic User Data Evaluation plan version 1.0 of 12/28/2022. The comparison of the intervention group with the control group shows no relevant group differences. Accordingly, the randomization was successful with respect to the defined randomization strata. The primary analyses defined in the Systematic User Data Evaluation Plan under 7.3, are cited in Chapter 3 of this document. The ITT analysis for the ESS with Reference Based Imputation with the specified ANCOVA shows a significant difference ( $p < 0.001$ ) to the baseline-adjusted score difference (end minus beginning) of -3.324 in the intervention group and -0.889 in the control group.

ITT analysis for the ESS with Normal Imputation with the prespecified ANCOVA shows a significant difference ( $p = 0.004$ ) to the baseline-adjusted score difference (end minus beginning) of -3.464 in the intervention group and -0.846 in the control group.

ITT analysis for the PSQI with Reference Based Imputation with the prespecified ANCOVA shows a significant difference ( $p < 0.001$ ) to the baseline-adjusted score difference (end minus beginning) of -1.93 in the intervention group and -0.23 in the control group.

ITT analysis for the PSQI with Normal Imputation with the prespecified ANCOVA shows a significant difference ( $p = 0.005$ ) to the baseline-adjusted score difference (end minus beginning) of -1.922 in the intervention group and -0.150 in the control group.

The responder analyses defined in the Systematic User Data Evaluation Plan in 7.5 are presented below in Chapter 5. All responder analyses are significant relative to the group (at significance level 0.05), with the exception of the univariate assessment of response in the PSQI ( $p = 0.054$ ). The sensitivity analyses defined in the Systematic User Data Evaluation Plan in 7.7 are presented below in Chapter 6. Since the normal distribution assumptions were confirmed, only the calculation on the Linear Mixed Models (LMM) were performed. Both LMM analyses for ESS and PSQI are significant in relation to the group ( $p < 0.001$ ).

The evaluation of the oxygen measurements did not reveal any relevant results in the group comparison. This is to be expected, since the mean oxygen saturation at t0 ( $\emptyset$ .-aver..O2\_t0) in both groups is above 95% and thus in the normal range of 95-99%. See values in chapter 7.3 " $\emptyset$ .-average..O2\_t0" in the intervention group of 95.07 and in the control group of 95.24. The requested subgroup analyses for age (65≤, >65) and sex revealed overall similar effects across subgroups. For some subgroups, the effect size could not be determined with high precision due to few cases for combinations of features.

## 2. Demographie | Demographics

**\*\*Tabelle\*\***

Variable	Overall, N = 89 <sup>1</sup>	Interventionsgruppe, N = 43 <sup>1</sup>	Kontrollgruppe, N = 46 <sup>1</sup>	p-value <sup>2</sup>
<b>Alter</b>				0.688
N	89.00	43.00	46.00	
Mean (SD)	52.44 (11.99)	51.91 (11.81)	52.93 (12.27)	

Variable	Overall, N = 89 <sup>1</sup>	Interventionsgruppe, N = 43 <sup>1</sup>	Kontrollgruppe, N = 46 <sup>1</sup>	p-value <sup>2</sup>
Median (IQR)	55.00 (45.00, 61.00)	53.00 (44.00, 61.00)	55.50 (45.25, 61.00)	
Range	20.00, 76.00	20.00, 71.00	29.00, 76.00	
<b>Geschlecht</b>				0.821
f	30 / 89 (34%)	15 / 43 (35%)	15 / 46 (33%)	
m	59 / 89 (66%)	28 / 43 (65%)	31 / 46 (67%)	
<b>BMI</b>				0.878
N	89.00	43.00	46.00	
Mean (SD)	25.21 (2.67)	25.26 (2.54)	25.17 (2.81)	
Median (IQR)	25.31 (23.55, 27.34)	25.53 (23.64, 26.60)	25.13 (23.26, 27.47)	
Range	19.79, 31.14	19.94, 31.14	19.79, 29.73	
<b>Diagnose</b>				0.802
Schnarchen	84 / 89 (94%)	40 / 43 (93%)	44 / 46 (96%)	
Schnarchen UARS	4 / 89 (4.5%)	2 / 43 (4.7%)	2 / 46 (4.3%)	
Schnarcher	1 / 89 (1.1%)	1 / 43 (2.3%)	0 / 46 (0%)	
<b>BMI.Strata</b>				0.419
< 25	37 / 89 (42%)	16 / 43 (37%)	21 / 46 (46%)	
≥ 25	52 / 89 (58%)	27 / 43 (63%)	25 / 46 (54%)	
<b>Alter.Strata</b>				0.889
< 40	15 / 89 (17%)	7 / 43 (16%)	8 / 46 (17%)	
≥ 40	74 / 89 (83%)	36 / 43 (84%)	38 / 46 (83%)	

<sup>1</sup>n / N (%)

<sup>2</sup>Welch Two Sample t-test; Pearson's Chi-squared test; Fisher's exact test

### 3. Intention-To-Treat Analyse (ITT) | Intention-To-Treat Analysis (ITT)

#### 3.1. ANCOVA Endpunkt - Epworth Sleepiness Scale (ESS) | ANCOVA endpoint - Epworth Sleepiness Scale (ESS)

##### 3.1.1 ESS Reference Based Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	189.13	1	5311823.52	18.80	0.000	0.19	0.20
Gruppe	11.22	1	3359.50	0.43	0.513	0.01	0.01
Geschlecht	9.76	1	5518.29	0.46	0.497	0.01	0.01
Alter	8.43	1	5657.83	0.37	0.544	0.01	0.01
BMI	11.98	1	4046.87	0.54	0.464	0.01	0.02
Residual	778.73	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-3.424	0.542	-4.494	-2.355
Kontrollgruppe	-0.889	0.436	-1.748	-0.029

	Difference	SD	Effect (d)
Empirical	2.97	3.25	0.91
Model	2.54	3.26	0.78

##### 3.1.2 ESS Normal Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	166.23	1	778.96	4.84	0.028	0.15	0.19
Gruppe	156.86	1	1321.10	8.15	0.004	0.14	0.18
Geschlecht	54.14	1	1813.62	2.85	0.092	0.05	0.07
Alter	10.56	1	3371.73	0.52	0.472	0.01	0.01
BMI	36.60	1	1795.54	1.88	0.171	0.03	0.05
Residual	699.06	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-3.464	0.538	-4.525	-2.402
Kontrollgruppe	-0.846	0.443	-1.721	0.028

	Difference	SD	Effect (d)
Empirical	2.97	3.25	0.91
Model	2.62	3.27	0.80

### 3.2. ANCOVA Endpunkt - Pittsburgh Sleep Quality Index (PSQI) | ANCOVA endpoint - Pittsburgh Sleep Quality Index (PSQI).

#### 3.2.1 PSQI Reference Based Imputation

	Estimate	Std. error	95% CI lower	95% CI upper	p
(Intercept)	6.176	2.402	1.439	10.914	0.011
Score_t0	-0.511	0.127	-0.761	-0.260	0.000
Gruppe	1.700	0.446	0.819	2.580	0.000
Geschlechtm	0.792	0.599	-0.389	1.972	0.187
Alter	-0.027	0.016	-0.058	0.004	0.082
BMI	-0.150	0.078	-0.304	0.004	0.057

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-1.93	0.361	-2.642	-1.218
Kontrollgruppe	-0.23	0.413	-1.045	0.584

	Difference	SD	Effect (d)
Empirical	1.92	2.47	0.78
Model	1.70	2.58	0.66

#### 3.2.2 PSQI Normal Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	117.52	1	736.78	6.60	0.010	0.20	0.24
Gruppe	73.00	1	1567.03	7.85	0.005	0.12	0.17
Geschlecht	9.98	1	1934.58	0.92	0.338	0.02	0.03
Alter	9.18	1	2526.25	0.99	0.319	0.02	0.02
BMI	11.36	1	2509.53	1.27	0.260	0.02	0.03
Residual	367.10	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-1.922	0.335	-2.584	-1.261
Kontrollgruppe	-0.150	0.419	-0.975	0.676

	Difference	SD	Effect (d)
Empirical	1.92	2.47	0.78
Model	1.77	2.52	0.70

#### 4. Per-Protokoll-Analyse (PP) | Per-Protocol Analysis (PP)

##### 4.1. ANCOVA Endpunkt - Epworth Sleepiness Scale (ESS) | ANCOVA endpoint - Epworth Sleepiness Scale (ESS)

Term	df	SSQ	MSQ	F	p	eta2	partial eta2
Gruppe	1	184.41	184.41	20.236	0.000	0.140	0.176
Score_t0	1	112.03	112.03	12.293	0.001	0.058	0.080
Alter	1	2.67	2.67	0.293	0.590	0.006	0.009
Geschlecht	1	44.54	44.54	4.888	0.030	0.058	0.081
BMI	1	25.50	25.50	2.799	0.098	0.024	0.035
Residuals	78	710.80	9.11	NA	NA	NA	NA

Gruppe	emmean	SE	lower.CL	upper.CL
Interventionsgruppe	-3.449	0.494	-4.433	-2.465
Kontrollgruppe	-0.742	0.470	-1.678	0.195

	Difference	SD	Effect (d)
Empirical	2.97	3.25	0.91
Model	1.77	2.52	0.70

##### 4.2. ANCOVA Endpunkt - Pittsburgh Sleep Quality Index (PSQI) | ANCOVA endpoint - Pittsburgh Sleep Quality Index (PSQI).

Term	df	SSQ	MSQ	F	p	eta2	partial eta2
Gruppe	1	76.72	76.72	16.247	0.000	0.106	0.141
Score_t0	1	104.62	104.62	22.155	0.000	0.169	0.208
Alter	1	6.14	6.14	1.300	0.258	0.015	0.023
Geschlecht	1	6.64	6.64	1.406	0.239	0.020	0.031
BMI	1	10.56	10.56	2.235	0.139	0.018	0.028
Residuals	78	368.32	4.72	NA	NA	NA	NA

Gruppe	emmean	SE	lower.CL	upper.CL
Interventionsgruppe	-1.891	0.354	-2.597	-1.185
Kontrollgruppe	-0.179	0.339	-0.853	0.495

	Difference	SD	Effect (d)
Empirical	1.92	2.47	0.78
Model	1.77	2.52	0.70

## 5. Responderanalyse | Responder Analysis

### 5.1. Endpunkt - Epworth Sleepiness Scale (ESS) | Endpoint - Epworth Sleepiness Scale (ESS)

**\*\*Tabelle\*\***

Variable	Overall, N = 89 <sup>1</sup>	Interventionsgruppe, N = 43 <sup>1</sup>	Kontrollgruppe, N = 46 <sup>1</sup>	p-value <sup>2</sup>
<b>Responder</b>				0.005
Gleich	31 / 84 (37%)	10 / 39 (26%)	21 / 45 (47%)	
Verbessert	38 / 84 (45%)	25 / 39 (64%)	13 / 45 (29%)	
Verschlechtert	15 / 84 (18%)	4 / 39 (10%)	11 / 45 (24%)	
Unknown	5	4	1	

<sup>1</sup>n / N (%)

<sup>2</sup>Pearson's Chi-squared test

### 5.2. Endpunkt - Pittsburgh Sleep Quality Index (PSQI) | Endpoint - Pittsburgh Sleep Quality Index (PSQI).

**\*\*Tabelle\*\***

Variable	Overall, N = 89 <sup>1</sup>	Interventionsgruppe, N = 43 <sup>1</sup>	Kontrollgruppe, N = 46 <sup>1</sup>	p-value <sup>2</sup>
<b>Responder</b>				0.054
Gleich	41 / 84 (49%)	16 / 39 (41%)	25 / 45 (56%)	
Verbessert	32 / 84 (38%)	20 / 39 (51%)	12 / 45 (27%)	
Verschlechtert	11 / 84 (13%)	3 / 39 (7.7%)	8 / 45 (18%)	
Unknown	5	4	1	

<sup>1</sup>n / N (%)

<sup>2</sup>Pearson's Chi-squared test

### 5.3. Logistische Regression - Epworth Sleepiness Scale (ESS) | Logistic regression - Epworth Sleepiness Scale (ESS)

var	OR	lower OR 95%-CI	upper OR 95%-CI	p.value
(Intercept)	0.318	0.034	2.938	0.313



var	OR	lower OR 95%-CI	upper OR 95%-CI	p.value
Alter	0.997	0.959	1.037	0.895
Geschlechtm	2.920	1.078	7.914	0.035
GruppeKontrollgruppe	4.458	1.723	11.531	0.002

#### 5.4. Logistische Regression - Pittsburgh Sleep Quality Index (PSQI) | Logistic Regression - Pittsburgh Sleep Quality Index (PSQI)

var	OR	lower OR 95%-CI	upper OR 95%-CI	p.value
(Intercept)	1.567	0.178	13.796	0.685
Alter	0.983	0.946	1.022	0.390
Geschlechtm	1.859	0.714	4.841	0.204
GruppeKontrollgruppe	2.883	1.141	7.283	0.025

### 6. Gemischte Lineare Modelle | Linear Mixed Models

#### Endpunkt - Epworth Sleepiness Scale (ESS) | Endpoint - Epworth Sleepiness Scale (ESS)

	coefficients	sigma	tstat	pvalues
(Intercept)	1.875	2.185	0.858	0.391
score_t0	1.057	0.069	15.311	0.000
GruppeKontrollgruppe	1.431	0.376	3.805	0.000
time1	1.591	0.839	1.897	0.058
time2	1.505	0.841	1.790	0.073
Alter	-0.020	0.016	-1.294	0.196
Geschlechtm	1.207	0.427	2.829	0.005
BMI	-0.116	0.075	-1.539	0.124
score_t0:time1	-0.285	0.080	-3.545	0.000
score_t0:time2	-0.331	0.081	-4.100	0.000

#### Randmittelwert | Estimated Marginal Means

Gruppe	emmean	SE	df	CI (lower)	CI (upper)
2					
Interventionsgruppe	7.213	0.329	80	6.558	7.869
Kontrollgruppe	8.645	0.314	80	8.020	9.269

#### Effekte | Effects

	Difference	SD	Effect (d)
Empirical	2.97	3.25	0.91
Model	1.43	2.14	0.67

### Kontraste | Contrasts

Zeitpunkt	term	contrast	null.value	estimate	std.error	df	statistic	p	Effect size (d)	d (lower)	d (upper)
2	Gruppe	Interventionsgruppe - Kontrollgruppe	0.000	-1.431	0.376	80	-3.805	0.000	0.687	-	-0.246

### Endpoint - Pittsburgh Sleep Quality Index (PSQI) | Endpoint - Pittsburgh Sleep Quality Index (PSQI).

	coefficients	sigma	tstat	pvalues
(Intercept)	2.557	1.473	1.736	0.083
score_t0	1.015	0.081	12.499	0.000
GruppeKontrollgruppe	0.875	0.246	3.553	0.000
time1	1.687	0.676	2.494	0.013
time2	2.745	0.693	3.960	0.000
Alter	-0.021	0.010	-2.067	0.039
Geschlechtm	0.218	0.271	0.804	0.421
BMI	-0.085	0.049	-1.746	0.081
score_t0:time1	-0.359	0.099	-3.625	0.000
score_t0:time2	-0.557	0.102	-5.455	0.000

### Randmittelwert | Estimated Marginal Means

Gruppe	emmean	SE	df	CI (lower)	CI (upper)
2					
Interventionsgruppe	5.142	0.219	80	4.706	5.578
Kontrollgruppe	6.017	0.209	80	5.600	6.433

### Effekte | Effects

	Difference	SD	Effect (d)
Empirical	1.92	2.47	0.78
Model	0.87	1.43	0.61

## Kontraste | Contrasts

Zeitpunkt	term	contrast	null.value	estimate	std.error	df	statistic	p	Effect size (d)	d (lower)	d (upper)
2	Gruppe	Interventionsgruppe - Kontrollgruppe	0.000	-0.875	0.246	80	-3.553	0.001	0.630	-1.070	-0.191

## 7. Deskriptive Statistik | Descriptive statistics

### 7.1. Deskriptive Statistik - Epworth Sleepiness Scale (ESS) | Descriptive statistics - Epworth Sleepiness Scale (ESS)

**\*\*Tabelle\*\***

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
<b>Score_t0</b>				0.545
N	86.00	40.00	46.00	
Mean (SD)	9.70 (3.86)	9.98 (4.38)	9.46 (3.37)	
Median (IQR)	9.00 (7.00, 11.00)	9.00 (7.00, 11.25)	9.00 (7.00, 11.00)	
Range	1.00, 20.00	1.00, 20.00	3.00, 18.00	
Unknown	3	3	0	
<b>Score_t2</b>				0.012
N	84.00	39.00	45.00	
Mean (SD)	7.95 (4.26)	6.69 (4.39)	9.04 (3.86)	
Median (IQR)	8.00 (5.00, 11.00)	6.00 (4.00, 10.00)	8.00 (7.00, 12.00)	
Range	0.00, 21.00	0.00, 21.00	2.00, 20.00	
Unknown	5	4	1	
<b>Score_Differenz_t2_t0</b>				<0.001
N	84.00	39.00	45.00	
Mean (SD)	-1.69 (3.61)	-3.28 (4.12)	-0.31 (2.38)	

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
Median (IQR)	-1.00 (-4.00, 1.00)	-3.00 (-5.00, -1.00)	0.00 (-2.00, 1.00)	
Range	-16.00, 5.00	-16.00, 4.00	-5.00, 5.00	
Unknown	5	4	1	

<sup>1</sup>Welch Two Sample t-test

## 7.2. Deskriptive Statistik - Pittsburgh Sleep Quality Index (PSQI) | Descriptive Statistics - Pittsburgh Sleep Quality Index (PSQI)

**\*\*Tabelle\*\***

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
<b>Score_t0</b>				0.770
N	86.00	40.00	46.00	
Mean (SD)	6.48 (2.16)	6.55 (2.06)	6.41 (2.27)	
Median (IQR)	6.00 (5.00, 8.00)	7.00 (5.00, 8.00)	6.00 (5.00, 8.00)	
Range	2.00, 13.00	3.00, 13.00	2.00, 12.00	
Unknown	3	3	0	
<b>Score_t2</b>				0.003
N	84.00	39.00	45.00	
Mean (SD)	5.60 (2.50)	4.74 (2.21)	6.33 (2.53)	
Median (IQR)	5.00 (4.00, 7.00)	4.00 (3.00, 6.00)	6.00 (5.00, 8.00)	
Range	0.00, 14.00	0.00, 10.00	2.00, 14.00	
Unknown	5	4	1	
<b>Score_Differenz_t2_t0</b>				<0.001
N	84.00	39.00	45.00	
Mean (SD)	-0.85 (2.63)	-1.87 (2.56)	0.04 (2.37)	
Median (IQR)	-1.00 (-2.00, 1.00)	-2.00 (-3.00, -0.50)	0.00 (-2.00, 1.00)	

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
Range	-11.00, 9.00	-11.00, 2.00	-3.00, 9.00	
Unknown	5	4	1	

<sup>1</sup>Welch Two Sample t-test

### 7.3. Deskriptive Statistik - Sauerstoffmessungen | Descriptive statistics - oxygen measurements

**\*\*Tabelle\*\***

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
<b>Ø.-.durchschnittl..O2_t0</b>				0.135
N	83.00	40.00	43.00	
Mean (SD)	95.63 (1.32)	95.85 (1.14)	95.42 (1.45)	
Median (IQR)	96.00 (95.00, 97.00)	96.00 (95.00, 97.00)	96.00 (94.50, 96.00)	
Range	90.00, 98.00	92.00, 98.00	90.00, 97.00	
Unknown	6	3	3	
<b>O2-Wert_t0</b>				0.347
N	85.00	40.00	45.00	
Mean (SD)	9.36 (1.30)	9.50 (0.74)	9.24 (1.65)	
Median (IQR)	9.80 (9.40, 9.90)	9.85 (9.55, 9.90)	9.80 (9.10, 9.90)	
Range	0.00, 10.00	7.10, 10.00	0.00, 10.00	
Unknown	4	3	1	
<b>Wie.oft.sinkt.um.&gt;4%.die.ganze.Nacht.über_t0</b>				0.151
N	86.00	40.00	46.00	
Mean (SD)	11.88 (31.95)	6.83 (13.28)	16.28 (41.63)	
Median (IQR)	2.00 (0.00, 10.50)	2.00 (0.00, 6.75)	2.00 (0.00, 11.00)	

<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p-value<sup>1</sup></b>
Range	0.00, 255.00	0.00, 73.00	0.00, 255.00	
Unknown	3	3	0	
<b>Sinkt.&gt;4%.pro.Stunde_t0</b>				0.454
N	86.00	40.00	46.00	
Mean (SD)	1.77 (4.99)	1.35 (4.14)	2.14 (5.64)	
Median (IQR)	0.22 (0.00, 1.50)	0.20 (0.00, 1.20)	0.30 (0.00, 1.50)	
Range	0.00, 35.50	0.00, 25.90	0.00, 35.50	
Unknown	3	3	0	
<b>Wie.oft.sinkt.um.&gt;3%.die.ganze.Nacht.über_t0</b>				0.138
N	86.00	40.00	46.00	
Mean (SD)	18.66 (37.17)	12.55 (19.57)	23.98 (47.07)	
Median (IQR)	6.00 (1.00, 22.00)	5.50 (1.00, 17.25)	7.50 (1.25, 23.75)	
Range	0.00, 255.00	0.00, 108.00	0.00, 255.00	
Unknown	3	3	0	
<b>sinkt.&gt;3%.pro.Stunde_t0</b>				0.528
N	86.00	40.00	46.00	
Mean (SD)	2.77 (6.13)	2.32 (6.06)	3.16 (6.23)	
Median (IQR)	0.80 (0.20, 2.88)	0.75 (0.18, 2.38)	0.90 (0.20, 3.00)	
Range	0.00, 38.30	0.00, 38.30	0.00, 35.50	
Unknown	3	3	0	
<b>die.Sekunden.der.Sauerstoffsättigung.&lt;90%_t0</b>				0.190
N	86.00	40.00	46.00	

<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p-value<sup>1</sup></b>
Mean (SD)	231.92 (1,232.14)	55.68 (135.19)	385.17 (1,673.37)	
Median (IQR)	10.00 (0.00, 47.50)	10.00 (0.00, 19.50)	10.00 (0.00, 83.00)	
Range	0.00, 11,210.00	0.00, 552.00	0.00, 11,210.00	
Unknown	3	3	0	
<b>Wie.viel.%der.Schlafzeit.&lt;90%. Sauerstoffsättigung_t0</b>				0.210
N	86.00	40.00	46.00	
Mean (SD)	0.86 (4.84)	0.19 (0.47)	1.43 (6.59)	
Median (IQR)	0.00 (0.00, 0.10)	0.00 (0.00, 0.10)	0.00 (0.00, 0.10)	
Range	0.00, 44.20	0.00, 2.00	0.00, 44.20	
Unknown	3	3	0	
<b>die.Sekunden.der.Sauerstoff- sättigung.90-94%_t0</b>				0.262
N	86.00	40.00	46.00	
Mean (SD)	5,310.41 (7,009.40)	4,408.35 (6,291.95)	6,094.80 (7,559.23)	
Median (IQR)	1,701.00 (195.50, 9,077.00)	1,536.00 (234.50, 5,272.50)	2,195.00 (151.00, 11,875.50)	
Range	0.00, 24,004.00	0.00, 22,680.00	0.00, 24,004.00	
Unknown	3	3	0	
<b>Wie.viel.%der.Schlafzeit.90- 94%.Sauerstoffsättigung_t0</b>				0.343
N	86.00	40.00	46.00	
Mean (SD)	19.59 (24.57)	16.91 (22.81)	21.93 (26.04)	

<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p- value<sup>1</sup></b>
Median (IQR)	5.98 (1.00, 34.65)	5.98 (1.45, 26.50)	6.15 (1.00, 45.10)	
Range	0.00, 94.00	0.00, 94.00	0.00, 74.00	
Unknown	3	3	0	
<b>Ø.-.durchschnittl..O2_t2</b>				0.194
N	82.00	39.00	43.00	
Mean (SD)	95.66 (1.26)	95.85 (1.04)	95.49 (1.42)	
Median (IQR)	96.00 (95.00, 97.00)	96.00 (95.00, 96.50)	96.00 (94.50, 97.00)	
Range	92.00, 98.00	94.00, 98.00	92.00, 97.00	
Unknown	7	4	3	
<b>02-Wert_t2</b>				0.994
N	82.00	39.00	43.00	
Mean (SD)	9.23 (1.39)	9.23 (1.04)	9.23 (1.65)	
Median (IQR)	9.80 (8.90, 9.90)	9.60 (8.75, 9.90)	9.90 (9.45, 9.90)	
Range	0.00, 10.00	5.30, 10.00	0.00, 10.00	
Unknown	7	4	3	
<b>Wie.oft.sinkt.um.&gt;4%. die.ganze.Nacht.über_t2</b>				0.327
N	82.00	39.00	43.00	
Mean (SD)	10.16 (28.98)	6.97 (9.02)	13.05 (39.09)	
Median (IQR)	2.00 (0.00, 13.00)	2.00 (0.00, 14.00)	2.00 (0.00, 10.50)	
Range	0.00, 255.00	0.00, 35.00	0.00, 255.00	
Unknown	7	4	3	
<b>Sinkt.&gt;4%.pro.Stunde_t2</b>				0.483



<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p-value<sup>1</sup></b>
N	82.00	39.00	43.00	
Mean (SD)	1.45 (3.91)	1.15 (1.83)	1.74 (5.13)	
Median (IQR)	0.39 (0.00, 1.80)	0.38 (0.00, 1.90)	0.40 (0.00, 1.46)	
Range	0.00, 33.38	0.00, 9.73	0.00, 33.38	
Unknown	7	4	3	
<b>Wie.oft.sinkt.um.&gt;3%.die.ganze.Nacht.über_t2</b>				0.505
N	82.00	39.00	43.00	
Mean (SD)	17.85 (32.33)	15.41 (19.57)	20.07 (40.72)	
Median (IQR)	7.00 (2.00, 22.00)	5.00 (3.00, 22.00)	7.00 (1.00, 21.50)	
Range	0.00, 255.00	0.00, 84.00	0.00, 255.00	
Unknown	7	4	3	
<b>sinkt.&gt;3%.pro.Stunde_t2</b>				0.893
N	82.00	39.00	43.00	
Mean (SD)	2.62 (4.79)	2.55 (4.21)	2.69 (5.31)	
Median (IQR)	1.12 (0.30, 2.94)	1.04 (0.35, 3.30)	1.20 (0.15, 2.90)	
Range	0.00, 33.38	0.00, 23.35	0.00, 33.38	
Unknown	7	4	3	
<b>die.Sekunden.der.Sauerstoffsättigung.&lt;90%_t2</b>				0.167
N	85.00	39.00	46.00	
Mean (SD)	165.67 (700.28)	59.03 (157.94)	256.09 (936.01)	
Median (IQR)	0.00 (0.00, 42.00)	4.00 (0.00, 43.00)	0.00 (0.00, 39.50)	

<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p-value<sup>1</sup></b>
Range	0.00, 5,946.00	0.00, 877.00	0.00, 5,946.00	
Unknown	4	4	0	
<b>Wie.viel.%der.Schlafzeit.&lt;90%. Sauerstoffsättigung_t2</b>				0.185
N	83.00	39.00	44.00	
Mean (SD)	0.66 (2.69)	0.26 (0.82)	1.01 (3.59)	
Median (IQR)	0.00 (0.00, 0.11)	0.00 (0.00, 0.08)	0.00 (0.00, 0.15)	
Range	0.00, 22.06	0.00, 4.00	0.00, 22.06	
Unknown	6	4	2	
<b>die.Sekunden.der. Sauerstoffsättigung.90-94%_t2</b>				0.224
N	85.00	39.00	46.00	
Mean (SD)	4,531.21 (6,109.71)	3,682.26 (4,549.38)	5,250.98 (7,144.81)	
Median (IQR)	1,544.00 (282.00, 6,986.00)	1,550.00 (503.00, 4,965.00)	1,319.00 (175.50, 10,546.50)	
Range	0.00, 22,390.00	0.00, 16,501.00	0.00, 22,390.00	
Unknown	4	4	0	
<b>Wie.viel.%der.Schlafzeit.90-94%.Sauerstoffsättigung_t2</b>				0.162
N	83.00	39.00	44.00	
Mean (SD)	18.36 (23.62)	14.60 (16.95)	21.69 (28.04)	
Median (IQR)	6.44 (1.68, 27.00)	7.59 (2.19, 19.97)	6.22 (1.00, 43.75)	
Range	0.00, 91.00	0.00, 57.02	0.00, 91.00	
Unknown	6	4	2	

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
<b>Ø.-.durchschnittl..O2_Differenz_t2_t0</b>				0.613
N	80.00	39.00	41.00	
Mean (SD)	-0.05 (0.86)	0.00 (0.86)	-0.10 (0.86)	
Median (IQR)	0.00 (-0.25, 0.00)	0.00 (0.00, 0.00)	0.00 (-1.00, 0.00)	
Range	-3.00, 2.00	-3.00, 2.00	-2.00, 2.00	
Unknown	9	4	5	
<b>O2-Wert_Differenz_t2_t0</b>				0.117
N	81.00	39.00	42.00	
Mean (SD)	0.14 (0.95)	0.32 (1.06)	-0.02 (0.82)	
Median (IQR)	0.00 (-0.10, 0.30)	0.00 (-0.10, 0.50)	0.00 (-0.10, 0.20)	
Range	-3.10, 4.70	-1.50, 4.70	-3.10, 1.40	
Unknown	8	4	4	
<b>Wie.oft.sinkt.um.&gt;4%.die.ganze.Nacht.über_Differenz_t2_t0</b>				0.169
N	82.00	39.00	43.00	
Mean (SD)	1.89 (16.25)	-0.64 (9.86)	4.19 (20.25)	
Median (IQR)	0.00 (-2.00, 2.00)	0.00 (-2.00, 2.00)	0.00 (-3.00, 2.00)	
Range	-30.00, 85.00	-22.00, 38.00	-30.00, 85.00	
Unknown	7	4	3	
<b>Sinkt.&gt;4%.pro.Stunde_Differenz_t2_t0</b>				0.492
N	82.00	39.00	43.00	
Mean (SD)	0.32 (2.64)	0.11 (2.84)	0.52 (2.47)	
Median (IQR)	0.00 (-0.43, 0.28)	-0.05 (-0.30, 0.15)	0.00 (-0.55, 0.30)	

<b>Variable</b>	<b>Overall, N = 89</b>	<b>Interventionsgruppe, N = 43</b>	<b>Kontrollgruppe, N = 46</b>	<b>p-value<sup>1</sup></b>
Range	-3.40, 16.17	-3.40, 16.17	-3.39, 9.80	
Unknown	7	4	3	
<b>Wie.oft.sinkt.um.&gt;3%.die.ganze.Nacht.über_Differenz_t2_t0</b>				0.108
N	82.00	39.00	43.00	
Mean (SD)	1.13 (23.77)	-3.18 (13.54)	5.05 (29.84)	
Median (IQR)	0.00 (-6.00, 3.00)	-1.00 (-7.00, 2.50)	0.00 (-5.00, 4.00)	
Range	-67.00, 114.00	-42.00, 24.00	-67.00, 114.00	
Unknown	7	4	3	
<b>sinkt.&gt;3%.pro.Stunde_Differenz_t2_t0</b>				0.238
N	82.00	39.00	43.00	
Mean (SD)	0.17 (3.37)	-0.29 (3.08)	0.59 (3.60)	
Median (IQR)	-0.08 (-0.78, 0.50)	-0.23 (-0.97, 0.30)	0.00 (-0.70, 0.55)	
Range	-7.59, 14.95	-5.70, 14.95	-7.59, 13.51	
Unknown	7	4	3	
<b>die.Sekunden.der.Sauerstoffsättigung.&lt;90%_Differenz_t2_t0</b>				0.310
N	85.00	39.00	46.00	
Mean (SD)	66.20 (662.14)	-7.97 (193.59)	129.09 (882.01)	
Median (IQR)	0.00 (-6.00, 10.00)	0.00 (-14.00, 10.00)	0.00 (-1.50, 14.50)	
Range	-1,894.00, 5,264.00	-877.00, 552.00	-1,894.00, 5,264.00	
Unknown	4	4	0	

Variable	Overall, N = 89	Interventionsgruppe, N = 43	Kontrollgruppe, N = 46	p-value <sup>1</sup>
<b>Wie.viel.%der.Schlafzeit.&lt;90%. Sauerstoffsättigung_Differenz_t2_t0</b>				0.319
N	83.00	39.00	44.00	
Mean (SD)	0.22 (2.78)	-0.09 (0.93)	0.49 (3.72)	
Median (IQR)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	
Range	-8.00, 22.14	-4.00, 2.00	-8.00, 22.14	
Unknown	6	4	2	
<b>die.Sekunden.der. Sauerstoffsättigung.90-94%_ Differenz_t2_t0</b>				0.947
N	85.00	39.00	46.00	
Mean (SD)	814.25 (4,416.97)	779.36 (4,669.44)	843.83 (4,243.12)	
Median (IQR)	46.00 (-540.00, 1,494.00)	76.00 (-616.50, 1,590.50)	45.00 (-441.50, 1,419.00)	
Range	-14,701.00, 14,684.00	-14,701.00, 14,684.00	-8,362.00, 12,424.00	
Unknown	4	4	0	
<b>Wie.viel.%der.Schlafzeit.90-94%.Sauerstoffsättigung_ Differenz_t2_t0</b>				0.732
N	83.00	39.00	44.00	
Mean (SD)	1.75 (16.80)	2.43 (18.19)	1.14 (15.66)	
Median (IQR)	0.00 (-3.00, 3.79)	0.00 (-2.63, 3.29)	0.00 (-3.25, 6.08)	
Range	-50.44, 75.00	-50.44, 75.00	-41.00, 44.64	
Unknown	6	4	2	

<sup>1</sup>Welch Two Sample t-test