

SnoreFree - OSAS Pilotstudie - Ergebnisbericht Update

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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 -3,456 in der Interventionsgruppe und -0,525 in der Kontrollgruppe.

Die ITT-Analyse für den ESS mit Normal Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ($p < 0,001$) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -3,484 in der Interventionsgruppe und -0,515 in der Kontrollgruppe.

Die ITT-Analyse für den PSQI mit Reference Based Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ($p = 0,002$) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -2,286 in der Interventionsgruppe und -0,314 in der Kontrollgruppe.

Die ITT-Analyse für den PSQI mit Normal Imputation mit der vorgegebenen ANCOVA zeigt einen signifikanten Unterschied ($p = 0,002$) zur baseline-adjustierten Score-Differenz (Ende minus Anfang) von -2,280 in der Interventionsgruppe und -0,311 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 (alle $p \leq 0,002$). Dies umfasst die univariaten Responderanalysen für ESS und PSQI, sowie die die Logistischen Regressionen für ESS und PSQI.

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 (LLM) durchgeführt. Beide LLM-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 “Ø.-.durchschnittl..O2_t0” in der Interventionsgruppe von 95,07 und in der Kontrollgruppe von 95,24. 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 and the requested additional analyses by BfArM on 02/02/2024. 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 -3.456 in the intervention group and -0.515 in the control group.

ITT analysis for the ESS with Normal Imputation with the prespecified ANCOVA shows a significant difference ($p < 0.001$) to the baseline-adjusted score difference (end minus beginning) of -3.484 in the intervention group and -0.276 in the control group.

ITT analysis for the PSQI with Reference Based Imputation with the prespecified ANCOVA shows a significant difference ($p = 0.002$) to the baseline-adjusted score difference (end minus beginning) of -2.286 in the intervention group and -0.314 in the control group.

ITT analysis for the PSQI with Normal Imputation with the prespecified ANCOVA shows a significant difference ($p = 0.002$) to the baseline-adjusted score difference (end minus beginning) of -2.280 in the intervention group and -0.311 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 (all $p \leq 0.002$) relative to the group. This includes the univariate responder analyses for ESS and PSQI, as well as the logistic regressions for ESS and PSQI.

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 Mixed Linear Models (LLM) were performed. Both LLM 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 (Ø.-.aver..O2_t0) in both groups is above 95% and thus in the normal range of 95-99%. See values in chapter 7.3 “Ø.-.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 = 92 ¹	Interventionsgruppe, N = 47 ¹	Kontrollgruppe, N = 45 ¹	p-value ²
Alter				0.956

Variable	Overall, N = 92¹	Interventionsgruppe, N = 47¹	Kontrollgruppe, N = 45¹	p-value²
N	92.00	47.00	45.00	
Mean (SD)	57.05 (9.15)	57.11 (9.19)	57.00 (9.22)	
Median (IQR)	58.00 (52.00, 63.00)	59.00 (50.50, 63.50)	57.00 (52.00, 63.00)	
Range	33.00, 77.00	37.00, 76.00	33.00, 77.00	
Geschlecht				0.712
f	31 / 92 (34%)	15 / 47 (32%)	16 / 45 (36%)	
m	61 / 92 (66%)	32 / 47 (68%)	29 / 45 (64%)	
BMI				0.710
N	92.00	47.00	45.00	
Mean (SD)	26.02 (2.81)	26.13 (3.05)	25.91 (2.55)	
Median (IQR)	26.23 (24.20, 27.87)	26.30 (24.00, 28.47)	25.98 (24.34, 27.12)	
Range	20.02, 34.80	20.20, 34.80	20.02, 30.52	
Diagnose				
OSAS	92 / 92 (100%)	47 / 47 (100%)	45 / 45 (100%)	
BMI.Strata				0.340
< 25	31 / 92 (34%)	18 / 47 (38%)	13 / 45 (29%)	
≥ 25	61 / 92 (66%)	29 / 47 (62%)	32 / 45 (71%)	
Alter.Strata				0.865
> 65	17 / 92 (18%)	9 / 47 (19%)	8 / 45 (18%)	
≤ 65	75 / 92 (82%)	38 / 47 (81%)	37 / 45 (82%)	
Alter.Strata2				0.330
30 - 40	4 / 92 (4.3%)	2 / 47 (4.3%)	2 / 45 (4.4%)	
40 - 50	14 / 92 (15%)	9 / 47 (19%)	5 / 45 (11%)	
50 - 60	33 / 92 (36%)	13 / 47 (28%)	20 / 45 (44%)	
60 - 70	37 / 92 (40%)	22 / 47 (47%)	15 / 45 (33%)	

Variable	Overall, N = 92 ¹	Interventionsgruppe, N = 47 ¹	Kontrollgruppe, N = 45 ¹	p-value ²
70 +	4 / 92 (4.3%)	1 / 47 (2.1%)	3 / 45 (6.7%)	

¹n / N (%)

²Welch 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	213.51	1	1503.76	14.11	0.000	0.20	0.26
Gruppe	201.84	1	1288.26	12.18	0.000	0.18	0.25
Geschlecht	47.72	1	1225.31	2.40	0.122	0.04	0.07
Alter	8.65	1	4049.94	0.51	0.473	0.01	0.01
BMI	15.56	1	2364.85	0.90	0.342	0.01	0.02
Residual	606.78	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-3.456	0.512	-4.466	-2.445
Kontrollgruppe	-0.525	0.392	-1.297	0.247

	Difference	SD	Effect (d)
Empirical	2.92	3.10	0.94
Model	2.93	3.07	0.95

3.1.2 ESS Normal Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	205.61	1	1640.55	14.47	0.000	0.19	0.26
Gruppe	205.47	1	1368.63	13.11	0.000	0.19	0.26
Geschlecht	50.71	1	1174.89	2.50	0.114	0.05	0.08
Alter	7.03	1	5760.17	0.47	0.491	0.01	0.01
BMI	16.17	1	2004.81	0.88	0.349	0.01	0.03
Residual	596.22	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-3.484	0.511	-4.492	-2.475
Kontrollgruppe	-0.515	0.422	-1.348	0.317

	Difference	SD	Effect (d)
Empirical	2.92	3.10	0.94
Model	2.97	3.17	0.94

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

3.2.1 PSQI Reference Based Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	82.40	1	956.92	6.22	0.013	0.14	0.18
Gruppe	93.34	1	1469.25	9.39	0.002	0.16	0.20
Geschlecht	5.76	1	4196.20	0.57	0.452	0.01	0.01
Alter	5.92	1	4109.12	0.59	0.441	0.01	0.02
BMI	11.81	1	2517.52	1.20	0.273	0.02	0.03
Residual	383.57	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-2.286	0.318	-2.913	-1.658
Kontrollgruppe	-0.314	0.356	-1.016	0.387

	Difference	SD	Effect (d)
Empirical	2.03	2.36	0.86
Model	1.97	2.28	0.86

3.2.2 PSQI Normal Imputation

	SSQ	df1	df2	F	p	eta2	partial eta2
Score_t0	83.41	1	1048.52	6.93	0.009	0.14	0.18
Gruppe	92.74	1	1508.72	9.63	0.002	0.16	0.20
Geschlecht	6.02	1	3949.26	0.59	0.442	0.01	0.02
Alter	5.69	1	5148.76	0.65	0.420	0.01	0.01
BMI	12.60	1	1930.14	1.11	0.293	0.02	0.03

	SSQ	df1	df2	F	p	eta2	partial eta2
Residual	379.55	NA	NA	NA	NA	NA	NA

	Estimate	Std. error	95% CI lower	95% CI upper
Interventionsgruppe	-2.280	0.302	-2.877	-1.684
Kontrollgruppe	-0.311	0.361	-1.023	0.402

	Difference	SD	Effect (d)
Empirical	2.03	2.36	0.86
Model	1.97	2.25	0.88

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	189.32	189.32	24.920	0.000	0.181	0.236
Score_t0	1	208.49	208.49	27.443	0.000	0.142	0.195
Alter	1	0.18	0.18	0.024	0.878	0.001	0.002
Geschlecht	1	42.70	42.70	5.621	0.020	0.039	0.063
BMI	1	9.10	9.10	1.198	0.277	0.008	0.014
Residuals	83	630.56	7.60	NA	NA	NA	NA

Gruppe	emmean	SE	lower.CL	upper.CL
Interventionsgruppe	-3.541	0.432	-4.399	-2.683
Kontrollgruppe	-0.574	0.421	-1.411	0.264

	Difference	SD	Effect (d)
Empirical	2.03	2.36	0.86
Model	2.97	2.89	1.03

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	91.52	91.52	18.916	0.000	0.144	0.171
Score_t0	1	69.34	69.34	14.332	0.000	0.103	0.129
Alter	1	2.24	2.24	0.463	0.498	0.004	0.006
Geschlecht	1	2.90	2.90	0.600	0.441	0.004	0.006

Term	df	SSQ	MSQ	F	p	eta2	partial eta2
BMI	1	8.97	8.97	1.854	0.177	0.016	0.022
Residuals	83	401.58	4.84	NA	NA	NA	NA

Gruppe	emmean	SE	lower.CL	upper.CL
Interventionsgruppe	-2.287	0.344	-2.972	-1.601
Kontrollgruppe	-0.348	0.336	-1.016	0.320

	Difference	SD	Effect (d)
Empirical	2.03	2.36	0.86
Model	1.94	2.31	0.84

5. Responderanalyse | Responder Analysis

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

****Tabelle****

Variable	Overall, N = 92 ¹	Interventionsgruppe, N = 47 ¹	Kontrollgruppe, N = 45 ¹	p-value ²
Responder				0.002
Gleich	33 / 89 (37%)	11 / 44 (25%)	22 / 45 (49%)	
Verbessert	42 / 89 (47%)	29 / 44 (66%)	13 / 45 (29%)	
Verschlechtert	14 / 89 (16%)	4 / 44 (9.1%)	10 / 45 (22%)	
Unknown	3	3	0	

¹n / N (%)

²Pearson's Chi-squared test

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

****Tabelle****

Variable	Overall, N = 92 ¹	Interventionsgruppe, N = 47 ¹	Kontrollgruppe, N = 45 ¹	p-value ²
Responder				0.002
Gleich	39 / 89 (44%)	13 / 44 (30%)	26 / 45 (58%)	
Verbessert	38 / 89 (43%)	27 / 44 (61%)	11 / 45 (24%)	

Variable	Overall, N = 92 ¹	Interventionsgruppe, N = 47 ¹	Kontrollgruppe, N = 45 ¹	p-value ²
Verschlechtert	12 / 89 (13%)	4 / 44 (9.1%)	8 / 45 (18%)	
Unknown	3	3	0	

¹n / N (%)

²Pearson'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)	0.083	0.003	2.095	0.131
Alter	1.019	0.968	1.072	0.476
Geschlechtm	2.874	1.045	7.904	0.041
GruppeKontrollgruppe	5.482	2.125	14.140	0.000

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

var	OR	lower OR 95%-CI	upper OR 95%-CI	p.value
(Intercept)	0.342	0.015	7.657	0.499
Alter	1.003	0.954	1.055	0.901
Geschlechtm	1.840	0.692	4.894	0.222
GruppeKontrollgruppe	5.186	2.047	13.142	0.001

6. Gemischte Lineare Modelle | Linear Mixed Models

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

	coefficients	sigma	tstat	pvalues
(Intercept)	-2.050	2.089	-0.981	0.327
score_t0	1.013	0.062	16.462	0.000
GruppeKontrollgruppe	1.540	0.345	4.466	0.000
time1	1.441	0.833	1.730	0.084
time2	1.932	0.835	2.313	0.021
Alter	0.024	0.019	1.276	0.202
Geschlechtm	0.764	0.372	2.053	0.040
BMI	-0.028	0.063	-0.445	0.657
score_t0:time1	-0.263	0.076	-3.456	0.001
score_t0:time2	-0.367	0.076	-4.821	0.000

Randmittelwert | Estimated Marginal Means

Gruppe	emmean	SE	df	CI (lower)	CI (upper)
2					
Interventionsgruppe	7.604	0.305	85	6.998	8.210
Kontrollgruppe	9.144	0.304	85	8.541	9.748

Effekte | Effects

	Difference	SD	Effect (d)
Empirical	2.92	3.10	0.94
Model	1.54	2.06	0.75

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	-1.540	0.345	85	-4.466	0.000	-0.759	-1.190	-0.329

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

	coefficients	sigma	tstat	pvalues
(Intercept)	0.529	1.500	0.352	0.725
score_t0	1.021	0.073	14.026	0.000
GruppeKontrollgruppe	1.039	0.244	4.260	0.000
time1	1.211	0.712	1.702	0.089
time2	1.511	0.715	2.113	0.035
Alter	0.016	0.013	1.161	0.246
Geschlechtm	0.137	0.260	0.527	0.598
BMI	-0.083	0.044	-1.894	0.058
score_t0:time1	-0.255	0.091	-2.789	0.005
score_t0:time2	-0.374	0.092	-4.079	0.000

Randmittelwert | Estimated Marginal Means

Gruppe	emmean	SE	df	CI (lower)	CI (upper)
2					
Interventionsgruppe	5.622	0.217	85	5.190	6.054
Kontrollgruppe	6.661	0.216	85	6.231	7.092

Effekte | Effects

	Difference	SD	Effect (d)
Empirical	2.03	2.36	0.86

	Difference	SD	Effect (d)
Model	1.04	1.47	0.71

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	-1.039	0.244	85	-4.260	0.000	-0.719	-1.148	-0.290

7. Deskriptive Statistik | Descriptive statistics

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

****Tabelle****

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p-value ¹
Score_t0				0.837
N	91.00	46.00	45.00	
Mean (SD)	10.13 (4.10)	10.04 (4.14)	10.22 (4.11)	
Median (IQR)	10.00 (8.00, 12.00)	10.00 (7.00, 12.75)	10.00 (8.00, 12.00)	
Range	0.00, 23.00	0.00, 19.00	1.00, 23.00	
Unknown	1	1	0	
Score_t2				<0.001
N	89.00	44.00	45.00	
Mean (SD)	8.39 (4.09)	6.89 (3.75)	9.87 (3.90)	
Median (IQR)	8.00 (6.00, 12.00)	7.00 (4.00, 10.25)	9.00 (7.00, 13.00)	
Range	0.00, 20.00	0.00, 13.00	1.00, 20.00	
Unknown	3	3	0	
Score_Differenz_t2_t0				<0.001
N	89.00	44.00	45.00	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p-value ¹
Mean (SD)	-1.80 (3.50)	-3.27 (3.92)	-0.36 (2.29)	
Median (IQR)	-1.00 (-4.00, 1.00)	-2.00 (-6.00, -1.00)	-1.00 (-2.00, 1.00)	
Range	-12.00, 5.00	-12.00, 4.00	-5.00, 5.00	
Unknown	3	3	0	

¹Welch Two Sample t-test

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

****Tabelle****

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p-value ¹
Score_t0				0.716
N	91.00	46.00	45.00	
Mean (SD)	7.38 (2.47)	7.48 (2.45)	7.29 (2.51)	
Median (IQR)	7.00 (5.50, 9.00)	7.00 (5.25, 9.00)	7.00 (6.00, 9.00)	
Range	3.00, 13.00	3.00, 13.00	3.00, 13.00	
Unknown	1	1	0	
Score_t2				0.002
N	89.00	44.00	45.00	
Mean (SD)	6.16 (2.84)	5.25 (2.38)	7.04 (2.99)	
Median (IQR)	5.00 (4.00, 7.00)	5.00 (4.00, 7.00)	6.00 (5.00, 9.00)	
Range	1.00, 15.00	1.00, 13.00	2.00, 15.00	
Unknown	3	3	0	
Score_Differenz_t2_t0				<0.001
N	89.00	44.00	45.00	
Mean (SD)	-1.25 (2.56)	-2.27 (2.40)	-0.24 (2.33)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p-value ¹
Median (IQR)	-1.00 (-3.00, 0.00)	-2.00 (-4.00, -1.00)	0.00 (-1.00, 1.00)	
Range	-7.00, 6.00	-7.00, 3.00	-5.00, 6.00	
Unknown	3	3	0	

¹Welch Two Sample t-test

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

****Tabelle****

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p-value ¹
Ø.-.durchschnittl..O2_t0				0.576
N	87.00	42.00	45.00	
Mean (SD)	95.16 (1.41)	95.07 (1.63)	95.24 (1.19)	
Median (IQR)	95.00 (94.00, 96.00)	95.00 (94.25, 96.00)	95.00 (94.00, 96.00)	
Range	89.00, 98.00	89.00, 98.00	92.00, 97.00	
Unknown	5	5	0	
O2-Wert_t0				0.611
N	91.00	46.00	45.00	
Mean (SD)	8.90 (1.60)	8.81 (2.03)	8.98 (1.01)	
Median (IQR)	9.60 (8.40, 9.80)	9.70 (8.63, 9.80)	9.40 (8.10, 9.90)	
Range	0.00, 10.00	0.00, 10.00	6.60, 10.00	
Unknown	1	1	0	
Wie.oft.sinkt.um.>4%.die.ganze.Nacht.über_t0				0.456
N	91.00	46.00	45.00	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Mean (SD)	20.40 (36.77)	23.24 (47.27)	17.49 (21.53)	
Median (IQR)	6.00 (2.00, 26.00)	5.00 (2.25, 16.75)	11.00 (2.00, 27.00)	
Range	0.00, 255.00	0.00, 255.00	0.00, 105.00	
Unknown	1	1	0	
Sinkt.>4%.pro.Stunde_t0				0.425
N	91.00	46.00	45.00	
Mean (SD)	2.66 (4.65)	3.04 (6.01)	2.26 (2.64)	
Median (IQR)	0.90 (0.30, 3.20)	0.70 (0.33, 2.29)	1.40 (0.30, 3.90)	
Range	0.00, 29.30	0.00, 29.30	0.00, 12.70	
Unknown	1	1	0	
Wie.oft.sinkt.um.>3%.die. ganze.Nacht.über_t0				0.581
N	91.00	46.00	45.00	
Mean (SD)	31.70 (44.54)	34.26 (54.20)	29.09 (32.25)	
Median (IQR)	16.00 (4.00, 37.00)	11.00 (4.00, 29.50)	19.00 (5.00, 41.00)	
Range	0.00, 255.00	0.00, 255.00	0.00, 149.00	
Unknown	1	1	0	
sinkt.>3%.pro.Stunde_t0				0.513
N	90.00	45.00	45.00	
Mean (SD)	4.13 (5.62)	4.52 (7.00)	3.74 (3.82)	
Median (IQR)	2.05 (0.53, 5.05)	1.50 (0.50, 4.00)	3.10 (0.70, 5.60)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Range	0.00, 29.30	0.00, 29.30	0.00, 18.10	
Unknown	2	2	0	
die.Sekunden.der. Sauerstoffsättigung.<90%_t0				0.366
N	91.00	46.00	45.00	
Mean (SD)	394.27 (1,573.94)	541.76 (2,143.44)	243.51 (567.84)	
Median (IQR)	42.00 (10.00, 166.00)	39.00 (14.50, 109.50)	50.00 (10.00, 240.00)	
Range	0.00, 14,150.00	0.00, 14,150.00	0.00, 3,535.00	
Unknown	1	1	0	
Wie.viel.%.der.Schlafzeit.<90%. Sauerstoffsättigung_t0				0.348
N	91.00	46.00	45.00	
Mean (SD)	1.36 (5.21)	1.86 (7.11)	0.84 (1.83)	
Median (IQR)	0.10 (0.00, 0.64)	0.05 (0.00, 0.45)	0.10 (0.00, 1.00)	
Range	0.00, 46.00	0.00, 46.00	0.00, 10.90	
Unknown	1	1	0	
die.Sekunden.der.Sauerstoff- sättigung.90-94%_t0				0.917
N	91.00	46.00	45.00	
Mean (SD)	6,855.74 (6,936.77)	6,780.07 (6,730.12)	6,933.09 (7,217.25)	
Median (IQR)	5,054.00 (1,361.00, 9,103.00)	5,402.00 (2,197.00, 8,670.00)	4,574.00 (1,094.00, 9,546.00)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Range	0.00, 33,083.00	10.00, 33,083.00	0.00, 27,044.00	
Unknown	1	1	0	
Wie.viel.%.der.Schlafzeit.90- 94%.Sauerstoffsättigung_t0				0.896
N	91.00	46.00	45.00	
Mean (SD)	26.14 (24.91)	25.79 (23.90)	26.49 (26.16)	
Median (IQR)	18.30 (4.95, 39.72)	19.10 (8.25, 35.25)	18.30 (4.00, 46.00)	
Range	0.00, 93.00	0.00, 93.00	0.00, 83.42	
Unknown	1	1	0	
Ø.-.durchschnittl..O2_t2				0.807
N	88.00	44.00	44.00	
Mean (SD)	95.51 (1.30)	95.48 (1.28)	95.55 (1.32)	
Median (IQR)	96.00 (95.00, 96.00)	96.00 (95.00, 96.00)	96.00 (95.00, 96.00)	
Range	92.00, 98.00	92.00, 98.00	92.00, 98.00	
Unknown	4	3	1	
02-Wert_t2				0.905
N	88.00	44.00	44.00	
Mean (SD)	9.13 (1.07)	9.12 (1.14)	9.15 (0.99)	
Median (IQR)	9.70 (8.68, 9.90)	9.70 (8.60, 9.90)	9.65 (8.78, 9.90)	
Range	5.30, 10.00	5.30, 10.00	5.70, 10.00	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Unknown	4	3	1	
Wie.oft.sinkt.um.>4%.die.ganze. Nacht.über_t2				0.943
N	88.00	44.00	44.00	
Mean (SD)	12.11 (17.67)	11.98 (19.28)	12.25 (16.13)	
Median (IQR)	4.00 (0.00, 17.00)	4.00 (0.00, 16.00)	3.50 (1.00, 18.25)	
Range	0.00, 84.00	0.00, 84.00	0.00, 61.00	
Unknown	4	3	1	
Sinkt.>4%.pro.Stunde_t2				0.977
N	88.00	44.00	44.00	
Mean (SD)	1.69 (2.42)	1.70 (2.70)	1.68 (2.15)	
Median (IQR)	0.55 (0.00, 2.41)	0.56 (0.00, 2.13)	0.55 (0.10, 2.61)	
Range	0.00, 10.90	0.00, 10.90	0.00, 8.98	
Unknown	4	3	1	
Wie.oft.sinkt.um.>3%.die.ganze. Nacht.über_t2				0.880
N	88.00	44.00	44.00	
Mean (SD)	21.53 (25.95)	21.95 (28.61)	21.11 (23.32)	
Median (IQR)	13.00 (2.00, 28.25)	15.00 (1.00, 28.00)	11.50 (2.75, 31.25)	
Range	0.00, 114.00	0.00, 114.00	0.00, 83.00	
Unknown	4	3	1	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value ¹
sinkt.>3%.pro.Stunde_t2				0.848
N	86.00	42.00	44.00	
Mean (SD)	3.00 (3.60)	3.08 (4.12)	2.93 (3.08)	
Median (IQR)	1.68 (0.22, 4.75)	1.58 (0.14, 3.50)	1.68 (0.51, 4.93)	
Range	0.00, 14.90	0.00, 14.90	0.00, 12.22	
Unknown	6	5	1	
die.Sekunden.der.Sauerstoff- sättigung.<90%_t2				0.943
N	90.00	45.00	45.00	
Mean (SD)	265.43 (775.61)	259.53 (673.20)	271.33 (873.82)	
Median (IQR)	6.00 (0.00, 115.00)	4.00 (0.00, 126.00)	6.00 (0.00, 84.00)	
Range	0.00, 4,437.00	0.00, 3,377.00	0.00, 4,437.00	
Unknown	2	2	0	
Wie.viel.%der.Schlafzeit.<90%. Sauerstoffsättigung_t2				0.946
N	88.00	44.00	44.00	
Mean (SD)	1.01 (2.73)	1.03 (2.52)	0.99 (2.96)	
Median (IQR)	0.00 (0.00, 0.48)	0.00 (0.00, 0.71)	0.00 (0.00, 0.30)	
Range	0.00, 14.49	0.00, 11.00	0.00, 14.49	
Unknown	4	3	1	
die.Sekunden.der.Sauerstoff- sättigung.90-94%_t2				0.936
N	91.00	46.00	45.00	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Mean (SD)	5,018.57 (6,469.63)	4,964.15 (6,137.65)	5,074.20 (6,861.61)	
Median (IQR)	1,828.00 (215.00, 8,004.50)	2,128.50 (104.50, 8,202.75)	1,786.00 (434.00, 7,956.00)	
Range	0.00, 24,211.00	0.00, 24,211.00	0.00, 22,939.00	
Unknown	1	1	0	
Wie.viel.%.der.Schlafzeit.90- 94%.Sauerstoffsättigung_t2				0.996
N	88.00	44.00	44.00	
Mean (SD)	20.99 (25.43)	20.97 (24.41)	21.00 (26.69)	
Median (IQR)	7.91 (1.26, 36.94)	8.65 (0.84, 36.94)	7.12 (1.80, 33.08)	
Range	0.00, 86.82	0.00, 83.00	0.00, 86.82	
Unknown	4	3	1	
Ø.-.durchschnittl..O2_ Differenz_t2_t0				0.818
N	86.00	42.00	44.00	
Mean (SD)	-0.35 (1.23)	-0.38 (1.53)	-0.32 (0.88)	
Median (IQR)	0.00 (- 1.00, 0.00)	0.00 (-1.00, 0.00)	0.00 (-1.00, 0.00)	
Range	-8.00, 2.00	-8.00, 2.00	-3.00, 1.00	
Unknown	6	5	1	
O2-Wert_Differenz_t2_t0				0.571
N	88.00	44.00	44.00	
Mean (SD)	-0.26 (1.58)	-0.35 (2.05)	-0.16 (0.92)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Median (IQR)	-0.10 (-0.50, 0.10)	-0.10 (-0.53, 0.25)	0.00 (-0.40, 0.10)	
Range	-9.90, 3.40	-9.90, 2.40	-2.70, 3.40	
Unknown	4	3	1	
Wie.oft.sinkt.um.>4%.die.ganze. Nacht.über_Differenz_t2_t0				0.401
N	88.00	44.00	44.00	
Mean (SD)	8.89 (36.51)	12.18 (46.93)	5.59 (21.74)	
Median (IQR)	1.50 (-1.00, 10.00)	3.00 (-0.50, 15.00)	1.00 (-1.00, 9.25)	
Range	-53.00, 255.00	-53.00, 255.00	-43.00, 103.00	
Unknown	4	3	1	
Sinkt.>4%.pro.Stunde_ Differenz_t2_t0				0.401
N	88.00	44.00	44.00	
Mean (SD)	1.04 (4.65)	1.46 (5.99)	0.63 (2.75)	
Median (IQR)	0.19 (-0.12, 1.76)	0.40 (-0.05, 1.77)	0.10 (-0.12, 1.41)	
Range	-7.53, 29.30	-7.53, 29.30	-6.58, 12.43	
Unknown	4	3	1	
Wie.oft.sinkt.um.>3%.die.ganze. Nacht.über_Differenz_t2_t0				0.573
N	88.00	44.00	44.00	
Mean (SD)	11.05 (42.40)	13.61 (52.78)	8.48 (28.95)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value¹
Median (IQR)	3.00 (- 2.00, 14.25)	3.00 (-4.25, 13.50)	2.50 (-2.00, 14.25)	
Range	-62.00, 254.00	-62.00, 254.00	-60.00, 140.00	
Unknown	4	3	1	
sinkt.>3%.pro.Stunde_Differenz_t2_t0				0.568
N	86.00	42.00	44.00	
Mean (SD)	1.21 (5.45)	1.56 (6.88)	0.87 (3.64)	
Median (IQR)	0.33 (- 0.48, 2.19)	0.35 (-0.83, 2.41)	0.33 (-0.25, 2.08)	
Range	-9.79, 29.16	-9.79, 29.16	-9.12, 16.91	
Unknown	6	5	1	
die.Sekunden.der.Sauerstoff- sättigung.<90%_Differenz_t2_t0				0.361
N	90.00	45.00	45.00	
Mean (SD)	132.53 (1,647.74)	292.89 (2,238.08)	-27.82 (655.93)	
Median (IQR)	7.00 (- 14.00, 45.50)	6.00 (-46.00, 42.00)	8.00 (-4.00, 72.00)	
Range	-3,967.00, 14,150.00	-3,022.00, 14,150.00	-3,967.00, 1,044.00	
Unknown	2	2	0	
Wie.viel.%der.Schlafzeit.<90%. Sauerstoffsättigung_Differenz_t2_t0				0.377
N	88.00	44.00	44.00	
Mean (SD)	0.39 (5.55)	0.92 (7.55)	-0.14 (2.17)	
Median (IQR)	0.00 (- 0.01, 0.12)	0.00 (-0.33, 0.10)	0.00 (0.00, 0.22)	

Variable	Overall, N = 92	Interventionsgruppe, N = 47	Kontrollgruppe, N = 45	p- value ¹
Range	-12.49, 46.00	-9.95, 46.00	-12.49, 3.69	
Unknown	4	3	1	
die.Sekunden.der.Sauerstof- fsättigung.90-94%_Differenz_t2_t0				0.971
N	91.00	46.00	45.00	
Mean (SD)	1,837.16 (5,623.51)	1,815.91 (5,326.00)	1,858.89 (5,972.71)	
Median (IQR)	822.00 (- 169.00, 4,593.00)	1,242.00 (12.50, 5,225.00)	388.00 (- 356.00, 4,105.00)	
Range	- 17,694.00, 24,638.00	-17,694.00, 9,084.00	-9,812.00, 24,638.00	
Unknown	1	1	0	
Wie.viel.%der.Schlafzeit.90- 94%.Sauerstoffsättigung_ Differenz_t2_t0				0.925
N	88.00	44.00	44.00	
Mean (SD)	5.59 (21.87)	5.37 (20.42)	5.81 (23.46)	
Median (IQR)	2.00 (- 1.00, 16.00)	2.50 (-1.00, 19.07)	1.15 (-1.25, 13.58)	
Range	-59.10, 79.00	-59.10, 54.63	-53.26, 79.00	
Unknown	4	3	1	

¹Welch Two Sample t-test