

SnoreFree - OSAS Pilot study - Result report

Dr. Alexander Krannich, BioStats GmbH

24.09.2023

Table of Contents

Table of Contents	2
1. Statistical evaluation of the primary results	3
2. Demographics	4
3. Intention-To-Treat Analysis (ITT)	5
3.1. ANCOVA endpoint - Epworth Sleepiness Scale (ESS).....	5
3.1.1 ESS Reference Based Imputation.....	5
3.1.2 ESS Normal Imputation.....	5
3.2. ANCOVA endpoint - Pittsburgh Sleep Quality Index (PSQI).....	6
3.2.1 PSQI Reference Based Imputation.....	6
3.2.2 PSQI Normal Imputation.....	6
4. Per-Protocol Analysis (PP)	7
4.1. ANCOVA endpoint - Epworth Sleepiness Scale (ESS).....	7
4.2. ANCOVA endpoint - Pittsburgh Sleep Quality Index (PSQI).....	7
5. Responder Analysis	8
5.1. Endpoint - Epworth Sleepiness Scale (ESS).....	8
5.2. Endpoint - Pittsburgh Sleep Quality Index (PSQI).....	8
5.3. Logistic regression - Epworth Sleepiness Scale (ESS).....	8
5.4. Logistische Regression - Pittsburgh Schlafqualitätsindex (PSQI).....	9
6. Linear Mixed Models	10
Endpoint - Epworth Sleepiness Scale (ESS).....	10
Endpoint - Pittsburgh Sleep Quality Index (PSQI).....	10
7. Descriptive statistics	11
7.1. Descriptive statistics - Epworth Sleepiness Scale (ESS).....	11
7.2. Descriptive Statistics - Pittsburgh Sleep Quality Index (PSQI).....	11
7.3. Descriptive statistics - oxygen measurements.....	13

1. Statistical evaluation of the primary results

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 -3.242 in the intervention group and -0.293 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 -3.235 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 ($p < 0.001$) to the baseline-adjusted score difference (end minus beginning) of -2.239 in the intervention group and -0.251 in the control group. ITT analysis for the PSQI with Normal Imputation with the prespecified ANCOVA shows a significant difference ($p < 0.001$) to the baseline-adjusted score difference (end minus beginning) of -2.225 in the intervention group and -0.245 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 ($p \leq 0.001$) 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 (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 (\bar{O}_2) in both groups is above 95% and thus in the normal range of 95-99%. See values in chapter 7.3 " \bar{O}_2 " in the intervention group of 95.07 and in the control group of 95.24.

2. Demographics

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Age				0.956
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	
Gender				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	
Diagnosis				
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%)	
Age.Strata				>0.999
< 40	4 / 92 (4.3%)	2 / 47 (4.3%)	2 / 45 (4.4%)	
≥ 40	88 / 92 (96%)	45 / 47 (96%)	43 / 45 (96%)	

3. Intention-To-Treat Analysis (ITT)

3.1. ANCOVA endpoint - Epworth Sleepiness Scale (ESS)

3.1.1 ESS Reference Based Imputation

	Estimate	Std. error	95% CI lower	95% CI upper	p-value
(Intercept)	0.577	0.748	-0.897	2.052	0.441
Score_t0	-0.377	0.058	-0.492	-0.262	<0.001
Group	2.949	0.606	1.754	4.144	<0.001

	Mean	Std. error	95% CI lower	95% CI upper
Intervention group	-3.242	0.531	-4.288	-2.195
Control group	-0.293	0.324	-0.932	0.346

3.1.2 ESS Normal Imputation

	Estimate	Std. error	95% CI lower	95% CI upper	p-value
(Intercept)	0.549	0.740	-0.910	2.008	0.459
Score_t0	-0.373	0.058	-0.487	-0.260	<0.001
Group	2.959	0.591	1.793	4.124	<0.001

	Mean	Std. error	95% CI lower	95% CI upper
Intervention group	-3.235	0.533	-4.286	-2.184
Control group	-0.276	0.355	-0.977	0.424

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

3.2.1 PSQI Reference Based Imputation

	Estimate	Std. error	95% CI lower	95% CI upper	p-value
(Intercept)	0.436	0.735	-1.014	1.886	0.554
Score_t0	-0.361	0.095	-0.549	-0.173	<0.001
Group	1.988	0.494	1.014	2.962	<0.001

	Mean	Std. error	95% CI lower	95% CI upper
Intervention group	-2.239	0.324	-2.878	-1.600
Control group	-0.251	0.366	-0.974	0.471

3.2.2 PSQI Normal Imputation

	Estimate	Std. error	95% CI lower	95% CI upper	p-value
(Intercept)	0.473	0.741	-0.988	1.933	0.524
Score_t0	-0.364	0.094	-0.549	-0.179	<0.001
Group	1.980	0.474	1.046	2.915	<0.001

	Mean	Std. error	95% CI lower	95% CI upper
Intervention group	-2.225	0.316	-2.848	-1.602
Control group	-0.245	0.369	-0.973	0.484

4. Per-Protocol Analysis (PP)

4.1. ANCOVA endpoint - Epworth Sleepiness Scale (ESS)

Analysis of Variance Model

	Df	Sum Sq	Mean Sq	F value	p-value
Group	1	189.3	189.3	23.85	<0.001
Score_t0	1	208.5	208.5	26.27	<0.001
Residuals	86	682.5	7.937		

Group	Mean	SE	lower.CL	upper.CL
Intervention group	-3.285	0.425	-4.129	-2.440
Control group	-0.344	0.420	-1.179	0.491

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

Analysis of Variance Model

	Df	Sum Sq	Mean Sq	F value	p-value
Group	1	91.52	91.52	18.93	<0.001
Score_t0	1	69.34	69.34	14.35	<0.001
Residuals	86	415.7	4.834		

Group	Mean	SE	lower.CL	upper.CL
Intervention group	-2.230	0.332	-2.890	-1.571
Control group	-0.286	0.328	-0.938	0.366

5. Responder Analysis

5.1. Endpoint - Epworth Sleepiness Scale (ESS)

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Responder				<0.001
Yes	42 / 89 (47%)	29 / 44 (66%)	13 / 45 (29%)	
No	47 / 89 (53%)	15 / 44 (34%)	32 / 45 (71%)	
Unknown	3	3	0	

5.2. Endpoint - Pittsburgh Sleep Quality Index (PSQI)

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Responder				<0.001
Yes	38 / 89 (43%)	27 / 44 (61%)	11 / 45 (24%)	
No	51 / 89 (57%)	17 / 44 (39%)	34 / 45 (76%)	
Unknown	3	3	0	

5.3. 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
Age	1.019	0.968	1.072	0.476
Gender:m	2.874	1.045	7.904	0.041
Group:Control group	5.482	2.125	14.140	<0.001

5.4. 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
Age	1.003	0.954	1.055	0.901
Gender:m	1.840	0.692	4.894	0.222
Group:Control group	5.186	2.047	13.142	0.001

6. Linear Mixed Models

Endpoint - Epworth Sleepiness Scale (ESS)

	coefficients	sigma	tstat	p-value
(Intercept)	1.305	0.521	2.502	0.012
score_t0	0.786	0.043	18.421	<0.001
Group	1.531	0.349	4.387	<0.001
time	-0.900	0.166	-5.421	<0.001

Endpoint - Pittsburgh Sleep Quality Index (PSQI).

	coefficients	sigma	tstat	p-value
(Intercept)	0.947	0.429	2.206	0.027
score_t0	0.799	0.050	15.931	<0.001
Group	1.056	0.247	4.281	<0.001
time	-0.627	0.117	-5.344	<0.001

7. Descriptive statistics

7.1. Descriptive statistics - Epworth Sleepiness Scale (ESS)

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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_Difference_t2_t0				<0.001
N	89.00	44.00	45.00	
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	

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

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Score_t0				0.716

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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_Difference_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)	
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	

7.3. Descriptive statistics - oxygen measurements

Table

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Ø.-average..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-Value_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	
How.often.drops.by.>4%.throughout.the.night_t0				0.456
N	91.00	46.00	45.00	
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	
Decreases.>4%.per.hour_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	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
How.often.drops.by.>3%.throughout.the.night_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	
decreases.>3%.per.hour_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)	
Range	0.00, 29.30	0.00, 29.30	0.00, 18.10	
Unknown	2	2	0	
__the.seconds.of.oxygen.saturation.<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	
How.much.of.sleep.time.<90%.oxygen.saturation_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	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
__the.seconds.of.oxygen.saturation.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)	
Range	0.00, 33,083.00	10.00, 33,083.00	0.00, 27,044.00	
Unknown	1	1	0	
How.much.of.sleep.time.90-94%.oxygen.saturation_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.-average..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-Value_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	
Unknown	4	3	1	
How.often.drops.by.>4%.throughout.the.night_t2				0.943

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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	
Decreases.>4%.per.hour_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	
How.often.drops.by.>3%.throughout.the.night_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	
decreases.>3%.per.hour_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	
__the.seconds.of.oxygen.saturation.<90%_t2__				0.943
N	90.00	45.00	45.00	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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	
How.much.of.sleep.time.<90%.oxygen.saturation_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	
_the.seconds.of.oxygen.saturation.90-94%.t2__				0.936
N	91.00	46.00	45.00	
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	
How.much.of.sleep.time.90-94%.oxygen.saturation_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.-average..O2_Difference_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)	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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	
02-Value_Difference_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)	
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	
How.often.drops.by.>4%.throughout.the.night_Difference_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	
Decreases.>4%.per.hour_Difference_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	
How.often.drops.by.>3%.throughout.the.night_Difference_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)	
Median (IQR)	3.00 (-2.00, 14.25)	3.00 (-4.25, 13.50)	2.50 (-2.00, 14.25)	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
Range	-62.00, 254.00	-62.00, 254.00	-60.00, 140.00	
Unknown	4	3	1	
decreases.>3%.per.hour_Difference_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	
_the.seconds.of.oxygen.saturation.<90%_Difference_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	
How.much.of.sleep.time.<90%.oxygen.saturation_Difference_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)	
Range	-12.49, 46.00	-9.95, 46.00	-12.49, 3.69	
Unknown	4	3	1	
_the.seconds.of.oxygen.saturation.90-94%_Difference_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)	

Variable	Overall, N = 92	Intervention group, N = 47	Control group, N = 45	p-value
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	
How.much.of.sleep.time.90-94% .oxygen.saturation_Difference_t 2_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	