

Effects of LegCare on Restless Leg Syndrome

Survey Summary

-An update after 5 months-

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Introduction

We previously reported findings from a survey of 459 subjects who suffered from Restless Leg Syndrome. The median duration of symptoms in subjects surveyed was 10 years.

It was found that after analysing the symptoms reported before and after the use of the LegCare device, that there was a statistically significant reduction ($p < 10^{-5}$ for all symptoms) in all the symptoms associated with RLS (pain, tingling, loss of sleep) with overall symptoms being reduced by 50% ($p < 10^{-5}$). This was statistically significantly better than the amount of relief that these subjects had obtained with drugs (20%, $p < 10^{-4}$) and other non-drug treatments (10%, $p < 10^{-4}$). 66.1% of subjects had greater than 30% improvement and 45% had greater than 50% improvement in symptoms. Moreover, a statistically significant improvement in quality of life was also reported.

The same group of subjects were asked to report back by questionnaire after 5 months use of the device.

Methods

The *LegCare* wrap contains four powerful neodymium magnets (2000gauss). Each magnet has patented and unique directional plates that allow the negative (south-facing) enhanced magnetic field to be absorbed deeper into the tissues; it is thought that this gives more effective and longer lasting effect. The wraps are fitted below the knee and above the calf muscle (not under compression) and are held in place by “hook and loop” fastening tape. The leg wraps are double lined for comfort, and are adjustable and washable (available in 3 standard sizes). The product is registered as a Class 1 Medical Device. A similar device 4UlcerCare has been found to expedite healing (Eccles & Holinworth, 2005) of chronic leg ulcers and also to prevent their recurrence (Eccles, 2006).

456 of the 459 original subjects who took part in the survey at 4 weeks completed the questionnaire at 5 months. Three subjects had died since the first survey. Subjects were again asked to complete a questionnaire that requested them to report the duration of symptoms and to rate their symptoms (on a scale of 0-10 (where 1 represented mild symptoms and 9-10 more severe symptoms); after 5 months of using the device. Symptoms rated were: level of pain, tingling, sleep disturbance, quality of life as well as overall symptoms. Patients had been instructed to wear the device 24 hours a day (except during bathing) for the duration of the assessment. Two devices had been supplied for subjects to wear on both legs.

Results

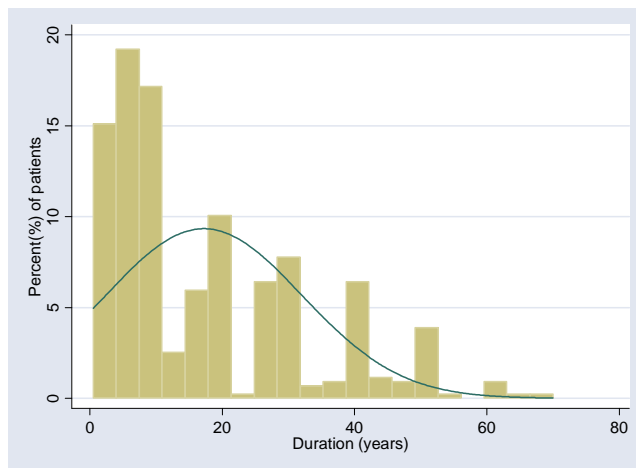


Fig 1.Duration of Symptoms

Median duration of symptoms was 10 years (5 -25 inter quartile ranges, IQR).

Results with LegCare

Restless Legs Study (n=456)

LEVELS OF PAIN:

Frequency distributions:

At start	Freq.	Percent	Cum.
0	155	33.99	33.99
1	17	3.73	37.72
2	51	11.18	48.90
3	19	4.17	53.07
4	11	2.41	55.48
5	50	10.96	66.45
6	65	14.25	80.70
7	15	3.29	83.99
8	19	4.17	88.16
9	26	5.70	93.86
10	28	6.14	100.00
Total	456	100.00	

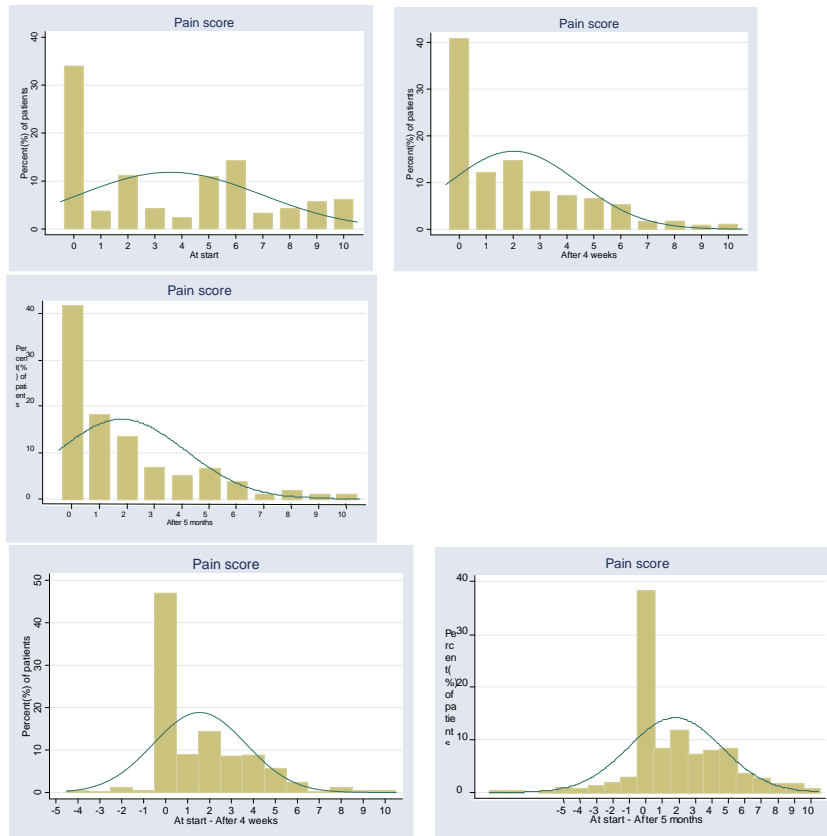
After 4 weeks	Freq.	Percent	Cum.
0	186	40.79	40.79
1	55	12.06	52.85
2	67	14.69	67.54
3	37	8.11	75.66
4	33	7.24	82.89
5	30	6.58	89.47
6	24	5.26	94.74
7	7	1.54	96.27
8	8	1.75	98.03
9	4	0.88	98.90
10	5	1.10	100.00
Total	456	100.00	

After 5 months	Freq.	Percent	Cum.
0	187	41.56	41.56
1	82	18.22	59.78
2	60	13.33	73.11
3	31	6.89	80.00
4	22	4.89	84.89
5	29	6.44	91.33
6	17	3.78	95.11
7	4	0.89	96.00
8	8	1.78	97.78
9	5	1.11	98.89
10	5	1.11	100.00
Total	450	100.00	

At start - After 4 weeks	Freq.	Percent	Cum.
-4	2	0.44	0.44
-3	1	0.22	0.66
-2	5	1.10	1.75
-1	2	0.44	2.19
0	214	46.93	49.12
1	41	8.99	58.11
2	65	14.25	72.37
3	39	8.55	80.92
4	40	8.77	89.69
5	26	5.70	95.39
6	11	2.41	97.81
7	1	0.22	98.03
8	5	1.10	99.12
9	2	0.44	99.56
10	2	0.44	100.00
Total	456	100.00	

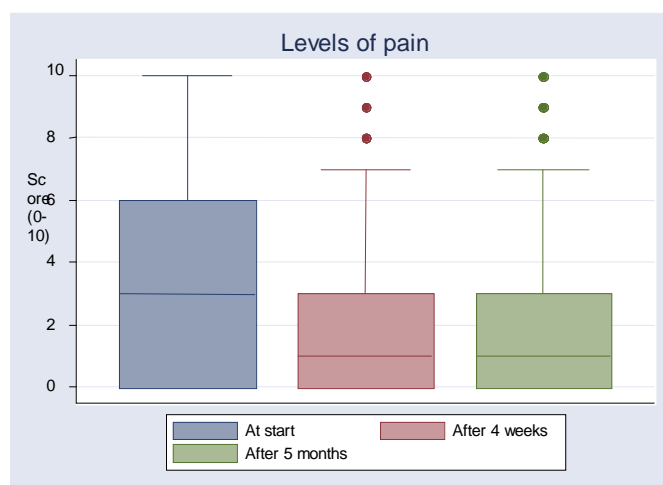
At start - After 5 months	Freq.	Percent	Cum.
-9	1	0.22	0.22
-8	1	0.22	0.44
-6	1	0.22	0.67
-5	4	0.89	1.56
-4	3	0.67	2.22
-3	6	1.33	3.56
-2	8	1.78	5.33
-1	13	2.89	8.22
0	172	38.22	46.44
1	37	8.22	54.67
2	53	11.78	66.44
3	32	7.11	73.56
4	36	8.00	81.56
5	38	8.44	90.00
6	16	3.56	93.56
7	12	2.67	96.22
8	7	1.56	97.78
9	7	1.56	99.33
10	3	0.67	100.00
Total	450	100.00	

Fig 2. Graphs and Stats:



The median and 25th and 75th percentiles are the most appropriate statistics to report as the distributions are skewed. For the same reason, box plots bordered at 25th and 75th percentiles with a median line at 50th percentile are used.

Fig 3. Levels of Pain



Friedman's Analysis of Variance Test: $p < 10^{-5}$ (Highly Statistically Significant)

Levels of pain	N	mean	SE(mean)	25 th percentile	median	75 th percentile
At start	456	3.58	0.1580	0	3	6
After 4 weeks	456	2.03	0.1120	0	1	3
After 5 months	450	1.82	0.1094	0	1	3
At start - After 4 weeks	456	1.55	0.0991	0	1	3
At start - After 5 months	450	1.78	0.1325	0	1	4

TINGLING SYMPTOMS:

Frequency distributions:

At start	Freq.	Percent	Cum.
0	90	19.74	19.74
1	25	5.48	25.22
2	37	8.11	33.33
3	8	1.75	35.09
4	17	3.73	38.82
5	52	11.40	50.22
6	94	20.61	70.83
7	21	4.61	75.44
8	40	8.77	84.21
9	37	8.11	92.32
10	35	7.68	100.00
Total	456	100.00	

After 4 weeks	Freq.	Percent	Cum.
0	130	28.51	28.51
1	51	11.18	39.69
2	68	14.91	54.61
3	52	11.40	66.01
4	59	12.94	78.95
5	31	6.80	85.75
6	25	5.48	91.23
7	13	2.85	94.08
8	12	2.63	96.71
9	9	1.97	98.68
10	6	1.32	100.00
Total	456	100.00	

After 5 months	Freq.	Percent	Cum.
0	143	31.78	31.78
1	70	15.56	47.33
2	81	18.00	65.33
3	43	9.56	74.89
4	25	5.56	80.44
5	37	8.22	88.67
6	28	6.22	94.89
7	7	1.56	96.44
8	6	1.33	97.78
9	4	0.89	98.67
10	6	1.33	100.00
Total	450	100.00	

At start - After 4 weeks	Freq.	Percent	Cum.
-4	1	0.22	0.22
-3	2	0.44	0.66
-2	4	0.88	1.54
-1	8	1.75	3.29
0	152	33.33	36.62
1	51	11.18	47.81
2	77	16.89	64.69
3	46	10.09	74.78
4	32	7.02	81.80
5	35	7.68	89.47
6	24	5.26	94.74
7	7	1.54	96.27
8	14	3.07	99.34
9	2	0.44	99.78
10	1	0.22	100.00
Total	456	100.00	

At start - After 5 months	Freq.	Percent	Cum.
-6	1	0.22	0.22
-5	3	0.67	0.89
-4	2	0.44	1.33
-3	2	0.44	1.78
-2	4	0.89	2.67
-1	11	2.44	5.11
0	133	29.56	34.67
1	43	9.56	44.22
2	45	10.00	54.22
3	49	10.89	65.11
4	45	10.00	75.11
5	36	8.00	83.11
6	31	6.89	90.00
7	21	4.67	94.67
8	9	2.00	96.67
9	12	2.67	99.33
10	3	0.67	100.00
Total	450	100.00	

Fig 4. Graphs and Stats:

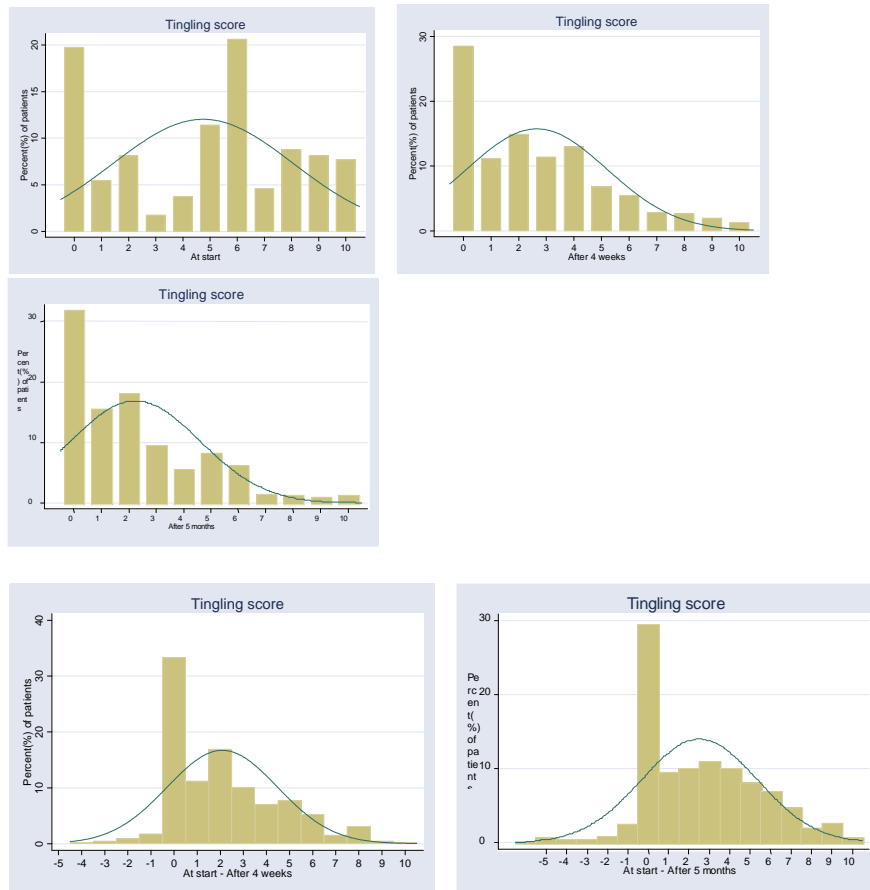
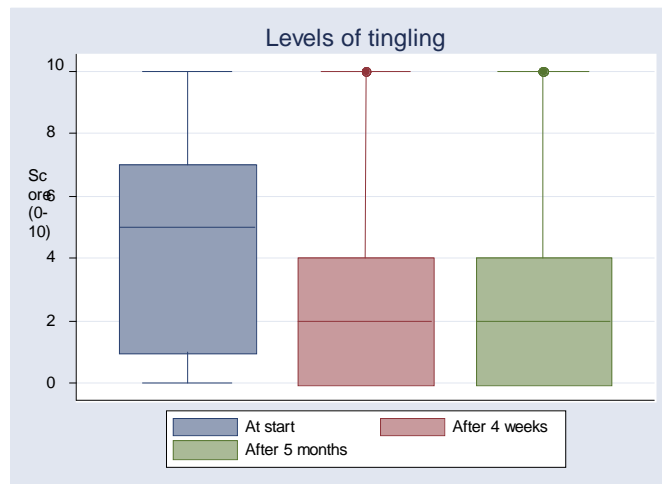


Fig 5. Levels of Tingling



Friedman's Analysis of Variance Test: $p < 10^{-5}$ (Highly Statistically Significant)

Tingling symptoms	N	mean	SE(mean)	25 th percentile	median	75 th percentile
At start	456	4.75	0.1554	1	5	7
After 4 weeks	456	2.66	0.1187	0	2	4
After 5 months	450	2.24	0.1115	0	2	4
At start - After 4 weeks	456	2.09	0.1117	0	2	4
At start - After 5 months	450	2.51	0.1341	0	2	4

SLEEP DISTURBANCE:

Frequency distributions:

At start	Freq.	Percent	Cum.
0	4	0.88	0.88
1	3	0.66	1.54
2	14	3.07	4.61
3	10	2.19	6.80
4	11	2.41	9.21
5	37	8.11	17.32
6	85	18.64	35.96
7	29	6.36	42.32
8	56	12.28	54.61
9	83	18.20	72.81
10	124	27.19	100.00
Total	456	100.00	

After 4 weeks	Freq.	Percent	Cum.
0	53	11.62	11.62
1	49	10.75	22.37
2	67	14.69	37.06
3	50	10.96	48.03
4	40	8.77	56.80
5	53	11.62	68.42
6	29	6.36	74.78
7	35	7.68	82.46
8	32	7.02	89.47
9	23	5.04	94.52
10	25	5.48	100.00
Total	456	100.00	

After 5 months	Freq.	Percent	Cum.
0	57	12.67	12.67
1	64	14.22	26.89
2	86	19.11	46.00
3	46	10.22	56.22
4	42	9.33	65.56
5	41	9.11	74.67
6	31	6.89	81.56
7	20	4.44	86.00
8	25	5.56	91.56
9	19	4.22	95.78
10	19	4.22	100.00
Total	450	100.00	

At start - After 4 weeks	Freq.	Percent	Cum.
-7	2	0.44	0.44
-3	2	0.44	0.88
-2	4	0.88	1.75
-1	4	0.88	2.63
0	63	13.82	16.45
1	41	8.99	25.44
2	73	16.01	41.45
3	57	12.50	53.95
4	54	11.84	65.79
5	49	10.75	76.54
6	47	10.31	86.84
7	24	5.26	92.11
8	20	4.39	96.49
9	9	1.97	98.46
10	7	1.54	100.00
Total	456	100.00	

At start - After 5 months	Freq.	Percent	Cum.
-7	1	0.22	0.22
-3	3	0.67	0.89
-2	2	0.44	1.33
-1	5	1.11	2.44
0	50	11.11	13.56
1	33	7.33	20.89
2	55	12.22	33.11
3	49	10.89	44.00
4	62	13.78	57.78
5	58	12.89	70.67
6	46	10.22	80.89
7	30	6.67	87.56
8	38	8.44	96.00
9	13	2.89	98.89
10	5	1.11	100.00
Total	450	100.00	

Fig 6. Graphs and Stats:

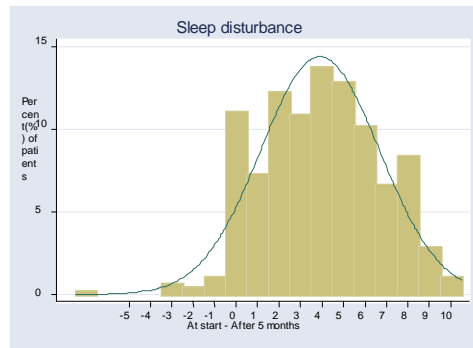
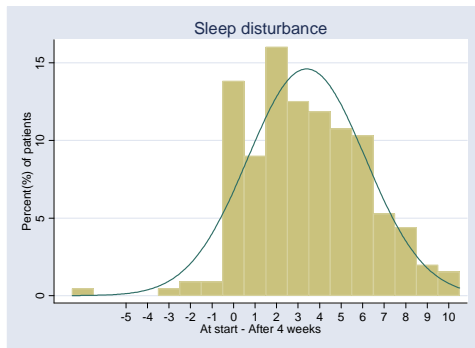
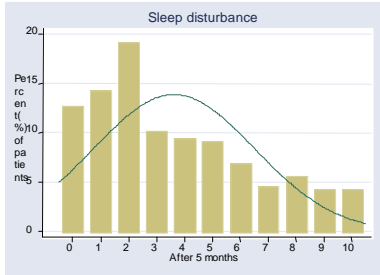
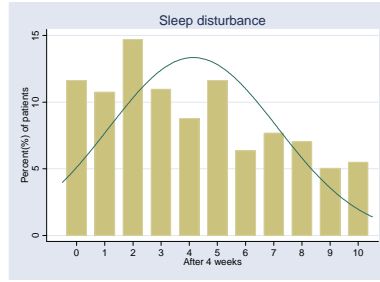
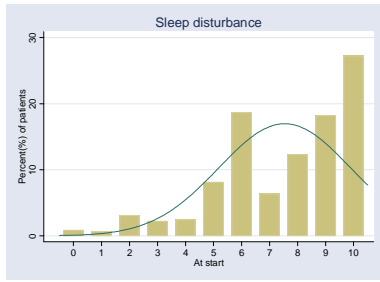
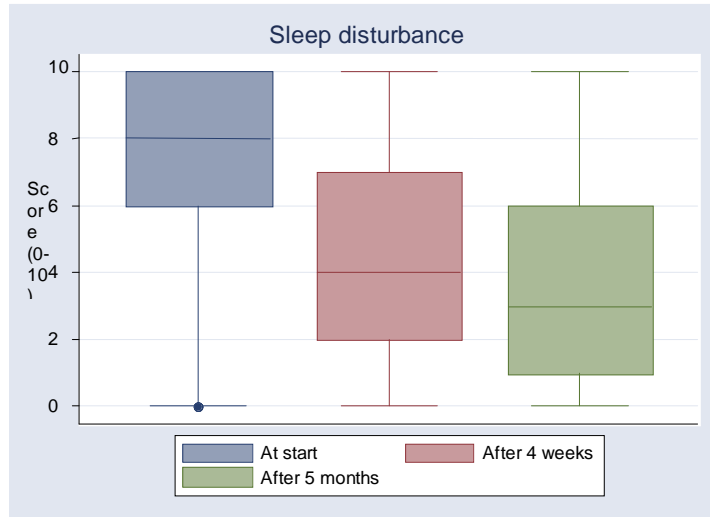


Fig 7. Sleep Disturbance



Friedman's Analysis of Variance Test: $p < 10^{-5}$ (Highly Statistically Significant)

Sleep Disturbance	N	mean	SE(mean)	25 th percentile	median	75 th percentile
At start	456	7.54	0.1101	6	8	10
After 4 weeks	456	4.14	0.1400	2	4	7
After 5 months	450	3.63	0.1357	1	3	6
At start - After 4 weeks	456	3.40	0.1279	1	3	5
At start - After 5 months	450	3.91	0.1307	2	4	6

QUALITY OF LIFE:

Frequency distributions:

At start	Freq.	Percent	Cum.
0	15	3.29	3.29
1	6	1.32	4.61
2	20	4.39	8.99
3	13	2.85	11.84
4	11	2.41	14.25
5	65	14.25	28.51
6	99	21.71	50.22
7	28	6.14	56.36
8	54	11.84	68.20
9	64	14.04	82.24
10	81	17.76	100.00
Total	456	100.00	

After 4 weeks	Freq.	Percent	Cum.
0	48	10.53	10.53
1	55	12.06	22.59
2	74	16.23	38.82
3	50	10.96	49.78
4	56	12.28	62.06
5	58	12.72	74.78
6	29	6.36	81.14
7	20	4.39	85.53
8	27	5.92	91.45
9	24	5.26	96.71
10	15	3.29	100.00
Total	456	100.00	

After 5 months	Freq.	Percent	Cum.
0	66	14.67	14.67
1	76	16.89	31.56
2	86	19.11	50.67
3	48	10.67	61.33
4	38	8.44	69.78
5	44	9.78	79.56
6	26	5.78	85.33
7	15	3.33	88.67
8	21	4.67	93.33
9	18	4.00	97.33
10	12	2.67	100.00
Total	450	100.00	

At start - After 4 weeks	Freq.	Percent	Cum.
-8	1	0.22	0.22
-5	2	0.44	0.66
-3	2	0.44	1.10
-2	4	0.88	1.97
-1	5	1.10	3.07
0	85	18.64	21.71
1	50	10.96	32.68
2	77	16.89	49.56
3	49	10.75	60.31
4	59	12.94	73.25
5	48	10.53	83.77
6	37	8.11	91.89
7	21	4.61	96.49
8	9	1.97	98.46
9	2	0.44	98.90
10	5	1.10	100.00
Total	456	100.00	

At start - After 5 months	Freq.	Percent	Cum.
-8	1	0.22	0.22
-5	3	0.67	0.89
-3	1	0.22	1.11
-2	5	1.11	2.22
-1	5	1.11	3.33
0	66	14.67	18.00
1	33	7.33	25.33
2	61	13.56	38.89
3	50	11.11	50.00
4	64	14.22	64.22
5	58	12.89	77.11
6	39	8.67	85.78
7	30	6.67	92.44
8	18	4.00	96.44
9	9	2.00	98.44
10	7	1.56	100.00
Total	450	100.00	

Fig 8. Graphs and Stats:

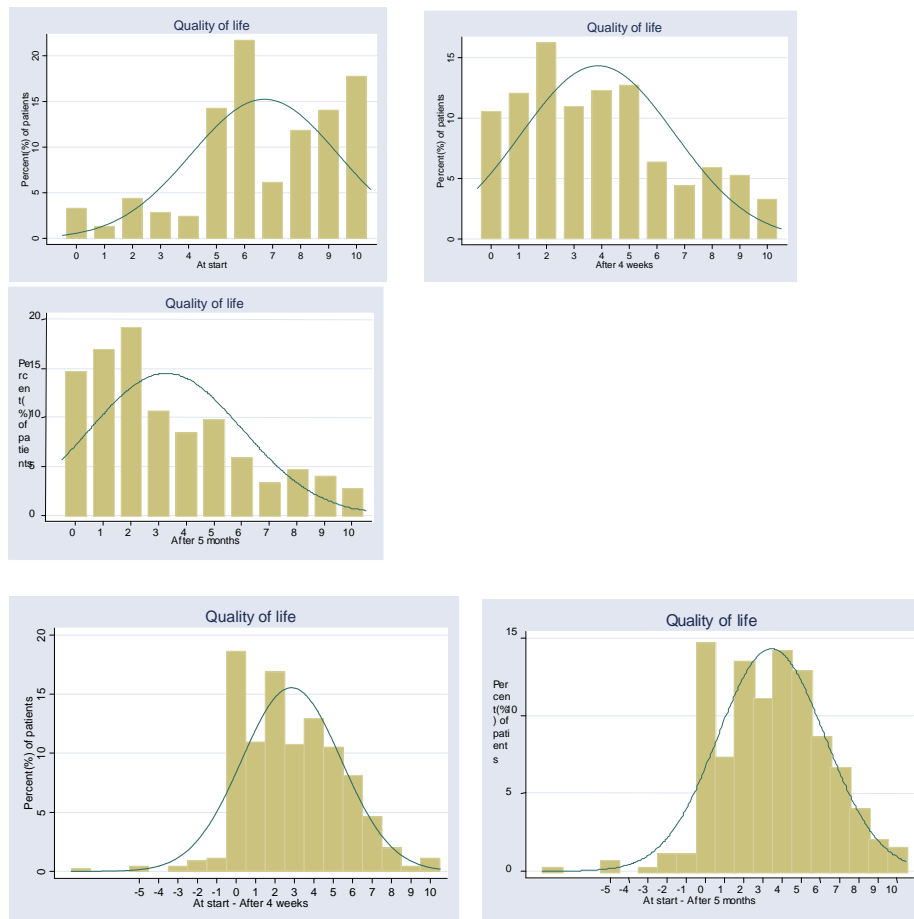


Fig 9. Quality of Life



Friedman's Analysis of Variance Test: $p < 10^{-5}$ (Highly Statistically Significant)

Quality of life	N	mean	SE(mean)	25 th percentile	median	75 th percentile
At start	456	6.71	0.1226	5	6	9
After 4 weeks	456	3.87	0.1304	2	4	6
After 5 months	450	3.28	0.1297	1	2	5
At start - After 4 weeks	456	2.85	0.1201	1	3	5
At start - After 5 months	450	3.44	0.1315	1	3.5	5

OVERALL SYMPTOMS:

Frequency distributions:

At start	Freq.	Percent	Cum.
0	6	1.32	1.32
2	2	0.44	1.75
3	10	2.19	3.95
4	7	1.54	5.48
5	41	8.99	14.47
6	90	19.74	34.21
7	35	7.68	41.89
8	76	16.67	58.55
9	86	18.86	77.41
10	103	22.59	100.00
Total	456	100.00	

After 4 weeks	Freq.	Percent	Cum.
0	31	6.80	6.80
1	32	7.02	13.82
2	80	17.54	31.36
3	55	12.06	43.42
4	72	15.79	59.21
5	45	9.87	69.08
6	46	10.09	79.17
7	23	5.04	84.21
8	29	6.36	90.57
9	22	4.82	95.39
10	21	4.61	100.00
Total	456	100.00	

After 5 months	Freq.	Percent	Cum.
0	38	8.44	8.44
1	81	18.00	26.44
2	84	18.67	45.11
3	47	10.44	55.56
4	48	10.67	66.22
5	45	10.00	76.22
6	35	7.78	84.00
7	12	2.67	86.67
8	19	4.22	90.89
9	21	4.67	95.56
10	20	4.44	100.00
Total	450	100.00	

At start - After 4 weeks	Freq.	Percent	Cum.
-7	1	0.22	0.22
-6	1	0.22	0.44
-4	3	0.66	1.10
-3	1	0.22	1.32
-2	3	0.66	1.97
-1	2	0.44	2.41
0	64	14.04	16.45
1	33	7.24	23.68
2	78	17.11	40.79
3	58	12.72	53.51
4	68	14.91	68.42
5	52	11.40	79.82
6	39	8.55	88.38
7	18	3.95	92.32
8	22	4.82	97.15
9	8	1.75	98.90
10	5	1.10	100.00
Total	456	100.00	

At start - After 5 months	Freq.	Percent	Cum.
-7	1	0.22	0.22
-4	1	0.22	0.44
-2	3	0.67	1.11
-1	6	1.33	2.44
0	56	12.44	14.89
1	34	7.56	22.44
2	40	8.89	31.33
3	43	9.56	40.89
4	68	15.11	56.00
5	80	17.78	73.78
6	32	7.11	80.89
7	28	6.22	87.11
8	31	6.89	94.00
9	20	4.44	98.44
10	7	1.56	100.00
Total	450	100.00	

Fig 9. Graphs and Stats:

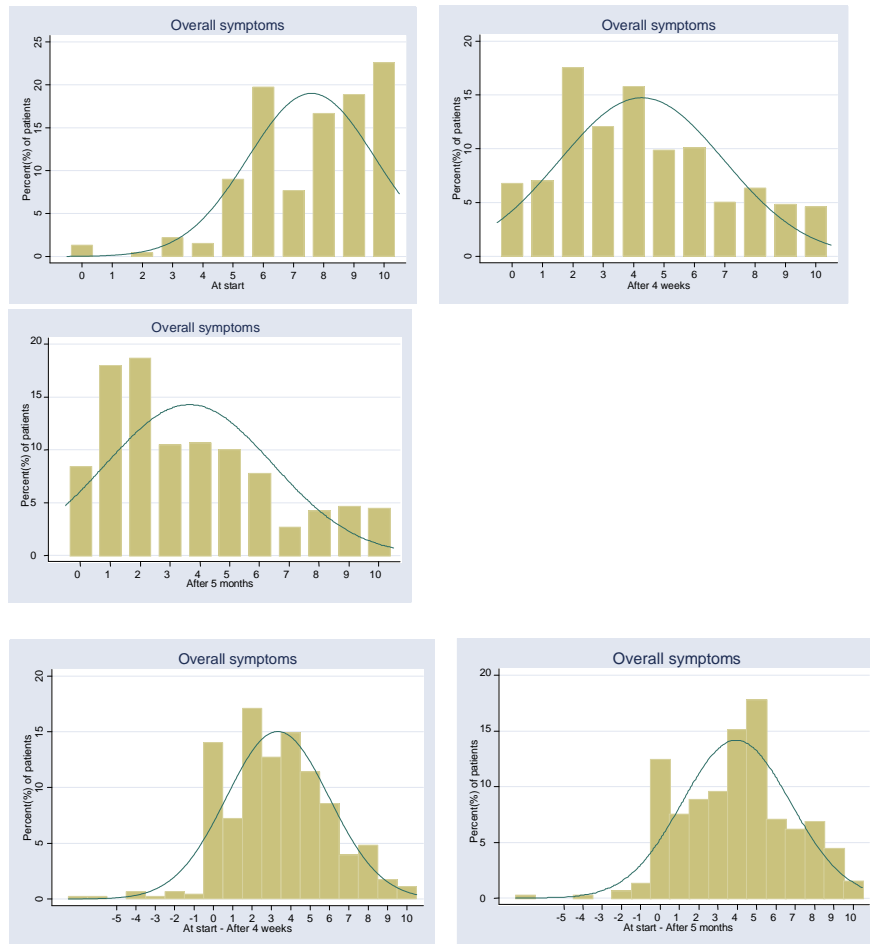
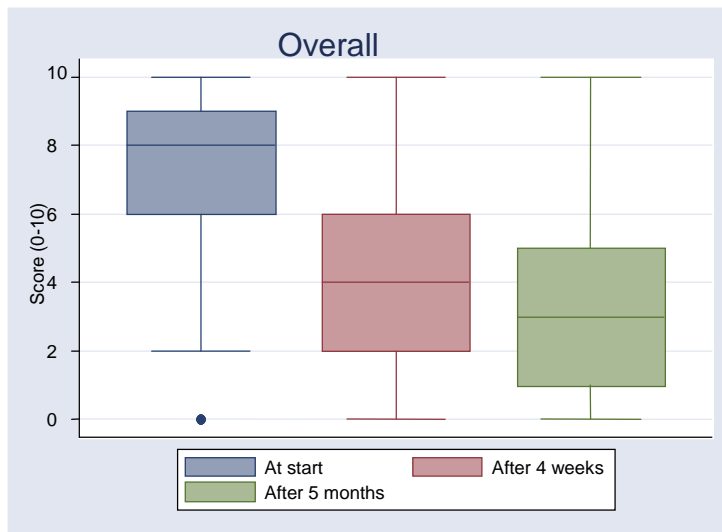


Fig 10. Overall Symptoms



Friedman's Analysis of Variance Test: $p < 10^{-5}$ (Highly Statistically Significant)

Overall symptoms	N	mean	SE(mean)	25 th percentile	median	75 th percentile
At start	456	7.60	0.0983	6	8	9
After 4 weeks	456	4.27	0.1267	2	4	6
After 5 months	450	3.65	0.1317	1	3	5
At start - After 4 weeks	456	3.33	0.1243	2	3	5
At start - After 5 months	450	3.95	0.1326	2	4	6

RLS Statistical Analysis:

As we have 3 repeated measurements for each patient, which are ordinal-scaled, the Friedman Analysis of Variance test was chosen to assess the effect of the device over time. This is the non-parametric form of the two-way Analysis of Variance. The null hypothesis is that the distributions of the ranks at each time point are the same.

For each of the 5 symptoms a highly statistically significant result ($p < 10^{-5}$) was obtained indicating that the reported scores were highly statistically significantly lower after the use of LegCare with regard to the baseline values. Moreover, by visual examination of the box-plots and the median score values, there is a highly statistically significant greater effect ($p < 10^{-5}$) at 4 weeks and this reduction in symptoms remains significant at the same level after 5 months. For this latter comparison the Wilcoxon matched pair signed ranks test was used i.e. the non-parametric equivalent of the paired t-test.

Comparison of LegCare effectiveness in relieving symptoms against drug and other non-drug treatments

The median relief obtained with drug treatments (about 20% reduction of symptoms), for those that tried drug treatments (n=193), was statistically significantly less compared with the median reduction in symptoms with the LegCare ($p < 10^{-4}$).

The median relief obtained with other non-drug treatments (about 10% reduction of symptoms), for those that tried non-drug treatments (n=145), was statistically significantly less when compared with the median reduction in symptoms with the LegCare ($p < 10^{-4}$).

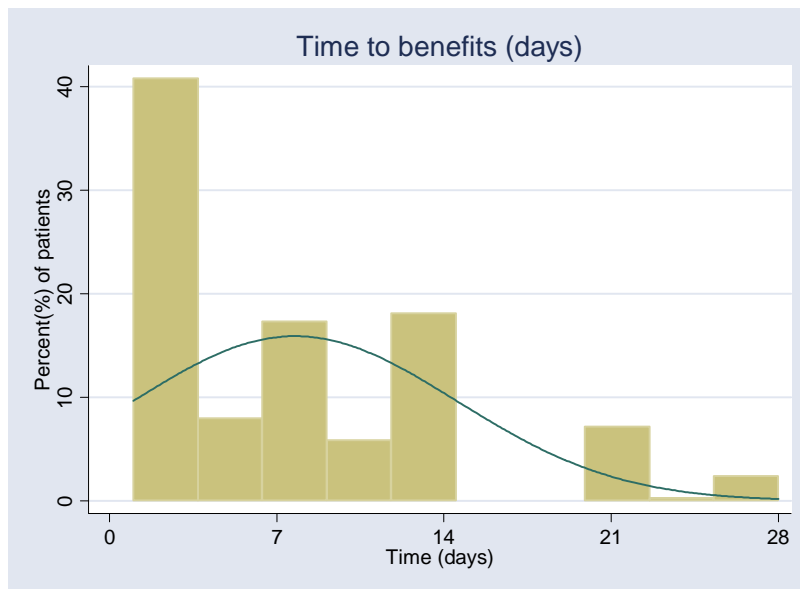
TIME TO BENEFITS

TIME TO BENEFITS:

Time to benefits (days)	Freq.	Percent	Cum.
1*	64	17.07	17.07
2	38	10.13	27.20
3	51	13.60	40.80
4	14	3.73	44.53
5	11	2.93	47.47
6	5	1.33	48.80
7	60	16.00	64.80
8	4	1.07	65.87
9	1	0.27	66.13
10	22	5.87	72.00
14	68	18.13	90.13
20	1	0.27	90.40
21	25	6.67	97.07
22	1	0.27	97.33
25	1	0.27	97.60
28	9	2.40	100.00
Total	375	100.00	

* including 3 cases where time to benefits < 1

Fig 11. Time to Benefits



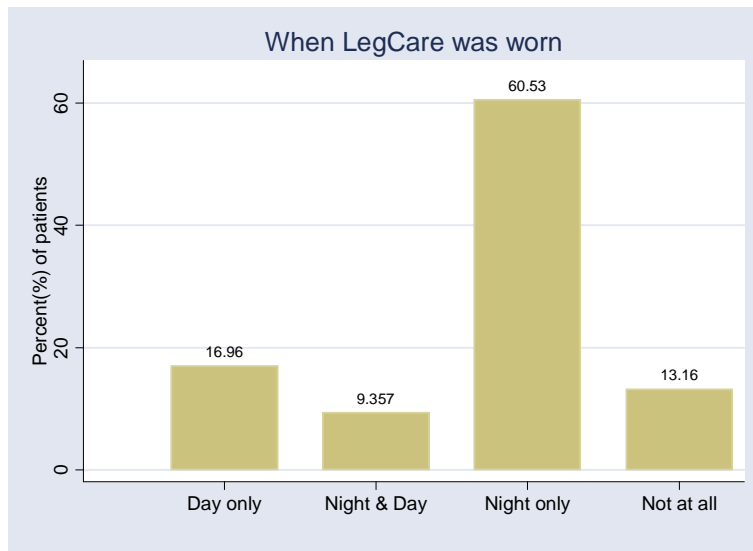
time	N	mean	se(mean)	min	max	p25	p50	p75
	375	7.76	0.3497	1	28	2	7	14

p25: 25th percentile
 p50: median
 p75: 75th percentile

WHEN LEGCARE WAS WORN:

	Freq.	Percent	Cum.
Day only	58	16.96	16.96
Night & Day	32	9.36	26.32
Night only	207	60.53	86.84
Not at all	45	13.16	100.00
Total	342	100.00	

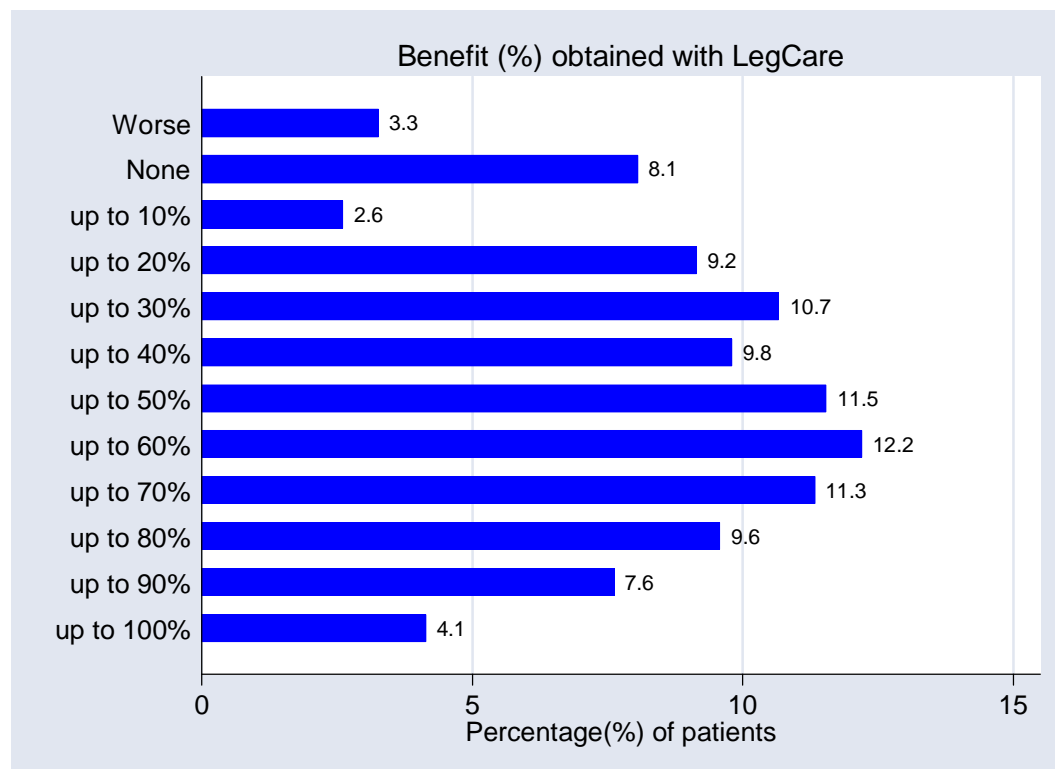
Fig 12. When was LegCare worn



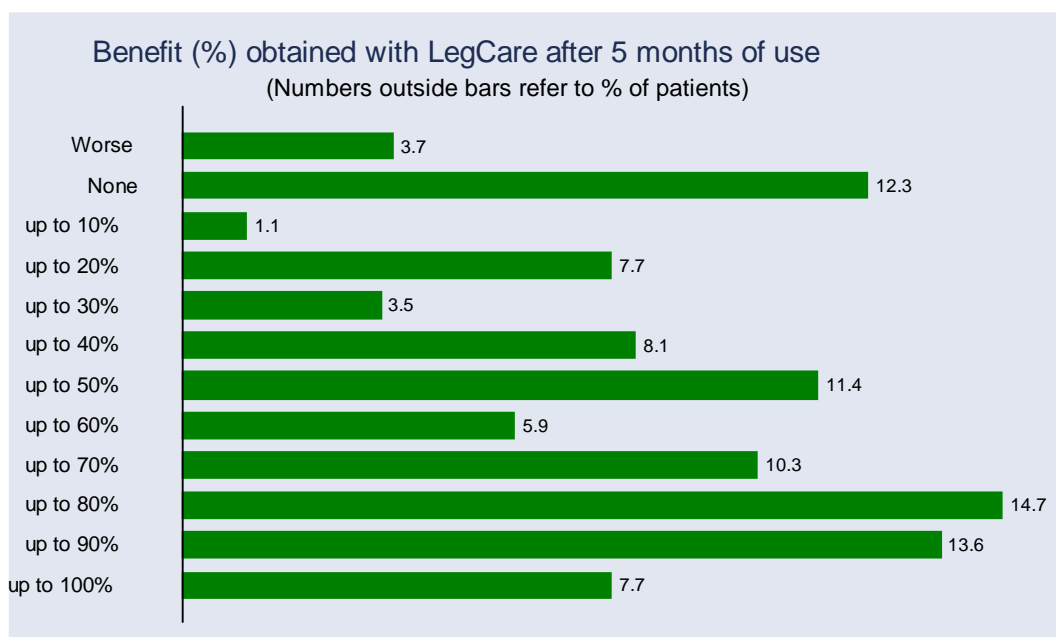
Discussion

Fig 13. Percentage relief of RLS symptoms obtained with LegCare a) at 1 month and b) at 5 months

a)



b)



COMPARISON OF RELIEF OBTAINED AFTER 1 AND 5 MONTHS (Derived from the 2 graphs above)

	At 1 month (%)	At 5 months (%)
>20% improvement	77.8	75.2
>30% improvement	66.1	71.7
>50% improvement	45.0	52.2

The graph of “time to benefit” suggests that the majority (90%) of subjects noticed some benefit of the LegCare on their symptoms after 14 days.

Less than 10% wore the device for 24 hours as instructed. The majority (60.5%), as one would expect, wore the device only at night. Surprisingly, 13% confessed to not wearing the device at all. This would suggest that the results may even be an underestimate of the results that could be obtained.

Symptom Level at 1 and 5 months after wearing LegCare (expressed as % change in median symptom rating in the whole group).

	% reduction in symptom rating at 4 weeks	% reduction in symptom rating at 5 months
Pain	66%	66%
Tingling	60%	60%
Sleep disturbance	50%	63%
Quality of Life	33%	66%
Overall Symptoms	50%	63%

There are several conclusions that can be drawn from the above table:

- 1) There was a trend to even greater symptom reduction after 5 months than after 1 month
- 2) There was no reduction in effect after 5 months
- 3) Overall symptoms were still significantly and more profoundly reduced at 5 months
- 4) There was an even greater improvement in quality of life reporting at 5 months compared with after 1 month

The effects of the LegCare device reported by patients themselves with the syndrome are noteworthy. The size of the effects reported should generate interest in this novel non-invasive method for treating this difficult syndrome. A 66% reduction in overall symptoms as well as a 66% improvement in quality of life together with the non-invasiveness of this treatment would compare favourably with the benefits that these patients reported from their previous use of drugs (20% improvement) and other non-drug treatments (10% improvement).