

## 清华大学慢性下腰痛研究报告（简要）

### 实验介绍：

该科研实验在中国北京清华大学脊骨神经医学研究中心开展进行。一共 62 名慢性下腰痛（下腰痛超过 90 天）受试者，其中女性占 79.0%，年龄从 13 岁到 66 岁，平均年龄为 44 岁。受试者被随机分配到以下四组：1. 控制组（Control）16 名，87.5% 女性；2. 仅治疗组（C）16 名，75% 女性；3. 仅睡眠系统组（SS）14 名，64.3% 女性；4. 同时接受睡眠与治疗的组（SS&C）16 名，81.3% 女性。治疗包括脊骨神经医学医生对受试者进行脊柱的检查与治疗；睡眠系统包括提供的一张床垫和一个枕头（由中国“Sinomax 赛诺家居用品（深圳）有限公司”提供的“医生的选择”睡眠系统）在睡眠时对脊柱相对应支撑。基于受试者在实验前签订的知情同意书，受试者将接受实验开始前和结束后的身体检查、植物神经系统检查以及 SF-36 的身体健康指标问卷的作答。所有四组受试者的年龄都吻合（ $p > 0.9620$ ），BMI 和身体以及心理组成部分的汇总分数也相吻合（ $p > 0.1200$ ）

### 实验结果：

表 1. 仅使用睡眠系统组（SS）在一段时间后，身体质量平均分数比控制组有显著的提高（7.2%， $p = 0.0337$ ）。有显著变化的身体质量分数分别为身体疼痛（ $p = 0.0237$ ）和整体健康（ $p = 0.0279$ ）。同时接受睡眠与治疗的组（SS&C）在自我评定上也高于控制组。所有的身体指标参数都有显著变化。最显著的分别是身体疼痛（BP）（ $p = 0.0005$ ）和整体身体健康（GH）（ $p = 0.0083$ ）。该组的平均心理健康分数并没有显著的改变（ $p = 0.0521$ ），但是心理健康（MH）有明显下降（6.3%， $p = 0.0592$ ），身体活力（VT）有显著提升（ $p = 0.0087$ ）。SS&C 小组的整体健康分数比仅使用睡眠系统组（SS）（ $p = 0.0053$ ）和仅治疗组（C）（ $p = 0.00234$ ）提高得都更加显著。仅治疗组（C）显示了血压平均值有显著的降低（6/5mmHg）（ $p = 0.0494$ ）。同时接受睡眠与治疗的组（SS&C）也同时显示了显著的血压值降低（11/5mmHg）（ $p = 0.0130$ ）。

**Table 1:** Changes in Self-Assessed health status (SF-36 questionnaire) results and hemodynamic (Blood Pressure & Heart Rate) responses upon follow-up for the individual experimental subgroups and controls.

	Control	Sleep System		Chiropractic		SS&C	
Parameter*	Ave	Ave	p**	Ave	p**	Ave	p**
PF	48.5	50.1	0.1822	52.6	0.0054	50.4	0.0448
RP	41.6	45.1	0.0617	48.3	0.0241	53.5	0.0196
BP	50.8	51.8	0.0237	53.2	0.0086	52.5	0.0005
GH	42.1	46.7	0.0279	48.5	0.0018	48.5	0.0083
VT	56.5	57.0	0.0969	57.0	0.0540	57.4	0.0087
SF	48.1	52.1	0.0979	51.7	0.0360	49.2	0.2741
RE	42.7	44.8	0.2245	48.1	0.0536	49.6	0.1777
MH	48.0	47.7	0.1303	45.8	0.0587	45.0	0.0592
PCS	44.6	47.8	0.0337	50.8	0.0160	51.4	0.0012
MCS	49.0	48.7	0.1569	49.1	0.0504	49.7	0.0521
HR (bpm)	77.1	74.8	0.2549	71.1	0.2194	77.1	0.4035
Blood Pressure (mmHg)	113/67	110/64	0.3601	107/62	0.0494	102/62	0.0130

\*SF-36 Norm-based Scale Scores. \*\*Correlations are with the Control Group. PF = Physical Function; RP = Role-Physical Function; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Functioning; RE = Role-Emotional Function; MH = Mental Health; PCS = Physical Component Score; MCS = Mental Component Score; HR = Heart Rate; Δ = change; p<0.05 is significant. See text for details.

表一注释：

\*=SF-36 给予正常值分数。\*\*=与对照组的相关性。PF=身体功能；RP=身体任务功能；BP=身体疼痛；GH=整体身体健康；VT=身体活力；SF=社交能力；RE=情绪任务功能；MH=心理健康；PCS=身体部分分数；MCS=心理部分分数；HR=心率； $\Delta$ =变化； $p < 0.05$  属于显著

表 2. 同时接受睡眠与治疗的组 (SS&C) 试验后的时间域比率 (TDR) 都有一致的提升，只有瓦尔萨尔瓦比率有显著提升 ( $p=0.0118$ )。仅睡眠系统组 (SS) 试验后的平均参数数据都有下降，只有逐次心搏的标准偏差均方根 (rmsSD) 平均值有显著变化 ( $p=0.0475$ )。仅治疗组 (C) 试验后整体频域平均值都是呈下降趋势，但是只有逐次心搏的标准偏差 (sdNN) 的平均值有显著降低 ( $p=0.0674$ )。同时接受睡眠与治疗的组 (SS&C) 试验后整体频域平均值都有一致的上升，但是只有逐次心搏的标准偏差均方根 (rmsSD) 平均值有显著变化 ( $p=0.0504$ )。

**Table 2:** Average, resting standard, HRV-based, autonomic response changes upon follow-up by experimental sub-group as compared with controls.

	Control	Sleep System		Chiropractic		SS&C	
Parameter	Ave Δ (%)	Ave Δ (%)*	p**	Ave Δ (%)*	p**	Ave Δ (%)*	p**
E/I Ratio	0.2	-1.4	0.8248	-4.8	0.1662	2.9	0.4365
Valsalva Ratio	-0.2	2.9	0.5206	-2.7	0.0668	10.1	0.0118
30:15 Ratio	-1.6	-4.3	0.8299	-11.0	0.0550	10.0	0.4455
LF (msec <sup>2</sup> )	5.3	-23.3	0.3194	-116.6	0.2005	96.7	0.5123
HF (msec <sup>2</sup> )	-9.5	-93.0	0.1241	-57.4	0.1231	9.8	0.2399
LF/HF	50.0	16.6	0.0171	-0.9	0.1382	30.4	0.5693
TSP (msec <sup>2</sup> )	-0.4	-52.9	0.1751	-90.2	0.1522	59.9	0.4413
sdNN (msec)	-1.5	-4.4	0.3631	-20.2	0.0674	30.1	0.3167
rmsSD (msec)	1.9	-22.9	0.0475	-25.7	0.1050	12.2	0.0504
pNN50 (%)	51.2	-5.9	0.0636	-64.9	0.1274	24.7	0.1343

Δ = change; p<0.05 is significant. \*Change with respect to Control. \*\*Correlations are with the Control Group. E/I = Exhalation/Inhalation; 30:15 = Stand; LF = Low Frequency; HF = High Frequency; TSP = Total Spectral Power; sdNN = standard deviation of beat-to-beat; rmsSD = root mean square of the standard deviation of the beat-to-beat; pNN50 = percent of beat-to-beat greater than 50msec.

See text for details.

表二注释：Δ=变化；p<0.05 属于显著；\*=与对照组相比的变化；\*\*=与对照组的相关性。E/I=呼气/吸

气；30/15=站立；LF=低频；HF=高频；TSP=总谱能力；sdNN=心率逐拍的标准偏差；rmsSD=心率逐拍的标准偏差的均方根；pNN50=心率逐拍百分比大于 50 毫秒

表 3. 与控制组相比，同时接受睡眠与治疗的组（SS&C）显示了交感神经活动度的降低，同时可预见的副交感神经活动度的上升，且两者变化都有数据的显著性（ $p < 0.0461$ ）。和仅治疗组(C)不同的是，同时接受睡眠与治疗的组（SS&C）还显示出了交感 - 迷走神经平衡（SB）的有显著的降低（ $p = 0.0369$ ），表明有净交感神经活动度的下降。

**Table 3:** Average resting P&S response changes upon follow-up by experimental sub-group as compared with controls.

	Control	Sleep System		Chiropractic		SS&C	
Parameter	Ave Δ (%)	Ave Δ (%)*	p**	Ave Δ (%)*	p**	Ave Δ (%)*	p**
S-activity (bpm <sup>2</sup> )	-14.8	-1.3	0.1087	-40.6	0.0185	-98.4	0.0349
P-activity (bpm <sup>2</sup> )	-42.2	52.6	0.1659	54.3	0.0165	42.7	0.0460
SB (unitless)	45.5	28.4	0.0105	22.5	0.0087	-33.3	0.0369

See text for abbreviations and details;  $p < 0.05$  is significant.

**表三注释：** parameter=参数；S-activity=交感神经活动度；P-activity=副交感神经活动度；SB=交感迷走神经平衡

表 5. 仅睡眠系统组（CC）除了心率之外的其他血液动力学参数都有显著变化（ $p < 0.0480$ ）。仅睡眠系统组（CC）中有少部分站立位和静息血压较高的实验对象出现了不正常血压变化。

**Table 5:** Follow-up changes in numbers of patients with abnormal HRV-alone, P&S, or hemodynamic clinical indications. These changes are by experimental sub-group, as compared with controls.

Parameters	Control	Sleep System		Chiropractic		SS&C	
		$\Delta\#$	$\Delta\#$	p	$\Delta\#$	p	$\Delta\#$
<b>HRV-alone</b>							
<b>Low E/I Ratio</b>	-4	0	0.1686	3	0.0318	2	0.0490
<b>Low V Ratio</b>	-6	-3	0.6794	2	0.2182	3	0.1048
<b>Low 30:15 Ratio</b>	-4	1	0.3778	3	0.0578	2	0.1890
<b>AAD</b>	-4	0	0.1886	3	0.0358	1	0.3889
<b>CAN</b>	-4	1	0.7922	4	0.0467	3	0.0390
<b>P&amp;S</b>							
<b>AAD</b>	-2	1	0.1414	2	0.0348	2	0.0100
<b>CAN</b>	0	0	1.0000	0	1.0000	0	1.0000
<b>PE</b>	-2	-4	0.3162	2	0.0159	2	0.0491
<b>SW</b>	-4	1	0.2582	1	0.0219	3	0.0189
<b>PC-SE</b>	-7	2	0.1132	2	0.0326	5	0.0154
<b>High SB</b>	0	-1	0.2369	-2	0.0436	-2	0.0429
<b>Low SB</b>	0	0	0.9269	-2	0.0429	-3	0.0058
<b>Hemodynamics</b>							
<b>Abn <math>\Delta</math> HR</b>	0	0	1.0000	0	1.0000	0	1.000
<b>Abn <math>\Delta</math> BP</b>	-4	2	0.0476	1	0.0933	2	0.0547
<b>High BP</b>	-5	3	0.0122	0	1.0000	3	0.0392

$\Delta$  = change; AAD = Advanced Autonomic Dysfunction, includes Diabetic Autonomic Neuropathy, if a diabetic; CAN = Cardiovascular Autonomic Neuropathy; V = Valsalva; PE = Parasympathetic Excess; SW = Sympathetic Withdrawal; PC = Postural Change (stand); SE = Sympathetic Excess; SB = Sympathovagal Balance. Control group changes as compared with baseline conditions. See text for details.

**表五注释：**  $\Delta$ =变化；AAD=严重植物神经功能障碍，如果是糖尿病患者则包含糖尿病型植物神经性神经病；CAN=心血管植物神经性神经病；V=瓦尔萨尔瓦测试；PE=副交感神经过旺；SW=交感神经回撤；PC=姿势改变（突然站立）；SE=交感神经过旺；SB=交感迷走神经平衡

## 讨论：

从个人自我评定与交感&副交感检测中显示，仅睡眠系统组（SS）报告（SF-36）得出身体健康有明显改善，其中包括身体疼痛（BP）和整体身体健康（GH），但是并没有对心理健康（MH）有改善。同时接受睡眠与治疗的组（SS&C）报告显示所有身体健康参数都有明显提升，其中身体疼痛（BP）和整体身体健康（GH）最为突出。并且同时接受睡眠与治疗的组（SS&C）对身体健康的改善也大于其他各实验组。尽管整体的心理健康水平没有显著改善，但是身体活力（VT）有明显提升。仅治疗组（C）和同时接受睡眠与治疗的组（SS&C）相比控制组（Control）都显示了静息血压平均值有降低。仅治疗组（C）的降低数值为仅睡眠系统组（CC）的两倍，而同时接受睡眠与治疗的组（SS&C）降低数值又是仅治疗组（C）的两倍。

血压主要是交感神经活动度通过压力感受性反射控制的。副交感神经是通过交感神经活动度的反应变化间接影响血压的。各实验组内静息血压的下降（详见表1）表示静态交感神经活动度的降低，可能有或没有副交感神经活动度的提升，但是整体表明（静态）交感-迷走神经平衡的正常化（详见表3）。其中三个干预组的绝对交感-迷走神经平衡变化相比控制组都很显著（详见表3）。但是只有仅治疗组（C）和同时接受睡眠与治疗的组（SS&C）的变化足够显著而引起临床指示（详见表5）。

对于仅睡眠系统组 (CC) 的各种激发反应变化除了姿势改变到站立位时的心率以外,其他变化都不明显。仅治疗组 (C) 中,深呼吸和瓦尔萨尔瓦激发测试都有显著变化,但是对姿势改变为站立位时没有明显变化。深呼吸和瓦尔萨尔瓦测试是分别对副交感神经和交感神经系统的激发。而变位到站立位激发测试则是评测两个系统的协调度,所以会容易出现混合反应,也就会导致数据变化不明显。尽管变化不够显著,但是仅治疗组 (C) 和同时接受睡眠与治疗的组 (SS&C) 相比,还是在临床状态 (SW,sSE,&PE) 中有相对小的变化 (详见表 5)。这也能帮助解释同时接受睡眠与治疗的组 (SS&C) 的所有激发反应都有明显的变化 (详见表 4)。事实上,他们的变化已经大到足以改变同时接受睡眠与治疗的组 (SS&C) 的临床状态 (详见表 5)。显著的身体健康,自我评测,分数的提升以及心理健康的改善,包括自我评测,分数尤其是社会功能侧评分,这些改善都和静态 SB 平衡与受刺激反应的改善有密切相关的联系。当受试者身体上感觉有改善,他们对自我感知也会变好,同时提升他们的心理状态,使他们可以有更多的自信出去参与社交。



**Table 4:** Average changes in challenge P&S and Hemodynamic responses upon follow-up by experimental sub-group as compared with controls.

Parameters	Control	Sleep System		Chiropractic		SS&C	
	Ave $\Delta$ (%)	Ave $\Delta$ (%)	p	Ave $\Delta$ (%)	p	Ave $\Delta$ (%)	p
DB P-activity (bpm <sup>2</sup> )	23.0	-40.8	0.1746	60.1	0.0134	68.5	0.0312
DB HR (bpm)	3.2	-3.9	0.4197	7.0	0.0317	4.2	0.0443
DB BP (mmHg)	-8.5	-1.9	0.2658	-9.5	0.0119	-20.9	0.0428
V S-activity (bpm <sup>2</sup> )	8.7	-25.6	0.3011	-15.9	0.0037	34.1	0.0397
V P-activity (bpm <sup>2</sup> )	-0.6	-56.7	0.2180	-36.9	0.0235	48.4	0.0301
V HR (bpm)	3.8	0.3	0.1517	-5.6	0.1033	4.2	0.1352
V BP (mmHg)	6.5	-2.9	0.2542	-8.7	0.2457	-11.9	0.1135
PC S-activity (bpm <sup>2</sup> )	-0.3	10.8	0.3168	63.4	0.1486	87.1	0.0195
PC P-activity (bpm <sup>2</sup> )	9.5	-29.6	0.1000	-109.9	0.0545	-42.1	0.0294
PC HR (bpm)	4.1	3.4	0.0106	-3.5	0.2153	9.2	0.0209
PC BP (mmHg)	6.0	-5.1	0.2675	-4.7	0.1504	-11.7	0.0422

$\Delta$  = change; DB = Deep Breathing challenge; V = Valsalva challenge; PC = Postural Change (stand) challenge. See text for details;  $p < 0.05$  is significant.

表四注释： $\Delta$  = 变化；DP= 深呼吸刺激；V=瓦尔萨尔瓦测试；PC= 姿势刺激（突然站立） $p < 0.05$  属于显著

**结论：**

这些结果显示出了不同实验组中之中和之间的不同。同时接受睡眠与治疗的组（SS&C）得到了最大的缓解，其次是仅治疗组（C），再其次是仅睡眠系统组（SS）。这些结果都通过各干预组与控制组的受试者自我评测反应与血液动力学反应的对比得到证实。各干预组的效果排名和受试者自我评测反应与血液动力学反应都在交感神经与副交感神经检测中有着最好的体现。

# Brief Report of Research of Chronic Low Back Pain at Tsinghua University

## Introduction:

At a Chiropractic research clinic at Tsinghua University in Beijing, China, 62 (79.0% female, ages 13 to 66 years of age, average age 44 years) chronic lower back pain patients were followed. At baseline [ref earlier art], patients were randomly assigned to one of four (4) sub-groups as per protocol: 1) Control (16 patients, 87.5% female), 2) Chiropractic therapy only (16 patients, 75.0% female), 3) new Sleep System therapy (14 patients, 64.3% female), and 4) Sleep System and Chiropractic therapy (SS&C) (16 patients, 81.3% female). Treatment included chiropractic exams and spinal adjustments. The Sleep System (SS) sub-population were provided a new and improved mattress and pillow sleep system to properly support their spine which are specially designed pillow and mattress based on memory foam technology (Doctors Solution Sleep System, Sinomax Health&Household Products (Shenzhen) Ltd, China). Based on consent, patients submitted to pre- and post-treatment autonomic monitoring and quality of life (QoL, SF-36) questionnaires [refs]. Among the four sub-groups, they were well age matched ( $p > 0.9620$ ), and BMI and physical and mental component summary scores are matched ( $p > 0.1200$ ).

## Results:

**Table 1.** After time with an improved Sleep System only, the average general physical score is significantly increased (7.2%,  $p = 0.0337$ ) over the Control group. The significant changes in the general physical score include Body Pain and General Health (GH;  $p = 0.0237$  and  $p = 0.0279$ , respectively). The subgroup that received both an improved

Sleep System and Chiropractic therapies (SS&C) also self-assessed at higher levels than Controls. All physical parameters changed significantly. The most significant changes are in the BP and GH parameters ( $p=0.0005$  and  $p=0.0083$ , respectively). The SS&C only groups' average mental score does not change significantly ( $p=0.0521$ ). While Mental Health (MH) decreased significantly (6.3%,  $p=0.0592$ ), VT did improve significantly ( $p=0.0087$ ). The SS&C subgroup' s increased general physical score is significantly increased over both the Sleep System only ( $p=0.0053$ ) and Chiropractic only ( $p=0.0234$ ) subgroups. The Chiropractic only subgroup demonstrate, on average, a decrease in blood pressure (6/5 mmHg), and it is significant ( $p=0.0494$ ). The combined therapy (SS&C) subgroup demonstrates, on average, a decrease in blood pressure (11/5 mmHg), which is also significant ( $p=0.0130$ ).

**Table 1:** Changes in Self-Assessed health status (SF-36 questionnaire) results and hemodynamic (Blood Pressure & Heart Rate) responses upon follow-up for the individual experimental subgroups and controls.

	Control	Sleep System		Chiropractic		SS&C	
Parameter*	Ave	Ave	p**	Ave	p**	Ave	p**
PF	48.5	50.1	0.1822	52.6	0.0054	50.4	0.0448
RP	41.6	45.1	0.0617	48.3	0.0241	53.5	0.0196
BP	50.8	51.8	0.0237	53.2	0.0086	52.5	0.0005
GH	42.1	46.7	0.0279	48.5	0.0018	48.5	0.0083
VT	56.5	57.0	0.0969	57.0	0.0540	57.4	0.0087
SF	48.1	52.1	0.0979	51.7	0.0360	49.2	0.2741
RE	42.7	44.8	0.2245	48.1	0.0536	49.6	0.1777
MH	48.0	47.7	0.1303	45.8	0.0587	45.0	0.0592
PCS	44.6	47.8	0.0337	50.8	0.0160	51.4	0.0012
MCS	49.0	48.7	0.1569	49.1	0.0504	49.7	0.0521
HR (bpm)	77.1	74.8	0.2549	71.1	0.2194	77.1	0.4035
Blood Pressure (mmHg)	113/67	110/64	0.3601	107/62	0.0494	102/62	0.0130

\*SF-36 Norm-based Scale Scores. \*\*Correlations are with the Control Group. PF = Physical Function; RP = Role-Physical Function; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Functioning; RE = Role-Emotional Function; MH = Mental Health; PCS = Physical Component Score; MCS = Mental Component Score; HR = Heart Rate; Δ = change; p<0.05 is significant. See text for details.

Notes for Table 1 :

SF-36 Norm-based Scale Scores. \*\*Correlations are with the Control Group. PF = Physical Function; RP = Role-Physical Function; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Functioning; RE = Role-Emotional Function; MH = Mental Health; PCS = Physical Component Score; MCS = Mental Component Score; HR = Heart Rate;  $\Delta$  = change;  $p < 0.05$  is significant. See text for details.

Table 2. The post-therapy, combination-therapy (SS&C) sub-groups' average TDR changes are consistently increased, with only the average Valsalva Ratio change significant ( $p=0.0118$ ). The post-therapy, Sleep System-only sub-groups' average statistical parameter changes are decreased, with only the average rmsSD change significant ( $p=0.0475$ ). The post-therapy, Chiropractic-only sub-groups' average changes in spectral-domain parameters are consistently decreased, with only the average sdNN change significant ( $p=0.0674$ ). The post-therapy, combination-therapy (SS&C) sub-groups' average changes in spectral-domain parameters are consistently increased, with only the average rmsSD change significant ( $p=0.0504$ ).

**Table 2:** Average, resting standard, HRV-based, autonomic response changes upon follow-up by experimental sub-group as compared with controls.

Parameter	Control	Sleep System		Chiropractic		SS&C	
	Ave Δ (%)	Ave Δ (%)*	p**	Ave Δ (%)*	p**	Ave Δ (%)*	p**
E/I Ratio	0.2	-1.4	0.8248	-4.8	0.1662	2.9	0.4365
Valsalva Ratio	-0.2	2.9	0.5206	-2.7	0.0668	10.1	0.0118
30:15 Ratio	-1.6	-4.3	0.8299	-11.0	0.0550	10.0	0.4455
LF (msec <sup>2</sup> )	5.3	-23.3	0.3194	-116.6	0.2005	96.7	0.5123
HF (msec <sup>2</sup> )	-9.5	-93.0	0.1241	-57.4	0.1231	9.8	0.2399
LF/HF	50.0	16.6	0.0171	-0.9	0.1382	30.4	0.5693
TSP (msec <sup>2</sup> )	-0.4	-52.9	0.1751	-90.2	0.1522	59.9	0.4413
sdNN (msec)	-1.5	-4.4	0.3631	-20.2	0.0674	30.1	0.3167
rmsSD (msec)	1.9	-22.9	0.0475	-25.7	0.1050	12.2	0.0504
pNN50 (%)	51.2	-5.9	0.0636	-64.9	0.1274	24.7	0.1343

Δ = change; p<0.05 is significant. \*Change with respect to Control. \*\*Correlations are with the Control Group. E/I = Exhalation/Inhalation; 30:15 = Stand; LF = Low Frequency; HF = High Frequency; TSP = Total Spectral Power; sdNN = standard deviation of beat-to-beat; rmsSD = root mean square of the standard deviation of the beat-to-beat; pNN50 = percent of beat-to-beat greater than 50msec.

See text for details.

Table 3. Compared with controls, the combined-therapy (SS&C) group demonstrates a decrease in S-activity with an increase in P-activity, as expected. Both of these changes are significant ( $p < 0.0461$ ). Different from the individual therapy sub-groups, the SS&C group also demonstrates a significant decrease in SB ( $p = 0.0369$ ), indicating a net decrease in S-activity.

**Table 3:** Average resting P&S response changes upon follow-up by experimental sub-group as compared with controls.

	Control	Sleep System		Chiropractic		SS&C	
Parameter	Ave $\Delta$ (%)	Ave $\Delta$ (%)*	p**	Ave $\Delta$ (%)*	p**	Ave $\Delta$ (%)*	p**
<b>S-activity (bpm<sup>2</sup>)</b>	-14.8	-1.3	0.1087	-40.6	0.0185	-98.4	0.0349
<b>P-activity (bpm<sup>2</sup>)</b>	-42.2	52.6	0.1659	54.3	0.0165	42.7	0.0460
<b>SB (unitless)</b>	45.5	28.4	0.0105	22.5	0.0087	-33.3	0.0369

See text for abbreviations and details;  $p < 0.05$  is significant.

Table 5. The other hemodynamic changes in the Sleep System-only sub-group are significant ( $p < 0.0480$ ). As a result of the Sleep System therapy, there are fewer patients with abnormal changes in BP upon standing and those demonstrating high resting BP.



**Table 5:** Follow-up changes in numbers of patients with abnormal HRV-alone, P&S, or hemodynamic clinical indications. These changes are by experimental sub-group, as compared with controls.

Parameters	Control	Sleep System		Chiropractic		SS&C	
		Δ#	Δ#	p	Δ#	p	Δ#
<b>HRV-alone</b>	<b>Δ#</b>	<b>Δ#</b>	<b>p</b>	<b>Δ#</b>	<b>p</b>	<b>Δ#</b>	<b>p</b>
<b>Low E/I Ratio</b>	-4	0	0.1686	3	0.0318	2	0.049
<b>Low V Ratio</b>	-6	-3	0.6794	2	0.2182	3	0.1048
<b>Low 30:15 Ratio</b>	-4	1	0.3778	3	0.0578	2	0.189
<b>AAD</b>	-4	0	0.1886	3	0.0358	1	0.3889
<b>CAN</b>	-4	1	0.7922	4	0.0467	3	0.039
<b>P&amp;S</b>							
<b>AAD</b>	-2	1	0.1414	2	0.0348	2	0.01
<b>CAN</b>	0	0	1	0	1	0	1
<b>PE</b>	-2	-4	0.3162	2	0.0159	2	0.0491
<b>SW</b>	-4	1	0.2582	1	0.0219	3	0.0189
<b>PC-SE</b>	-7	2	0.1132	2	0.0326	5	0.0154
<b>High SB</b>	0	-1	0.2369	-2	0.0436	-2	0.0429
<b>Low SB</b>	0	0	0.9269	-2	0.0429	-3	0.0058
<b>Hemodynamics</b>							
<b>Abn Δ HR</b>	0	0	1	0	1	0	1
<b>Abn Δ BP</b>	-4	2	0.0476	1	0.0933	2	0.0547
<b>High BP</b>	-5	3	0.0122	0	1	3	0.0392

$\Delta$  = change; AAD = Advanced Autonomic Dysfunction, includes Diabetic Autonomic Neuropathy, if a diabetic; CAN = Cardiovascular Autonomic Neuropathy; V = Valsalva; PE = Parasympathetic Excess; SW = Sympathetic Withdrawal; PC = Postural Change (stand); SE = Sympathetic Excess; SB = Sympathovagal Balance. Control group changes as compared with baseline conditions.  
See text for details.

### **Discussion:**

From follow-up Personal Assessment (Table1) and P&S Monitoring, the Sleep System-only subgroup reported (via Personal Assessment, SF-36 scores) an improved physical health, including improvements in bodily pain (BP) and general health (GH), but no improvement in mental health. The sub-group receiving combined Sleep System and Chiropractic therapy (SS&C) report a significant increase in all physical health parameters, with BP & GH as the leading parameters. As a result the SS&C group's reports of improved physical health are also significantly greater than the other sub-groups' as well. In addition, while the changes in overall mental health were still not significant, Vitality (VT) did improve significantly. The Chiropractic-only and SS&C sub-groups also demonstrated decreases in average, resting BP within the groups as compared with controls, and these decreases were significant; with the Chiropractic-only sub-group's decrease twice that of the Sleep System-only, and the SS&C sub-group's decrease twice that of the Chiropractic-only sub-group.

Blood pressure is primarily controlled by S-activity via baroreceptor reflex. P-influence on blood pressure is indirect via reactive changes in S-activity. The decreases in resting blood pressure (Table 1) within the sub-groups indicate decreases in resting S-activity, with or without

increases in resting P-activity, generally indicated as normalization of (resting) SB (Table 3). While the changes in absolute SB responses for all three sub-groups were significant as compared with the Controls (Table 3), only the changes in the Chiropractic-only and SS&C sub-groups were significant enough to cause significant improvements in clinical indications (Table 5).

The changes in challenge responses from the Sleep System-only sub-group are not significant, except for the HR response to stand (PC). The changes in the Chiropractic-only group are significant for deep breathing and Valsalva challenges, but not for the stand challenge. Deep breathing and Valsalva<sup>1</sup> challenges are singular challenges of the P- and S-systems respectively, whereas the stand challenge, tests the coordination between the two systems, and therefore are prone to mixed responses, leading to the lack of significance. This lack of significance is highlighted in the relatively few changes in clinical state (SW, sSE, & PE) in the Chiropractic-only group as compared with the SS&C group (see Table 5). This also helps to explain the fact that virtually all of the challenge responses for the SS&C sub-group are significant (Table 4); in fact they are significant enough to provide significant numbers of changes in clinical state in the SS&C sub-group (see Table 5). The improved (resting) balance (SB) and improved challenge states are associated with the highest improvements in physical health, self-assessment, scores and the only improvement in the mental health, self-assessment, scores; specifically the Social Function scores. As patients begin to feel better, physically, they begin to feel better about themselves and their mental state improves, enabling them to go out into society with more confidence.

---

<sup>1</sup> The Valsalva maneuvers are short, less than 15 seconds, which keeps them S-challenges.

Valsalva maneuvers over 20 seconds in duration become significant P-challenges.

**Table 4:** Average changes in challenge P&S and Hemodynamic responses upon follow-up by experimental sub-group as compared with controls.

Parameters	Control	Sleep System		Chiropractic		SS&C	
	Ave $\Delta$ (%)	Ave $\Delta$ (%)	p	Ave $\Delta$ (%)	p	Ave $\Delta$ (%)	p
<b>DB P-activity (bpm<sup>2</sup>)</b>	23.0	-40.8	0.1746	60.1	0.0134	68.5	0.0312
<b>DB HR (bpm)</b>	3.2	-3.9	0.4197	7.0	0.0317	4.2	0.0443
<b>DB BP (mmHg)</b>	-8.5	-1.9	0.2658	-9.5	0.0119	-20.9	0.0428
<b>V S-activity (bpm<sup>2</sup>)</b>	8.7	-25.6	0.3011	-15.9	0.0037	34.1	0.0397
<b>V P-activity (bpm<sup>2</sup>)</b>	-0.6	-56.7	0.2180	-36.9	0.0235	48.4	0.0301
<b>V HR (bpm)</b>	3.8	0.3	0.1517	-5.6	0.1033	4.2	0.1352
<b>V BP (mmHg)</b>	6.5	-2.9	0.2542	-8.7	0.2457	-11.9	0.1135
<b>PC S-activity (bpm<sup>2</sup>)</b>	-0.3	10.8	0.3168	63.4	0.1486	87.1	0.0195
<b>PC P-activity (bpm<sup>2</sup>)</b>	9.5	-29.6	0.1000	-109.9	0.0545	-42.1	0.0294
<b>PC HR (bpm)</b>	4.1	3.4	0.0106	-3.5	0.2153	9.2	0.0209
<b>PC BP (mmHg)</b>	6.0	-5.1	0.2675	-4.7	0.1504	-11.7	0.0422

$\Delta$  = change; DB = Deep Breathing challenge; V = Valsalva challenge; PC = Postural Change (stand) challenge. See text for details;  $p < 0.05$  is significant.

**Conclusion:**

These results describe the differences within and between the sub-groups. The combination therapy (SS&C) sub-group provides the most relief, followed by the Chiropractic-only therapy sub-group, followed by the new Sleep System-only therapy sub-group. These data are substantiated by the different self-assessment responses and hemodynamic responses between the three sub-groups as compared with Control. The ranking of the therapy modalities and the self-assessment and hemodynamic responses are also best described with P&S Monitoring.