Appendix for article Home vs Office Biofeedback therapy by Rao SS et al (18-00198)

Supplemental Table S1. Per-protocol analysis comparing bowel symptoms and stool diary data between home biofeedback and office biofeedback groups

Subjective parameters	Time	Home Biofeedback (n=38) Mean (SEM or 95% CI)	Office Biofeedback (n=45) Mean (SEM or 95% CI)	Test of non-inferiority Ho: Bound	Mean Difference or ratio[1]	90% CI	p-value
No. of CSBM/week	Baseline	0.68 (0.19)	1.29 (0.31)				
	Post	3.61 (0.44)	5.13 (0.62)	<0.70	0.70	(**0.53**, 0.93)	0.492
	Ratio[2]	5.27 (3.20, 8.68)*	3.98 (2.55, 6.22)*	<0.70	1.32	(**0.76**, 2.30)	0.030
No. of stools/week	Baseline	5.24 (0.58)	5.92 (0.76)				
	Post	6.29 (0.63)	8.84 (0.93)	<0.75	0.71	(**0.56**, 0.90)	0.642
	Ratio[2]	1.20 (0.94, 1.54)	1.49 (1.10, 2.03)*	<0.75	0.80	(**0.58**, 1.11)	0.361
Stool strain score (1-3)	Baseline	1.84 (0.08)	1.96 (0.09)				
	Post	1.39 (0.06)	1.66 (0.07)	>0.25	-0.27	(-0.45, -**0.12**)	<0.0001
	Change[2]	-0.45 (-0.64, -0.25)*	-0.30 (-0.51, -0.10)*	>0.25	-0.15	(-0.38, **0.08**)	0.003
Stool consistency (1-7)	Baseline	3.44 (0.18)	3.29 (0.20)				
	Post	3.48 (0.17)	3.51 (0.20)	<-0.50	-0.03	(-**0.47**, 0.41)	0.039
	Change[2]	0.05 (-0.34, 0.43)	0.22 (-0.26, 0.70)	<-0.50	-0.17	(-**0.68**, 0.33)	0.152

Bowel satisfaction-VAS (mm)	Baseline	13.3 (2.5)	17.8 (3.1)				
	Post	59.9 (4.7)	59.9 (3.9)	<-13	0.0	(**-12.0**, 12.1)	0.017
	Change[2]	46.6 (36.7, 56.5)*	42.1 (33.5, 50.7)*	<-13	4.5	(**-6.2**, 15.2)	0.004
Digital assistance (%)	Baseline	19 (50%)	24 (53%)				
	Post	6 (16%)	4 (9%)	>5%	7%	(-5%, **19%**)	0.604

[1]Difference=Home-Office; Ratio=Home/Office

[2]Ratio=Post/Baseline; Change=Post-Baseline

*Significant change from baseline

Supplemental Table S2. Per protocol analysis comparing the anorectal physiology parameters and colonic transit time results between home biofeedback and office biofeedback groups

Physiological parameters	Time	Home Biofeedback (n=38) Mean (SEM or 95% CI)	Office Biofeedback (n=45) Mean (SEM or 95% CI)	Test of non-inferiority			
				Ho: Bound	Mean Difference or ratio[1]	90% CI	p-value
Dyssynergia (%)	Baseline	38 (100%)	45 (100%)				
	Post	3 (8%)*	7 (16%)*	>10%	-8%	(-20%, **5%**)	0.046
Balloon expulsion time (s)+	Baseline	68.1 (13.8)	54.2 (11.4)				
	Post	11.8 (1.6)	14.9 (2.5)	>1.70	0.79	(0.55, **1.14**)	<0.001
	Ratio[2]	0.17 (0.12, 0.26)*	0.28 (0.19, 0.41)*	>1.70	0.63	(0.36, **1.10**)	<0.001
Abnormal BET (%)	Baseline	22 (58%)	23 (51%)				
	Post	2 (5%)*	5 (11%)*	>5%	-6%	(-17%, **5%**)	0.050
Defecation index+	Baseline	0.51 (0.05)	0.49 (0.05)				
	Post	2.44 (0.32)	1.87 (0.26)	<0.65	1.30	(**0.94**, 1.80)	<0.001
	Ratio[2]	4.81 (3.40, 6.79)*	3.83 (2.83, 5.18)*	<0.65	1.26	(**0.80**, 1.97)	0.002
Slow transit (%)	Baseline	23 (61%)	20 (44%)				
	Post	10 (26%)*	14 (32%)	>10%	-5%	(-21%, **12%**)	0.071
Responder (%)	Post	32 (84%)	35 (78%)	<-10%	6%	(**-8%**, 21%)	0.034

[1]Difference=Home-Office; Ratio=Home/Office

[2]Ratio=Post/Baseline; Change=Post-Baseline

*Significant change from baseline

+Log transformed data

Supplemental Table S3. Per-protocol analysis comparing the rectal sensory thresholds between the home biofeedback and office biofeedback groups

Sensory Threshold	Time	Home Biofeedback (n=38) Median (IQR)	Office Biofeedback (n=45) Median (IQR or 95% CI)	Home-Office Median Difference	90% CI
First sensation	Baseline	10 (10-30)	20 (10-30)		
	Post	10 (10-20)	20 (10-20)	-10	(-15.5, **-4.5**)
	Post-Baseline	0 (-20-0)	0 (-10-0)*	0	(-3.9, **3.9**)
Desire to defecate	Baseline	75 (60-130)	80 (70-120)		
	Post	70 (70-110)	80 (50-100)	-10	(-26.5, **6.5)**
	Post-Baseline	0 (-60-30)	0 (-30-30)	0	(-24.5, **24.5)**
Urge to defecate	Baseline	170 (100-250)	150 (110-220)		
	Post	170 (100-190)	140 (110-170)	30	(4.0, **56.0)**
	Post-Baseline	0 (-50-30)	-10 (-50-20)	10	(-12.0, **32.0**)

Table 5. Post-treatment survey comparing the use and effects of Home and Office biofeedback training and devices

Survey Question	Home Biofeedback (n=38)	Office Biofeedback (n=43)	p-valu
I missed work to attend training	11 (29%)	18 (42%)	0.22
I had to make special arrangements	3 (8%)	17 (40%)	0.0
Verbal Instructions were helpful	37 (97%)	42 (98%)	1.0
Written Instructions were helpful	36 (95%)	--	--
Training sessions were not time consuming	15 (39%)	22 (51%)	0.29
Training interfered with other things	11 (29%)	7 (16%)	0.17
Training created social problems at home	10 (26%)	1 (2%)	0.00
Probe insertion was painful	12 (32%)	8 (19%)	0.17
Using device/Biofeedback training was messy	14 (37%)	5 (12%)	0.00
Device/Training was embarrassing	17 (45%)	18 (42%)	0.79
Using home device was easy	26 (68%)	NA	
Caring for home device was easy and convenient	35 (92%)	NA	
Helped me carry out my daily tasks	19 (50%)	18 (42%)	0.46
I felt better after biofeedback training	28 (74%)	30 (70%)	0.69
Biofeedback training was rewarding	33 (87%)	38 (88%)	1.0
I would recommend this training	35 (92%)	38 (88%)	0.71

*p-value from Chi-square test or Fisher's exact test

Figure 2. This shows the effects of home and office biofeedback therapy on the number of CSBMs/week, the defecation index and the number of subjects with dyssynergic pattern of defecation.

Figure 2. This shows the effects of home and office biofeedback therapy on the number of CSBMs/week, the defecation index and the number of subjects with dyssynergic pattern of defecation.

A — No. of CSBMs/week

B — Defecation Index

C — Dyssynergia (%)