

A Pilot Study to Evaluate the Big Barker Therapeutic Mattress in Dogs with Osteoarthritis

Final Study Report Summary

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1. Introduction

Big Barker designs and manufactures therapeutic mattresses for dogs. Their flagship product, the Big Barker Bed, has a stated purpose of providing therapeutic comfort and orthopedic support to large dogs with existing or potential joint and mobility problems. The purpose of this clinical trial was to evaluate the ability of the Big Barker bed to decrease orthopedic pain, improve joint mobility & function, increase activity and improve quality/quantity of sleep.

2. Study Design

- This clinical trial was a single center, open-label, proof of concept study. In order to participate, dogs had to be greater than three years of age and weigh more than seventy pounds. A diagnosis of osteoarthritis was confirmed by a veterinary radiologist at the Ryan Small Animal Hospital of the University of Pennsylvania.
- Dogs with significant underlying illness were excluded, such as neoplasia, clinically significant neurologic disease, unregulated chronic disease such as diabetes mellitus or hypothyroidism, as well as any clinically significant abnormalities discovered during review of medical history.
- Participants were enrolled for 38 days: 10 days prior to randomization, and 28 days following randomization. Day 28 served as the primary endpoint for the study.
- Enrolled canines wore an animal activity monitor – an omni-directional (3-axis) accelerometer - to collect activity as well as sleep data for the duration of the study.
- Assessment tools, including the Canine Orthopedic Index (COI), Canine Brief Pain Inventory (CBPI), Canine Symptom Assessment Scale (CSAS), Global Assessment of Change (GAC), and Canine/Owner Level of Interaction (LOI) were completed by the owners weekly.

3. Study Device

The Big Barker 7” dog bed, a therapeutic mattress constructed using Big Barker’s proprietary 3-layered OrthoMedic™ blend of high-density foam.

4. Results

In this open label single arm study of forty dogs that slept on the Big Barker bed:

- Owners reported that their dogs had significant reductions in pain and joint stiffness.
- Owners reported significant improvements in their dog’s joint function, gait, energy, and quality of life.
- Data collected from activity monitors worn on the dogs’ collars demonstrated 50% of dogs had at least a 13% decrease in night-time activity and 25% of dogs had at least a 33% decrease in night-time activity, suggesting improved nighttime restfulness in these dogs.

5. Ethical Considerations

The University of Pennsylvania’s Institutional Animal Care & Use Committee and the School of Veterinary Medicine’s Privately-Owned Animal Protocol committee approved all work related to this companion animal clinical trial.

Data Summary

The areas listed within achieved statistically significant results at the $\alpha = 0.02$ significance level using a paired Student's t-test or a non-parametric Wilcoxon Signed-Rank test of the difference in mean baseline versus mean endpoint.

Statistical analysis in this included summary was performed by an independent statistician not affiliated with Big Barker or the University of Pennsylvania.

The summary on the following page is provided by Big Barker as a companion to the Final Study Report Summary in order to highlight key sections of the raw data included in Appendix I and Appendix II of the Report and to provide definitions of the terms used in the Assessment Tools.

Pain

19.9% improvement to mean score, as measured by the Canine Symptom Assessment Scale¹. Assesses the frequency and severity of a dog's pain and the level of distress caused by pain.

Pain Severity Score

21.6% improvement to mean score, as measured by the Canine Brief Pain Inventory². Assesses pain at its "worst", "least", "average", and "now" (current pain). The responses are averaged to deliver an overall pain severity score.

Pain Interference Score

14.3% improvement to mean score, as measured by the Canine Brief Pain Inventory. Reflects how much pain interferes with six different daily activities, including general activity, enjoyment of life, rising to standing, walking, running, and climbing.

Joint Stiffness

12.5% improvement to mean score, as measured by the Canine Orthopedic Index³. Stiffness is the restriction or slowness in the ease with which the dog moves his/her joints.

Joint Function

17.6% improvement to mean score, as measured by the Canine Orthopedic Index. Indicates how much of a problem a dog has with four different activities, including jumping up (as in getting into the car or onto the bed), jumping down, climbing up (as on stairs, ramps, or curbs), and climbing down.

Gait

9.6% improvement to mean score, as measured by the Canine Orthopedic Index. Gait refers to the manner in which a dog uses their legs as it moves, including observations of limp severity and increased pain or stiffness following periods of over-activity.

Quality of Life

15.1% improvement to mean score, as measured by the Canine Orthopedic Index.

The remainder of the statistical tests did not result in rejections of the null hypotheses, i.e., no statistically significant difference between mean baseline and mean endpoint values, with the exception of Pacing - which measured an 83% improvement to the mean score on the Canine Symptom Assessment Scale, and resulted in a z-statistic equal to 1.999 and subsequent p-value of 0.0456 which is statistically significant at the $\alpha = 0.05$ significance level.

¹ <https://www.vet.upenn.edu/research/clinical-trials-vcic/our-services/pennchart/canine-symptomscale>

² <https://www.vet.upenn.edu/research/clinical-trials-vcic/our-services/pennchart/cbpi-tool>

³ <https://www.vet.upenn.edu/research/clinical-trials-vcic/our-services/pennchart/canine-orthopedic-index>

Appendix I: Raw Data from Assessment Tools

Demographics

Age is not normally distributed: use median and range
Age (yrs)

Percentiles		Smallest		
1%	3	3		
5%	3	3		
10%	4	4	Obs	39
25%	6	4	Sum of Wgt.	39
50%	9			
		Largest	Mean	8.487179
			Std. Dev.	2.873397
75%	11	12	Variance	8.25641
90%	12	12	Skewness	-.4922679
95%	12	12	Kurtosis	1.966605
99%	12	12		

Breed	Freq.	Percent	Cum.
AKIA	1	2.56	2.56
APBT	1	2.56	5.13
BOXE	2	5.13	10.26
BULL	1	2.56	12.82
BULM	2	5.13	17.95
DOBE	1	2.56	20.51
GERM	3	7.69	28.21
GLDR	2	5.13	33.33
GRPY	1	2.56	35.90
GTDN	1	2.56	38.46
LABR	7	17.95	56.41
MIXB	14	35.90	92.31
ROTW	2	5.13	97.44
SBRN	1	2.56	100.00
Total	39	100.00	

Sex	Freq.	Percent	Cum.
F	16	41.03	41.03
M	23	58.97	100.00
Total	39	100.00	

Weight is not normally distributed - use median and range

Weight (kgs)

Percentiles		Smallest		
1%	30.2	30.2		
5%	31.4	31		
10%	32.05	31.8	Obs	40
25%	34.1	32	Sum of Wgt.	40
50%	38			
		Largest	Mean	41.1125
			Std. Dev.	10.18702
75%	44.95	54.4	Variance	103.7755
90%	53.6	55.2	Skewness	2.050328
95%	58.5	61.8	Kurtosis	8.565894
99%	83.2	83.2		

Physical Exam**Temperature:**

Baseline

Variable	Obs	Mean	Std. Dev.	Min	Max
tempf	40	101.6	.6733009	100.4	103.6

Endpoint

Variable	Obs	Mean	Std. Dev.	Min	Max
tempf	40	101.65	.6275718	100.2	102.7

Pulse (Not normal):

Baseline

Pulse (BMP)

Percentiles		Smallest		
1%	44	44		
5%	87	78		
10%	100	96	Obs	40
25%	104	100	Sum of Wgt.	40
50%	120		Mean	113.25
		Largest	Std. Dev.	16.39692
75%	120	128		
90%	126	128	Variance	268.859
95%	132	136	Skewness	-2.041282
99%	140	140	Kurtosis	9.373584

Endpoint

Pulse (BMP)

Percentiles		Smallest		
1%	75	75		
5%	89	82		
10%	96	96	Obs	40
25%	106	96	Sum of Wgt.	40
50%	119		Mean	113.05
		Largest	Std. Dev.	12.89196
75%	122	124		
90%	124	128	Variance	166.2026
95%	128	128	Skewness	-1.035377
99%	133	133	Kurtosis	3.658702

Respiration:

Baseline

Resp (BPM)	Freq.	Percent	Cum.
24	2	5.00	5.00
P	28	70.00	75.00
p	10	25.00	100.00
Total	40	100.00	

Endpoint

Resp (BPM)	Freq.	Percent	Cum.
20	1	2.50	2.50

Total		40	100.00
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Canine Brief Pain Inventory

Pain Severity Score

Baseline					
Variable	Obs	Mean	Std. Dev.	Min	Max
BaselinePSS	40	4.24375	1.853174	.5	8.75

Endpoint Variable	Obs	Mean	Std. Dev.	Min	Max
EndpointPSS	40	3.31875	2.015157	0	8

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Basel~SS	40	4.24375	.2930126	1.853174	3.651076	4.836424
Endpo~SS	40	3.31875	.3186243	2.015157	2.674272	3.963228
diff	40	.925	.2497114	1.579313	.4199111	1.430089

mean(diff) = mean(BaselinePSS - EndpointPSS) t = 3.7043

Ho: mean(diff) = 0 degrees of freedom = 39

```
Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0007
```

Pain Interference Score

Baseline	Variable	Obs	Mean	Std. Dev.	Min	Max
BaselinePIS		40	4.545833	2.461958	.3333333	9.166667

Endpoint	Variable	Obs	Mean	Std. Dev.	Min	Max
EndpointPIS		40	3.895833	2.573614	0	10

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Basel~IS	40	4.545833	.3892697	2.461958	3.758461	5.333206
Endpo~IS	40	3.8951	.4068611	2.573216	3.072146	4.718054

diff	40	.6507334	.2483725	1.570846	.1483526	1.153114
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mean(diff) = mean(BaselinePIS - EndpointPIS) t = 2.6200
Ho: mean(diff) = 0 degrees of freedom = 39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0125

Quality of Life

Baseline

Variable	Obs	Mean	Std. Dev.	Min	Max
-----+-----					
BaselineCB~L	40	2.525	.8766925	0	4

Endpoint

Variable	Obs	Mean	Std. Dev.	Min	Max
-----+-----					
EndpointCB~L	40	2.6	.9554164	0	4

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]
-----+-----					
Ba~PIQOL	40	2.525	.1386173	.8766925	2.24462 2.80538
En~PIQOL	40	2.6	.1510646	.9554164	2.294443 2.905557
-----+-----					
diff	40	-.075	.1404548	.8883145	-.3590967 .2090967

mean(diff) = mean(BaselineCBPIQOL - EndpointCBPIQOL) t = -0.5340
Ho: mean(diff) = 0 degrees of freedom = 39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.5964

Canine Orthopedic Index

Stiffness

Baseline

Variable	Obs	Mean	Std. Dev.	Min	Max
-----+-----					
BaselineSt~s	40	7.825	2.135025	4	13

Endpoint

Variable	Obs	Mean	Std. Dev.	Min	Max
-----+-----					
EndpointSt~s	40	6.85	2.806129	2	15

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]
-----+-----					
Baseli~s	40	7.825	.3375772	2.135025	7.142186 8.507814
Endpoi~s	40	6.6	.4540417	2.871612	5.681614 7.518386
-----+-----					
diff	40	1.225	.4550113	2.877744	.3046528 2.145347

```

-----
      mean(diff) = mean(BaselineStiffn~s - EndpointStiffn~s)      t =    2.6922
Ho: mean(diff) = 0                      degrees of freedom =    39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0104

```

Function

```

Baseline
  Variable |      Obs      Mean  Std. Dev.      Min      Max
-----+-----
BaselineFu~n |      40      7.975   3.230365        1      16

```

```

Endpoint
  Variable |      Obs      Mean  Std. Dev.      Min      Max
-----+-----
EndpointFu~n |      40      6.575   3.775002        0      16

```

Paired t test

```

-----
Variable |      Obs      Mean  Std. Err.  Std. Dev.  [95% Conf. Interval]
-----+-----
Ba~ction |      40      7.975   .5107655   3.230365   6.941879   9.008121
En~ction |      40      6.575   .5968802   3.775002   5.367696   7.782304
-----+-----
diff |      40      1.4    .4015994   2.539937   .5876886   2.212311

```

```

      mean(diff) = mean(BaselineFunction - EndpointFunction)      t =    3.4861
Ho: mean(diff) = 0                      degrees of freedom =    39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0012

```

Gait

```

Baseline
  Variable |      Obs      Mean  Std. Dev.      Min      Max
-----+-----
BaselineGait |      40     11.45   3.856064        3      20

```

```

Endpoint
  Variable |      Obs      Mean  Std. Dev.      Min      Max
-----+-----
EndpointGait |      40     10.35   5.081641        1      20

```

Paired t test

```

-----
Variable |      Obs      Mean  Std. Err.  Std. Dev.  [95% Conf. Interval]
-----+-----
Base~ait |      40     11.45   .6096973   3.856064   10.21677   12.68323
Endp~ait |      40     10.35   .803478   5.081641   8.724812   11.97519
-----+-----
diff |      40      1.1    .4263741   2.696627   .237577   1.962423

```

```

      mean(diff) = mean(BaselineGait - EndpointGait)      t =    2.5799
Ho: mean(diff) = 0                      degrees of freedom =    39

```

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0138

Quality of Life

Baseline

Variable	Obs	Mean	Std. Dev.	Min	Max
BaselineCO~L	40	5.95	2.469818	1	12

Endpoint

Variable	Obs	Mean	Std. Dev.	Min	Max
EndpointCO~L	40	5.05	2.864012	0	12

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Ba~OIQOL	40	5.95	.3905125	2.469818	5.160114	6.739886
En~OIQOL	40	5.05	.45284	2.864012	4.134045	5.965955
diff	40	.9	.3559026	2.250926	.180119	1.619881

mean(diff) = mean(BaselineCOIQOL - EndpointCOIQOL) t = 2.5288
Ho: mean(diff) = 0 degrees of freedom = 39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0156

Canine Symptom Assessment Scale

Pain

Baseline

Variable	Obs	Mean	Std. Dev.	Min	Max
BaselineCS~n	39	1.483333	.6708531	0	3.1

Endpoint

Variable	Obs	Mean	Std. Dev.	Min	Max
EndpointCS~n	39	1.188462	.780474	0	2.65

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Basel~in	40	1.44625	.1110756	.7025035	1.221578	1.670922
Endpo~in	40	1.15875	.1253826	.7929891	.9051398	1.41236
diff	40	.2875	.1184806	.7493373	.0478503	.5271497

mean(diff) = mean(BaselineCSPain - EndpointCSPain) t = 2.4266
Ho: mean(diff) = 0 degrees of freedom = 39

Ha: mean(diff) != 0
Pr(|T| > |t|) = 0.0200

Energy (not normal)

Baseline

BaselineCSEnergy

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	38
25%	0	0	Sum of Wgt.	38
50%	.4		Mean	.6355263
		Largest	Std. Dev.	.6642317
75%	1.1	1.75		
90%	1.75	1.8	Variance	.4412038
95%	1.95	1.95	Skewness	.6668506
99%	2.15	2.15	Kurtosis	2.238849

Endpoint

EndpointCSEnergy

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	39
25%	0	0	Sum of Wgt.	39
50%	0		Mean	.4551282
		Largest	Std. Dev.	.7975122
75%	.65	1.75		
90%	1.75	1.75	Variance	.6360256
95%	2.65	2.65	Skewness	1.832114
99%	3.1	3.1	Kurtosis	5.51953

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	17	476.5	342
negative	7	207.5	342
zero	16	136	136
all	40	820	820

unadjusted variance 5535.00
 adjustment for ties -1.38
 adjustment for zeros -374.00

adjusted variance 5159.63

Ho: BaselineCSEnergy = EndpointCSEnergy

z = 1.872

Prob > |z| = 0.0611

Panting (not normal)

Baseline

BaselineCSPant

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40

50%	.125		Mean	.435
		Largest	Std. Dev.	.5781491
75%	.775	1.5		
90%	1.45	1.55	Variance	.3342564
95%	1.6	1.65	Skewness	1.065078
99%	1.75	1.75	Kurtosis	2.655718

Endpoint

		EndpointCSPant			
Percentiles		Smallest			
1%	0	0			
5%	0	0			
10%	0	0	Obs	39	
25%	0	0	Sum of Wgt.	39	

50%	0		Mean	.2282051	
		Largest	Std. Dev.	.4824274	
75%	.25	.7			
90%	.7	1.15	Variance	.2327362	
95%	1.95	1.95	Skewness	2.695235	
99%	2	2	Kurtosis	9.73534	

Wilcoxon signed-rank test

sign	obs	sum ranks	expected

positive	15	462	315
negative	6	168	315
zero	19	190	190

all	40	820	820

unadjusted variance	5535.00
adjustment for ties	-0.63
adjustment for zeros	-617.50

adjusted variance	4916.88

Ho: BaselineCSPant = EndpointCSPant

z = 2.096
 Prob > |z| = 0.0360

Coughing (not normal)

Baseline

		BaselineCSCough			
Percentiles		Smallest			
1%	0	0			
5%	0	0			
10%	0	0	Obs	40	
25%	0	0	Sum of Wgt.	40	

50%	0		Mean	.01125	
		Largest	Std. Dev.	.0711512	
75%	0	0			
90%	0	0	Variance	.0050625	
95%	0	0	Skewness	6.08487	
99%	.45	.45	Kurtosis	38.02564	

Endpoint

EndpointCSCough

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.0225
		Largest	Std. Dev.	.1423025
75%	0	0		
90%	0	0	Variance	.02025
95%	0	0	Skewness	6.08487
99%	.9	.9	Kurtosis	38.02564

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	0	0	20
negative	1	40	20
zero	39	780	780
all	40	820	820

unadjusted variance 5535.00
 adjustment for ties 0.00
 adjustment for zeros -5135.00

 adjusted variance 400.00

Ho: BaselineCSCough = EndpointCSCough
 z = -1.000
 Prob > |z| = 0.3173

Pacing (not normal)

Baseline

BaselineCSPace

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	39
25%	0	0	Sum of Wgt.	39
50%	0		Mean	.0884615
		Largest	Std. Dev.	.2787334
75%	0	.65		
90%	.65	.65	Variance	.0776923
95%	.85	.85	Skewness	3.139132
99%	1.3	1.3	Kurtosis	12.04458

Endpoint

EndpointCSPace

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40

50%	0		Mean	.015
		Largest	Std. Dev.	.0948683
75%	0	0		
90%	0	0	Variance	.009
95%	0	0	Skewness	6.08487
99%	.6	.6	Kurtosis	38.02564

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	4	154	77
negative	0	0	77
zero	36	666	666
all	40	820	820

unadjusted variance	5535.00
adjustment for ties	-0.13
adjustment for zeros	-4051.50
adjusted variance	1483.38

Ho: BaselineCSPace = EndpointCSPace
 z = 1.999
 Prob > |z| = 0.0456

Sleep Disturbance (not normal)

Baseline

BaselineCSSleep

Percentiles	Smallest		
1%	0		
5%	0		
10%	0	Obs	40
25%	0	Sum of Wgt.	40
50%	0	Mean	.10125
	Largest	Std. Dev.	.3062359
75%	.6		
90%	.65	Variance	.0937804
95%	.85	Skewness	3.381853
99%	1.55	Kurtosis	14.60369

Endpoint

EndpointCSSleep

Percentiles	Smallest		
1%	0		
5%	0		
10%	0	Obs	40
25%	0	Sum of Wgt.	40
50%	0	Mean	.12875
	Largest	Std. Dev.	.415391
75%	.85		
90%	.9	Variance	.1725497
95%	1.5	Skewness	3.221709
99%	1.9	Kurtosis	12.37731

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	3	111	95
negative	2	79	95
zero	35	630	630
all	40	820	820

unadjusted variance 5535.00
 adjustment for ties 0.00
 adjustment for zeros -3727.50

 adjusted variance 1807.50

Ho: BaselineCSSleep = EndpointCSSleep
 z = 0.376
 Prob > |z| = 0.7067

Aggression (not normal)

Baseline

BaselineCSAggression

Percentiles	Smallest		
1%	0		
5%	0		
10%	0	Obs	40
25%	0	Sum of Wgt.	40
50%	0	Mean	.05375
	Largest	Std. Dev.	.2426846
75%	0		
90%	0	Variance	.0588958
95%	.425	Skewness	4.423049
99%	1.3	Kurtosis	21.33869

Endpoint

EndpointCSAggression

Percentiles	Smallest		
1%	0		
5%	0		
10%	0	Obs	40
25%	0	Sum of Wgt.	40
50%	0	Mean	.0275
	Largest	Std. Dev.	.1739253
75%	0		
90%	0	Variance	.03025
95%	0	Skewness	6.08487
99%	1.1	Kurtosis	38.02564

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	2	79	39.5
negative	0	0	39.5

zero	38	741	741
-----+-----			
all	40	820	820

```

unadjusted variance      5535.00
adjustment for ties      0.00
adjustment for zeros     -4754.75
-----
adjusted variance        780.25

```

Ho: BaselineCSAggression = EndpointCSAggression
 z = 1.414
 Prob > |z| = 0.1573

Sleepiness (not normal)

Baseline

BaselineCSSleepy

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.13375
		Largest	Std. Dev.	.3406983
75%	0	.95		
90%	.725	1.05	Variance	.1160753
95%	1.1	1.15	Skewness	2.446279
99%	1.25	1.25	Kurtosis	7.410472

Endpoint

EndpointCSSleepy

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.14375
		Largest	Std. Dev.	.4308887
75%	0	1		
90%	.6	1.25	Variance	.1856651
95%	1.4	1.55	Skewness	2.857352
99%	1.75	1.75	Kurtosis	9.625881

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	3	111	112.5
negative	3	114	112.5
zero	34	595	595
-----+-----			
all	40	820	820

```

unadjusted variance      5535.00
adjustment for ties      0.00
adjustment for zeros     -3421.25
-----

```

adjusted variance 2113.75

Ho: BaselineCSSleepy = EndpointCSSleepy

z = -0.033

Prob > |z| = 0.9740

Vomiting (not normal)

Baseline

BaselineCSVomit

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0	Largest	Mean	0
			Std. Dev.	0
75%	0	0		
90%	0	0	Variance	0
95%	0	0	Skewness	.
99%	0	0	Kurtosis	.

Endpoint

EndpointCSVomit

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0	Largest	Mean	0
			Std. Dev.	0
75%	0	0		
90%	0	0	Variance	0
95%	0	0	Skewness	.
99%	0	0	Kurtosis	.

Diarrhea (not normal)

Baseline

BaselineCSDiarrhea

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0	Largest	Mean	.0425
			Std. Dev.	.1930026
75%	0	0		
90%	0	0	Variance	.03725
95%	.325	.65	Skewness	4.493119
99%	1.05	1.05	Kurtosis	22.11183

Endpoint

EndpointCSDiarrhea

Percentiles		Smallest		
1%	0	0		

5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.0225
		Largest	Std. Dev.	.1423025
75%	0	0		
90%	0	0	Variance	.02025
95%	0	0	Skewness	6.08487
99%	.9	.9	Kurtosis	38.02564

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	2	78	58.5
negative	1	39	58.5
zero	37	703	703
all	40	820	820

unadjusted variance	5535.00
adjustment for ties	0.00
adjustment for zeros	-4393.75
adjusted variance	1141.25

Ho: BaselineCSDiarrhea = EndpointCSDiarrhea
 z = 0.577
 Prob > |z| = 0.5638

Whining (not normal)

Baseline

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	39
25%	0	0	Sum of Wgt.	39
50%	0		Mean	.3371795
		Largest	Std. Dev.	.6031407
75%	.65	1.5		
90%	1.5	1.55	Variance	.3637787
95%	1.95	1.95	Skewness	1.711092
99%	2.2	2.2	Kurtosis	4.86473

Endpoint

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.15
		Largest	Std. Dev.	.3824684
75%	0	.9		
90%	.875	1.1	Variance	.1462821

95%	1.1	1.1	Skewness	2.39112
99%	1.55	1.55	Kurtosis	7.446871

Yelping (not normal)

Baseline

BaselineCSYelp

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.19
		Largest	Std. Dev.	.5550699
75%	0	.9		
90%	.775	1.95	Variance	.3081026
95%	1.95	1.95	Skewness	2.831579
99%	2.15	2.15	Kurtosis	9.500384

Endpoint

EndpointCSYelp

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.13125
		Largest	Std. Dev.	.3887336
75%	0	.6		
90%	.5	.85	Variance	.1511138
95%	1.075	1.3	Skewness	3.336258
99%	1.9	1.9	Kurtosis	13.80115

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	5	181	146
negative	3	111	146
zero	32	528	528
all	40	820	820

unadjusted variance	5535.00
adjustment for ties	-0.13
adjustment for zeros	-2860.00
adjusted variance	2674.88

Ho: BaselineCSYelp = EndpointCSYelp

z = 0.677

Prob > |z| = 0.4986

Appetite (not normal)

Baseline

BaselineCSAppetite

Percentiles	Smallest
-------------	----------

1%	0	0		
5%	0	0		
10%	0	0	Obs	39
25%	0	0	Sum of Wgt.	39
50%	0		Mean	.0230769
		Largest	Std. Dev.	.0864856
75%	0	0		
90%	0	.2	Variance	.0074798
95%	.25	.25	Skewness	3.898392
99%	.45	.45	Kurtosis	17.79493

Endpoint

EndpointCSAppetite

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.045
		Largest	Std. Dev.	.203747
75%	0	0		
90%	0	0	Variance	.0415128
95%	.35	.7	Skewness	4.457214
99%	1.1	1.1	Kurtosis	21.71622

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	2	75	77
negative	2	79	77
zero	36	666	666
all	40	820	820

unadjusted variance 5535.00
adjustment for ties 0.00
adjustment for zeros -4051.50

adjusted variance 1483.50

Ho: BaselineCSAppetite = EndpointCSAppetite
z = -0.052
Prob > |z| = 0.9586

Constipation

Baseline

BaselineCSConstipation

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.03875
		Largest	Std. Dev.	.1719002
75%	0	0		

90%	0	0	Variance	.0295497
95%	.35	.7	Skewness	4.196193
99%	.85	.85	Kurtosis	18.8058

Endpoint

EndpointCSConstipation

Percentiles		Smallest		
1%	0	0		
5%	0	0		
10%	0	0	Obs	40
25%	0	0	Sum of Wgt.	40
50%	0		Mean	.0325
		Largest	Std. Dev.	.205548
75%	0	0		
90%	0	0	Variance	.04225
95%	0	0	Skewness	6.08487
99%	1.3	1.3	Kurtosis	38.02564

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	1	40	39.5
negative	1	39	39.5
zero	38	741	741
all	40	820	820

unadjusted variance	5535.00
adjustment for ties	0.00
adjustment for zeros	-4754.75
adjusted variance	780.25

Ho: BaselineCSConstipation = EndpointCSConstipation

z = 0.018

Prob > |z| = 0.9857

Appetite (not normal)

Baseline

BaselineAppetite

Percentiles		Smallest		
1%	5	5		
5%	5	5		
10%	5.5	5	Obs	40
25%	8	5	Sum of Wgt.	40
50%	10		Mean	8.675
		Largest	Std. Dev.	1.74514
75%	10	10		
90%	10	10	Variance	3.045513
95%	10	10	Skewness	-1.044704
99%	10	10	Kurtosis	2.714336

Endpoint

EndpointAppetite

Percentiles		Smallest
1%	4	4

5%	5	5		
10%	5.5	5	Obs	40
25%	8	5	Sum of Wgt.	40
50%	10		Mean	8.775
		Largest	Std. Dev.	1.761228
75%	10	10		
90%	10	10	Variance	3.101923
95%	10	10	Skewness	-1.363629
99%	10	10	Kurtosis	3.596742

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	7	228	272
negative	10	316	272
zero	23	276	276
all	40	820	820

unadjusted variance 5535.00
adjustment for ties -28.13
adjustment for zeros -1081.00

adjusted variance 4425.88

Ho: BaselineAppetite = EndpointAppetite
z = -0.661
Prob > |z| = 0.5084

Global Assessment of Change

GAC 1	Freq.	Percent	Cum.
0	1	2.50	2.50
1	1	2.50	5.00
2	1	2.50	7.50
3	14	35.00	42.50
4	11	27.50	70.00
5	9	22.50	92.50
6	3	7.50	100.00
Total	40	100.00	

GAC 2	Freq.	Percent	Cum.
0	1	2.50	2.50
1	1	2.50	5.00
2	1	2.50	7.50
3	14	35.00	42.50
4	9	22.50	65.00
5	10	25.00	90.00
6	4	10.00	100.00
Total	40	100.00	

GAC 3	Freq.	Percent	Cum.
0	1	2.50	2.50
1	1	2.50	5.00
2	1	2.50	7.50
3	14	35.00	42.50
4	12	30.00	72.50
5	7	17.50	90.00
6	4	10.00	100.00
Total	40	100.00	

Appendix II: Raw Activity Data

All activity is not normally distributed so median and range values would be reported.
A dozen dogs are missing the 4th week of data (days 22-28) so I used the day 21 endpoint.
I looked at the change in total weekly counts as well as daily counts over 1 or 3 weeks.

Total Weekly counts (Days -7 to -1 and Days 15 to 21)

Night time

Baseline

		Baseline7DayNight		

	Percentiles	Smallest		
1%	5924	5924		
5%	6108	6108		
10%	7100	6901	Obs	38
25%	10854	7100	Sum of Wgt.	38
50%	24881		Mean	31285.29
		Largest	Std. Dev.	26717.74
75%	43229	62271		
90%	62271	63354	Variance	7.14e+08
95%	67476	67476	Skewness	2.462337
99%	150601	150601	Kurtosis	11.46958

Endpoint

		Endpoint7DayNight		

	Percentiles	Smallest		
1%	0	0		
5%	5442	5442		
10%	6982.571	5497.429	Obs	38
25%	12995.86	6982.571	Sum of Wgt.	38
50%	20475.21		Mean	31396.45
		Largest	Std. Dev.	26554.03
75%	44107.57	71641.57		
90%	71641.57	81520.86	Variance	7.05e+08
95%	101074.9	101074.9	Skewness	1.172739
99%	101428.4	101428.4	Kurtosis	3.583856

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	22	400	370.5
negative	16	341	370.5
zero	0	0	0
-----+-----			
all	38	741	741

unadjusted variance 4754.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4754.75

Ho: baseline7daynight = endpoint7daynight
z = 0.428

Prob > |z| = 0.6688

Day time

Baseline

Baseline7DayDay				

Percentiles		Smallest		
1%	180744	180744		
5%	263091	263091		
10%	300070	299256	Obs	38
25%	480418	300070	Sum of Wgt.	38
50%	634901.5		Mean	722202.7
		Largest	Std. Dev.	381499.4
75%	869634	1323450		
90%	1323450	1456891	Variance	1.46e+11
95%	1591576	1591576	Skewness	1.227275
99%	1910938	1910938	Kurtosis	4.36868

Endpoint

Endpoint7DayDay				

Percentiles		Smallest		
1%	0	0		
5%	282135.6	282135.6		
10%	354900.2	325079.4	Obs	38
25%	447361.8	354900.2	Sum of Wgt.	38
50%	571408.3		Mean	671796.4
		Largest	Std. Dev.	357272.9
75%	818969.3	1288132		
90%	1288132	1299475	Variance	1.28e+11
95%	1449742	1449742	Skewness	1.062176
99%	1706747	1706747	Kurtosis	3.834155

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	23	463	370.5
negative	15	278	370.5
zero	0	0	0
-----+-----			
all	38	741	741

unadjusted variance 4754.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4754.75

Ho: baseline7dayday = endpoint7dayday
z = 1.341
Prob > |z| = 0.1798

Baseline

Baseline7Day24Hour				

	Percentiles	Smallest		
1%	204151	204151		
5%	303339	303339		
10%	330485	305364	Obs	38
25%	516062	330485	Sum of Wgt.	38
50%	669587		Mean	753488
		Largest	Std. Dev.	392713.7
75%	882430	1390926		
90%	1390926	1483325	Variance	1.54e+11
95%	1598477	1598477	Skewness	1.342885
99%	2061539	2061539	Kurtosis	4.947975

Endpoint

Endpoint7Day24Hour				

	Percentiles	Smallest		
1%	0	0		
5%	296258.8	296258.8		
10%	380009.8	362893.4	Obs	38
25%	490399.2	380009.8	Sum of Wgt.	38
50%	592960.6		Mean	703192.8
		Largest	Std. Dev.	365378.7
75%	844223	1295780		
90%	1295780	1318221	Variance	1.34e+11
95%	1462766	1462766	Skewness	1.077863
99%	1808175	1808175	Kurtosis	4.062659

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	22	457	370.5
negative	16	284	370.5
zero	0	0	0
-----+-----			
all	38	741	741

unadjusted variance 4754.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4754.75

Ho: baseline7day24hour = endpoint7day24hour
z = 1.254
Prob > |z| = 0.2097

Daily Counts over 1 or 3 weeks

Baseline Data (average of days -7 to -1)

Night time

Baseline NightTime				

	Percentiles	Smallest		
1%	846.2857	846.2857		
5%	872.5714	872.5714		
10%	1014.286	985.8571	Obs	38
25%	1550.571	1014.286	Sum of Wgt.	38
50%	3554.428		Mean	4469.327
		Largest	Std. Dev.	3816.82
75%	6175.571	8895.857		
90%	8895.857	9050.571	Variance	1.46e+07
95%	9639.429	9639.429	Skewness	2.462336
99%	21514.43	21514.43	Kurtosis	11.46958

Day time

Baseline Daytime				

	Percentiles	Smallest		
1%	25820.57	25820.57		
5%	37584.43	37584.43		
10%	42867.14	42750.86	Obs	38
25%	68631.14	42867.14	Sum of Wgt.	38
50%	90700.21		Mean	103171.8
		Largest	Std. Dev.	54499.91
75%	124233.4	189064.3		
90%	189064.3	208127.3	Variance	2.97e+09
95%	227368	227368	Skewness	1.227276
99%	272991.2	272991.2	Kurtosis	4.368681

24 hours

Baseline24Hour				

	Percentiles	Smallest		
1%	29164.43	29164.43		
5%	43334.14	43334.14		
10%	47212.14	43623.43	Obs	38
25%	73723.14	47212.14	Sum of Wgt.	38
50%	95655.29		Mean	107641.1
		Largest	Std. Dev.	56101.96
75%	126061.4	198703.7		
90%	198703.7	211903.6	Variance	3.15e+09
95%	228353.9	228353.9	Skewness	1.342885
99%	294505.6	294505.6	Kurtosis	4.947975

Endpoint Data and Comparison to Baseline Data

A dozen dogs are missing the 4th week of data (days 22-28) so I used the day 21 endpoint for the activity data and I looked at it 2 ways:

1. The endpoint being the average of all 3 weeks (i.e. days 1-21)

2. The endpoint being the average of the 3rd week (i.e. days 15-21)

1. Endpoint is average of all 3 weeks (i.e. days 1-21)

Night time

Endpoint3WeekNightTime				

	Percentiles	Smallest		
1%	636.9048	636.9048		
5%	1108.857	1108.857		
10%	1229.095	1174.714	Obs	39
25%	2067.572	1229.095	Sum of Wgt.	39
50%	3269.81		Mean	4302.694
		Largest	Std. Dev.	3030.548
75%	5816.095	9189.286		
90%	9189.286	10622.38	Variance	9184221
95%	11227.67	11227.67	Skewness	1.01003
99%	12046.29	12046.29	Kurtosis	3.131691

Wilcoxon signed-rank test

sign	obs	sum ranks	expected

positive	20	393	351.5
negative	17	310	351.5
zero	0	0	0

all	37	703	703

unadjusted variance	4393.75
adjustment for ties	0.00
adjustment for zeros	0.00

adjusted variance	4393.75

Ho: baselinenighttime = endpoint3weeknighttime
 z = 0.626
 Prob > |z| = 0.5313

Day time

Endpoint3WeekDayTime				

	Percentiles	Smallest		
1%	39603.29	39603.29		
5%	44498.29	44498.29		
10%	52009.81	45012.76	Obs	39
25%	67849	52009.81	Sum of Wgt.	39
50%	89017.19		Mean	98755.88
		Largest	Std. Dev.	42825.94
75%	123051.4	169530		
90%	169530	182610	Variance	1.83e+09
95%	193022.8	193022.8	Skewness	.9654288
99%	217509.5	217509.5	Kurtosis	3.402118

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	17	369	351.5
negative	20	334	351.5
zero	0	0	0
all	37	703	703

unadjusted variance 4393.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4393.75

Ho: baselinedaytime = endpoint3weekdaytime
z = 0.264
Prob > |z| = 0.7918

Total 24 hour

Endpoint3Week24Hour				
Percentiles		Smallest		
1%	40778	40778		
5%	47633.95	47633.95		
10%	54077.38	52992.57	Obs	39
25%	73118.43	54077.38	Sum of Wgt.	39
50%	92081.52			
		Largest	Mean	102943.1
75%	127615.8	171322.5	Std. Dev.	43580.77
90%	171322.5	185187	Variance	1.90e+09
95%	195938.4	195938.4	Skewness	.9739527
99%	228737.2	228737.2	Kurtosis	3.532544

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
positive	17	374	351.5
negative	20	329	351.5
zero	0	0	0
all	37	703	703

unadjusted variance 4393.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4393.75

Ho: baseline24hour = endpoint3week24hour
z = 0.339
Prob > |z| = 0.7343

2. Endpoint is the average of the 3rd week (i.e. days 15-21)

Night time

Endpoint3WeekNightTimePoint

Percentiles		Smallest		
1%	690.2857	690.2857		
5%	795	795		
10%	915.5714	814.4286	Obs	39
25%	1826.143	915.5714	Sum of Wgt.	39
50%	2926.857			
		Largest	Mean	4831.465
75%	7092.714	11148.71	Std. Dev.	3765.016
90%	11148.71	12602.86	Variance	1.42e+07
95%	13130.43	13130.43	Skewness	.8753771
99%	13240.57	13240.57	Kurtosis	2.648756

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	22	356	351.5
negative	15	347	351.5
zero	0	0	0
-----+-----			
all	37	703	703

unadjusted variance 4393.75
adjustment for ties 0.00
adjustment for zeros 0.00

adjusted variance 4393.75

Ho: baselinenighttime = endpoint3weeknighttimepoint
z = 0.068
Prob > |z| = 0.9459

Day time

Endpoint3WeekDayTimePoint

Percentiles		Smallest		
1%	42699.57	42699.57		
5%	45725.29	45725.29		
10%	46461.43	45968.57	Obs	39
25%	65052.14	46461.43	Sum of Wgt.	39
50%	83624.57			
		Largest	Mean	97991.31
75%	118492.7	164796	Std. Dev.	47100.23
90%	164796	195267.7	Variance	2.22e+09
95%	196202.3	196202.3	Skewness	1.307541
99%	248128.6	248128.6	Kurtosis	4.367859

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	18	395	351.5
negative	19	308	351.5
zero	0	0	0
-----+-----			
all	37	703	703


```

unadjusted variance      4393.75
adjustment for ties      0.00
adjustment for zeros     0.00
-----
adjusted variance        4393.75

```

```

Ho: baselinedaytime = endpoint3weekdaytimepoint
      z =      0.656
      Prob > |z| = 0.5117

```

Total 24 hours

Endpoint3Week24HourPoint				

	Percentiles	Smallest		
1%	45245.86	45245.86		
5%	46658.86	46658.86		
10%	55081.43	47872.86	Obs	39
25%	71552.14	55081.43	Sum of Wgt.	39
50%	85165.29		Mean	102822.8
		Largest	Std. Dev.	47954.92
75%	124263.9	171876.3		
90%	171876.3	197665	Variance	2.30e+09
95%	199129.1	199129.1	Skewness	1.342333
99%	261259	261259	Kurtosis	4.640469

Wilcoxon signed-rank test

sign	obs	sum ranks	expected
-----+-----			
positive	17	381	351.5
negative	20	322	351.5
zero	0	0	0
-----+-----			
all	37	703	703

```

unadjusted variance      4393.75
adjustment for ties      0.00
adjustment for zeros     0.00
-----
adjusted variance        4393.75

```

```

Ho: baseline24hour = endpoint3week24hourpoint
      z =      0.445
      Prob > |z| = 0.6563

```