# **Clinical Studies**

# Effectiveness of Integrated Medical Treatment for Thunderstorm Aversion: A Case Series of 23 Dogs

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#### ABSTRACT

Canine thunderstorm aversion (CTA) is a significant challenge to pets, owners, and veterinarians. The objective of this research was to determine if traditional Chinese veterinary medicine (TCVM) treatment with acupuncture, Chinese herbal medicine, basic desensitization and counterconditioning (DSCC) with a behavior modification drug, could lessen the severity of CTA in dogs. A total of 23 dogs that exhibited behaviors typical of thunderstorm aversion were enrolled in the study. At study start, all dogs received a TCVM Pattern diagnosis and were treated with Pattern-specific Chinese herbal medicine and acupuncture points. In addition, owners received DSCC behavior modification protocols and a conventional drug (alprazolam) to be used as needed during thunderstorms. Dogs were examined once a month for 4 months and Chinese herbal medicine formulations and acupuncture treatment adjusted as TCVM Patterns changed. After 120 days of treatment, the mean $\pm$ SD improvement in overall thunderstorm aversion behaviors in study participants was 77.2% $\pm$ 27.7% (p < 0.0001). This result was significantly greater than 52% (p = 0.002), a reported mean improvement percentage for conventional treatment only, after 4 months. Six of the 7 individual aversion behaviors (panting, pacing, trembling, hiding, excess salivation, excess vocalization) had a significant reduction (range: p = 0.046 to p = 0.008) over the course of treatment. The study results demonstrated that integrative management of CTA with TCVM Pattern-specific treatments combined with a conventional medical management only. Randomized controlled trials are warranted to validate these preliminary findings.

Keywords: canine, thunderstorm, anxiety, fear, phobia, aversion, acupuncture, traditional Chinese veterinary medicine, Chinese herbal medicine, behavior

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#### ABBREVIATIONS

AP	Acupuncture
BZD	Benzodiazepine
CHM	Chinese herbal medicine
СТА	Canine thunderstorm aversion
DNAP	Dry needle acupuncture
DSCC	Desensitization and counterconditioning
HRV	Heart rate variability
SPA	Storm phobia assessment
SSRI	Selective serotonin reuptake inhibitor
TCA	Tricyclic antidepressant
TCVM	Traditional Chinese veterinary medicine

Canine thunderstorm aversion (CTA) is a significant challenge to pets, owners and veterinarians.<sup>1</sup> Aversion to thunderstorms decreases the life quality of both the pet and owner and threatens the health of the canine patient through stress-induced diseases, behaviors that may cause

self-injury and risk of euthanasia or relinquishment.<sup>2-6</sup> The behavior is considered a clinically abnormal noise aversion. The prevalence of noise aversion in canines is estimated to be between 23% and 49% with the most prevalent causes being fireworks, thunderstorms and gunfire.<sup>1,5,7-11</sup> A study of 13,700 pet dogs showed noise sensitivity to be the most common anxiety-related trait with a prevalence of 32% and half of those dogs (16% of total) reactive to thunderstorm noise.<sup>9</sup> Thunderstorm aversion is a potentially fatal disease as behavior problems are the leading cause of euthanasia and relinquishment of dogs to shelters in the United States.<sup>4,6</sup> Veterinarians appear under-equipped to address CTA as only 15% of pet caregivers said they would consult their veterinarian for advice and only 25% of veterinarians inquire regularly about their patient's behavior.<sup>1,10</sup>

A complex of multiple sensory triggers in addition to thunder can be involved in CTA, including changes in illumination, lightning, wind, rain, changes in barometric pressure or even smell.<sup>4,12</sup> Aversive dogs exhibit reactions ranging in severity from mild to extreme which may include: panting, pacing, trembling, shaking, salivation, mydriasis, immobility, vocalization, escape behaviors,

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urination, defecation, destruction of property, vomiting and diarrhea.<sup>1,4</sup> Left untreated, clinical and physiological symptoms progress in severity with increase in intensity of aversive behavior, broadening of the stimulus trigger and increase in recovery time.<sup>4,13</sup>

Recent efforts to accurately diagnose and treat patients have resulted in more clearly defined diagnostic terminologies of abnormal behaviors. "Aversion" is a catch-all phrase describing the response of dogs exhibiting undesired behaviors during weather events. Anxiety, fear and phobia each refer to a specific behavior diagnosis. Fear and anxiety are normal, adaptive responses when appropriate to a potential threat as they cause an animal to remove itself from harm's way.<sup>14-16</sup> Fear and anxiety that are inappropriate to the actual or perceived threat or fail to reasonably dissipate are clinically abnormal.<sup>15</sup> Phobias are always maladaptive and interfere with normal function.<sup>14</sup> Inappropriate canine thunderstorm aversion can be diagnostically classified as anxiety, fear and phobia.

Conventional treatment plans for CTA vary depending on the clinical diagnosis, severity of disease and capability of the owners. Treatment outcomes undoubtedly vary among patients due to individual neurochemistry and neuroanatomy that have resulted from differing environmental and genetic effects.<sup>17</sup> All treatments are considered to cause their effects through modulation of neurotransmitters. This commonly includes serotonin (5-HT), dopamine, gamma-aminobutyric acid (GABA) and glutamic acid in the neurons of the limbic system of the brain and/or adrenaline and noradrenaline in the sympathetic nervous system.<sup>4,18</sup> Available prescription and non-prescription treatment modalities cover a wide variety of products that demonstrates the prevalence of the condition and difficulties associated with treating this behavior.4,14,19-35

Prescription medications to treat CTA fall into 3 main classes: benzodiazepines (BZDs), tricvclic antidepressants (TCAs) and selective serotonin reuptake inhibitors (SSRIs).<sup>4</sup> One of the most recommended conventional treatments of CTA is alprazolam given 30 minutes to 2 hours before a storm and every 4-6 hours during a storm. Alprazolam is the BZD of choice because it is quickly absorbed, is panicolytic and causes less drowsiness than other BZDs. An additional daily antidepressant such as the TCAs (e.g., clomipramine) or an SSRI such as fluoxetine, fluvoxamine or paroxetine are recommended for more severely affected dogs.13 Additional considerations include trazodone and dexmedetomidine gel.<sup>13,36,37</sup> Phenothiazine tranquilization has been prescribed for CTA but is no longer recommended because, although destructive behavior may be curbed, the dog is offered no relief from fear or anxietv.4

In traditional Chinese veterinary medicine (TCVM), CTA is considered a disturbance of the *Shen* (Spirit or Mind).<sup>38</sup> It refers to the functions of processing all incoming sensory and intuitive information and supervising reactions of the body and mind to that

information.<sup>39</sup> General signs of Shen disturbance include restlessness, nervousness, anxiety, insomnia, forgetfulness, hyperactivity, frightfulness, inability to focus attention, or any abnormal behavioral changes.<sup>38</sup> Each of the clinical states of fear, anxiety, and phobia associated with CTA are Heart Shen disturbances. The Shen, though associated with the Mind, is housed in the Heart and requires nourishment from the Heart Yin and Blood to remain healthy.<sup>38</sup> The Heart belongs to Fire and with imbalance is prone to excesses of Heat, Phlegm or Fire, and deficiencies of Blood, Yin and Qi.38 Excess patterns can be caused by Heat (hot foods, environmental factors, Phlegm, Liver *Qi* Stagnation), which can result in Heart Fire.<sup>39</sup> Patterns of deficiency that result in Shen disturbance include Heart Blood, Oi, and/or Yin deficiencies. Deficient Kidney Jing may result in a reduced amount of Body Fluids and failure of their distribution, which means it is essential, not only to anchor Shen, but also to manifest Shen.<sup>40</sup> It is associated with Shen disturbance, especially in young patients with congenital Jing deficiency, as well as older patients suffering depletion of Kidney Jing. Mixed patterns result when excesses of Fire, Phlegm or Liver Qi stagnation combine with depletion of Blood, Yin or Qi.40

The TCVM treatment of CTA focuses on calming the Shen, clearing Heat, Fire, Damp or Phlegm if present, moving *Oi* Stagnation and tonifying any deficiencies of Blood, Yin or Qi. TCVM treatment modalities may include acupuncture (AP), Chinese herbal medicine (CHM), Tui-na, and food therapy. The objective of this study was to determine if, over a 4-month period, TCVM modalities (AP, CHM) integrated with basic DSCC and a rescue drug (alprazolam), could lessen the severity of CTA behaviors in dogs more effectively than conventional treatment (behavior modifying drugs, DSCC). The study hypothesis was that TCVM treatment added to conventional CTA management would result in improved efficacy documented through statistical evaluation of behavior change in an affected group of dogs over a 4-month period and when compared to literature documented standard of treatment.

# MATERIALS AND METHODS

Study subjects recruited for enrollment were clientowned dogs between 2 and 14 years of age that had demonstrated clinical fear and/or anxiety associated with thunderstorms. Participants were sought in the Southeast Missouri Tri-State area via contact with veterinary offices, businesses offering pet services or products, social media and print media. Inclusion criteria for the study included: 1) good health with up-to-date vaccines/titers, negative heartworm/ intestinal parasite status and veterinary approval; 2) exhibiting 1 or more thunderstorm aversive behaviors including panting, pacing, trembling, keeping close proximity to the owner, hiding, excessive salivation, destructiveness, excessive vocalization, self-trauma, or elimination in response to the natural elements of at least 3 of the most recent thunderstorms; and 3) pet owner was open to TCVM treatment modalities and provided informed consent for animal participation in the study. Exclusion criteria for the study included 1) unwillingness of the client to participate in study treatments/appointments/recordkeeping, 2) insufficient medical/behavioral history, 3) lack of vaccination history, 4) lack of true thunderstorm aversion, 5) other primary behavior problem, 6) uncontrolled medical issue, or 7) aggressive tendencies. Before study inclusion, all dogs received conventional and TCVM examinations, complete blood cell analysis, serum biochemical analysis and urinalysis tests. In addition, owners completed a behavioral health history questionnaire.<sup>4</sup> Weather conditions were recorded by owners with daily scores for each of 5 weather events (clouds, wind, rain, lightning, thunder) as "0" (none), "1" (mild), "2" (moderate), or "3" (severe). This was paired with scoring their dog's aversive behaviors (10 CTA behaviors) on a scale of "0" (none) to "10" (severe) on a Storm Phobia Assessment (SPA) form for 2 weeks prior to study start. Data gathered was used to determine study eligibility.

 Table 1: The traditional Chinese veterinary medicine (TCVM)

 Pattern diagnoses used to group study dogs for treatment.\*

	TCVM Pattern Diagnosis
Excess Patterns	Heart Fire with Damp Heat/Phlegm Liver <i>Qi</i> Stagnation
	Heart Yin Deficiency Heart Blood Deficiency Heart Qi Deficiency Kidney Yin Deficiency +/- with False Heat Kidney Qi +/- Jing Deficiency
Deficiency Patterns	Gall Bladder Deficiency Heat Blood Deficiency Blood Deficiency due to Spleen <i>Qi</i> Deficiency Liver Blood Deficiency
	<i>Yin</i> Deficiency with False Heat (specific organ signs lacking)

\*Dogs with CTA will always have an associated Heart imbalance even if the Heart pattern is not the primary diagnosis.

The TCVM treatment protocols for study dogs combined AP and CHM based on the current Excess and Deficiency TCVM Patterns determined at the pretreatment clinical exam (Day 0) for each dog (Table 1). Acupoints considered for use to calm *Shen* included: *An-shen*, HT-7, PC-6, *Da-feng-men*, BL-15, BL-17, BL-43, CV-15, GV-14, GV-20 and GV-24. These points were to be stimulated with dry needles (DNAP) or aqua-acupuncture (Aqua-AP). Electro-acupuncture, although not contraindicated, was considered more difficult to facilitate in this study's *Shen* disturbed dogs and not used. Other acupoints and CHM formulas were added consistent with the prescription to treat the *Zang-fu* pattern associated with the *Shen* disturbance (Table 2).<sup>39-42</sup>

Dogs included in the study were scheduled for monthly visits on Day 0, Day 30, Day 60, Day 90 and Day 120. At each visit, complete histories (conventional, TCVM, behavioral) were taken. Clinical examinations (conventional and TCVM examination with tongue and pulse evaluation) were performed and specific TCVM Pattern diagnosis/diagnoses associated with Shen disturbance was determined. Treatment consisted of Aqua-AP at An-shen with 1 ml of diluted vitamin  $B_{12}$ (50% sterile saline) administered with a sterile 22 g x 1.5" needle/3cc syringe<sup>a</sup> and DNAP using 32 g x 0.5" or 1.0" stainless steel needles<sup>b</sup> to treat Shen disturbance and the TCVM Pattern. A 1-month prescription of the TCVM pattern specific CHM<sup>c</sup> (0.08-0.1gm/kg) was dispensed at the same time with instructions to be given twice daily. Alprazolam (0.02 - 0.1 mg/kg, per os) was dispensed to be used as needed every 6-8 hours during a thunderstorm to lessen the severity of clinical episodes of thunderstorm aversion. During monthly AP treatments, acupoints to calm Shen were given priority. Not all Shen calming or pattern specific acupuncture points were required, allowing selection of acupoints readily accepted by each individual dog. Owners were given written behavior modification protocols: "Protocol for Deference" and "Protocol for Relaxation" to be performed daily at home. In addition, a third protocol, to be used during thunderstorms to guide proper dog/human interaction was given: "Do's and Don'ts During a Thunderstorm". The behavior modification protocols, sourced from literature recommendations, were explained verbally and reviewed at each visit (Table 3).<sup>4</sup> Owners were given notebooks with SPA forms to daily score each of the 5 weather events and each of their dog's aversive behaviors during the study. On Day 120, complete blood cell analysis, serum biochemical analysis and urinalysis tests were repeated.

On Day 0, baseline scores of thunderstorm aversion were collected by asking owners to rate their dog's thunderstorm aversive behaviors on a scale of 0 (never) to 10 (severe) for each of the 10 aversive behaviors (panting, pacing, trembling, keeping close proximity to the owner, hiding, excessive salivation, destructiveness, excessive vocalization, self-trauma, or elimination) with regards to the 3 most recent significant thunderstorm exposures. Completed SPA forms were collected at each monthly visit. The SPA scores associated with the most recent severe weather event were summated on Days 30, 60, 90, and 120 for each individual dog and for the group to determine if a statistically significant change occurred over the course of treatment. If no significant thunderstorm including both thunder and lightning had occurred or been witnessed by the owner within 3 weeks prior or 1 week after a treatment, then that dog was not included in the statistical analysis for that month. SPA scores of each clinical behavior was also summated for all included dogs

on Days 0, 30, 60, 90, and 120 to determine statistically significant changes in each clinical behavior. To assess the significance of overall SPA score reduction after 4 months of treatment compared to the baseline, Wilcoxon signed rank test was applied. The study also used McNemar's Z-test to determine, for each clinical sign of storm phobia, whether the proportion of presence was less after 120 days of treatment with TCVM modalities. In all tests, statistical significance was considered p<0.05 (\*) or p<0.01 (\*\*).

#### RESULTS

The study was initially able to recruit a total of 24 subjects that fit the inclusion/exclusion criteria. One subject could not stay in the trial due to owner personal reasons (illness); therefore, 23 dogs completed the study. Among those 23 dogs, 11 were spayed females (47.8%) and 12 were neutered males (52.18%). The mean $\pm$ SD age was 7.53 $\pm$ 3.87 years (range: 1.17 ~ 13.33) and the mean

body weight was  $48.83\pm30.93$  lbs (range:  $7.00 \sim 104.00$ ). The group included a total of 16 breeds (purebred, mixed breed) (Table 4). Each of the 5 TCVM constitutions was represented (Figure 1). Fire constitution had the greatest presence in study dogs, representing 43% of the subjects (10 of 23). It was followed by Water constitution, representing 22% of the subjects (5 of 23). Equal numbers of Wood and Earth constitutions occurred at 13% of the subjects each (3 of 23). The least common constitution was Metal, which represented 9% of the subjects (2 of 23).

The TCVM Pattern diagnoses associated with *Shen* disturbance related to thunderstorm aversion occurred in 3 large categories: Excess Pattern only (35%), Mixed Pattern-Excess/Deficiency (17%), or Deficiency Pattern(s) only (48%) (Table 5). The most common pattern among the 23 study subjects on Day 0 was Heart Fire with Damp Heat and/or Phlegm (either as a single pattern or mixed pattern), which accounted for 43% of the subjects (10 of the 23). On Day 0, 35% (8 of 23) had the Excess Pattern of Heart Fire with Damp Heat and/or Phlegm only

Table 2: The traditional Chinese veterinary medicine (TCVM) Pattern determined acupuncture and Chinese herbal medicine treatments used for study dogs.<sup>39-42</sup>

Dogs	TCVM Pattern	Acupuncture Points and Chinese Herbal Medicine
All Study Dogs	Shen disturbance	Aqua-AP: An-shen DNAP: HT-7, PC-6, Da-feng-men, BL-15, BL-17, CV-15, GV-20, GV-14, GV-24, BL-43
	Heart Fire or Heart Fire with Damp-Heat and/or Phlegm	DNAP: ST-36, ST-40, ST-44, SP-6, BL-27, BL-44, BL-15, CV-12, Tai-yang, Er-jian, Wei-jian CHM: Zhen Xin San
	Liver Qi Stagnation	DNAP: LI-4, ST-36, SP-6, BL-15, BL-18, LIV-3, LIV-13, CV-12, CV-14 CHM: Liver Happy <sup>c</sup> , <i>Chai Hu Shu Gan</i>
	Kidney <i>Qi</i> Deficiency +/- <i>Jing</i> Deficiency	DNAP: BL-23, BL-39, BL-52, KID-3, KID-12, CV-3, GV-4 <u>CHM</u> : Epimedium Formula <sup>c</sup> ( <i>Jing</i> Deficiency); Hindquarter Weakness <sup>c</sup> (Kidney <i>Qi-Yin</i> Def/ Bony <i>Bi</i> ); <i>Jin Suo Gu Jing</i> (strengthens Kidney, do not use if <i>Yin</i> Deficiency or Damp-Heat)
Protocol	Kidney and Heart <i>Yin</i> Def or Kidney <i>Yin</i> Def with False Heat	DNAP: ST-25, SP-6, HT-5, HT-6, KID-3, KID-7, KID-9, KID-10, CV-4, Wei-jian, Er-jian CHM: Er Yin Jian; Di Gu Pi (Kidney Yin-Qi /Bony Bi)
Treatment TCVM	Heart Yin Deficiency	DNAP: SP-6, SP-10, HT-3, BL-17, BL-44, KID-3 CHM: Er Yin Jian
Pattern(s)	Heart Qi Deficiency	DNAP: BL-14, BL-44 CHM: Heart <i>Qi</i> Tonic <sup>c</sup>
	Gall Bladder Deficient Heat	DNAP: ST-40, BL-19, PC-5, GB-13, GB-34, GB-40 CHM: Wen Dan Tang
	Yin Deficiency with False Heat (specific organ signs lacking)	DNAP: SP-6, BL-23, KID-3, Wei-jian, Er-jian CHM: Er Yin Jian
	Blood Deficiency	DNAP: SP-6, SP-10, BL-17; Liver Blood Deficiency -add ST-36, BL-18, LIV-3, LIV-8, CV-4; Heart Blood Deficiency -add BL-14, BL-15, BL-44; Blood Deficiency due to Spleen <i>Qi</i> Deficiency -add ST-36, LIV-13, CV-12 <u>CHM</u> : <i>Si Wu Tang</i> (Blood Deficiency only); <i>Shen</i> Calmer <sup>c</sup> (Blood and <i>Yin</i> Deficiency); <i>Gui Pi Tang</i> (Blood Deficiency and <i>Qi</i> Deficiency, especially Spleen <i>Qi</i> Deficiency)

DNAP = dry needle acupuncture; Aqua-AP= aqua-acupuncture; CHM = Chinese herbal medicine

and 9% (2 of 23) had this pattern mixed with a Deficiency Pattern (Kidney *Qi/Yin* Deficiency or Heart *Qi* Deficiency). Additional mixed patterns comprised 9% (2 of 23) and included 1 subject with Liver *Qi* Stagnation with Heart *Yin* Deficiency and another with Liver *Qi* Stagnation with *Jing* Deficiency. Deficiency Patterns (single or multiple) diagnosed on Day 0 were present in 65% of the subjects (15 of 23). Dogs with single deficiency patterns (17%) were less numerous than combinations of deficiencies which were present in 30% of subjects. In total, Blood or *Yin* Deficiency was present in 52% of the subjects, *Qi* Deficiency in 22%, and *Jing* Deficiency was in 9% of the subjects (Table 5).

Table 3: Short summary of detailed	guideline sheets	given to owners for	behavior modification	during the study.
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	Goals	Behavior Modification Techniques
Deference Protocol	1) Dog begins to sit calmly and look to human for needs/guidance, 2) Creates foundation for relaxation training	<ol> <li>Dog-Owner establish eye contact/dog gets reward, 2) Clear communication, 3) No punishment, 4) Ignore undesirable behavior,</li> <li>Repeat intermittently throughout day at times of low distraction</li> </ol>
Do's and Don'ts Training	<ol> <li>Do look at dog, 2) Don't stare at dog,</li> <li>Don't react adversely, 4) walk away if needed</li> </ol>	Encourage eye contact in shy dog by holding concealed treat to owner's forehead
Relaxation Protocol	1) Relaxation, 2) Defer to human, 3) Attention to cues, 4) Expect rewards, 5) Develop foundation to relieve stress and learn new behavior patterns	<ol> <li>Long, slow head/body strokes paired with a calming phrase or location, 2) Slow, deep breaths, 3) Spontaneous reward for calm behavior, 4) No tension in jaw, 5) Even weight distribution on feet,</li> <li>No tension in body, 7) Eyes calm, 8) After mastery use during times of stress to calm dog, 9) Repeat exercises during daytime during periods of relaxation, low activity, and at bedtime</li> </ol>
Task Sheets	1) Gradual changes, 2) Only reward good behavior	1) Train for 15-20 minutes, 1-2 times /day, 2) Find good behavior to reward, 3) Expect only tiny improvements, 4) If anxiety occurs, stop, go back to previous successful task
Do's and Don'ts Thunderstorm	1) Do go to safe area, 2) Don't pet/reward the anxious behavior, 3) Don't tell dog it's okay, 4) Do stay quietly by dog, 5) Do be calm and use calm gentle steady touch	1) Can try darker rooms, smaller spaces for calming, 2) Can try leaving dog alone in quiet space if safe, 3) Watch dog for signs of anything that calms behavior, 4) Can try various items (e.g., calming caps, anxiety wraps) with supervision if helps dog

**Table 4:** Study dog signalment with traditional Chinese veterinary medicine (TCVM) Pattern diagnosis at baseline (Day 0) and after 4 months of integrated treatment for thunderstorm aversion.

Fire Constitution Dogs											
Case	TCVM Pattern Day 0	TCVM Pattern Day 120	Chinese Herbal Medicine Day 0	Chinese Herbal Medicine Day 120	SPA Day 0	SPA Day 120	Decrease (%)				
Beagle	HT Fire w/ Damp Heat Phlegm	Liver Qi Stagnation	Zhen Xin San	Chai Hu Shu Gan	54	19	65				
G. Retriever Mix	HT <i>Qi/Yin</i> Def	HT Qi/Yin Def	Heart Qi Tonic	Heart Qi Tonic	56	6*	89				
Jack Russell Terrier	HT Fire w/ Damp Heat Phlegm	HT/Liver Blood Def	Zhen Xin San	Shen Calmer	44	7	84				
Min Poodle	HT Fire w/ Damp Heat Phlegm	Resolved	Zhen Xin San	none	11	2	82				
Terrier Mix	HT <i>Qi</i> Def	HT Qi Def	Heart Qi Tonic	Heart Qi Tonic	45	9	80				
G Retriever	HT Yin Def, KID Qi/Yin Def	KID <i>Qi/Yin</i> Def	Shen Calmer, HQW	Er Yin Jian	19	9*	53				
Lab Mix	HT Fire w/ Damp-Heat Phlegm	Liver Qi Stagnation	Zhen Xin San	none	27	2*	93				
Lab Mix	KID/HT Yin Def	KID Qi Def	Er Yin Jian	none	52	7*	87				
Labrador	HT Fire w/ Damp-Heat Phlegm	Resolved	Zhen Xin San	none	43	1*	98				
Chihuahua Mix	HT Yin Def, LIV Qi Stagnation	HT Phlegm Fire	Shen Calmer	Zhen Xin San	40	6	85				

SPA=Storm Phobia Assessment, R=right, L=left, Superfi =superficial, HT=Heart, KID=Kidney, Def=Deficiency, LIV=Liver, w/=with, HQW=Hindquarter Weakness, Stag=Stagnation; G=Golden; \* = Thunderstorm aversion considered resolved by the owner

## Water Constitution Dogs

Case	TCVM Pattern Day 0	TCVM Pattern Day 120	Chinese Herbal Medicine Day 0	Chinese Herbal Medicine Day 120	SPA Day 0	SPA Day 120	Decrease (%)
Am Stafford	HT BL/Yin Def, KID Yin Def	Yin Deficiency Shen Calmer Di Gu Pi				0*	100
Beagle	HT BL/ Yin Def, LIV BL Def	L Spleen Qi Def, Liver Shen Calmer, Liver Happy, Qi Stag Liver Happy Shen Calmer			9	0*	100
Chihuahua Mix	HT Fire w/ Damp Heat Phlegm, KID <i>Qi/Yin</i> Def	Heart Qi Deficiency	Zhen Xin San	Heart Qi Tonic	29	31	0
Carolina Dog Mix	HT BL Def	<sup>^</sup> Kidney <i>Jing</i> Def, HT Blood Def	y Jing Def, od Def Shen Calmer <sup>^</sup> Gui Pi Tang, Suo Quan Wan		32	^2*	^ 94
Pug Mix	HT Fire w/ Damp Heat Phlegm, HT <i>Qi</i> Def	Fire w/ Damp Heat egm, HT Qi DefLiver Qi Stagnation, HT Qi Def, KID Jing DeficiencyZhen Xin S Heart Qi T		Heart Qi Tonic	36	6*	83

 $^{\circ}$  = Results until Day 90 (none for Day 120) as owner decided dog was cured; \* = Thunderstorm aversion considered resolved by the owner; Am Stafford= American Staffordshire; BL= Blood

#### Wood Constitution Dogs

Case	TCVM Pattern Day 0	TCVM Pattern Day 120	Chinese Herbal Medicine Day 0	Chinese Herbal Medicine Day 120	SPA Day 0	SPA Day 120	Decrease (%)
Terrier Mix	HT Fire w/ Damp-Heat Phlegm	KID <i>Qi/Yin</i> Def	Zhen Xin San	Rehmannia 11	60	5*	92
Min Schnauzer	HT BL Def, KID Jing Def	^^ Kidney <i>Jing</i> Def, Liv <i>Qi</i> Stag	Epimedium, Si Wu Tang	^^ <i>Shen</i> Calmer, Epimedium	32	^^4	88
Malamute Mix	HT/LIV BL Def, Global <i>Yin</i> /BL Def	Blood Def	Gui Pi Tang	Gui Pi Tang	63	12	81

 $^{\wedge}$  = Results from Day 60 as owner discontinued before Day 90 due to desire to use tranquilizer for July 4, \* = Thunderstorm aversion considered resolved by the owner

#### **Earth Constitution Dogs**

Case	TCVM Pattern Day 0	TCVM Pattern Day 120	Chinese Herbal Medicine Day 0	Chinese Herbal Medicine Day 120	SPA Day 0	SPA Day 120	Decrease (%)
Am Stafford Mix	HT Yin Def	#		#	41	#	#
Great Pyrenees	HT Fire w/ Damp-Heat Phlegm	Resolved	Zhen Xin San	none	58	0*	100
American Staffordshire Mix	HT Fire w/ Damp-Heat Phlegm	Resolved	Zhen Xin San	none	48	0*	100

# = withdrawn from study due to personal reason (family illness), \* = Thunderstorm aversion considered resolved by the owner

## **Metal Constitution Dogs**

Case	TCVM Pattern Day 0	TCVM Pattern Day 120	Chinese Herbal Medicine Day 0	Chinese Herbal Medicine Day 120	SPA Day 0	SPA Day 120	Decrease (%)
German Shepherd	Gallbladder Def Heat	Heart Qi Def	Wen Dan Tang	Heart Qi Tonic	39	4	90
Mix (59lb)	LIV <i>Qi</i> Stag, KID <i>Jing</i> Def	HT Blood Deficiency	Zhen Xin San	Gui Pi Tang	20	11	45

The AP and CHM treatments were selected based on the primary *Shen* disturbing pattern. Whereas most subjects were able to have tongue and pulse examined, 1 subject was too reactive to palpate femoral pulses and others received brief or incomplete tongue examination due to a reactive constitution. As the study progressed, reactive subjects became calmer, allowing more complete examinations. The number of AP points stimulated during treatment was limited in Wood, Fire and Water subjects (18 of 23), requiring a flexible AP prescription that included acupoints the subject would accept. In general, the CHM therapies were well accepted. An effort was made to begin patients with 1 CHM prescription for both the purpose of the study and to improve owner/subject compliance. Four dogs initially received a combination of 2 CHM prescriptions with the remaining 19 subjects receiving 1. The CHM prescriptions were modified at subsequent visits if indicated to treat a change in TCVM pattern presentation.



Figure 1: Constitutions of study dogs

The mean overall SPA score assessed prior to treatment (Day 0) demonstrated an overall SPA score of  $38.52\pm15.20$ . Among the 23 subjects, only 1 (4.3%) had an overall score below 10, whereas 6 subjects (26.1%) had scores above 50. After 30 days of treatment, the mean $\pm$ SD overall SPA score dropped to  $17.06\pm11.13$  (Table 6). This was a 55.7% drop from Day 0, which was statistically significant ( $p = 7.63 \times 10^{-6}$ ). Among the 18 subjects assessed, 6 (33.3%) had overall scores below 10

and none (0%) were above 50. The remaining 5 subjects' scores were not available. The overall SPA score further reduced after 60 days (mean±SD = 10.00±8.22) with 13 out of 22 (59.1%) subjects below 10 (1 subject's score was not available). The score remained almost unchanged at Day 90 and Day 120 assessments (mean±SD = 10.38±9.95 and 7.95±8.85, respectively with 7 and 3 subjects' scores not available, respectively). The reductions (from Day 0) at Day 60, Day 90, and Day 120, respectively, were all statistically significant ( $p = 4.77 \times 10^{-7}$ ,  $3.05 \times 10^{-5}$ , and  $3.82 \times 10^{-6}$ ) (Figure 2). The differences between overall SPA score post-treatment time points were compared. These statistical comparisons revealed that the greatest behavior change occurred over the first 60 days of the study.

For each of the 10 behaviors assessed, the change of proportion of dogs exhibiting the behavior after receiving 4 months of the proposed treatments was investigated. The incidence of destructiveness (n = 1), self-trauma (n = 1), and elimination (n = 2) had too few occurrences (at Day 0 and Post-treatment times) for these individual behavior analyses, hence, the inference was only performed on the remaining 7 behavior symptoms.

All thunderstorm aversion behaviors assessed had a statistically significant reduction (exception, "remain by owner") at the end of the 4-month treatment period (Table 7). Panting behavior decreased from 80% of study dogs to 35% (p = 0.016). The proportion of pacing went from 90% to 30% (p = 0.001). Trembling changed from 85% of dogs at Day 0 to 50% at Day 120 (p = 0.046). Hiding had a reduction from 100% of dogs exhibiting the behavior at study start to 35% at 4 months (p = 0.001). Excess salivation and excess vocalization had significant reductions from 55% and 40% respectively, at Day 0 to 10% at Day 120 (p = 0.008 and p = 0.041, respectively). The "remain by owner" behavior did not have as large a reduction after 4 months as the other behaviors and was not statistically significant (95%  $\rightarrow$  80%, p = 0.371).

Table 5:	Incidence	of dogs	exhibiting	specific	traditional	Chinese	veterinary	medicine	(TCVM)	patterns a	nd their	constitutio	n at pre-
treatment	assessmen	t (Day 0)	•										

Pre-treatment TCVM Pattern Diagnosis (Animal Incidence/Constitution)	Dogs Affected Day 0
Excess Pattern Only Heart Fire with Damp Heat/Phlegm (F-5, E-2, Wd-1)	35% (8/23)
Mixed Excess and Deficiency Heart Fire with Damp Heat/Phlegm + Kidney <i>Qi/Yin</i> Def (Wt-1); Heart Fire with Damp Heat/Phlegm + Heart <i>Qi</i> Def (Wt-1); Liver <i>Qi</i> Stagnation + Kidney <i>Jing</i> Def (M-1); Liver <i>Qi</i> Stag + Heart <i>Yin</i> Def (F-1)	17% (4/23)
Deficiency Pattern Only Single Deficiency: Heart Blood Deficiency (Wt-1); Gall Bladder Deficiency Heat (M-1); Heart <i>Qi</i> Def (F-1); Heart <i>Yin</i> Deficiency (E-1)	Single Deficiency: 17% (4/23)
Combination Deficiencies: Heart <i>Qi/Yin</i> Deficiency (F-1); Kidney/Heart <i>Yin</i> Deficiency (F-1); Heart <i>Yin</i> Def +Kidney <i>Qi/Yin</i> Deficiency (F-1); Heart BL/Yin Def + Kidney <i>Yin</i> Def (Wt-1); Heart BL/ <i>Yin</i> Deficiency + Liver BL Deficiency (Wt-1); Heart BL Deficiency + Kidney <i>Jing</i> Def (Wd-1); Heart/Liver Blood Deficiency + Global <i>Yin</i> /BL Deficiency (Wd-1)	Combination Deficiency: 30% (7/23)
Total animal incidence of at least 1 Deficiency at Day 0	65% (15/23)

F=Fire constitution, Wd=Wood constitution, E=Earth constitution, Wt=Water constitution, M=Metal constitution, BL=Blood, Def=Deficiency

Table 6: The overall Storm Phobia Assessment (SPA) score	(mean±SD) prior to treatment	t (Day 0) and each of the $4$	post-treatment time
points with mean improvement and statistical significance.			

	Day 0	Day 30	Day 60	Day 90	Day 120
SPA Score (mean±SD)	38.52±15.20	17.06±11.13	10.00±8.22	10.38±9.95	7.95±8.85
Behavior Improvement (mean±SD)		56.7%±23.0%	72.4%±24.1%	71.3%±28.1%	77.2%±27.7%
<i>p</i> -value		$p = 7.63 \times 10^{-6} ***$	$p = 4.77 \times 10^{-7} * * *$	$p = 3.05 \times 10^{-5} ***$	$p = 3.82 \times 10^{-6} ***$

\*\*\* statistical significance at p<0.0001

Table 7: Assessment of thunderstorm aversion behaviors pre-treatment and change after 120 days of integrative medical treatment

	Day 0 Pre-Treatment		Day 120 After 4 Months Treatment		Behavior Reduction
Behavior	Incidence ^	Percent of Dogs	Incidence ^	Percent of Dogs	<i>p</i> -value
Panting	16/20	80%	7/20	35%	<i>p</i> = 0.016*
Pacing	18/20	90%	6/20	30%	p = 0.001 **
Trembling	17/20	85%	10/20	50%	<i>p</i> = 0.046*
Hiding	20/20	100%	7/20	35%	p = 0.001 **
Excess salivation	11/20	55%	2/20	10%	<i>p</i> = 0.008**
Excess vocalization	8/20	40%	2/20	10%	<i>p</i> = 0.041*
Remain by owner	18/20	95%	16/20	80%	<i>p</i> = 0.371

^ only includes the 20 subjects reporting outcomes on Day 120; \*statistical significance at p<0.05; \*\* statistical significance at p<0.01

This study was able to include 23 subjects in the final statistical analyses, which offered over 95% power and 95% confidence to conclude statistical significance of behavior improvement, assuming an effective size of the sample standard deviation. For McNemar's Z-test (used to assess 7 behaviors), the sample size had over 90% power with 0.05 significance level to reject the null hypothesis, assuming that about 80% of the subjects had the clinical symptom and only 50% of them remained having the symptoms after the treatment, and that 10% of the initially asymptomatic cases had the symptom after the treatment. Commercial computer software<sup>d</sup> was used for all data graphic presentations and a commercial statistical software was used for statistical analysis<sup>e</sup>.

No adverse effects occurred during the study from any of the TCVM treatments or alprazolam, nor were any owners injured by dogs during thunderstorm aversive behavior or while training dogs. No significant changes were noted on analysis of results from blood or urine analysis run at the end of the study.

#### DISCUSSION

Thunderstorm aversion in dogs is a serious problem both from the suffering that affected animals experience as evidenced by crying, trembling, hiding and the destruction of property associated with aversive behaviors. Conventional medical treatment of the condition has been predominately approached using behavior modifying drugs along with desensitization training. The present study investigated adding TCVM Pattern appropriate AP and CHM to conventional treatment to improve treatment efficacy of this challenging behavioral syndrome. Scoring of behaviors associated with thunderstorm aversion were documented in 23 dogs and monitored for each animal (SPA score) over a 4-month period. With the proposed treatment (TCVM + conventional therapy), pre-treatment SPA scores consistently decreased at the 4 post-treatment assessments by 55.7% ( $p = 7.63 \times 10^{-6}$ ), 74.0% ( $p = 4.77 \times 10^{-7}$ ), 73.1%  $(p = 3.05 \times 10^{-5})$ , and 79.4%  $(p = 3.82 \times 10^{-6})$  on treatment days 30, 60, 90, and 120, respectively (Table 7).

As there was no control group in this study, a comparison study was selected instead of a placebocontrolled trial due to welfare and ethical concerns of placebo treatment of dogs exhibiting a clinical behavior disorder.<sup>43</sup> The comparison study was a well-designed clinical trial performed at a veterinary college that evaluated a currently recommended conventional CTA treatment. The study dogs received clomipramine (2-3mg/kg, PO) every 12 hours for 3 months. During the 4<sup>th</sup> month, the drug dose was tapered by half for 2 weeks and then decreased again by half for the last 2 weeks of the study. The owners were also given alprazolam (0.02 mg/kg) to be used as needed 1 hour before anticipated thunderstorms and a DSCC protocol, which included exposure to audio simulation of storm sounds, to be followed at home. Total SPA scores decreased 52% during 120 days of treatment in the comparison study.<sup>43</sup>

The sample size (23 dogs) completing the current study offered over a 95% power and 95% confidence to conclude a statistical significance of behavior improvement (assuming effective sample size standard deviation). This sample size also provided an approximately 74% power for comparison with the 52% improvement percentage of the comparison study. The overall SPA score improvements with the added TCVM treatment in the present study were compared with the reported 52% mean conventional treatment improvement at 120 days (Figure 3). Among the 20 subjects in the present study reporting assessment at Day 30, the mean±SD percentage of overall SPA score improvement compared to Day 0 was 56.7%±23.0% (Table 6). Although the observed mean was above 52%, at 0.05 significance level, the statistical noninferiority to 52% could not be concluded (p = 0.088). At Day 60, however, among the 22 subjects reporting assessment, the mean±SD improvement was  $72.4\% \pm 24.1\%$ , with 19 subjects (86.4%) having greater than 52% improvement when compared to the score at Day 0. Such a group improvement was not only noninferior to 52% (p = 0.0005), it was in fact statistically superior to 52% (p = 0.0013). Similar conclusions could be made for assessments on Day 90 (mean $\pm$ SD =  $71.3\% \pm 28.1\%$ ) and Day 120 (mean  $\pm$  SD =  $77.2\% \pm 27.7\%$ ),

Mean Overall SPA Score Over Time 3 **Overall SPA Score** 8 2 0 Day0 Day 30 Day 60 Day 90 Day 120 (N = 23) (N = 18)(N = 22) (N=16) (N = 20)



respectively. The group improvements at Day 90 and at Day 120 were both statistically superior to 52% (p = 0.0151 and 0.0019, respectively). When compared to conventional treatment, the results of the proposed integrative treatment (TCVM, basic DSCC, alprazolam) supported the hypothesis of improved treatment efficacy for lessening the severity of CTA in dogs.

When investigating changes of the individual behaviors observed in study dogs with CTA, the involuntary behaviors of panting, salivation, and trembling showed significant reduction (p < 0.05) over the course of the 4-month treatment. This suggests successful decrease of the sympathetic tone of the autonomic "fight or flight" reflex that occurs with anxiety, fear or phobia. Significant reduction (p < 0.05) of the voluntary behaviors of pacing, hiding and vocalization over the course of the 4-month treatment also indicates decreased psychological effects associated with anxiety, fear or phobia disorders. One behavior that bears further analysis, "remaining by the owner", did not have a statistically significant decrease. That the dogs would seek contact with their owners during a thunderstorm is not surprising. The owners had been instructed to perform daily sessions to teach their dog relaxation in association with a relaxation phrase and specific location (Table 3). This training was to distract and counter-condition the dog with the relaxation technique, and if possible, to be used during a thunderstorm to desensitize the dog to the weather events. This would result in the dog having proximity to the owner during thunderstorms and if the counterconditioning was done properly, the dog would seek the owner for relaxation in response to thunderstorm stimuli. In fact, in 1 study subject this behavior actually



**Figure 3:** Mean percentage (with standard error bar) improvement (compared to Day 0) among subjects under assessment at each post-treatment time; with comparison to a clinical study using conventional medical therapy only (red dotted line).<sup>43</sup>

increased from baseline to Day 120 while all other behaviors decreased. Perhaps future studies should replace this categorical behavior with "undesirable clinginess". The behaviors of elimination, self-injury and destruction of property did not occur with a high enough frequency to allow statistical analysis of those individual behaviors. The lack of these cases in the study may be an indication that more severely affected dogs have already been relinquished, euthanized, or have suffered breakdown in the human-animal bond resulting in lack of veterinary care.

All TCVM constitutions were represented in this study. Fire and Water constitution dogs represented approximately 2/3 of the subjects with nearly twice as many Fire as Water constitution dogs. Although animals of every TCVM constitution may suffer Shen disturbance, animals with a Fire constitution may be most susceptible. When imbalanced, Fire constitution animals are prone to patterns related to Heat and exhaustion of Yin creating Yin and Blood Deficiency resulting in Shen disturbance. Wood and Water constitution animals also have special risk of Shen disturbance. Wood constitution animals are prone to Liver *Qi* Stagnation causing Liver *Yang* rising with depletion of Yin. Water constitution animals may be prone to Kidney Yin Deficiency that may cause Heart Yin and Blood Deficiency resulting in Shen disturbance.<sup>38</sup> Findings in this study demonstrated good response to the experimental treatment and improvement for all TCVM constitutions. There was some variation in percentage of improvement depending on the constitution of the dogs, however, due to the unequal number of dogs in a constitution group (e.g., 2 dogs in Earth vs. 10 dogs in Fire), a larger study with more equal constitution groups would be needed for valid conclusions (Table 4).

Evaluation of the percentage of dogs completing a behavior modification study is important. The current integrative TCVM treatment study, when compared to the conventional study, demonstrated better subject retention. The comparison study had a completion rate of 80% of subjects while the current study had a 95% study completion by enrolled dogs. The authors of the comparison study stated that the lack of follow-up and completion of a study is a strong indication that either the side effects of medications, lack of efficacy of the treatment or unwillingness to carry out the DSCC training caused the owners to withdraw their dogs. Side effects of conventional medications noted in that study included vomiting, lethargy, diarrhea, constipation, increased or decreased appetite, increased or decreased thirst, seizure, irritability and changes in sleep.43 Of 24 dogs enrolled in the TCVM study, 1 failed to start the study and a second began but did not complete the study due to owner illness. Only 1 subject was withdrawn for a non-personal reason. The owner of this study subject wanted to use tranquilizers during the Fourth of July fireworks which would have interfered with accurate SPA scoring. This study subject had shown SPA improvement on Days 30 and 60 but regressed on Day 90, 1 week after the owner had discontinued the CHM prescription. No adverse side

effects of TCVM treatment or conventional medication associated with the study caused any TCVM study participants to withdraw from the study. In addition, owners did not provide any negative feedback concerning the DSCC protocols (Table 3).

Based on SPA scores, the conventional treatment study group showed improvement of 52% which is only slightly higher than the placebo effect which has been shown to be responsible for 50% or more of the treatment effects in behavioral studies.<sup>14,20,43</sup> The TCVM study group documented an improvement rate that well exceeded that noted with a placebo effect as well as that noted in the comparison study. Compared to the conventional treatment study, as measured by SPA scores, 20 of 21 dogs (95%) that completed the current study experienced some degree of improvement. The only study dog that did not have an improved Day 0 SPA score compared to Day 120 score demonstrated a decrease in all SPA behaviors other than "remain by owner", which increased, causing the total SPA average score to remain unchanged.

Overall, 12 dogs were considered free of CTA by their owners at the completion of the study. The largest degree of improvement occurred within the first month of treatment with the average SPA score dropping just over 50%. The continued improvement through days 60, 90, and 120 to a 77% improvement validate treatment efficacy when compared to the reported conventional treatment at 52% and the suspected placebo effect (50%). Whereas over 95% of the study participants showed some improvement, over 80% of subjects improved by more than 80% with 19% of subjects scoring zero for all SPA behaviors and over 50% of owners considering their dogs cured of clinical CTA. One study participant skipped the Day 120 treatment because the owner considered the CTA condition resolved and treatment was no longer needed.

Studies have demonstrated the efficacy of acupuncture to treat a variety of human clinical emotional disturbances as well as propose some of the physiologic mechanisms responsible for the efficacy of acupuncture.44 Rodent and human studies have shown acupuncture as an effective treatment of stress and clinical anxiety.<sup>45-52</sup> Human patients suffering "Generalized Anxiety Disorder" that were treated with AP demonstrated statistically significant improvement over control groups that received placebo AP as well as those with anxiety disorders accompanied by insomnia.47,48 In addition, post-stroke anxiety disorder in humans responded just as well to AP treatment as to conventional treatment with anti-anxiety medication.<sup>49</sup> Whereas rodent and human stress or anxiety patterns may not exactly parallel CTA, these studies demonstrate the efficacy of AP to calm Shen.

Canine studies of clinical CTA are few due to the difficulties associated with quantification of canine fear or anxiety. The canine behaviors associated with fear or anxiety are easily detectable but measurement by subjective scoring may be biased by pet caregivers or vary due to intensity variations of the stimulus. Methods that have been used to study stress responses include behavioral scoring by observers, blood cortisol measurement and analysis of the cardiac parameters of heart rate variability (HRV).53 The HRV measurement shows the most promise of an objective assessment of the autonomic stress response to evaluate the efficacy of treatment modalities.<sup>54</sup> Studies of TCVM treatment of Shen disturbance associated with CTA to date have been lacking, but a study of HRV in healthy beagle dogs demonstrated that a single AP treatment before noise exposure can reduce acute noise stress.53 This study demonstrated the application of HRV to measure autonomic response in dogs and proposed that AP can modulate acoustic stress as well as recommending further evaluation of TCVM treatment for clinical CTA patients.53 Considering this, utilizing HRV in future studies to assess the autonomic response associated with CTA could provide an objective outcome measure to pair with subjective assessments furthering the knowledge base concerning pattern-specific TCVM treatments of Shen disturbances associated with CTA.

The most significant challenge of this CTA study involved scheduling. Every effort was made to start treatments in late winter or early spring in order to score aversive behaviors during the thunderstorm season. This sometimes overlapped with the Fourth of July fireworks season causing some dogs that were aversive to fireworks to experience transient increases in SPA scores. The TCVM treatment, however, was still considered of benefit by many of these owners. Other challenges occurred due to the reliance on owner compliance with treatments. This required a level of flexibility that may have affected outcome measures. Lapses in herbal medicine treatment occurred occasionally but usually lasted no more than a few days. Owners were allowed a 5-day grace period for monthly visits. Missed appointments occurred with 5 owners who completed the treatment to Day 120, missing 1 AP appointment each. Missed appointments were most commonly unavoidable personal situations. No participant discontinued or missed appointments due to side effects or adverse reactions of the treatment or medications. Other limitations to the study included the potential for owner bias when scoring dogs on the SPA form. Since owners were not blinded to treatment, bias either for or against treatment improvement could have affected scoring, and thus, study findings.

This study demonstrates clinical efficacy of TCVM treatment of CTA in a study population that was varied in age, breed and body size; nearly equal in gender; and comprised of neutered animals that closely represents the variety of patients seen by veterinarians. The level of thunderstorm aversion in the study group was most commonly an advanced moderate aversion or early severe aversion, and pet owners were active participants in treating their pets. The results of the study would be expected to correlate well with patient outcomes in a clinical setting and support the efficacy of treatment of CTA with TCVM, alprazolam and recommended protocols of basic behavior modification for 120 days. The use of TCVM, in addition to increased treatment

efficacy, avoided the use of daily psychotropic medications which many owners decline due to canine personality changes, side effects and cost. In addition, the use of simple, enjoyable exercises with their dogs versus the stress of exposing them to increasing unpleasant noise levels of simulated recordings of storms, was a more positive experience that encouraged owners to continue participation in the behavior modification part of the study.

In summary, integrative management of CTA with TCVM Pattern-specific treatments combined with a conventional rescue drug and behavior modification improved CTA behaviors and suggests greater efficacy than conventional medical management only. Study findings suggest practitioners should expect to see early improvements in CTA behavior at 30 days and extending treatment to 120 days provides improvement greater than conventional medical treatment only. Future studies to determine the effect of the proposed treatment on the more severe behaviors of destructiveness, self-trauma and elimination are indicated as well as randomized controlled trials to validate the findings of the present study.

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#### **FOOTNOTES**

- <sup>a.</sup> Monject needle and syringe, Cardinal Health, Dublin, Ohio USA
- <sup>b.</sup> Acupuncture needles (Jing Tang color handle), Dr Xie's Jing Tang Herbal, Inc; Ocala, Florida USA
- Chinese herbal medicine, Dr Xie's Jing Tang Herbal, Inc; Ocala, Florida USA
- <sup>d.</sup> Microsoft Excel (Excel 2013), Microsoft for Windows, Redmond, Washington USA
- R version 3.5.2 (2018-12-20), The R Foundation for Statistical Computing, Vienna Austria; http://www.R project.org

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