Available online at www.sciencedirect.com
ScienceDirect
The Veterinary Journal 177 (2008) 80–88
The Veterinary Journal
www.elsevier.com/locate/tvjl

A double-blind placebo-controlled study into the efficacy of a homeopathic remedy for fear of firework noises in the dog (*Canis familiaris*)

Nina R. Cracknell, Daniel S. Mills *

Animal Behaviour, Cognition and Welfare Group, Department of Biological Sciences, University of Lincoln, Riseholme Park, Lincoln LN2 2LG, UK

Accepted 7 April 2007

Abstract

Seventy-five dogs that showed a fear response to fireworks participated in a double-blinded, placebo-controlled clinical trial to assess the efficacy of a homeopathic remedy for the alleviation of their behavioural signs. Dogs were randomly assigned to one of two treatments; the homeopathic treatment or the placebo treatment. At the baseline assessments the owners identified the behavioural signs of fear that their dogs normally displayed in response to fireworks, rated their frequency and intensity, and assessed the global severity of their dog's responses. These measures were repeated at the final assessment and owners also completed weekly diaries for the length of the trial. There were significant improvements in the owners' rating of 14/15 behavioural signs of fear in the placebo treatment group and all 15 behavioural signs in the homeopathic treatment group. Both treatment groups also showed significant improvement in the owners' rating of the global severity of their dog's responses. However, there was no significant difference in the response seen between the two treatment groups.

Keywords: Dog; Fear; Fireworks; Homeopathy; Placebo

Introduction

The fear response is a normal, self-protecting behaviour which acts to promote the survival of the individual by triggering defence reactions to potentially threatening stimuli. It can, however, be considered abnormal if it is consistently triggered by non-threatening stimuli, or the intensity or duration of the response is excessive compared to the actual threat from the stimulus that elicits it (Shull-Selcer and Stagg, 1991). A fear of noises can be demonstrated by behaviours such as hiding, destructiveness (in an attempt to escape from the noise), and excessive panting, drooling and trembling (Landsberg et al., 2003). It has been suggested that perhaps nearly 40% of dogs suffer from some sort of fear of noises (Voith and Borchelt, 1996).

Sudden loud noises such as gunshots, thunderstorms and fireworks appear to be the most common type of fear eliciting noise in domestic dogs (Landsberg et al., 2003; Shull-Selcer and Stagg, 1991), with the RSPCA reporting an 82% increase in the number of telephone calls about distressed and injured animals during the 2005 November fireworks season in the UK (RSPCA, 2006). With the traditional November fireworks events in the UK reportedly lasting for up to 3 weeks in some areas, and a general increase in the use of fireworks throughout the year for private celebrations, there is growing concern for the welfare of dogs who suffer from such fears. However, it is increasingly recognised that such fears are not a homogeneous or simple entity. For example, it is frequently assumed that the problem relates to the loudness, frequency (pitch) or suddenness of the noise. But such events are often associated with secondary stimuli such as light flashes, odours or even changes in barometric pressure and the role of such

* Corresponding author. Tel.: +44 1522 895356; fax: +44 1522 895328.
E-mail address: dmills@lincoln.ac.uk (D.S. Mills).

1090-0233/$ - see front matter © 2007 Elsevier Ltd. All rights reserved.
doi:10.1016/j.tvjl.2007.04.007

indirect factors on noise perception and individual endogenous factors remain largely unknown, although anecdotally they clearly appear important in specific cases (D.S. Mills, personal observation).

Fears may also develop through a range of different processes (Poulton and Menzies, 2002) and the relationship between purported aetiology, phenotype and treatment response is only just beginning to be explored (Iimura, 2006). Despite this complexity, generic treatments for fear of noises are widely available. Typically, fears of noises are resolved using a system of desensitisation and counter-conditioning, whereby the dog is exposed to the trigger stimuli according to an intensity gradient scale, starting with a low level of exposure and moving gradually towards the highest natural intensity exposure level in association with some form of reward, making sure a fear response is not elicited at any level (Overall, 2002). This procedure typically takes several weeks or months to complete. In cases where prior desensitisation has not been undertaken, there are immediate control methods available to manage the problem. These are appealing to owners as they provide a 'quick fix' although they can lead to many owners not treating the problem in the long-term (Mills et al., 2003).

The use of veterinary medications such as sedatives and anxiolytics is a popular choice for owners of noise phobic dogs, even if the use of sedatives is now considered outdated by experts in the field (Overall, 2002). Even appropriate medication can be unacceptable to owners for reasons relating to their beliefs (unfounded or otherwise) concerning the financial cost involved, the predictability of efficacy and side-effects or personal resistance to the use of drugs for the control of behaviour problems, so alternative or complementary forms of treatment for their pets' behavioural problems may be considered. Such interventions include dog appeasing pheromone (DAP, Ceva Santé Animale), herbal preparations, Bach flower remedies and homeopathic treatments. However, to date, of these only the efficacy of DAP in combination with behaviour therapy has been investigated scientifically (Sheppard and Mills, 2003).

Homeopathy has been used in human medicine for more than 200 years. It is generally defined as a system of treatment based on the serial dilution and potentisation of minute quantities of substances which, in larger doses, might produce symptoms similar to those of the ailment being treated (Gray, 2000). However, despite numerous accounts of the effectiveness of homeopathy in humans and animals, many scientists remain sceptical about the efficacy of these "remedies" (NCCAM, 2003).

Practitioners of homeopathy generally claim that the greater the dilution of a remedy, the more potent it becomes (Gray, 2000). In some cases the remedies are so dilute that there is virtually no chance that even one molecule of the original substance remains in the solution. For example, Park (2000) calculated that for a 30X dilution, the patient would need to consume 7874 gallons (29,806 L) of the solution to expect to consume a single molecule of the "remedy substance". The currently most popular explanation for this is that the solvent retains some "memory" of the molecules that were once dissolved in it (Gray, 2000). However, the lack of a chemical mechanism to explain how ultra-dilute solutions can retain an imprint of a molecule that no longer exists in solution is one of the primary criticisms of homeopathy.

Another criticism of homeopathy lies in the lack of evidence in the form of clinical trials conforming to a high scientific standard (Cucherat et al., 2000). Whilst it is sometimes claimed by homeopaths that homeopathy does not lend itself to clinical trials due to the individuality of treatments (Gray, 2000), generic treatments are available through non-specialist outlets and so such products might reasonably be considered amenable to evaluation by such a scientific process. Trials need to be placebo controlled and appropriately blinded in order to control for spontaneous recovery and 'the placebo effect' (Hektoen, 2005). The placebo effect is the measurable, observable, or felt improvement, either physically or psychologically, that is not attributable to the specific treatment being tested (McMillan, 1999). Data from a previous uncontrolled study conducted by Homeopet (Westhampton Beach USA) concerning the potential efficacy of a homeopathic remedy for fear of fireworks in pet dogs, suggested that there might be a 65% response rate to intervention (E.D. Levine and D.S. Mills, unpublished data).

Therefore the aim of this study was to conduct a suitably controlled and blinded study into the efficacy of a similar generic homeopathic treatment for fear of noises in dogs.

Materials and methods

The UK Home Office were contacted for clarification of the study in relation to Animals (Scientific Procedures) Act 1986 (ASPA), and ethical approval was obtained from the relevant university ethics committee.

Recruitment of dogs

Dogs with a fear of noises were recruited into the study via notices in veterinary practices and advertisements in the national media. Potential dogs had to meet a number of inclusion criteria (Table 1). These related to selecting subjects with a stable and easily assessable response to firework noises whilst excluding those that might confound any response to the homeopathic treatment.

Owners of dogs that satisfied all inclusion criteria were briefed in writing about the procedures involved in the study and informed written consent was obtained from both the owners and their veterinary surgeon before the dog was enrolled onto the trial. Owners also had to complete two questionnaires relating to their dog's fear of noises; a behavioural history questionnaire which provided both demographic data and a detailed evaluation of the dog's problem, and a baseline assessment questionnaire detailing the behaviours that the dog displayed in response to fireworks which included a rating of the severity of each behaviour during the most recent firework exposures (without medication). This allowed elimination of differentials of fear of noises, such as attention seeking behaviours and an assessment of the dog's baseline level of response.

The owners were instructed that during firework or similar noise exposures they should use the trial treatment first but, if they were not satisfied with the response, they could elect to use any other form of

Table 1
Inclusion criteria for dogs participating in the study

Dog is at least 6 months old
Dog should not show aggression in any context
Dogs should not be receiving any significant psychoactive medication (i.e. primary psychoactive agents)
Dog is not currently receiving any homeopathic treatments
Dog is not exposed to strong odours in the home (e.g. essential oil aromatherapy, air fresheners, or camphor based products) – homeopathic provision
Dog's diet excludes coffee, garlic, mint and sweets – homeopathic provision
The dog displays fear responses to specific, identifiable firework noises
The fear responses should occur in the home
The fear response must be reliably elicited by the natural occurring noise stimulus
Fear should not have generalised to the extent that the eliciting cues are too numerous to be identifiable and the dog rarely appears relaxed

Table 2
Behavioural advice for dogs with a fear of fireworks

Don't punish your dog when he is scared, it only confirms that there was something to be afraid of
Don't fuss or try to reassure your dog when he is scared, as this rewards the behaviour
Ignore any fearful behaviour that occurs for no good reason
Make sure your dog is kept in a safe and secure environment at all times so that it doesn't bolt and escape if a sudden noise occurs
Try to move your dog to a blacked out room at sundown with toys for him and preferably things for you to do as well, so he is not abandoned in the room. Blacking out the room removes the potentially additional problems of flashing lights, etc.
Provide your pet with a safe and secure retreat, such as a cupboard under the stairs or wardrobe. Pack the area with old pillows and duvets to make it comfortable and muffle the noise around
Ignore the noises yourself and try to engage your pet in some form of active game
If you know of a dog that is not scared by the noises and which gets on with your own dog then keeping the two together during the evenings may help. Playing with the non-fearful dog if your own dog becomes scared may help to encourage the fearful dog that all is not so bad after all

treatment if they wished. This decision to switch treatments was decided upon as one of the potential parameters for comparison between the two treatment groups, whilst helping to protect the welfare of the subjects in the trial.

Treatment blinding and randomisation

Two interventions were used in the study; a potentised homeopathic remedy (verum), based on phosphorus, rhododendron, borax, theridion, and chamomilla (6C and 30C in 20% alcohol), and a 'control' (placebo) preparation of water and 20% alcohol in an identical bottle with integrated dropper. Sampling of the mass of drops from one randomly chosen bottle of verum and placebo suggested drop size was relatively consistent with a mean mass of 0.0231 ± 0.0006 g.

The treatment blinding process was carried out by an independent university researcher not involved further in the study. This researcher was provided with two batches of preparation differing externally only in their batch numbers. The identity of the two batches was contained within a sealed envelope and so the identity of verum and placebo remained blind to all researchers at this time. The batch numbers on the bottles were then removed and replaced with individual bottle numbers by the independent researcher using her own unique six and seven digit code system. In this way only the independent researcher could determine to which batch bottles belonged. This procedure controlled for any bias that might have occurred due to perceived batch effects as the study progressed. It also ensured that no one associated directly with the project could determine either the specific (verum or placebo) or batch identity of the bottles. The extra level of blinding allowed analysis of results by group without revealing the identity of verum and placebo. A block randomisation procedure was then used with ten bottles in each block, consisting of five verum and five placebo treatments, provided by the independent researcher a priori of subject recruitment.

Treatments were then allocated randomly to study participants by the study researcher in blocks of 10, in order to reduce the risk of unequal sample sizes in the placebo and verum groups.

Treatment instructions

All cases were managed through the client's normal veterinary practice. Owners were provided with brief written instructions on how to manage their dog's fear response behaviourally (Table 2) and their designated treatment bottle. Owners also received written instructions on how and when to dose the dog, as well as how many drops of treatment constituted one dose based on the weight of their dog. Five drops/10 kg were used up to 20 kg (equivalent to approximately 1.9 mg alcohol/kg) and 15 drops for dogs over 20 kg (equivalent to 57.1 mg total alcohol, or a max dose of 2.85 mg alcohol/kg).

Owners were instructed to give the treatment dosage onto any available mucous membrane, for example into the mouth or onto the external gum of the dog. The dose was given once a day for the length of the trial. Owners were advised to give the dose in the afternoon, as it was predicted that this was likely to be before any fireworks would begin. During firework episodes owners were then advised to give follow up doses every 20 min until either the dog calmed down, or they decided to stop dosing due to a lack of effect. Dosing with the treatment began 2 weeks before it was predicted the 2006 New Year's firework period would begin.

Monitoring of behaviour and response to treatment

Assessment of a dog's fear severity was based on the owners' perception of their dog's behaviour, both before, during and after they had completed the trial period, in a manner similar to that previously used by Levine et al. (2007).

The baseline assessment asked owners to rate the frequency (0 never, 1 rarely, 2 frequently, 3 always) and intensity (1 small amount to 5 extensive amount) of each behaviour that their dog displayed to fireworks, from a list of behaviours provided (Table 3). These owner's perceptions of the dog's fear were then converted into a severity score for each behaviour by multiplying the frequency score by the intensity score. A total severity score was also calculated by summing the severity scores for each behaviour the dog exhibited. The owners were also asked to rate the global severity of their dog's firework fear (without any medication) on a scale from 0 to 10 (0 mild fear, 10 maximum fear they could imagine an animal experiencing).

Owners were provided with daily diaries with specific sections in which to record any firework exposures, exposures to any other noises that caused a fear reaction, the number of doses of treatment given, and any unusual side effects. A supplementary section allowed the recording of further details in the case of exposure to a real noise event. Owners were asked to fill this in every time the dog was exposed to real fireworks, detailing the intensity and duration of the firework exposure, the dog's behavioural response, whether the behavioural advice given had been undertaken, and whether any other treatments had been given to the dog. Owners were also asked to rate their dog's fear response at each firework exposure compared to the response that they would have expected with no treatment on a five point scale (1 much better than expected, 2 a bit better

Table 3
Fearful behaviours analysed in the baseline assessment

Running around
Drooling saliva
Hiding (e.g. under furniture, behind owner, etc.)
Destructiveness (e.g. furniture, doors, carpets, etc.)
Cowering (e.g. tucks tail flattens ears, etc.)
Restlessness/pacing
Aggression (e.g. growling, snapping or biting)
Freezing to the spot
Barking/whining/howling
Panting
Elimination (vomiting, defecating, urinating and/or diarrhoea)
Owner seeking behaviour
Vigilance/scanning of the environment
Bolts
Exaggerated response when startled (i.e. level to which the startle response to noise exceeds that which would be expected for the sound intensity present)
Shaking or trembling
Self harm

than expected, 3 same as expected, 4 a bit worse than expected, 5 much worse than expected). Finally owners were asked to state whether they thought any change in their dog's response to fireworks was due to the treatment that they were using. These diaries were returned on a weekly basis to the university in a stamped addressed envelope for 4 weeks during the dates of 19th December 2005 and 16th January 2006.

The owners were telephoned for a final assessment after 4 weeks of treatment. At this time owners were asked to rate the overall improvement that they had seen from the treatment they were using on a scale from −5 to 5 (−5 no fear shown to 5 fear was much worse). They were also asked to rate their satisfaction with the treatment, the likelihood that they would use the treatment again, and whether they thought the treatment they had been using was verum or placebo. Finally owners were once again asked to rate the frequency (0 never, 1 rarely, 2 frequently, 3 always) and intensity (1 small amount to 5 extensive amount) of each behaviour that their dog displayed to fireworks during the treatment period, and final severity scores were calculated as before.

Statistical analysis

Once all data had been entered into the spreadsheet, the first level of unblinding occurred to allow the segregation of subjects into two groups (A and B), using the code provided by the independent researcher. Fearful behaviours that were shown by fewer than five dogs were excluded from statistical analysis, due to their rarity. Similarly, if any dog did not show one or more of the behavioural signs of fear (listed in Table 3) both before and after treatment, then that dog was excluded from the analysis of those particular behavioural signs.

As the data were not normally distributed, non-parametric tests were used in the analysis using Minitab 13 (Minitab Ltd). Mann–Whitney *U* tests were used to compare the ages of dogs in both treatment groups, the owner rated global score of their dog's fear, the total severity of the dog's fear and the severity of the individual behavioural signs of fear between the two treatment groups. It was also used to compare the number of pieces of behavioural advice that owners complied with, both between the treatment groups and between the upper and lower quartile of responders. When comparing the age, number of fears to noise and age of onset of fear for the dogs that completely recovered and those that did not, Mann–Whitney *U* tests were also used.

Chi-squared tests were used to compare the sex distribution of the treatment groups and also the sex distribution of those dogs that completely recovered against those that did not. They were also used to analyse the breed distribution of the treatment groups, the owners' rating of their satisfaction with the treatment, and the owners' compliance with each piece of behavioural advice provided to them, both between treatment groups and between the upper and lower quartile of responders.

A typical firework exposure response from each subject was picked for analysis before treatments were unblinded. The selection criteria for this exposure were that the fireworks were of a typical sound and light intensity (as rated by the owner), and the exposure was 15–30 min in length, as this was the most common length of exposure during the trial. Data from these real firework exposures were also analysed using chi squared tests, specifically the length of time for behavioural signs to subside (divided into standard time frame blocks) and whether the owner rated this length of time as an improvement compared to before treatment.

Results

Demographic data

Seventy-five dogs were recruited onto the study. After unblinding, 40 dogs were found to be in the placebo group, and 35 in the verum treatment group. The two groups appeared well matched with no significant difference between the two groups in the age of dogs, ($U = 1469.5$ $P = 0.59$, placebo group (P); median = 7 years, range 1–13 years; verum group (V); median = 7 years, range 1–14 years), the sex distribution (P 12 male, 28 female; V 15 male, 20 female; $\chi^2 = 1.339$, 1df, $P = 0.247$) or breed groups with the two most commonly represented U.K. Kennel Club groups in both groups being pastoral and then terrier breeds (χ^2 on pastoral, terrier and other breed groups = 2.880, 2df, $P = 0.237$).

Owner compliance during the study was evaluated from responses in the weekly record sheets and final assessment interview, and was found to be very good. No owners administered sedative or anxiolytic medication during the period of the study. One owner from each treatment group used dog appeasing pheromone (DAP, Ceva Santé Animale) during at least one firework exposure, and one dog in the placebo group was exposed to a strong odour in the home (air freshener). These subjects were excluded from analysis.

Both treatment groups had a median level of exposure of one firework event per week of the study.

Changes in overall severity of fear response

Sixty-eight per cent of owners from both treatment groups reported some degree of improvement in their dog's fear following treatment. In the placebo group, 26/40 (65%) owners reported improvement, compared to 25/35 (71%) owners in the verum group. There was no difference between the total severity scores for the two treatment groups at baseline (P Median = 90.5, V Median = 84, $U = 1555$, $P = 0.71$). Both treatment groups showed significant improvement in the total severity of the behavioural signs shown from baseline to final assessment (P $U = 2197.5$, $P < 0.0001$; V $U = 1556.5$, $P = 0.0001$). However, at the final assessment there was no difference between the two treatment groups in either the units of

improvement in the total severity score (P median = 43, V median = 29, $U = 1431.5$, $P = 0.35$), or the per cent improvement in the total severity score (P Median = 50.95%, V Median = 38.20%, $U = 1504$, $P = 0.87$).

Likewise, there was no difference between the groups in the owners' ratings of their dogs' global fear at the start of the study (P Median = 9.75, V Median = 9, $U = 1595$, $P = 0.4$). The change in the owner ratings of their dogs' global fear before and after treatment was also not significantly different between the two treatment groups (P Median = 3, V Median = 2, $U = 1527.5$, $P = 0.94$).

Changes in individual behavioural signs

Both groups reported the following behaviours with the highest severity scores at baseline; panting (median = 15), and hiding, cowering, and shaking or trembling (median for all = 12), with the placebo group also scoring owner-seeking behaviour similarly (12), whilst the median score in the verum group for this behaviour was 6. The behaviours aggression and self harm were excluded from analysis in both groups as they were exhibited by five or less dogs.

At the final assessment it was found that all 15 of the remaining behavioural signs of fear had significantly decreased in both groups with the exception of 'barking/whining/howling', which did not significantly improve in the placebo group. Table 4 shows that there was a significant level of improvement made in both groups, for many of the signs; however, a comparison of the change in severity scores of each behavioural sign between each treatment group showed no differences between the groups for any sign.

Table 4
Change in severity of the behavioural signs of fear as rated by the dogs' owners at the baseline and final assessment

Sign of fear	Homeopathic		Placebo		*P* (verum vs. placebo)
	Change in severity (median)	*P*	Change in severity (median)	*P*	
Running around	−1	<0.001	−1	<0.001	0.9
Drooling saliva	0	<0.05	−0.5	0	0.12
Hiding	−2	<0.05	−2.5	<0.001	0.41
Destructiveness	0	<0.05	0	<0.05	0.57
Cowering	−3	<0.001	−2.5	<0.001	0.65
Restlessness	0	<0.05	−2	0	0.16
Freezing to the spot	0	<0.001	0	<0.05	0.84
Barking/whining/howling	0	<0.05	0	>0.05	0.39
Panting	−3	0	−4.5	0	0.93
Elimination	0	<0.05	0	<0.05	0.61
Owner seeking behaviour	0	<0.05	−1	<0.05	0.97
Vigilance	−1	0	−2	<0.001	0.26
Bolts	−1	<0.001	0	<0.001	0.53
Exaggerated startle	−2	<0.001	−1	0	0.51
Shaking or trembling	−3	<0.05	−3.5	0	0.14

Comparison of responses to typical firework exposures

Owners were asked to record the duration of 10 behavioural signs of fear, and whether this was an improvement compared to firework exposures without treatment, i.e. whether the behaviour persisted for a shorter amount of time than without treatment. There was no difference between the groups for any behaviour, with respect to either the amount of time it took to subside or the number of owners that reported their dog to have improved in a shorter amount of time.

Analysis of weekly record sheets

All owners that took part in the study stated that their dog responded fearfully to at least one noise stimulus other than fireworks. The most common fear inducing noises were thunderstorms (P 35/40 = 88%, V 30/35 = 86%), bird scarers (devices that periodically emit loud noises in order to scare away birds, usually used by farmers to discourage birds from eating recently planted crops) (P 30/40 = 75%, V 25/35 = 71%) and gunshots (P 26/40 = 65%, V 24/35 = 69%). During the study, some owners who reported that their dog's fear of fireworks had improved also stated that their dog's fear of other noises had also improved (P 10 owners, V 12 owners).

Some owners reported positive and negative side effects that they felt were associated with giving the treatment. Although these were rare in both groups, the most commonly reported positive side effect was the observation that their dog generally seemed less fearful (P 4 owners, V 2 owners), and the most commonly reported negative side effect was drowsiness (P 2 owners, V 1 owner).

Owner ratings of treatment

In the placebo group 26 owners stated that they felt that their dog's fear had decreased, compared to 25 in the verum group. Thirteen owners in the placebo group and nine owners in the verum group stated that their dog's fear was exactly the same as before treatment, and one owner in each treatment group stated that they thought their dog's fear had deteriorated.

Owners were also asked about their satisfaction with the treatment and there was no significant difference between the ratings ($\chi^2 = 2.883$, 2df, $P = 0.237$). Twenty-two owners in the placebo group stated that they were either 'very satisfied' or 'quite satisfied' with the treatment they had used, while 13 owners in the verum group were either 'very satisfied' or 'quite satisfied'. Seven owners in the placebo group, and 11 owners in the verum group, stated that they were 'slightly satisfied' with the treatment, while 11 in both treatment groups were 'not at all satisfied'. Correlations

between owner ratings of satisfaction and improvement in both total and global severity scores were high in both groups ($r = 0.79$–0.89, $P < 0.001$ in all cases), suggesting some face validity in the owner ratings of improvement.

Twenty-nine owners in the placebo group stated that they would be 'very likely' or 'quite likely' to use the treatment they had been given again, while 26 owners in the verum group were either 'very likely' or 'quite likely' to use their treatment again. Eleven owners in the placebo group were either 'unlikely' or 'not at all likely' to use their treatment again, compared to nine owners in the verum group.

Influence of owner compliance with behavioural advice

Owner compliance with the behavioural advice was assessed firstly by giving each owner an overall score for the number of pieces of advice they followed from a possible total of eight provided (see Table 2). No difference was found in the level of owner compliance with the behavioural advice between the two treatment groups (P Median = 6, V Median = 6, $U = 1375.5$, $P = 0.63$).

Owner compliance with the individual pieces of advice was compared between the two groups. Only '*Provide your dog with a safe and secure retreat'* had a significantly different level of owner compliance between the two treatment groups, with more owners in the verum group complying with this behaviour ($\chi^2 = 6.818$, 1df, $P < 0.01$).

To further investigate the influence of the use of behavioural advice on the level of improvement shown in the dogs' fear of fireworks, the data from both groups were pooled and ranked in order of improvement in overall severity score. The top and bottom quartile of responders were then analysed to investigate whether the use of behavioural advice had an influence on these two extremes of responders. No difference was found in the level of owner compliance with the behavioural advice between the top and bottom responders when assessing the overall number of pieces of advice followed (top responders median = 5, bottom responders median = 6, $U = 350$, $P = 0.55$). Compliance with the individual pieces of advice was also compared for the top and bottom responders and only 'Ignore any fearful behaviour that occurs for no good reason' was found to be significantly different between the two groups, with more owners in the bottom quartile of responders complying with this behaviour ($\chi^2 = 4.378$, 1df, $P < 0.05$).

Complete recovery

Eight dogs were reported by their owners to have shown no fear towards fireworks following treatment. These dogs were classed as 'complete recoveries'. There were an equal number of these in each treatment group (P 4 dogs, V 4 dogs). No differences were found between the age (complete recovery (CR) median = 8.5 years, no complete recovery (NCR) median = 7 years, $U = 3\ 72$, $P = 0.11$), or sex ($\chi^2 = 0.762$, 1df, $P = 0.38$), of dogs that completely recovered versus those that did not. It was also found that neither the number of fears to noise each dog had (CR median = 3.5, NCR median = 3, $U = 311$, $P = 0.88$), nor the duration of the problem (CR median = 60 months, NCR median = 54 months, $U = 188.5$, $P = 1$) had an influence on whether a dog completely recovered. However, a significant difference was found in the age of onset of the problem between the two groups, with CR being typically related to a later age of onset (CR median = 36 months, NCR median = 12 months, $U = 283.5$, $P < 0.05$).

Discussion

Similarity between treatment groups

The demographic data suggest that the two groups were generally well matched for sex, age and breed. It was found that owners whose dogs were being treated with either verum or placebo reported a similar level of statistically significant improvement, between baseline and final assessment, in the rating of their dog's fear and the total severity of the behavioural signs that their dog showed in response to fireworks, with no significant difference found between the two groups in any measure.

Similar levels of improvement were also reported between verum and placebo for the severity of the individual behavioural signs of fear. Owners dosing their dog with the verum reported a significant improvement in all 15 of the individual behavioural signs assessed from baseline, while owners dosing with placebo reported a significant improvement in 14/15 signs (not vocalisation). However, there was no significant difference between the placebo and verum for the improvement recorded in any of the behavioural signs. These results therefore suggest that the verum was no more effective than placebo, but that both interventions had a marked effect on the owner's perception of the problem. The overall level of reported improvement was 45% on average (P = 51%, V = 38%). Given that both preparations used were based on 20% alcohol, it is possible that the effect reported was due to a genuine change brought about by the effects of alcohol consumption, however, the authors are unaware of any research which has examined the effect of such low doses of alcohol consumption (equivalent to less than 1 mL of beer) on the behaviour of dogs. Given the volume involved on each occasion, timing of dosing relative to any reported effect and apparent duration of effect we consider this unlikely, and in any case such an effect might be considered to be placebo related as it is not related to the specific treatment recommended.

The placebo effect

A placebo is any "*intervention that has a non-specific, psychological or psychophysiologic therapeutic effect ... but is without specific activity for the condition being treated*" (McMillan, 1999). Thus a placebo effect does not mean

there is no effect, especially when the condition being treated is a subjective report as is often the case in companion animal behaviour problem management. It is not uncommon for treatments aimed at behaviour or psychological problems to have a high placebo effect attached to them. Drugs for human depression are notorious for having a placebo effect as high as 50–70% in some studies (Dworkin et al., 2005). Walsh et al. (2002) analysed the results of 75 trials of medications for Major Depressive Disorder and found that, firstly, the response to placebo across the trials varied greatly, ranging from approximately 10% to more than 50% and, secondly, that in approximately half of the studies 30% or more of the patients assigned to placebo exhibited a clinically significant improvement.

In animals, King et al. (2000) tested a combination of behavioural advice with a high or low dose of clomipramine, or a placebo for the treatment of separation anxiety in dogs. The number of owners assigned to the placebo treatment that reported an improvement was typically high, both when analysing the owners' global fear score (62%), and the number of dogs that made improvement in the behavioural signs vocalization (64%), urination (50%), defecation (36%) and destruction (56%), but these effects were attributed to the efficacy of the behavioural advice rather than placebo effect. In the current study behavioural advice was quite limited suggesting either small changes in owner behaviour may be all that is required for a significant improvement in the behaviour of many subjects or a powerful placebo effect.

The authors are not aware of any reports in the scientific literature with a similar level of scientific rigour that have investigated the homeopathic treatment of a psychological problem in animals using a placebo. The level of placebo effect in the current study is much greater than some previous placebo controlled veterinary homeopathic studies, but similar to that reported in others. For example, Hektoen and colleagues (2004) compared a homeopathic remedy, placebo and antibiotic preparation for the treatment of clinical mastitis in dairy cows and also found no evidence for the efficacy of the homeopathic treatment beyond that of the placebo. However, the level of improvement in all treatment groups was poor (around 25% or less). When measuring both acute and chronic changes in disease state they found no difference between either the homeopathic group and the placebo group or the antibiotic group. In contrast, de Verdier et al. (2003) recorded an approximately 50% reduction in the duration of calf diarrhoea in both a homeopathic and placebo group, with no significant difference between the two treatment groups. It was concluded that they could find no specific efficacy for the homeopathic remedy.

The significant level of improvement reported in the placebo treatment group could be explained by several factors, including the effect of participation in the trial, the process of treatment or other events that happen to coincide with treatment. This study depended on owner report rather than independently verifiable data relating to the signs expressed, but this procedure is not uncommon in studies of behaviour where a problem is, by definition, a subjectively defined construct, dependent on owner perception (Gunn-Moore and Cameron, 2004; Scott et al., 2002; Sheppard and Mills, 2003). It might be argued that the consistency of the different measures (individual and global scores of severity, as well as measures of satisfaction) suggest a real, perceived benefit, but an expectation of improvement could cause owners to report some degree of improvement regardless of the treatment used. It is also possible that the process of dosing the dog either had an influence on the dog's behaviour because of the change to its routine, or made the owner feel more relaxed about the situation because they were delivering a treatment.

Many authors have commented on the importance of owner behaviour influencing fear responses in the dog (Landsberg et al., 2003; Overall, 1997, 2002; Heath, 2002) and so an indirect effect cannot be ruled out. Random effects should also be considered, since the natural variation in the severity of dogs' fear of noises without receiving any treatment remains unknown. It would therefore be misleading to conclude that the overall magnitude of response reported here (a median percent change in severity of 41.6%, and 68% of subjects reporting some response) is actually a measure of any specific or non-specific treatment effect. Although these values, do at least provide an indication of the potential magnitude of such effects that might be expected in similar studies.

Comparison with other studies

The results of this study and those discussed in the previous section highlight the caution required when interpreting the results of uncontrolled trials if up to a 70% improvement in condition can be expected from placebo alone. In the only other published clinical trial evaluating treatments for fear of firework noises in dogs known to the authors, Sheppard and Mills (2003) used DAP without a placebo control and reported an improvement of between 33% and 83% in the frequency of 13 of the 14 behavioural signs of fear analysed. Interestingly, another study of a different fear of noises (storm phobia), using alprazolam, clomipramine and behaviour therapy without a placebo control found a similar average improvement level of 53% in total owner ratings (range 25–100% for individual signs), but no change in behaviour ratings from video tape (Crowell-Davis et al., 2003). The current data suggest that a placebo effect may account for a significant proportion of the apparent improvement in both of these studies, especially in relation to those signs which improved least, and further investigation of the true efficacy of these reported treatments is warranted.

Effects of owner compliance

Owner compliance with the guidelines of the trial was found to be very high with 100% of owners not using any

sedative or anxiolytic medication, 97% not using any other form of complementary medicine, and 99% not exposing their dogs to strong odours during the trial.

Owner compliance with the provided behavioural advice seemed to be consistent across both treatment groups, suggesting that the use of behavioural advice is unlikely to have had an influence on the similarity in response between the two treatment groups. However, it was found that more owners in the verum treatment group provided dens for their dogs during a fireworks event than owners in the placebo group. The piece of behavioural advice best adhered to across both treatment groups was '*Don't punish you dog when he is scared*' and '*Make sure your dog is kept in a safe and secure environment at all times*', and it may be that these simple measures largely account for the effect seen.

When comparing the top and bottom quartile of responders it was again found that there was no difference in the total level of compliance with the behavioural advice provided, suggesting this did not significantly influence the level of improvement made by dogs. However, it was found that owners in the bottom quarter of responders tended to ignore the fear shown by their dogs more commonly than owners in the top quartile of responders. This might be of relevance if the responses were previously reinforced as ignoring might be expected to result in an extinction burst, i.e. the initial intensification of the behaviour in the absence of previous reinforcement, which might result in less perceived improvement (Lerman and Iwata, 1995).

Power of the study

A *post hoc* analysis was carried out using G * Power to investigate the likelihood that an effect could be detected with the sample size used. Given the assumption that a relatively substantial effect size of 0.65 was initially anticipated following use with homeopathy, then with a sample size of 40 subjects in the placebo group and 35 in the verum group and a critical threshold of 5%, the chances of picking up a difference between the placebo and verum treatments using a parametric *t* test is >85% (87.2%). Whilst we chose to use non-parametric analyses as a conservative estimate, we believe the clear lack of a value approaching significance, means we can be confident that there was a real lack of it in this study and the lack of significance is not a type II statistical error.

Conclusions

No evidence for the specific efficacy of homeopathy for the treatment of fear of noises was found in this study. However, significant improvements were reported with both the homeopathic and placebo treatments with approximately a 41–45% improvement in the behavioural signs of fear, an improvement seen in 68% of subjects and an approximate 10% complete recovery rate. Evidence from this study highlights the caution required when interpreting the results of uncontrolled treatment trials for the management of fear of noises in dogs. To find the true efficacy of a treatment it is necessary to compare results to that of a placebo under the same circumstances.

Acknowledgements

The authors thank Daniel Farrington (Homeopet, Westhampton Beach USA) who funded this study and supplied the homeopathic preparation being tested. Also, Tom Farrington, a veterinary homeopath who helped in the preparation of the methodology used in this study. Finally, we thank all of the veterinary practices and dog owners who allowed their dogs to participate in this study.

References

Crowell-Davis, S.L., Seibert, L.M., Sung, W., Parthasarathy, V., Curtis, T.M., 2003. Use of clomipramine, alprazolam, and behavior modification for treatment of storm phobia in dogs. Journal of the American Veterinary Medical Association 222, 744–748.

Cucherat, M., Haugh, M.C., Gooch, M., Boissel, J.P., 2000. Evidence of clinical efficacy of homeopathy – A meta-analysis of clinical trials. European Journal of Clinical Pharmacology 56, 27–33.

de Verdier, K., Ohagen, P., Alenius, S., 2003. No effect of a homeopathic preparation on neonatal calf diarrhoea in a randomized double blind, placebo-controlled trial. Acta Veterinaria Scandinavica 44, 97–101.

Dworkin, R.H., Katz, J., Gitlin, M.J., 2005. Placebo response in clinical trials of depression and its implications for research on chronic neuropathic pain. Neurology 65 (Suppl. 4), S7–S19.

Gray, B., 2000. Homeopathy; Science or Myth? vols. 7–16. North Atlantic Books, California, USA, pp. 51–74.

Gunn-Moore, D.A., Cameron, M.E., 2004. A pilot study using synthetic feline facial pheromone for the management of feline idiopathic cystitis. Journal of Feline Medicine and Surgery 6, 133–138.

Heath, S.E., 2002. Fear-related behaviour problems in dogs: diagnosis and treatment. In: Feline and Canine Behavioural Medicine. Henston, Peterborough, pp. 16–19.

Hektoen, L., Larsen, S., Odegaard, S.A., Loken, T., 2004. Comparison of homeopathy, placebo and antibiotic treatment of clinical mastitis in dairy cows. Methodological issues and results from a randomized-clinical trial. Journal of Veterinary Medicine Series A 51, 439–446.

Hektoen, L., 2005. Review of the current involvement of homeopathy in veterinary practice and research. The Veterinary Record 157, 224–229.

Iimura, K., 2006. The nature of noise fear in the domestic dog. MPhil Thesis, University of Lincoln.

King, J.N., Simpson, B.S., Overall, K.L., Appleby, D., Pageat, P., Ross, C., Chaurand, J.P., Heath, S., Beata, C., Weiss, A.B., Muller, G., Paris, T., Bataille, B.G., Parker, J., Petit, S., Wren, J., 2000. Treatment of separation anxiety in dogs with clomipramine: results from a prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter clinical trial. Applied Animal Behaviour Science 67, 255–275.

Landsberg, G.M., Hunthausen, W., Ackerman, L., 2003. Fears and phobias. In: Handbook of Behaviour Problems of the Cat and Dog. Saunders, Canada, pp. 227–268.

Lerman, D.C., Iwata, B.A., 1995. Prevalence of the extinction burst and it's attenuation during treatment. Journal of Applied Behavior Analysis 28, 93–94.

Levine, E.D., Ramos, D., Mills, D.S., 2007. A prospective study of two self-help CD based desensitisation and counter-conditioning programmes with the use of dog appeasing pheromone for the treatment of firework fears in dogs (*Canis familiaris*). Applied Animal Behaviour Science 105, 311–329.

McMillan, F.D., 1999. The placebo effect in animals. Journal of the American Veterinary Medical Association 215, 992–999.

Mills, D.S., Estelles, M.G., Coleshaw, P.H., Shorthouse, C., 2003. Retrospective analysis of the treatment of firework fears in dogs. The Veterinary Record 153, 561–562.

NCCAM, 2003. Questions and answers about homeopathy. <http://nccam.nih.gov/health/homeopathy/#q8> (accessed 17.01.07).

Overall, K.L., 1997. Fears, anxieties, and stereotypies. In: Clinical Behavioral Medicine for Small Animals. Mosby, St. Louis, pp. 209–250.

Overall, K.L., 2002. Noise phobias in dogs. In: Horwitz, D.F., Mills, D.S., Heath, S. (Eds.), BSAVA Manual of Canine and Feline Behavioural Medicine. BSAVA, UK, pp. 164–172.

Park, R., 2000. Voodoo Science; The Road from Foolishness to Fraud. Oxford University Press, New York.

Poulton, R., Menzies, R.G., 2002. Fears born and bred; toward a more inclusive theory of fear acquisition. Behaviour Research and Therapy 40, 197–208.

RSPCA, 2006. Fireworks; Campaign Facts. http://www.rspca.org.uk/servlet/Satellite?pagename=RSPCA/RSPCARedirectandpg=fireworkshomepageandmarker=1andarticleId=1131549066228 (accessed 03.05.06).

Scott, D.W., Miller, W.H., Senter, D.A., Cook, C.P., Kirker, J.E., Cobb, S.M., 2002. Treatment of canine atopic dermatitis with a commercial homeopathic remedy: A single blinded, placebo controlled study. Canadian Veterinary Journal 43, 601–603.

Sheppard, G., Mills, D.S., 2003. Evaluation of dog appeasing pheromone as a potential treatment for dogs fearful of fireworks. The Veterinary Record 152, 432–436.

Shull-Selcer, E.A., Stagg, W., 1991. Advances in the understanding and treatment of noise phobias. Veterinary Clinics of North America (Small Animal Practice) 21, 353–367.

Voith, V.L., Borchelt, P.L., 1996. Fears and phobias in companion animals. In: Readings in Companion Animal Behaviour. Trenton, USA, pp. 140–153.

Walsh, B.T., Seidman, S.N., Sysko, R., Gould, M., 2002. Placebo response in studies of major depression: Variable, substantial and growing. Journal of the American Medical Association 287, 1840–1847.