

1 **Original article**

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3 **An open-label randomised clinical trial to compare the efficacy of dietary caloric**
4 **restriction and physical activity for weight loss in overweight pet dogs**

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20

21 **Abstract**

22 Canine obesity is usually managed with a combination of dietary caloric restriction and
23 increasing physical activity, but no previous study has compared both of these strategies in a
24 prospective randomised controlled trial.

25 Thirteen overweight dogs (body condition score 6-9/9) were randomised to one of two
26 interventions: dietary caloric restriction or physical activity. The dietary caloric restriction
27 intervention comprised feeding a therapeutic weight loss diet, whilst the physical activity
28 intervention comprised increasing the dog's current physical activity pattern by at least a third.
29 The primary outcome measure was change in body weight, whilst secondary outcome measures
30 included change in neck, thorax and abdominal circumference and change in physical activity
31 measured by triaxial accelerometer.

32 Bodyweight decreased significantly with the dietary caloric restriction (median -10% of
33 starting body weight [SBW], 5 to -12%; $P=0.028$) but not with the physical activity intervention
34 (-2% SBW, +3% to -6%; $P=0.107$). Abdominal circumference (dietary caloric restriction:
35 median -12.0%; physical activity: median -7.8%, $P=0.016$) and thoracic circumference (dietary
36 caloric restriction: median -7.5%, $P=0.031$; physical activity: median -3.6%, $P=0.031$) changed
37 significantly in both groups. There was no change in activity levels within the dietary caloric
38 restriction group, but vigorous activity increased significantly in the physical activity group
39 ($P=0.016$).

40 Dietary caloric restriction is more effective than physical activity for controlled weight loss
41 in overweight pet dogs. Although advising owners to increase their dog's activity by a third leads
42 to a modest increase in measured vigorous physical activity, this is insufficient to promote
43 weight loss on its own.

44

45 *Keywords:* Accelerometer; Canine; Diet; Exercise; Obesity

46

47 **Introduction**

48 Obesity is one of the most common medical disorders of domestic dogs (German et al.,
49 2010) and is a significant health and welfare concern by predisposing to other diseases (Lund et
50 al., 2006; Courcier et al., 2010; German et al., 2010), shortening lifespan (Kealy et al., 2002),
51 causing metabolic derangements (German et al., 2009, Tvarijonaviciute et al., 2012 & 2013) and
52 functional impairment (Mosing et al., 2013; Tropf et al., 2017), and adversely affecting quality
53 of life (German et al., 2012). Recent studies have indicated that this is a problem of global
54 significance (McGreevy et al., 2005; Colliard et al., 2006; Lund et al., 2006; Courcier et al.,
55 2010; Mao et al., 2013). Most concerning, prevalence has increased dramatically in recent
56 years¹, with many dogs now affected during their growth phase (German et al., 2018).

57 Obesity is managed with a combination of dietary caloric restriction, using a therapeutic
58 diet, and increasing energy expenditure. Whilst there have been many studies reporting outcomes
59 of such programmes, most studies have focused on the effect of caloric restriction (Blanchard et
60 al., 2004; German et al., 2007a, 2007b, 2010b, 2012 & 2015; Flanagan et al., 2017), with few
61 studies examining the effect of activity of the development and management of obesity in dogs.
62 In one study, obese dogs were less physically active than healthy weight dogs and did not appear
63 to increase their activity levels spontaneously with weight loss (Morrison et al., 2013). One study
64 incorporated physical activity into a conventional canine weight loss programme using a
65 treadmill, and rate of weight loss was reportedly increased as a result (Chauvet et al., 2011). In a
66 more recent study that also used a treadmill, rate of weight loss was unchanged but there was
67 better preservation of lean tissue mass (Vitger et al., 2016). In addition, compliance was
68 challenging due to the need for 3-times-weekly treadmill sessions and the fact that many dogs
69 appeared to be physically incapable of markedly increasing their physical activity level. To the

¹ See: <https://www.banfield.com/state-of-pet-health/obesity>. (accessed 17 July 2018).

70 authors' knowledge, the impact on weight loss of more practical methods of increasing physical
71 activity have never been assessed, for example asking owners to increase the amount of their
72 dog's usual activity (e.g. walking and play behaviour). Therefore, the primary aim of this study
73 was to compare the efficacy of either dietary caloric restriction (using a therapeutic weight loss
74 diet) or increased physical activity (e.g. increasing current activity by at least a third) for weight
75 loss in overweight dogs.

76

77 **Materials and methods**

78 *Trial design, site, dates, objectives, and ethical considerations*

79 The study was an open-label randomised controlled trial, using a two-group parallel
80 design, and the main objective was to compare the efficacy of dietary caloric restriction and
81 increased physical activity for weight loss in dogs. The Consolidated Standards of Reporting
82 Trials (CONSORT) statement guidelines² (S1 Checklist) were followed to ensure open and
83 honest reporting of the study. The trial was conducted at the University of Liverpool, Small
84 Animal Teaching Hospital (SATH). The recruitment phase for the study was between September
85 2016 and December 2016, and the study itself was conducted between January 2017 and March
86 2017.

87 The trial complied with the University of Liverpool Guidelines on Animal Welfare and
88 Experimentation, and was approved by the University of Liverpool Research Ethics Committee
89 (VREC474). Prior to enrolment, the nature of the study was explained to both owners and their
90 primary care veterinarians (see below), and both gave their informed consent in writing to enable
91 the dog to participate. At the end of the trial, all owners were asked to complete a trial feedback
92 form to ensure that they were happy with trial conduct. As far as possible (for a trial in a

² See: <http://www.consort-statement.org/media/default/downloads/consort%202010%20checklist.pdf>. (accessed 17 July 2018).

93 veterinary species), the studied complied with the principles of Good Clinical Practice³. No
94 financial incentive (e.g. monetary payment) was given to any of the owners for participating in
95 the study. However, as a reasonable reimbursement for their time and expense of participating
96 (e.g. travel costs to and from the SATH), the costs of all clinical assessments, weight
97 management support and interventions themselves (e.g. therapeutic weight loss diet, modified
98 feeding bowl, toys) were waived.

99

100 *Roles and responsibilities*

101 Two investigators (GW and AG) were responsible for liaising with the owners, performing
102 all clinical examinations and weight assessments, implementing the interventions, and follow up.
103 The respective primary care veterinarian was informed of case progress by letter. Two further
104 investigators (MC, CW) were responsible for the activity measurements, and also monitoring the
105 wellbeing of all participants during the study visits. The final investigator (CL) was responsible
106 for technical support and data analysis for the activity monitors.

107

108 *Eligibility criteria*

109 Dogs were eligible for the study if both the owner and primary care veterinarian consented
110 to their involvement, they were overweight (i.e. body condition score [BCS] 6-9/9), and if they
111 had a good temperament (i.e. easy to handle, not nervous or fearful, and not aggressive to other
112 dogs or people). Further, dogs could not have any pre-existing medical problem that would make
113 it clinically inappropriate to undergo controlled weight loss (e.g. significant systemic disease
114 such as chronic kidney disease, cardiac disease, liver disease, metastatic neoplasia etc),
115 inappropriate to change their food (e.g. on a therapeutic diet for a pre-existing medical disease or

³ See: <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html>. (accessed 17 July 2018).

116 have known dietary intolerances), or alter their level of physical activity (e.g. pre-existing
117 cardiac or severe orthopaedic disease). Finally, dogs were not eligible if they were already on a
118 weight loss regimen or had undertaken a weight loss regimen in the last 6-months prior to the
119 study.

120

121 *Recruitment process and veterinary pre-screening*

122 The study was featured on a British Broadcasting Corporation (BBC) television
123 documentary series entitled “Trust Me, I’m a Vet”, and was advertised with a combination of
124 social media, radio advertisements and leaflets sent to local veterinary practices. Before deciding
125 to participate, interested owners were sent an information sheet and discussed the study with
126 their primary care veterinarian. The veterinarian then conducted a pre-trial assessment to confirm
127 eligibility, by reviewing clinical history and performing a physical examination. In addition, the
128 veterinarian measured bodyweight, assessed body condition using a 9-point system BCS system
129 comprising a set of five size-specific BCS charts, for small, medium, large, and giant breeds,
130 respectively (Flanagan et al., 2017). The system was adapted from the system originally
131 described (Laflamme, 1997) and validated against body fat mass measured by dual-energy X-ray
132 absorptiometry (Flanagan et al., 2017). In addition, the temperament of each dog was assessed to
133 ensure that it would be suitable for participation (e.g. neither aggressive nor nervous meaning
134 that participation would be stressful). If the dog was deemed to be eligible, the dog was formally
135 referred to the SATH for inclusion in the study.

136

137 When the official referral request was received, one investigator (GW) reviewed the
138 paperwork to confirm study eligibility and contacted the owners by telephone. Details of the
139 study were again discussed in detail, and, provided that owners confirmed that they were happy

140 to participate, a study pack was sent to them by post. This pack contained a second copy of the
141 information sheet, a consent form, a questionnaire to obtain information about diet and activity, a
142 3-day food diary, and an activity monitor along with collar and written instructions on its use
143 (see below). Owners completed the questionnaire and sent it back to the study researcher before
144 the enrolment visit, and also ensured that their dog wore the accelerometer for at least 7 days.

145

146 *Enrolment visit*

147 All owners and dogs attended an enrolment visit at the SATH during the same 2-day period
148 in January 2017. During this visit, each dog had a 30-minute individual consultation with two of
149 the study investigators, one of whom was an EBVS[®] European Veterinary Specialist in Small
150 Internal Medicine (AG), and the other (GW) was a Royal College of Veterinary Surgeons
151 Registered Veterinary Nurse (RVN). After checking the paperwork and confirming that the
152 owners had read the information leaflet, owners signed the consent form. The medical history
153 and pre-study questionnaire were reviewed, and a full physical examination was performed.
154 Measurements taken included body weight, BCS, circumferential measurements, and physical
155 activity using activity monitors (see below). Once these screening procedures had been
156 performed the treatment arm was revealed to the owner and their individualised plan was
157 described in detail (see below).

158

159 *Interventions*

160 Dogs received one of two interventions, dietary caloric restriction or physical activity. The
161 dietary caloric restriction intervention comprised feeding a high protein high fibre purpose-
162 formulated weight loss diet (Satiety Support, Royal Canin; Table 1), for the duration of the study
163 period. The initial food allocation for weight loss was based upon an estimate of maintenance

164 energy requirement ($MER = 440 \text{ [kJ]} \times \text{body weight [kg]}^{0.75}/\text{day}$) using the ideal weight of the
165 dog, as determined by current body condition score (German et al., 2015). The degree of
166 restriction for each dog was then individualised based upon sex, neuter status and, if necessary,
167 other factors that might influence MER (i.e. presence of associated diseases such as orthopaedic
168 disease). The starting energy allocation was typically between 50-60% of MER at ideal weight.
169 Owners were instructed to measure out food portions using electronic weigh scales, and to feed
170 this in divided meals, using a provided modified feeding bowl (Slow Down Dog Bowl, Royal
171 Canin). They were also asked to avoid feeding any additional foodstuffs (e.g. table scraps or
172 treats) and not to change the dog's current physical activity plan.

173 The physical activity intervention comprised increasing the dog's current physical activity
174 pattern and was tailored to the capabilities of both the dog and the owner, with the intention that
175 the total weekly amount of physical be increased by at least a third. During the enrolment visit,
176 detailed information on the current physical activity undertaken by the dog was collected, and
177 tailored suggestions were given on increasing this activity through discussion with the owner.
178 This could involve increasing the frequency or duration (or both) of physical activity sessions
179 that the dog was currently undertaking. For example, an owner who was walking their dog once
180 daily for 30 min could be asked to walk their dog for 40 min, whilst an owner who exercised
181 their dogs three times a week could be asked to exercise them for four times per week. These
182 suggestions provided a guide to the minimum desired increase in activity for each dog, but
183 owners could increase activity levels beyond this if time allowed and if their dog could cope. In
184 addition, owners were provided with a toy (Kong® Squeezz stick, Kong Company Ltd.) and
185 encouraged to implement regular play sessions, with the number and frequency again determined
186 by what the owner and dog could manage. Besides the changes to physical activity, owners were

187 instructed not to alter any other aspect of their dog's lifestyle most notably their food and meal
188 pattern.

189

190 *Measurements*

191 Measurements taken at both the enrolment and final visits included bodyweight, BCS, and
192 circumferential measurements. For bodyweight measurements, dogs were weighed on a single
193 set of electronic scales (Veterinary Scale, Soehnle Professional), which were regularly calibrated
194 to verify precision and accuracy using certified test weights (Blake and Boughton Ltd). The 9-
195 point BCS system was used for body condition by two experienced investigators (AG, GW).
196 Initially, after each investigator had first independently assessed the dog, a final score was agreed
197 by discussion and consensus. One investigator (GW) took three circumferential measurements at
198 the enrolment and final visits using a fabric tape measure with measurements recorded in cm.
199 The measurements taken were mid-neck (mid-point of the neck, approximately half way between
200 occiput and cranial edge of the scapula), thorax (immediately caudal to the thoracic limb) and
201 abdomen (immediately cranial to the pelvic limb). Other measurements, for example muscle
202 condition scoring or measurement of thigh circumference, were not performed due to time
203 constraints.

204 Physical activity was monitored for a period of seven consecutive days before the study
205 commenced and for 7 days during the final two weeks of the study using a triaxial accelerometer
206 and ActivityScope analysis software (VetSens[®]) which had previously been validated in dogs
207 (Westgarth and Ladha, 2017). Before the enrolment visit, owners were sent the accelerometer by
208 post, along with a fabric collar⁴, modified with an elastic and Velcro pouch to secure the
209 accelerometer snugly, and instructions on its use. Owners fitted the collar around the dog's neck,

⁴ See: <https://www.dog-games-shop.co.uk/20mm-top-piece.html>. (accessed 17 July 2018)

210 and then left it in place for the 7-day period. Owners were instructed to keep the collar on except
211 for bathing or swimming activities. They also completed a diary where particular events and
212 times could be recorded, for instance if the collar had been removed.

213

214 After each 7-day period, data were downloaded from the accelerometers, and
215 ActivityScope software was used to translate the raw actigraphy into VM3 (vector magnitude)
216 counts, in order to filter out movement originating from mechanical sources such as vehicles
217 (Westgarth and Ladha, 2017). The time spent in states of light, moderate and vigorous activity
218 was calculated using a threshold approach (Table 2) as previously reported (Yam et al., 2011,
219 Morrison et al., 2013), and percentages were derived from the time spent in each state for the
220 whole 7-day period. The VetSens system automatically calculates non-wear periods, enabling
221 these to be excluded from calculations. Percentage rather than absolute values were compared
222 both within and between groups on account of the fact that the wear time for each 7-day period
223 varied between dogs.

224

225 *Owner support and study monitoring*

226 Owners maintained a diary in which they recorded feeding of the purpose-formulated diet
227 (amount offered and consumed), and any additional food that had been consumed (either given
228 as treats or stolen). These records were used subjectively to determine compliance with the
229 allocated intervention (see below). One study investigator (GW) contacted all owners every 2
230 weeks to monitor progress but, in addition, owners could contact the study investigators directly
231 by telephone at any stage if they needed urgent guidance. For dogs on the physical activity
232 intervention, compliance was discussed and encouragement was provided as required. As far as
233 possible, further encouragement was given to attempt to increase activity further, again

234 dependent on the capabilities of the individual dog. For the dietary caloric restriction
235 intervention, counselling was provided regarding maintaining compliance with the food
236 allocation, measuring food out, avoiding the feeding of additional foodstuffs, and strategies to
237 mitigate any food-seeking behaviour that manifested during the trial.

238

239 *Final visit and support after the trial*

240 Dogs and their owners returned to the SATH 8 weeks later for a follow-up visit, with
241 assessments for all dogs conducted over two consecutive days in March 2017. Each was re-
242 examined by the same two study investigators (AG, GW). The diary record was reviewed, and
243 the same measurements taken as for the enrolment visit (bodyweight, BCS, circumferential
244 measurements).

245

246 After the trial was completed, all owners were given either a complimentary toy (Kong®
247 Squeezz stick, caloric restriction intervention) or modified feeding bowl (Slow Down Dog Bowl,
248 Royal Canin; physical activity intervention), and given further guidance on its use. In addition,
249 all owners offered follow-up weight management support for their dog at SATH, and the
250 opportunity to implement a long-term weight loss plan involving both dietary caloric restriction
251 and increased activity. In total, the owners of six dogs chose to pursue this, comprising two dogs
252 originally on the dietary caloric restriction intervention and four dogs originally on the physical
253 activity intervention.

254

255 *Compliance with intervention*

256 The diary records of owners were reviewed to determine compliance with the allocated
257 intervention. Given that only limited handwritten text notes were available, only a subjective

258 assessment was possible. For the dietary caloric restriction group, compliance with the
259 therapeutic diet (amount and meal frequency), the recommendation to maintain the same
260 physical activity level, and the consumption of additional food (either offered or stolen) were
261 considered. For the physical activity group, compliance with the recommended increase in
262 physical activity, and with the recommendation to maintain the same feeding pattern were
263 considered.

264

265 *Patient welfare, adverse events and early trial discontinuation*

266 Throughout the study, all efforts were made to safeguard the welfare of the dogs enrolled.
267 For both the enrolment and final visits, two RCVS-registered veterinary nurses, one animal
268 behaviourist, and one veterinary student were on hand to supervise and monitor all dogs. During
269 the 8-week intervention period, owners observed the wellbeing of their dogs and alerted the
270 investigators if they were concerned. One study investigator (GW) was responsible for recording
271 the details of any welfare issues, protocol deviations, suspected adverse events, and development
272 of concurrent medical problems. If any adverse event was thought to be related to either
273 intervention, participation in the study was to be suspended immediately. If it was thought to be
274 unlikely that an adverse event was related to the intervention, the dog was allowed to continue
275 with the trial, provided that the owners agreed. Participation could also be suspended if an
276 enrolled dog developed an unrelated condition whilst enrolled in the trial. Finally, owners were
277 free to withdraw their dog at any stage, without needing to give a reason.

278

279 *Randomisation procedure and allocation concealment*

280 The *a priori* power calculation (see below) suggested that six dogs per group would be
281 sufficient to demonstrate a clinical difference between interventions and, as a result, we aimed to

282 recruit at least 12 and up to 24 dogs during the recruitment phase. Prior to recruitment, one
283 investigator (AG) used the random number generator of a computer statistics programme (Stats
284 Direct version 2.6.2, Stats Direct Ltd.) to create a random sequence of 24 treatments, with 12
285 labelled A and 12 labelled B. Given that it was unclear how many eligible dogs would ultimately
286 be available, a block size of 2 was used (i.e. each sequential block of two treatments contained
287 either an A or a B in random order). Therefore, the number of dogs assigned to each treatment
288 arm always remain closely balanced throughout the list. Once created, the list was placed in a
289 sealed envelope and not examined again until after recruitment was completed. A second study
290 investigator without knowledge of the treatment allocation (GW) assigned the study numbers to
291 the dogs as recruitment proceeded. Study numbers were assigned in strict chronological order
292 according to the date that their referral request was received. After all referral requests for any
293 eligible dogs had been received and the recruitment phase was closed, but before the treatment
294 allocation list was revealed, the second study investigator decided at random which treatment
295 (diet or physical activity) would be assigned to which treatment label (A or B). Only then, did
296 the first study investigator open the sealed envelope to reveal the final treatment allocation for
297 each dog. Once the treatment (diet or physical activity) was known, no attempt was made to
298 blind the study investigators because the treatments were distinct and needed to be tailored to the
299 individual.

300

301 *Outcome measures*

302 The primary outcome measure was change in body weight expressed as a percentage of the
303 starting (i.e. pre-intervention) weight (i.e. $[\text{pre-study measurement} - \text{post-study measurement}] /$
304 $[\text{pre-study measurement}] \times 100$). Secondary outcome measures included change in neck, thorax
305 and abdominal circumference and change in physical activity, all of which were again expressed

306 as a percentage of the starting measurement. All of these outcome measures were decided prior
307 to commencement of the trial.

308

309 *Sample size*

310 During the design phase of the study, one investigator (AG) performed a sample size
311 calculation using a statistical software package (Stats Direct version 2.6.2). The primary outcome
312 measure (percentage change in body weight) was used. The expected effect size (mean \pm
313 standard deviation) for the dietary caloric restriction was $8.7 \pm 4.85\%$, which was based upon the
314 percentage weight lost over 8 weeks in a recent study using the same therapeutic diet (Flanagan
315 et al., 2017). Given that a recent study incorporating physical activity using a treadmill did not
316 reveal a significant additional effect over dietary caloric restriction (Vitger et al., 2016), the
317 expected effect size was assumed to be equivalent to that of placebo as seen in previous
318 experimental weight loss studies, e.g. 2.6% body weight over an 8-week period (Gossellin et al.,
319 2007). A 1:1 test:control recruitment rate was used and calculations assumed that a power of
320 80% was required to identify this difference with a two-sided P of <0.05 . Based upon these
321 criteria, it was determined that six animals per group would be needed. In order to take account
322 of possible study drop-outs, the investigators attempted to recruit at least 12 and up to 24 dogs
323 within the short recruitment window.

324

325 *Data handling and statistical analysis*

326 Data were entered into an electronic spreadsheet (Microsoft Excel® for Mac version
327 16.19) and checked for errors, and this dataset is available as supporting information (S1
328 dataset). Two computer statistical packages were used for data analysis: StatsDirect version 2.6.2
329 and SPSS version 23.0 (IBM Corporation). The level of statistical significance was set at $P < 0.05$

330 for 2-sided analyses. Standard descriptive statistics were used to report continuous (age,
331 bodyweight, circumferential measurements, percentage change in weight and circumference) and
332 ordinal (BCS) data as median and range given the small study numbers, whilst categorical
333 variables were expressed as proportions (number with percentage in brackets). Given the small
334 group sizes, non-parametric tests were used throughout. Data comparisons were made with
335 Fisher's exact test (for proportions), and either the Wilcoxon signed ranks test or the Mann-
336 Whitney test (for continuous and ordinal variables). The Mann-Whitney test was used to
337 compare absolute continuous data at baseline between groups (e.g. age, starting bodyweight,
338 duration of physical activity before weight loss; Table 3), whilst Fisher's exact test was used to
339 compare differences in sex and the Cochran-Armitage trend test used for BCS. The Mann-
340 Whitney test was used to compare percentage changes in weight loss outcomes (e.g. body
341 weight, bodyweight, circumference and physical activity) between groups, and the Cochran-
342 Armitage trend test was used for changes in BCS again between groups. For within-group
343 comparisons (pre- vs. post-weight loss), a Chi square test for trend was used to assess changes in
344 BCS, whilst Wilcoxon signed ranks tests were used to compare changes (pre- and post-weight-
345 loss) in bodyweight, circumferential measurements, and physical activity. Outcome data were
346 analysed on an intention to treat basis. Full datasets were available for all dogs, with the
347 exception one dog where pre- and post-weight-loss zoometric data were missing (due to time
348 pressures) and post-weight-loss physical activity data were not available (because the owner did
349 not return the accelerometer after the second period of activity monitoring). In order to account
350 for missing data in the intention to treat analysis, imputation was performed using the method of
351 multivariate normal imputation (Lee and Carlin, 2010).

352

353 *Protocol changes*

354 Two protocol changes were made to study protocol during the enrolment visit due to
355 unexpected findings at this stage. During the enrolment visit, it was discovered that one dog
356 assigned to physical activity intervention was already on a weight loss regimen using a
357 therapeutic weight loss diet, and one dog in the dietary caloric restriction group was fed a dry
358 hydrolysed diet (Hypoallergenic Diet dry, Royal Canin), implying the presence of an adverse
359 reaction to food. These details had not been reported by the referring veterinarians or owners
360 before during the recruitment phase. These dogs had already been allocated to an intervention
361 arm and, therefore, were allowed to remain within the trial (according to the intention-to-treat
362 principle). In addition, the owner of dog already on the therapeutic weight loss diet was
363 instructed to continue feeding the current daily food allocation.

364 A second dog in the physical activity arm had significant osteoarthritis, which again had
365 not been reported by the primary care veterinarian or owner during the recruitment phase.
366 Although the dog was physically active and receiving regular daily walks, increasing this further
367 was not thought to be clinically appropriate. Instead, this dog received weekly 60-minute
368 hydrotherapy sessions using an underwater treadmill, supervised by a trained veterinary
369 physiotherapist. This dog also continued in the study and data was included in analyses.

370

371 **Results**

372 *Dogs*

373 Owners of 14 dogs expressed an interest in participating, 13 of which met the eligibility
374 criteria and proceeded to the enrolment phase. These 13 dogs were then randomly allocated to
375 the two treatment arms, with six dogs assigned to the dietary caloric restriction group and seven
376 assigned to the physical activity intervention (Table 3). Before the trial, all dogs were fed adult
377 maintenance diets, except for one dog in the dietary caloric restriction group that was fed a dry

378 hydrolysed diet (Hypoallergenic Diet dry, Royal Canin), and one dog in the physical activity
379 group that was fed a was fed a dry therapeutic weight loss diet (Satiety Diet dry, Royal Canin).
380 Owners also reported feeding a range of dog treats and table scraps on a regular basis. There
381 were no significant differences between groups for any of the baseline variables (Table 3). All
382 dogs finished the trial and complete datasets were available for all parameters, with the exception
383 of activity data post-intervention for one dog as discussed below.

384

385 *Adverse effects and withdrawals*

386 No significant adverse effects were reported, and no withdrawals occurred in any dogs
387 during the study. However, one dog in the diet group sustained a leg injury and which required
388 rest for 6 weeks. Despite this, it was possible to continue with the intervention as planned, and
389 the physical activity recorded post-intervention was included in the analysis.

390

391 *Compliance with intervention*

392 Diary records were available for ten of the dogs, comprising five of six and five of seven
393 from the dietary caloric restriction and physical activity groups, respectively. In the dietary
394 caloric restriction group, records indicated that all owners had fed the correct amount of the
395 therapeutic diet, whilst a review of activity suggested a similar amount to what had been
396 undertaken previously. However, against recommendations, all dogs received additional food,
397 usually given as treats but occasionally stolen. Items fed included additional therapeutic diet,
398 other dog food, meat (e.g. chicken, pate), yogurt, fruit (e.g. watermelon, orange, strawberry,
399 pear), vegetables (e.g. courgette, carrot), rawhide chews and chocolate. Given the limited
400 information written, it was not possible to estimate the energy intake from this food. In the
401 physical activity group, the written notes suggested good compliance with the recommendations

402 in all dogs, consistent with an activity increase of at least a third compared with baseline, and no
403 change in food intake.

404

405 *Bodyweight and body condition*

406 Bodyweight and BCS data from before and after weight loss are shown in Table 4. The
407 bodyweight of dogs in the dietary caloric restriction group changed by a median of -10% from
408 starting baseline (range -5 to -12%, $P=0.031$), but bodyweight in the physical activity group did
409 not (median change -2% SBW, range +3% to -6%; $P=0.109$). Therefore, weight loss was
410 significantly greater with dietary caloric restriction than with physical activity ($P=0.014$). There
411 was a significant decrease in BCS in the dietary caloric restriction group ($P=0.043$), with the
412 BCS decreasing by one category in four of the dogs and by two categories in the remaining two
413 dogs. In contrast, BCS did not change in 6 dogs in the physical activity group, and decreased by
414 one category in the remaining dog, with no significant change in the group as a whole ($P=0.798$).
415 As a result, the decrease in body condition was significantly greater with dietary caloric
416 restriction than with physical activity ($P=0.003$).

417

418 *Neck, thoracic and abdominal circumference*

419 Zoometric measurements taken from dogs from before and after weight loss are shown in
420 Table 4. Abdominal circumference (dietary caloric restriction: median -12.0%, range -5.0 to -
421 17.4, $P=0.031$; physical activity: median -7.8%, range -6.2 to -13.0, $P=0.016$) and thoracic
422 circumference (dietary caloric restriction: median -7.5%, range -5.5 to -18.2, $P=0.031$; physical
423 activity: median -3.6%, range 0.0 to -12.0, $P=0.031$) changed significantly in both groups. For
424 thoracic circumference, the magnitude of change was greater for the diet intervention group than
425 for the physical activity group ($P=0.027$), but there was no difference between interventions for

426 the change in abdominal circumference ($P=0.430$). Further, there was no change in neck
427 circumference in either group (dietary caloric restriction: median -4.5%, range 4.0 to -6.9,
428 $P=0.125$; physical activity: median -4.1%, range 0.0 to -13.3, $P=0.062$), and no difference in the
429 magnitude of change between groups ($P=1.000$).

430

431 *Physical activity*

432 Physical activity was monitored during the trial using triaxial accelerometer (Table 5), and
433 an example of the activity data for the trial for one dog in the physical activity group is shown in
434 Figure 1. There was some difference amongst dogs in the time the accelerometers were worn,
435 although there were no differences between groups or time periods (Table 5). There was no
436 difference in the percentage time spent in sedentary ($P=0.943$), light-moderate ($P=1.000$), and
437 vigorous ($P=0.720$) physical activity between groups before weight loss. There was no change in
438 activity levels within the dietary caloric restriction group, pre- and post-trial (sedentary:
439 $P=1.000$; light-moderate: $P=0.562$; vigorous: $P=0.312$). There was also no change in sedentary
440 ($P=0.469$) or light-moderate ($P=1.000$) activity in the physical activity group, but vigorous
441 activity increased significantly ($P=0.016$). However, there were no differences between groups
442 for the change in activity within each category (sedentary $P=0.617$; light-moderate, $P=0.721$;
443 vigorous $P=0.054$).

444

445 **Discussion**

446 This is the first randomised controlled trial to compare dietary caloric restriction and
447 physical activity as interventions for controlled weight loss in dogs. Although the study size was
448 small, a difference between interventions was evident. All dogs in the dietary caloric restriction
449 group lost weight, with the median percentage weight loss over being consistent with rates of

450 weight loss seen in previous studies (German et al., 2007 & 2010; Vitger et al., 2016; Flanagan
451 et al., 2017). In contrast, although six of seven dogs in the physical activity group did lose some
452 weight, the amount lost was relatively modest (i.e. up to 6%) and not statistically significant.
453 These results are consistent with human studies where clinically significant weight loss is
454 unlikely unless there is a high level of aerobic exercise training (reviewed by Swift et al., 2014).
455 For example, in the Studies of a Targeted Risk Reduction Intervention through Defined Exercise
456 (STRRIDE) study, average weight loss was only minimal when exercising at low-amount /
457 moderate-intensity (~0.6 kg weight loss with ~176 min activity per week) or at low-amount /
458 high-intensity (~0.2 kg weight loss with ~117 min activity per week), whilst even high-amount /
459 high intensity activity (171 min per week) only led to modest (~1.5 kg) weight loss (Kraus et al
460 2002). They are also consistent with other weight loss studies in dogs whereby exercise did not
461 increase rate of weight loss (Vitger et al., 2016). Of course, whilst physical activity might not be
462 suitable as a sole weight loss strategy, it arguably conveys other benefits that are desirable as part
463 of a weight loss regimen (Vitger et al. 2016). In a recent 12-week study, adding physical activity
464 to a canine weight loss regimen helped to minimise loss of lean tissue mass (Vitger et al., 2016).
465 It could be argued that the reason there was no significant change in bodyweight in the current
466 study was that loss of adipose tissue in the physical activity group was offset by an increase in
467 muscle mass. Although plausible, it is unclear as to whether the strategy for increasing physical
468 activity we used (which relied on owners increasing their dog's activity by at least a third) is
469 equivalent to the 3-times-weekly treadmill activity that the dogs of the previous study received.
470 For example, although an underwater treadmill was used in one dog in the physical activity
471 group, it was only used once weekly. Measurements of body composition, for instance using
472 dual-energy X-ray absorptiometry (German et al., 2007, Vitger et al., 2016), would have been

473 required to determine whether lean tissue mass was maintained but, unfortunately, this was not
474 performed.

475 Thoracic and abdominal circumferential measurements decreased in dogs on both
476 interventions. These zoometric changes are likely to be the result of loss of adipose tissue,
477 suggesting that body shape changed significantly even despite the short study duration. The
478 reason why thoracic and abdominal girth decreased, but neck circumference did not, is not
479 known, but might be due to differences in the relative change of visceral versus subcutaneous fat.
480 Most visceral fat is present within the abdomen whilst subcutaneous fat is distributed more
481 widely (Merlotti et al., 2017), and human weight loss studies have shown that the percentage
482 decrease in visceral fat is greater than the percentage decrease in subcutaneous fat (Merlotti et
483 al., 2017). Nonetheless, given that the study was short, it is unclear what might have happened in
484 the longer term, and whether or not other changes would have been seen. Alternatively, the
485 differences might have been caused by the known variability in zoometric measurements, since
486 this technique lacks precision even when conducted by the same person (German, 2016). Whilst
487 such variability would again not necessarily be expected to affect such measurements
488 systematically, we must accept that the study was unblinded and we cannot discount the effect of
489 unconscious bias.

490 Changes in physical activity were measured as another secondary outcome variable. Given
491 the logistic challenges involved in posting out and receiving accelerometers, it was only possible
492 to compare two 7-day periods of activity, one before and one at the end of the weight loss period.
493 There was no significant change in physical activity in dogs on the dietary caloric restriction
494 intervention but vigorous physical activity increased significantly in the physical activity group.
495 Although this suggests that owners in both groups were compliant with the instructions given
496 over physical activity (e.g. increasing exercise in the physical activity group, but not in the diet

497 group), the magnitude of increase seen in the physical activity group was less than would be
498 expected from the recommendation made (e.g. to increase activity by at least a third). In this
499 respect, the typical time that the devices were worn over the course of the week was 9998 min,
500 and a 0.6% increase equates to ~8 min additional vigorous activity per day, or 56 min per week.
501 It is unclear as to the amount of vigorous physical activity necessary for health benefits in dogs
502 (Wakshlag et al., 2012), but World Health Organization guidelines recommend that adult people
503 should have at least 75 min of vigorous physical activity per week⁵. Irrespective of whether the
504 increase was sufficient for a health benefit, it may well have been that maximum increase that
505 was feasible for the dogs and their owners. Indeed, previous work has suggested that it can be
506 challenging for both owner and dog to introduce meaningful amounts of physical activity into the
507 daily routine of an obese dog. In a previous weight loss study involving 3-times-weekly treadmill
508 sessions, dogs were often reluctant or unable to work energetically and, therefore, activity rarely
509 exceeded a light-to-moderate intensity (Vitger et al., 2016). Additional work is required to
510 explore the best forms of physical activity for obese dogs in order to maximise the benefits
511 during a weight loss regimen.

512 On a related note, a limitation of the study was that the recommendation to owners
513 regarding increasing physical activity was not based on previous scientific publications, for
514 example, those confirming that such a change in activity would be enough to lead to significant
515 weight loss. To the authors' knowledge, studies examining this have not been conducted in dogs.
516 It is possible that significant weight loss could have been achieved had owners been advised to
517 increase physical activity even more and, therefore, it could be argued that the current study
518 actually compared dietary caloric restriction with placebo, rather than physical activity. The

⁵ See: http://www.who.int/dietphysicalactivity/factsheet_adults/en/. (accessed July 2018)

519 recommendation made (i.e. increasing physical activity by at least a third) was based upon what
520 we believed would be feasible for the majority of owners, having made similar recommendations
521 on weight management to clients in the past. A review of diary records suggested that most
522 owners complied with this recommendation, although the increase in physical activity measured
523 by accelerometer was less marked. This suggests that it can be difficult for owners to increase
524 the physical activity of their dog even modestly, implying this is unlikely to be a suitable strategy
525 for managing overweight client-owned dogs.

526 There are a number of other limitations for this study that should be considered when
527 interpreting findings. First, sample size was small and the group of dogs studied was
528 heterogeneous. Therefore, although designed to be adequately-powered for the primary outcome
529 measure (percentage weight loss), we cannot be certain that it was adequately-powered for
530 secondary outcome measures such as zoometric measurements and physical activity. This was
531 compounded by the fact that we analysed data on an intention-to-treat basis, not least given that
532 the original study protocol was modified twice on account of unexpected findings at enrolment.
533 For example, eligibility criteria were not met for three dogs, one in the dietary caloric restriction
534 group that was fed a hydrolysed diet before the study, and two in the physical activity group, one
535 of which was already on a therapeutic weight loss diet, and the other that had pre-existing
536 osteoarthritis. These might feasibly have affected the response to each intervention although, to
537 an extent the effects might have counteracted one another. In this regard, greater weight loss
538 might be expected in the dog in the physical activity group that was already being fed a weight
539 loss diet; in contrast, it is possible that the efficacy of this intervention might be less for the dog
540 with pre-existing osteoarthritis. An alternative approach would have been to consider analysing
541 data on a 'per protocol' basis, whereby only dogs that complied with the intervention were
542 included. However, this approach is not recommended because it can introduce bias and

543 invalidate the randomisation process (Moher et al., 2010). These protocol deviations, whilst
544 unfortunate, are commonly-encountered when conducting trials in a clinical setting. Nonetheless,
545 the authors recommend further studies to explore physical activity effects during weight loss, and
546 the results of the current study could be used as a basis for a sample size estimation.

547 Second, unintended bias could have resulted from differences in owner compliance
548 between interventions. As discussed above, owners might have struggled to increase physical
549 activity by the expected amount whilst, conversely, owners used to feeding treats to their dog
550 might have struggled to comply with dietary recommendations. Although not all owners
551 completed the diary, the available records indicated relatively good compliance with both
552 interventions, with the main exception being feeding extra food in the dietary caloric restriction
553 intervention. Nonetheless, since these were based on self-reporting, these results should be
554 interpreted with caution, not least since under-reporting is known to be a problem in human
555 nutrition studies (Heitmann et al., 2000). In the current study, inaccurate self-reporting is
556 suggested by the fact that the magnitude of increase in physical activity was less than expected
557 based on the accelerometer data. Therefore, the extent to which poor compliance influenced the
558 current results is not known. Third, the study was only 8 weeks in duration, which is shorter than
559 most previous weight loss studies in dogs. Thus, the true effect of the interventions might have
560 been under-estimated. As a result, it would be sensible to consider repeating the study in a larger
561 population of dogs and following them for a longer period. Finally, the study was open-label
562 with no attempt made to mask the treatments from either owners or study investigators. The
563 decision not to mask the treatments was partly because they were completely different from each
564 other, and also that each required a degree of tailoring to the individual unique to that
565 intervention. With the dietary caloric restriction intervention, daily food portion recommended
566 for weight loss was calculated based upon patient factors such as sex, neuter status and estimated

567 ideal weight; for the physical activity intervention, the recommended increase was based on the
568 existing exercise pattern, any concurrent medical diseases, and the lifestyle of owner to ensure
569 the changes were feasible. For similar reasons, it was also not possible to mask the owner from
570 these interventions. Nonetheless, this is a study limitation and, as a consequence, we can be
571 certain that the results were affected by bias, for example if either study investigators or owners
572 had pre-conceived ideas as to which intervention would be more effective.

573 In conclusion, the results of the current study confirm that dietary caloric restriction is
574 more effective than physical activity for controlled weight loss in overweight pet dogs. A
575 recommendation to owners to increase the activity of their dog by a third resulted in a modest
576 increase in vigorous physical activity, but this was insufficient to promote weight loss. Further
577 studies should consider health benefits of physical activity in overweight dogs beyond weight
578 loss in overweight dogs.

579

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588

589 **Competing interests**

590 The diets used in this study was produced by Royal Canin. AG and GW are employees of
591 the University of Liverpool, but their posts are financially supported by Royal Canin. AG has
592 also received financial remuneration for providing educational material, speaking at conferences,
593 and consultancy work from this company; all such remuneration has been for projects unrelated
594 to the work reported in this manuscript. CL is an employee of VetSens, who supplied the triaxial
595 accelerometers for measuring physical activity during the trial. Neither Royal Canin nor VetSens
596 were involved in study design, data analysis, interpretation of results, drafting of the manuscript
597 or the decision to submit the work for publication.

598

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737 **Table 1.** Average composition of the therapeutic diets used for weight loss in dogs on the dietary energy restriction intervention.

<i>Criterion</i>	Dry food 1 ^a		Dry food 2 ^b		Wet food ^c	
	<u>g per 100g DM</u>	<u>g per 1000 kcal (ME)</u>	<u>g per 100g DM</u>	<u>g per 1000 kcal (ME)</u>	<u>g per 100g DM</u>	<u>g per 1000 kcal (ME)</u>
<i>ME content</i>	2595 kcal/kg		2670 kcal/kg		600 kcal/kg	
<i>Crude protein</i>	33.1	116	33.1	112	49.7	141
<i>Crude fat</i>	10.5	37	10.5	36	11.7	33
<i>Starch</i>	19.3	67	18.2	62	10.5	30
<i>NFE</i>	31.8	111	31.8	108	17.5	50
<i>Crude fibre</i>	18.2	64	17.1	58	11.7	33
<i>TDF</i>	30.7	107	30.7	104	18.7	53
<i>Ash</i>	6.3	22	7.4	25	8.8	25
<i>Fibre sources</i>	Cellulose, beet pulp, FOS, psyllium husk, diet cereals		Cellulose, chicory pulp, FOS, psyllium husk, diet cereals		Cellulose, beet pulp, carrageenan, xanthan, diet cereals	

738
739 ^a High protein high fibre dry food (Satiety Weight Management, Royal Canin); ^b high protein high fibre dry food (Satiety Small Dog, Royal
740 Canin); ^c high protein high fibre wet food (Satiety Wet, Royal Canin); ME = metabolisable energy content, calculated using a predictive equation
741 based on total dietary fibre (TDF) (Kienzle et al., 1998); AF = as fed; DM = dry matter; FOS = fructo-oligo-saccharides; NFE = nitrogen-free
742 extract.

743 **Table 2.** Cut points used to determine time spent in different states of physical activity in dogs,
 744 measured by accelomertry (Yam et al, 2011).

Cut Point (VM3 ^a counts per minute)	Cut point recorded as	Interpreting the cut point	Example of behaviour eliciting this level of activity
<1352	Sedentary	Little movement of the trunk	Resting, sleeping
1352-5695	Light-Moderate	Slow movement of the trunk	Slow walk on lead or around the house
>5695	Vigorous	Rapid movement of the trunk	Running outdoors or vigorous play indoors

745
 746 ^a VM3 count: triaxial vector magnitude count derived from the accelerometer.
 747

748 **Table 3.** Baseline details of the dogs on the dietary caloric restriction and physical activity
 749 interventions.

Variable	Dietary caloric restriction	Physical activity	<i>P</i> -value
Sex	3 male neuter 3 female neuter	3 male neuter 4 female neuter	1.000
Age (mo)	92 (20 to 96)	90 (25 to 117)	0.617
Breed	Border collie (1) Chihuahua (1) Golden retriever (1) Jack Russell terrier (1) Mixed breed (1) Shih Tzu (1)	Bichon Frise (1) Golden retriever (1) Mixed breed (4) Rottweiler (1)	---
Body Condition Score	8 (6 to 9)	8 (6 to 9)	0.823
Bodyweight (kg)	13.4 (7.4 to 35.0)	28.0 (11.0 to 60.0)	0.134
Diet before study	Therapeutic hydrolysed diet ^a , dry (1) Adult maintenance, wet (1) Adult maintenance, dry (1) Adult maintenance, wet & dry (3)	Therapeutic weight loss diet ^b , dry (1) Adult maintenance, wet (2) Adult maintenance, dry (4)	---
Physical activity before (min) ^c	40 (20 to 60)	35 (20 to 90)	0.497

750

751 ^a Hypoallergenic Diet, Royal Canin; ^b Satiety diet, Royal Canin; ^c Amount of physical activity
 752 undertaken each day before study enrolment, as estimated by the owner.

753

754 **Table 4.** Changes in bodyweight and zoometric measurements in the dogs on the dietary caloric
 755 restriction and physical activity interventions.

Measurement	Dietary caloric restriction	Physical activity	Intervention comparison
Weight (kg)			
Before	13.4 (7.4 to 35.0)	28.0 (11.0 to 60.0)	
After	12.4 (7.0 to 31.3)	28.8 (10.6 to 59.0)	
Change	-9.6 (-4.6 to -11.7)	-1.9 (2.9 to -6.4)	
<i>P</i> -value	0.031	0.109	0.014
Body condition score			
Before	8 (6 to 9)	8 (6 to 9)	
After	7 (5 to 8)	7 (6 to 9)	
Change	---	---	
<i>P</i> -value	0.043	0.798	0.003
Neck circumference (cm)			
Before	30 (25 to 67)	37 (29 to 53)	
After	30 (26 to 64)	36 (26 to 53)	
Change	-4.5 (4.0 to -6.9)	-4.1 (0.0 to -13.3)	
<i>P</i> -value	0.125	0.062	1.000
Abdominal circumference (cm)			
Before	48 (40 to 69)	60 (44 to 90)	
After	42 (38 to 60)	56 (40 to 83)	
Change	-12.0 (-5.0 to -17.4)	-7.8 (-6.2 to -13.0)	
<i>P</i> -value	0.031	0.016	0.430
Thoracic circumference (cm)			
Before	60 (49 to 73)	70 (50 to 96)	
After	52 (46 to 69)	67 (44 to 91)	
Change	-7.5 (-5.5 to -18.2)	-3.6 (0.0 to -12.0)	

<i>P</i> -value	0.031	0.031	0.027
756	Before and after values represent median with range shown in brackets. The change values		
757	represent the percentage change from baseline within each group. The <i>P</i> -values shown below		
758	each intervention (dietary caloric restriction and physical activity) are within-group comparisons		
759	for the respective measurement, whilst the <i>P</i> -value the ‘intervention comparison’ column are		
760	comparisons between treatment groups.		
761			

762 **Table 5.** Percentage of time spent in different intensities of physical activity at the start and end
 763 of the study, as determined by triaxial accelerometry.

Type of activity	Dietary caloric restriction	Physical activity	Intervention comparison
Wear time (min)			
Before	9916 (9246 to 10080)	9571 (9421 to 10080)	
After	9725 (8640 to 10080)	9991 (9480 to 10080)	
Change	-0.1 (-14.3 to 3.1)	0.0 (-0.9 to 7.0)	
<i>P</i> -value	1.000	0.562	0.391
Sedentary activity			
Before	77.4 (64.7 to 83.0)	79.5 (69.2 to 84.3)	
After	79.1 (66.8 to 82.4)	76.3 (71.2 to 83.1)	
Change	0.0 (-6.0 to 6.1)	-0.7(-5.6 to 5.0)	
<i>P</i> -value	1.000	0.469	0.617
Light-moderate activity			
Before	18.8 (15.4 to 31.4)	18.2 (14.7 to 24.6)	
After	19.1 (16.6 to 30.2)	20.0 (16.4 to 23.1)	
Change	6.7 (-14.7 to 16.4)	4.0 (-18.8 to 20.5)	
<i>P</i> -value	0.562	1.000	0.721
Vigorous activity			
Before	3.0 (1.6 to 4.2)	2.4 (0.4 to 6.2)	
After	2.8 (0.3 to 3.8)	3.4 (0.5 to 7.4)	
Change	-14.1 (-83.8 to 40.8)	16.7 (1.8 to 42.6)	
<i>P</i> -value	0.312	0.016	0.054

764
 765 Wear time refers to the median (range) time in min that the accelerometers were worn during
 766 each monitoring period. The change values represent the percentage change from baseline within
 767 each group. All other data represent median percentage daily average with the range shown in
 768 brackets. The *P*-values shown below each intervention (dietary caloric restriction and physical
 769 activity) are within-group comparisons for the respective measurement, whilst the *P*-value the
 770 ‘intervention comparison’ column are comparisons between treatment groups.

771 **Figure legend**

772

773 **Figure 1.** Example of physical activity monitoring using triaxial accelerometry in a dog in the
774 physical activity group. The figures show the VetSens® heat map before (a) and at the end of (b)
775 the trial. Non-wear is shown in grey, sedentary activity is shown in green, light-moderate activity
776 is shown in yellow and vigorous activity is shown in red. Subjectively, the time spent in vigorous
777 activity appears to be greater at the end of the trial compared with before the trial.
778

779 **Supplementary material**

780

781 **S1 checklist.** Checklist for the CONSORT statement. The table lists the items of the respective checklist,
782 and the location within the manuscript where they can be found.

783

784 **S1 dataset.** Complete study dataset. Electronic spreadsheet containing study data for all dogs in the study.

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