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Experimental studies investigating the impact of traditional dried fruits consumed as snacks on food intake, experience of appetite and body weight

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Complete List of Authors:	Harrold, Jo; University of Liverpool, Department of Psychological Sciences Sadler, Michele; Rank Nutrition Ltd Hughes, Georgina; University of Liverpool, Department of Psychological Sciences Boyland, Emma; University of Liverpool, Department of Psychological Sciences Williams, Nicola; University of Liverpool, 1Department of Psychological Sciences McGill, Rory; University of Liverpool, 1Department of Psychological Sciences Higgs, Jennette; Food to Fit Harland, Janice; Harland Hall Associates Halford, Jason; University of Liverpool, Department of Psychological Sciences
Keywords:	prunes, raisins, snacking, weight loss, appetite, bodyweight
Abstract:	This study investigated the impact of dried fruits on weight control. Phase 1 examined the effects of prunes and raisins on appetite. Phase 2 examined whether prunes are beneficial in a weight loss programme. Phase 1 followed a pre-load design. Compared with a control condition (100g/335kcal jelly babies), the effect on appetite of equi-weight or equi-caloric snacks of prunes (100g or 140g) and raisins (100g or 111g) was assessed. The 12-week intervention study (phase 2) followed a randomised, between-subjects design. Prunes (females: 140g, males: 171g/day) replaced usual snacks while following a weight loss programme. The active control group followed the same programme and was instructed on healthy snacking. Phase 1 showed a significant effect of condition on food intake (significantly lower grams intake in the 140g prune group), and on AUC fullness due to greater AUC fullness in the 140g prune condition vs control). In phase 2 a significant reduction in mean body weight in the prune group vs baseline was consistent with the phase 1 evidence that prunes can aid appetite control. Prunes did not produce a detrimental effect on mean weight loss over 12 weeks vs control (prune group: -1.99kg;

	active control: -1.53kg), the between-group difference being non-significant. Mean weight loss diverged after week 8 when a trend for greater weight loss in the prune group was identified. The daily intake of prunes was well tolerated. Including prunes in a weight loss intervention produced beneficial changes in appetite and body weight. Future studies should investigate longer-term effects.

TITLE PAGE

Experimental studies and randomised trial investigating the impact of traditional dried fruits consumed as snacks on food intake, experience of appetite and body weight

Short Running Title: Dried fruit snacks, appetite and body weight

Joanne A Harrold[1], Michele Sadler[2], Georgina M Hughes[1], Emma J Boyland[1], Nicola J Williams[1], Rory McGill[1], Jennette Higgs[3], Janice I Harland[4], Jason C G Halford[5]

[1]Department of Psychology, University of Liverpool, Liverpool, Merseyside L69 7ZA

[2]Rank Nutrition Ltd, Ashford, Kent TN26 3DP

[3]Food to Fit Ltd, Hampton Wick, Surrey KT1 4AE

[4]HarlandHall Associates, Poulton, Cirencester GL7 5HN, UK

[5]School of Psychology, University of Leeds, Leeds LS2 9JT

Corresponding Author: Dr Michele Sadler, Nutrition Scientist, Ashford, Kent UK TN26 3DP

email: msadler@btconnect.com

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Abstract

Two studies investigating the impact of dried fruits eaten as a snack on weight control were designed to examine the effects of prunes and raisins on appetite (phase 1), and whether prunes undermine weight loss when included in a structured weight loss programme (phase 2). Phase 1 compared the effect on appetite of equi-weight or equi-caloric snacks of prunes (100g or 140g) and raisins (100g or 111g) with a control condition (100g/335kcal jelly babies), in a pre-load, cross-over design (n=40 analysed). A significant effect of condition on food intake was observed, with significantly lower weight of food consumed in the 140g prune group vs control, and on AUC fullness, due to a greater effect in the 140g prune group vs control. In phase 2, change in body weight and waist circumference were measured in a 12-week randomised, parallel groups intervention study (n=100 analysed, 50 per group). Prunes (females: 140g, males: 171g/day) replaced usual snacks while following a weight loss programme. The active control group followed the same programme and participants were instructed on healthy snacking. A significant reduction in mean body weight in the prune group vs baseline was consistent with the phase 1 evidence that prunes can aid appetite control, although it could also be explained by overall diet in the context of a structured weight loss programme. Prunes did not produce a detrimental effect on mean weight loss over 12 weeks vs control (prune group: -1.99kg; active control: -1.53kg), or on decrease in waist circumference (prune group: -2.40cm; active control: -1.74cm). No additional benefit on weight loss was seen (between-group difference was non-significant). The daily intake of prunes was well tolerated. Phase 1 demonstrated that prune snacks produced beneficial changes in appetite. Phase 2 demonstrated that prunes did not undermine weight management, and this warrants further study.

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Keywords

Prunes, raisins, snacking, weight loss, appetite, body weight

Introduction

Snack foods can be substantial contributors to daily energy intake and therefore play a significant role in weight management. Preload studies have demonstrated that the type of food consumed, macronutrient content, energy density and volume have differential effects on satiety and subsequent energy intake. For example, high-carbohydrate snacks are more likely to promote lower subsequent energy intake than high-fat snacks (Green et al. 2000), and low-fat snacks have been related to an overall reduction in dietary fat intake (Lawton et al. 1998). It has also been suggested that energy-dense, highly palatable, high-sugar snacks, particularly beverages, may undermine appetite control, both during and after consumption (Martin et al. 2015; Zheng et al. 2015).

It is generally advised that eating fresh fruit as a snack may help weight management by promoting satiety (Dreher 2018). Fresh fruit is generally bulky, with a high content of water and a low energy content compared with other snack foods. Some types of fruit have also been shown to suppress glucose and insulin responses (Esfahani et al. 2010) and provide a good source of dietary fibre. Fibres exert effects on appetite through changes in gastric emptying rate (Benini et al. 1995) and/or the release of gut hormones GLP-1 and PYY, which may be related to colonic fermentation (Chambers et al. 2015). Additionally, fibre gives sensory characteristics to foods including fruit, which may slow intake and deter over-consumption through the development of satiation. However, weight loss interventions orientated towards decreasing the energy density of the diet through increased fruit (including dried fruit) and vegetable consumption have shown inconsistent effects on weight loss (Shintani et al. 1991) and weight maintenance (Greene et al. 2006) with some even resulting in weight gain (Houchins et al. 2013).

The form in which fruit is consumed can influence its impact on satiety (Flood-Obbagy et al. 2009). Fruit juices are relatively low in fibre and less satiating than whole fruits, regardless of energy content (Bolton et al. 1981). In contrast, drying fruit increases chewiness and oral viscosity, and naturally concentrates the inherent nutrients, including fibre. On a weight basis, drying fruit also naturally increases energy density (Cesarettin & Fereidoon 2013). Thus, dried fruits are often excluded from dietary advice aimed at promoting health and successful weight management (BHF 2009). In practical terms however, the energy content per individual fruit piece remains the same for dried as for fresh fruit. Ultimately, compared with their bulky and comparatively more expensive fresh counterparts, dried fruit provides a convenient and economical source of fibre and other micronutrients.

These differences have led to the suggestion that dried fruit should be studied independently from juices and fresh fruit in order to determine their individual effects on satiety, energy intake and body weight (Rolls et al. 2004). However, research to date has been limited. Prunes (dried plums) have traditionally been considered a satiating snack, and consistent with this Furchner-Evanson et al (2010) demonstrated reduced hunger ratings (using visual satiety index scales) following consumption of a prune-based snack compared with a cookie-based snack matched for sensory, energy and other nutritional characteristics.

Since the impact of consuming dried fruits on weight control has not been thoroughly investigated, it is currently unknown whether their inclusion in a weight loss diet specifically undermines weight control and whether advice to prohibit them is warranted. It has also been suggested that prunes given in sizable doses and for prolonged periods can cause gastro-intestinal distress, especially in low fibre consumers. However, few studies have examined the effects of long-term prune consumption in low fibre consumers.

An investigation of dried fruit eaten as a snack was therefore undertaken. The research was programmed in two phases - firstly to examine the effects of traditional dried fruits (prunes and raisins) on appetite (phase 1 – acute study, within-subjects crossover design) and secondly to examine the hypothesis that prunes do not undermine weight loss when included in a structured weight loss intervention (phase 2 - weight loss, parallel groups). The inconsistent results found in previous weight loss interventions with fruit suggest that the overall dietary advice given as part of the trial is important, in addition to energy displacement by substitution with fruit. A structured weight management approach was therefore taken.

The aims of phase 1 were to measure subjective ratings of satiety following ingestion of prunes and raisins as a snack food, to objectively measure subsequent food intake and to determine an appropriate daily intake for the weight loss study. The aims of phase 2 were to measure changes in body weight and investigate the potential for sustained changes in appetite ratings and energy intake in the context of a 12-week weight loss programme incorporating prunes in place of energy-dense snacks. A further aim was to test whether low fibre consumers could tolerate the inclusion of prunes in their diet for a 12-week period.

Materials and Methods

All protocols and study forms were approved by the University of Liverpool Committee on Research Ethics (generic protocol RETH000565) and by the School of Psychology Ethics Committee (under references PSY-1112-055 and PSYC-1011-080). The studies conformed to the British Psychological Society Code of Practice and were in line with the relevant sections of the Declaration of Helsinki. All participants gave informed consent and received financial compensation for their participation.

Phase 1 - Acute Study

The methodology for the acute study was based on a pre-load design, which was adapted by the research team in Liverpool to provide a bespoke final protocol appropriate for investigating the effects of dried fruits.

Participants

Recruitment to the study was via advertisement from the University of Liverpool and surrounding area of Merseyside in the north west of England. Potential participants received detailed information on the protocol and were screened no more than 21 days before commencing the study. Exclusion criteria included: age<18 or >65 years; BMI <25 kg/m^2 or >34.99 kg/m^2; pregnant, planning to become pregnant or breastfeeding; significant health problems (cardiac or blood pressure problems; stomach, bowel or digestive problems e.g. coeliac's disease; liver or kidney disease; diabetes); gastro-intestinal problems; previous bariatric surgery; known food allergies or food intolerance; receiving systemic or local treatment likely to interfere with evaluation of the study parameters; taking within the past month and/or during the study any medication or supplements known to affect appetite or weight; currently dieting; following specific food avoidance diets; abnormal eating behaviour assessed using the Dutch Eating Behaviour Questionnaire restraint sub-scale (DEBQ-R); non breakfast eaters; non-snackers; high fibre consumers including regular whole grain or dried fruit consumers (any of: >1 portion hi-fibre cereal or wholegrain bread and >3 portions fruit and veg/day; ≥5 portions fruit and veg/day; >2 portions dried fruit/month); disliking > 25% of the ad libitum study foods or any of the snack foods; smoking or having recently ceased smoking; working in appetite or feeding-related areas. A taste test of the study foods (jelly babies, dried plums and raisins) was administered, and volunteers were informed of the weight of each food they would be asked to consume. Eligible participants were recruited to the study and assigned a code number.

Study foods

The control snack was 100g Tesco Jelly Babies (JB) (335 kcal). The test snacks were 100g California prunes in an equivalent-weight condition (EWP) and 140g (336 kcal) in an equivalent-energy condition (ECP); 100g Sun-Maid Raisins in an equivalent-weight condition (EWR) and 111g (333 kcal) in an equivalent-energy condition (ECR) (see Table 1). Jelly Babies were chosen because of their fruit flavour and similar texture and chewiness to traditional dried fruits. The 100g serving was chosen because it reflects the test quantity in most other studies of dried fruits, is generally tolerated, and is associated with health benefits of prunes (Lever et al. 2014; Lever et al. 2019). A daily intake of 100g is also the condition of use for the authorised EU health claim that ‘prunes contribute to normal bowel function’ (EC 2013). The snacks were presented in a bowl with a glass of chilled water (200 ml) on a tray.

Table 1. Study Foods for phase 1 (acute) and phase 2 (weight loss) studies

Test meals included a standard fixed-load breakfast (541 kcal) with the option of hot tea or coffee with 35g milk and sugar. If requested, this was consumed on each subsequent visit. The *ad-libitum* test lunch included a selection of high- and low-fat savoury and sweet food items (see Table 2). The *ad-libitum* test dinner consisted of a hot pasta meal and a cold dessert. Water (500 ml) was offered at all test meals. A snack box, for optional consumption once the participants had left the study centre for the day, contained a selection of high- and low-fat savoury and sweet snack items (see Table 3). All food and water was weighed (Sartorius Ltd) to the nearest 0.1g before and after each meal to determine intake.

Table 2. Macronutrient and energy composition of lunch food items (phase 1 acute study)

Table 3. Macronutrient and energy composition of snack box items (phase 1 acute study and phase 2 intervention study)

Study design

A randomised, within-subjects design with five conditions was used to investigate the effect of two traditional dried fruit snacks (prunes and raisins) and control (jelly babies), eaten mid-morning and mid-afternoon, on subsequent *ad libitum* lunch, *ad libitu*m dinner and evening snack intake as well as feeding behaviour and appetite. As the nature of the snack foods was obvious to participants, the study conditions were non-blinded for the type of snack but were blinded for the equi-caloric or equi-weight conditions. There were five study visits during which the mid-morning snack was consumed 2h after the fixed load breakfast (2h before lunch), and the mid-afternoon snack was consumed 2h after lunch (2h before dinner). Both snacks were consumed at the study centre which was located at the University of Liverpool. The effect on appetite was assessed using repeated monitoring of subjective motivation to eat and using ad libitum simultaneous choice test meals and an evening snack box. Food intake was measured in grams (g) and kilocalories (kcal) over a 24-hour period. Participants were free to leave the study centre between meals and snacks and were instructed not to eat or drink anything except water that was provided by the study. There was a wash-out interval of at least one week between visits. For randomisation, participants were assigned to a counterbalanced treatment order using random number generator software (http://www.randomizer.org/form.htm) by the University of Leeds.

Power calculations ensured that sufficient participants were included in the study to detect the predicted effects of prunes on subjective appetite ratings and energy intake. Using a paired design and a power of 0.9 a difference of 5mm on fasting hunger can be detected with 70 subjects whilst 5mm on mean 4.5h ratings can be detected with 40 subjects (Flint et al, 2000). Using a power calculation based on the Farajian (2010) data, a group size of 25 gave 80% probability of detecting an effect on energy intake.

Appetite

Visual Analogue Scales (VAS; 100 mm horizontal lines anchored by "not at all" and "extremely" at opposite ends, on which participants marked their subjective ratings) were used to rate degrees of hunger, fullness, prospective consumption, and desire to eat. The VAS were completed immediately before and after each eating occasion, and at hourly intervals throughout the study day. A second set of VAS measured sensory and hedonic aspects of the pleasantness, palatability, tastiness, saltiness and sweetness of the meals and was given after breakfast, lunch and dinner. ~~A third set of VAS measured snack palatability and was given during and following mid-morning and mid-afternoon snack consumption.~~ As an objective measure of eating behaviour, food intake (g weight and energy) was also measured at subsequent meals and snacks. Questionnaires relating to general feelings over the day (EDQ), and to record gastro-intestinal effects (GIQ) were completed on the evening of each study visit. The EDQ consisted of a series of VAS questions assessing retrospective feelings that measured hunger motivation, mood and acceptability of the study foods. The GIQ (non-validated) recorded bowel habits and gut function during the day. Any reported adverse events experienced while taking part in the study were recorded.

Procedure

Participants were asked to keep to the same pattern of food/fluid intake and activity on each evening before study visits, and not to consume any alcohol. To ensure compliance they were requested to record food and drink consumed and activities undertaken in a diary from 17.00 hours onwards. They were instructed not to eat or drink anything except water from midnight until they attended the study centre the following morning.

Participants attended the study centre at 8.30am and were seated in individual cubicles. They were asked to consume the entire fixed-load breakfast within 20 minutes. Two hours from the start of breakfast they consumed the mid-morning snack over a 15-minute period, and two hours later (four hours from the start of breakfast) they consumed the *ad-libitum* lunch. They were instructed to eat as much as they liked, to take as long as they wished and to signal when they had finished. The afternoon snack was consumed two hours from the start of lunch and the *ad-libitum* dinner was served two hours later (four hours from the start of lunch). Before participants left the study centre, they were given the snack box for optional consumption. The same procedure was followed on all study days.

Phase 2 - Weight Loss Intervention Study

Participants

Healthy overweight men and women were recruited to the study. Since the efficacy of prunes on body weight loss has yet to be established, power calculations were based on the data of Jenkins et al (1993) and Reyna-Villasmil et al (2007) for fibre manipulations. As a result of receiving standard dietetic advice, the control group in the study may consume snacks higher in fibre and lower in fat from their normal diet, producing only a moderate dietary change from the prune group. Jenkins et al (1993) followed a conservative design, comparing soluble and insoluble fibre in a within-subjects design. With significance of $p=0.058$ for this data, a group size of 18 would give 80% probability of detecting an effect on weight loss compared with control at $p<0.05$. Using power calculations based on data from Reyna-Villasmil (2007) which followed a parallel group design, a group size of 10 was calculated to give 80% probability of detecting an effect on weight loss compared with control at $p<0.05$. From previous experience with a product of relatively well-known efficacy for weight loss in a trial of a similar design, a group size of 50 was necessary to detect an effect of weight loss over 12 weeks. As the efficacy of prunes on this outcome is yet to be established a larger group size was chosen for the study. Both male and female participants were included in the study although it was not powered to include gender effect.

The screening procedure was the same as that used for the acute study, as were the exclusion criteria with the added exclusion of volunteers with significant weight loss in the previous 12 months, or significant change to physical activity patterns in the previous 2-4 weeks or intention to change them during the study. On their first study visit eligible participants were enrolled to the study, assigned a code number and allocated to one of the two study groups by the University of Liverpool, using stratified (BMI, age and gender) and randomised sampling generated by the University of Leeds (see Table 4). The randomisation ensured an unpredictable allocation sequence. Allocation was undertaken by a team member not involved in enrolment. The allocation sequence was stored independently from other study documents and the enrolment location and was concealed until a decision on participant eligibility was made and informed consent was obtained.

Table 4. CONSORT flow diagram of intervention study

Study design

The 12-week, free-living intervention study followed a randomised, parallel-groups design with an allocation ratio of 1:1. The pre-specified primary outcome was weight loss over a 12-week period, assessed by morning measurement of body weight using standard calibrated scales to the nearest 0.1kg, and reduction in waist circumference measured by standard metric tape-measure to the nearest cm following the National Institute of Health (NIH) guidelines i.e. at a level midway between the lower rib margin and highest point of the iliac crest with the tape all around the body in a horizontal position. Measurements were taken at the study centre (University of Liverpool) by a member of the study team ~~on four occasions~~during study days~~, at~~ (~~ baseline~~week 1, ~~and ~~week~~s~~ 4 and week~~,~~ 8), and on visits for group dietary-advice sessions in weeks 2, 3, 6, 10 and 12. A secondary outcome was tolerance of prunes by low fibre consumers over a 12-week period, assessed by the Bristol Stool Chart (Lewis & Heaton 1997) and also by the GIQ (non-validated).

Based on the results of the phase 1 study, prunes were selected as the test food. They were eaten in place of usual snacks in the context of a structured weight management programme. The effects were compared with an active control group following the same programme and instructed on the inclusion of healthy snacks in their diet. Both groups received standard healthy eating dietetic advice, based on cutting-down portion size to reduce intake by approximately 500 kcal/day. With the inclusion of prune snacks in the intervention group, it was impossible to blind participants or researchers to study conditions. However, the analysis was undertaken in a blinded approach i.e. ‘group 1’ vs ‘group 2’. To maximise the daily intake of prunes, tolerability was assessed in a pilot study. The chosen daily intakes were 140g (females), based on the 140g portion investigated in the acute study, and a proportionally larger intake for males (171g) based on higher total energy requirements (SACN 2011) (see Table 1). The female dose of 140g, approximately 15 prunes at an average weight of 9.5g per prune (USDA 2018; NHS 2019) was well-tolerated in the phase 1 study as an energy matched equivalent to 100g jellybeans. A requirement for subjects following the structured weight management programme, developed for the study, was for women to consume 7 portions of fruit or vegetables daily of which for the prune group 3 portions were prunes (portion size based on UK advice; NHS 2018). To take account of the extra energy requirements for men (SACN 2011) a further daily portion of fruit/vegetables (or prunes for the prune group) were recommended for male subjects. Hence for men, this equated to 171g prunes daily (18 prunes/4 portions).

Daily intakes were within the range for acceptable intakes of sorbitol (EC 1994). Due to the variability of individual prune weights and the flexibility of timing for consuming the prunes, the daily intake of prunes (140g or 171g) was provided in manageable (120g) packs and subjects were instructed to consume the required number of packs over a week. In view of the high intake of prunes, their introduction was phased over the first 7 days of the study to reduce any issues of tolerance, such that the full allocation of prunes was not consumed until the second week of the study. The results were analysed for the 12-week period (against the week 0 baseline screening measure) as pre-specified. ~~An exploratory analysis was also~~

~~undertaken against the true baseline (week 1) for the remaining 11-weeks of the intervention period.~~

Participants attended the study centre on days 1 (~~baseline~~week 1 measure), 29 (4 weeks) and 57 (8 weeks) to consume meals and snacks following the methodology of the acute phase 1 study. On day 1 both intervention groups received the same control snack as used in phase 1 i.e., jelly babies (122g males; 100g females) to provide a baseline measure, and on probe days 29 (4 weeks) and 57 (8 weeks) the prune group received the prune snacks (171g males; 140g females) and the active control group again received jelly babies (122g males; 100g females). The methodology followed that of the acute study. Jelly babies were only consumed as the control condition on these 3 study days.

Additionally, after the fixed load breakfast, a Control of Eating Questionnaire (COEQ) was completed. Between study-day measures included the GIQ and the Bristol Stool Chart (Lewis & Heaton 1997), completed for two days following each study visit. The study ratings of appetite and mood (SRAM), and additional questions to assess experience of the weight management programme through measures such as satisfaction, convenience, enjoyment and ease of weight loss, were completed three times a week during the first 3 weeks, and once a week during the subsequent 9 weeks.

Both groups received similar contact-time, information and instruction before and during the study. Participants attended group dietary-advice sessions following each study visit in weeks 1, 4 and 8 with each session structured to deliver key nutritional information, practical advice and opportunity for discussion (s~~S~~ee supplementary Table - Outline of structured weight loss plan ~~5~~). ~~Between~~ Separate to the study-day visits participants attended the study centre in weeks 2, 3, 6, 10 and 12 at the same time of day for body weight and waist circumference measurement, and to dispense/collect questionnaires. Compliance was monitored and recorded through the return of packaging, signed and dated to indicate when the prunes had been consumed. Contact with all participants was made by telephone at a pre-arranged time of day on Weeks 5, 7, 9, and 11. Additional or similar dietary information (including example lunch and dinner ideas) was sent to participants following all or some of the calls.

No changes were made to the methods after trial commencement.

~~**TABLE 5. Outline of structured weight loss plan**~~

Statistical Analysis

All data used in the statistical analysis were rigorously checked. Analyses were performed using SPSS for Windows Version 19 (IBM, Chicago, IL 60606, USA). All tests were two-tailed unless stated, and $p<0.05$ was regarded as statistically significant in all tests. Data conformed to the requirements for parametric analysis and therefore Analysis of Variance (ANOVA) was used. Intake at the test meals was analysed for amount consumed (in grams and kcal) using a within-subjects ANOVA with the snack condition as the within-subjects factor. Planned (a-priori) comparisons were run between all four experimental conditions versus control (phase 1 study) and between prune and control groups in accordance with the phase 2 study hypothesis that prunes do not undermine weight loss when included in a structured weight loss intervention, to identify differences.

In accordance with the recommendations of Blundell et al (2010), subjective parameters (e.g. hunger, fullness) rated on the VAS were analysed using Area Under the Curve (AUC) analysis. AUC is a continuous parameter calculated using the trapezoid rule. Total AUC for the full study day (VAS T0 - T14) was calculated and compared across conditions using Analysis of Covariance (ANCOVA) for each ~~parameter~~ variable (e.g., hunger) individually with a one-way between-subjects design, with baseline (pre-breakfast) subjective ratings as a covariate, and participant and order of conditions as fixed factors in the model. As the snacks were consumed at two time points such that the maximum daily dose of fibre (from prunes and raisins) was consumed following the mid-afternoon snack, the planned (a-priori) comparisons included AUC for the period between each snack and the next *ad-libitum* meal (e.g. VAS ratings pre-morning snack to pre-lunch (T4 – T6, AM) and pre-afternoon snack to pre-dinner (T10 – T12, PM) across conditions for each ~~parameter~~ variable individually using a within-subjects ANOVA with the snack condition as the within-subjects factor. In all AUC analyses, post-hoc paired t-tests were run to identify significant differences.

~~For graphical purposes only, s~~Subjective parameters were also analysed using ANOVA for repeated measures. ~~-~~Visit (v~~V~~isit 1-5) and time (T0 – T14) were included in the model as within-subject factors, and appropriate post-hoc paired t-tests were run at individual time points between conditions to identify where differences lay. All tests were two tailed, and Bonferroni corrections were applied to VAS data for multiple comparisons when looking at individual time points, as comparisons of many single time points can lead to type 1 errors.

Additionally, to reduce variance in the appetite data, an appetite score was calculated from subjective parameters using the formula ((hunger + desire to eat) – fullness))/3. Analysis was performed using mixed ANOVA with time as the within subjects' factors and study group as the between subjects' factors. Appetite scores were calculated for the full study day (14 time points) and for the periods between each snack and the next *ad-libitum* meal and were compared across study groups. Appropriate post-hoc independent t-tests were run at individual time points between study groups to identify where differences lay.

Change in body weight and waist circumference from baseline to 12 weeks (absolute values and cumulative reductions) were analysed in a mixed-measures design (ANOVA), using two alternative baselines (week 0 – pre-specified 12-week analysis and week 1 – additional 11-week analysis) to account for the phased introduction of prunes during week one. For the 12-week period, tTemporal analysis was performed over 3 periods, each of 4-weeks duration. When relevant, post-hoc independent t-tests were run to identify significant differences.

For the SRAM and experience of the weight loss programme, the 18 separate measures were included in the analysis of experience of the programme. These ratings of appetite and mood were supplemented with additional ratings obtained during the study day visits (21 measures in total). Mixed ANOVAs were performed with within-subjects factor of time (18 or 21 time points) and between-subjects factor of study group. Post-hoc independent t-tests were used to analyse between-group differences at individual time points.

Independent t-tests were used at each time point i.e., baseline, visit 2 (week 4) and visit 3 (week 8) to examine for differences in responses to individual items on the COEQ between study groups. Additionally, a factorial analysis was undertaken using the five identified subscales (craving intensity, 6 items; positive mood, 5 items with scores from the "how anxious have you felt" item being reversed; craving for sweet foods, 5 items; craving for savoury foods, 4 items; and fullness, 1 item; Dalton, 2013). Analysis of the mean score for each subscale was performed using mixed ANOVA with time as the within subjects' factors and study group as the between subjects' factors.

The Bonferroni post-hoc test was applied to analysis of the GIQ in the weight loss study to ~~test~~ control for multiple comparisons.

Results

Phase 1 - Acute Study

Forty-two participants were recruited and 40 completed the study. Two participants withdrew, one for personal reasons and the other curtailed visits with no explanation. ~~There were no differences in t~~The demographic (age) and anthropometric (weight, height, BMI) characteristics of the completing participants are shown in Table 5~~6~~.

Table 5~~6~~. Baseline participant characteristics for the acute study (phase 1)

Intake across the study day

Food intake (amount and energy content) was measured at the *ad libitum* meals and snacks, and across the study day (see Table 6~~7~~). A significant main effect of condition on weight of food consumed across the study day was found ($F_{(4, 156)}$ = 2.496, p=0.045). Compared with control, mean intake in weight of food consumed was significantly lower in the 140g prune (-~~↓~~105.3g (9.9%); $F_{(1, 39)}$ = 7.581, p=0.009), 100g raisin (-~~↓~~79.5g; $F_{(1, 39)}$ = 5.140, p=0.029) and 111g raisin condition (-~~↓~~93.7g (8.8%); $F_{(1, 39)}$ = 7.070, p=0.011). Additionally, there was a significant main effect of condition on kcal intake across the study day ($F_{(4, 156)}$ ~~$F_{(4,36)}$~~ = 2.963, p=0.033 (violation of sphericity, multivariate tests used). Compared with control, mean kcal intake was significantly lower in the 140g prune (-↓224 kcal (8.6%); $F_{(1, 39)}$ = 7.151, p=0.011) and 111g raisin conditions (-↓178 kcal (6.8%); $F_{(1, 39)}$ = 5.191, p=0.028), but not the 100g raisin condition. No differences were observed for liking and pleasantness between prunes, raisins and jelly babies, and there was no change over time across the study day (results not shown).

Table 67. Energy intake at the ad-libitum study meals and across the study day (phase 1 acute study)

Measures of appetite

Applying Bonferroni corrections for multiple comparisons to the VAS scores, reduced the critical *p* value for significance to <0.0125 (0.05/4 comparisons to control at each time point). Reduced hunger 1-hour post-afternoon snack (140g prune condition) was the only significantly different measure.

After adjusting for baseline (pre-breakfast VAS rating), AUC and ANCOVA for the full study day showed no significant effect of condition on any appetite measures other than fullness. A significant effect of condition on AUC fullness ($F_{(4,109)}$ = 3.679, p=0.008, partial $\eta 2$ = 0.119) was identified. Post-hoc t-tests revealed that this was due to significantly greater AUC fullness in the 140g prune condition compared with control (50247.71 v 47672.59; t(77) = 0.914, p=0.032).

When AUC was calculated for two time periods, covering the pre-morning snack to pre-lunch period (AM), and the pre-afternoon snack to pre-supper period (PM) no effect of condition on AM hunger ($F_{(4, 156)}$ = 1.214, p=0.307) was found, and an effect of condition on

PM hunger failed to reach significance ($F_{(4, 35)} = 2.599$, p=0.053 (violation of sphericity, multivariate tests used). Similarly there was no effect of condition on AM fullness ($F_{(4, 156)} = 0.521$, p=0.720) and PM fullness failed to reach significance ($F_{(4, 156)} = 2.019$, p=0.095), and there was no effect of condition on AM desire to eat ($F_{(4, 152)} = 1.871$, p=0.118) and PM desire to eat failed to reach significance ($F_{(4, 35)} = 2.276$, p=0.081).

There was also no effect of condition on AM prospective consumption ($F_{(4, 156)} = 2.001$, p=0.097). However, a main effect of condition was found for PM prospective consumption ($F_{(4, 35)} = 2.795$, p=0.041 (violation of sphericity, multivariate tests used). Planned comparisons showed this was due to participants reporting that they could eat significantly less during the afternoon in the 100g prune (4086.00 v 5002.31, p=0.021) and 140g prune (3737.25 v 5002.31, p=0.008) conditions. Reduction in prospective intake in the 111g raisin condition failed to reach significance (3983.81 v 5002.31, p=0.056) compared with control.

Adverse Events and GI Tolerance

No adverse events were reported. A number of gastro-intestinal effects were reported**,** scored with a 5-point Likert scale ranging from 1 (not at all) to 5 (very). There was a significant effect of condition on abdominal pain/discomfort ($F_{(4,156)}$ 4.138, p=0.003) ~~with~~. Expressed as mean±SD there was less abdominal discomfort in the jelly babies group compared with the 100g prunes group (1.17±0.446 v 1.48±0.679) and the 140g prunes group (1.17±0.446 v 1.55±0.749), less feeling of bloating in the jelly babies group compared with the 140g prunes group (1.33±0.621 v 1.77±0.959), a significant effect of condition on increased flatulence ($F_{(4,156)}$ 11.591, p=<0.001) with the jelly babies group experiencing less wind compared with the 100g prunes (1.38±0.586 v 1.90±0.871), 140g prunes (1.38±0.586 v 2.12±1.017) and 100g raisins (1.38±0.586 v 1.72±0.751) groups, and a significant effect of condition on abdominal gurgling ($F_{(4,156)}$ 6.129, p=<0.001) with the jelly babies group experiencing less gurgling compared with the 100g prunes (1.33±0.616 v 1.60±0.672) and the 140g prunes group (1.33±0.616 v 1.82±0.931). There was a significant effect of condition on urgency to open bowels ($F_{(4,156)}$ 6.576, p=<0.001) with the jelly babies group experiencing less urgency compared with the 140g prunes condition (1.23±0.480 v 1.85±1.051).

Phase 2 - Weight Loss Intervention Study

In total, 104 participants were recruited over the period 21-03-2012 to 27-06-2013 and 100 completed the study (26 males and 74 females; 50 per group). Two male and 2 female participants withdrew from the study, one due to visa restrictions and 3 as a result of time constraints. There were no significant differences between the groups for any of the baseline characteristics (see Table 7~~8~~). The study was stopped at the end of the 12-week intervention period according to the protocol. All analyses were by original assigned groups, with 50 participants analysed per group.

Table 7~~8~~. Baseline participant characteristics (phase 2 – weight loss study)

Change in body weight

Compliance with prune consumption throughout the study was good. There was no significant difference in mean weight loss between the groups when measured over 12 ~~or 11~~ weeks. The reduction in absolute body weight over 12 weeks in the prune group (t=4.941 [df 49] p<0.001) was significant compared with baseline (week 0) as was the reduction in body weight in the active control group (t=4.981 [df 49] p<0.001) (see Table 8~~9~~). ANOVA (violation of sphericity; Greenhouse-Geisser correction) demonstrated a significant effect of time ($F_{(9,882)}$ = 26.90, p<0.001), however, no significant interaction between time (duration) and condition was found ($F_{(2.24, 219.25)}$ = 1.075, p=0.348). ~~For absolute body weight over the 11-week period using a week-1 baseline (allowing for adjustment to full allocation of prunes), ANOVA (violation of sphericity; Greenhouse-Geisser correction) again demonstrated a significant effect of time ($F_{(8,784)}$ = 21.95, p=<0.001). However, no significant interaction between time and condition was found ($F_{(2.15, 210.4)}$ = 1.339, p=0.265).~~

Table 8~~9~~. Mean body weight and waist circumference pre and post weight control programme over 12 weeks and mean percentage change (phase 2 – weight loss study)

Cumulative weight loss over 12 weeks showed a clear temporal profile with (i) an initial weight loss phase (baseline to week 4); (ii) a plateau phase (weeks 4 to 8), and (iii) a subsequent weight loss phase (weeks 8 to 12) (see Figure 1). There was no significant interaction between condition and time for phases (i) and (ii), but ANOVA (violation of sphericity; Greenhouse-Geisser correction) demonstrated a significant effect of time ($F_{(3,294)}$ = 8.640, p<0.001) for the subsequent weight loss phase (iii), though an interaction between condition and time failed to reach significance ($F_{(2.14, 209.6)}$ = 2.606, p=0.072.

Figure 1. Cumulative mean weight loss (kg) over 12 weeks

~~In view of the unequal duration of weight loss phases when the baseline was assigned as week 1, further exploratory temporal analysis of the 11-week data was not possible.~~

Change in waist circumference

There was no significant difference for change in mean waist circumference between groups when measured over 12 ~~or 11~~ weeks (see Table 8~~9~~). Reduction in mean waist circumference compared with baseline was significant in both groups (prune group: t=3.961 [df 49] p<0.001; active control group t=2.726 [df 49] p<0.009). For change in absolute waist circumference, ANOVA (violation of sphericity; Greenhouse-Geisser correction) demonstrated a significant effect of time ($F_{(9,882)} = 7.177$, p<0.001). However, no significant interaction between time and condition was found ($F_{(6.12,\ 599.8)} = 0.534$, $p = 0.786$).

~~The conclusions were unchanged for the exploratory analysis performed for changes with baseline defined as end of week 1.~~

Probe day measures of appetite, mood, experience of the intervention study and food intake

Appetite scores for the full study days conducted at weeks 4 and 8, showed that with Greenhouse-Geisser correction (violation of sphericity), a significant main effect of time was observed (week 4: $F_{(7.23,\ 701.3)} = 171.746$, $p < 0.001$; week 8 $F_{(6.73,\ 646.1)} = 202.167$, $p < 0.001$). There was no significant interaction of condition and time (week 4: $F_{(7.23,\ 701.3)} = 1.143$, $p = 0.334$; week 8 $F_{(6.73,\ 646.1)} = 1.480$, $p = 0.174$) (see Figure 2). Collective data for analysis of each post-snack period (AUC calculated for AM and PM on each of the probe days) were indicative of a potential benefit of prunes on appetite control, even after 8 weeks of consumption. For nearly all time points, mean values for appetite were lower in the prune group than the active control, although they failed to reach significance.

Figure 2. VAS Ratings – appetite score throughout test day (a) at 4 weeks and (b) at 8 weeks

For the full study days at weeks 4 and 8, AUC and ANCOVA, after adjusting for baseline (pre-breakfast VAS rating), showed no significant effect of condition on any appetite measures other than fullness. At week 8 a significant difference between control and prune group was identified ($F_{(1, 97)} = 3.976$, p=0.049, partial $\eta 2 = 0.039$). ~~Post-hoc t-tests revealed that this was due to significantly greater AUC fullness in the prune group (t=1.994 [df 97] p=0.049). As the statistics were not corrected for multiple comparisons this could be a chance finding~~Though significance is marginal, a 5% threshold is not a fixed cut-off, and P values are continuous.

~~Collective data for analysis of each post-snack period (AUC calculated for AM and PM) on each of the probe days were indicative of a potential benefit of prunes on appetite control, even after 8 weeks of consumption. For nearly all time points, mean values for appetite were lower in the prune group than the active control, although they failed to reach significance.~~

While undergoing active weight management, the prune group experienced greater levels of satisfaction, convenience and ease of keeping to the programme compared with the active weight management group without prunes (results not shown). However, there was no effect on general mood and the COEQ showed no significant differences between the groups (results not shown).

For the baseline measure (day 1) no significant difference between conditions was identified for weight of food consumed (t=0.271 [df 98] p=0.787) or energy intake (t=0.261 [df 98] p=0.795) across the whole study day including breakfast and the test snacks (see Table 9~~10~~). Similarly, on the probe days in weeks 4 and 8 there was no significant difference in the weight of food consumed or energy intake over the whole study day.

Table 910. Weight of food consumed and energy intake across the study day (mean ± SD) following consumption of mid-morning and mid-afternoon snacks (phase 2 weight loss study)

Although effect of time on weight of food consumed failed to reach significance ($F_{(1,98)}$ = 2.895, p=0.092), a significant main effect of time on energy intake across the whole study day including breakfast and snacks was observed ($F_{(1,98)}$ = 7.498, p=0.007). Post hoc tests revealed the latter effect was due to reduced energy intake in the active control condition in week 8 compared with week 4 (t=2.559 [df 98] p=0.014). No significant interaction between time and condition on weight of food consumed ($F_{(1,98)}$ = 0.691, p=0.408) or energy intake ($F_{(1,98)}$ = 0.546, p=0.462) was observed. Despite the lack of significance, energy intake was lower on both days in the prune group compared with the active control (week 4: ↓237 kcal, ↓6.9 %; week 8: ↓150 kcal, ↓4.6 %). There was no significant difference in energy intake at either time point.

Adverse Events and GI Tolerance

No adverse events were reported. Baseline scores on the Bristol Stool Chart in the control group were 3.86 ± 1.21 for consistency and 1.05 ± 0.53 for frequency. In the intervention group scores were and 4.15 ± 1.00 for consistency and 1.20 ± 0.67 for frequency indicating that participants were not constipated, and stools were within the normal frequency range for the population at large. After intervention scores in the control group were 3.77 ± 1.05 (consistency) and 1.00 ± 0.78 (frequency) and in the intervention group were 4.33 ± 0.94 (consistency) and 1.40 ± 0.76 (frequency), indicating good GI tolerance of the high prune intake. There was no significant main effect of time on consistency ($F_{(1.812,\ 164.921)}$=1.099,

$p=0.331$) or interaction between time and condition ($F_{(1.812, 164.921)}=0.804$, $p=0.438$) and no main effect of time on frequency ($F_{(1.733, 169.856)}=0.795$, $p=0.437$) or interaction between time and condition ($F_{(1.733, 169.856)}=1.768$, $p=0.178$).

A number of gastro-intestinal effects were reported. There was a significant effect of time ($F_{(2.19,5.85)}$ 5.846, $p=0.003$) on abdominal pain/discomfort with the prune group recording higher ratings (week 4: $t=3.131$ [df 99] $p=0.002$; week 8: $t=1.767$ [df 99] $p=0.08$). There was a significant interaction between time and condition on bloating ($F_{(1.73,162.3)}$ 4.287, $p=0.002$) with significantly higher ratings in the prune group at week 4 ($t=3.572$ [df 99] $p=0.001$) and week 8 ($t=2.331$ [df 99] $p=0.022$). There was a significant effect of time ($F_{(1.73,160.9)}$ 21.884, $p=<0.001$) and significant interaction between time and condition ($F_{(1.73,160.9)}$ 21.884, $p=<0.001$) on increased flatulence with increased ratings around days 29, 30 and 31 ($p=<0.001$) and days 57, 58 and 59 ($p=<0.001$) compared with baseline in the prune group (week 4 $t=5.498$ [df 99] $p=<0.001$; week 8 $t=4.558$ [df 99] $p=<0.001$). There was a significant effect of time ($F_{(2,182)}$ 34.856, $p=<0.001$) and significant interaction between time and condition ($F_{(2,182)}$ 15.097, $p=<0.001$) on stomach/abdominal gurgling with increased ratings around days 29, 30 and 31 ($p=<0.001$) and days 57, 58 and 59 ($p=0.001$) compared with baseline in the prune group (week 4 $t=4.603$ [df 99] $p=<0.001$; week 8 $t=4.791$ [df 99] $p=<0.001$). There was a significant effect of time ($F_{(1.88,176.4)}$ 6.196, $p=0.003$) and significant interaction between time and condition ($F_{(1.88,176.4)}$ 9.360, $p=<0.001$) on urgency to open bowels with increased ratings in the prune group around days 29, 30 and 31 ($p=0.007$) compared with baseline (week 4 $t=4.010$ [df 99] $p=<0.001$; week 8 $t=2.468$ [df 99] $p=0.015$).

Discussion

The intervention study (phase 2) is the first to demonstrate the impact of incorporating dried fruit into an active weight loss programme with weight loss as the primary objective. There was no significant difference between the groups for mean weight loss, or for decrease in mean waist circumference. However, there was a significant difference in body weight reduction and decrease in waist measurement from baseline for both the prune and active control groups. Similarities between the groups may be explained by the choice of an active control group following the same structured weight management programme as the prune group, which aimed at reducing intake by approximately 500 kcal per day. The results demonstrate that, in contrast to health advice available at the time that generally omitted recommending dried fruit for weight loss or specifically limited it (BHF 2009), including prunes in the diet did not undermine mean weight loss or reduction in waist circumference over a 12-week period. These results are generalisable to males and females aged 18-65 years, in good general health, without gastro-intestinal problems, and not already eating a high fibre diet following a structured diet programme. The effect of prunes as a snack replacement in other dietary scenarios remains to be examined. However, Lever et al (2019) showed that consumption of 80g or 120g prunes per day in a community study did not result in weight change over 4 weeks.

The exploratory temporal analysis revealed that mean weight loss between the groups started to diverge during the last 4 weeks of the study when a trend for greater weight loss in the prune group was identified. This may suggest that towards the end of the programme the active control group found losing further weight more difficult compared with the prune group, and this warrants further study.

The significant reduction in mean body weight in the active control group compared with baseline demonstrates the effectiveness of the structured weight loss programme that the participants were following. The inclusion of prunes in this programme (prune group) also resulted in a significant reduction in mean body weight compared with baseline, and this effect is consistent with evidence obtained in phase 1 of the study, that prune consumption can help to control appetite during active weight management. A significant increase in AUC fullness following a mid-morning and mid-afternoon prune snack compared with control was identified at week 8. Additionally, based on AUC measures, trends for effects over separate meal periods were observed at week 4 and week 8, with the prune group recording ~~decreased~~ non-significnatly lower subjective ratings of hunger and desire to eat at each time point ~~and additionally increased ratings of fullness at week 8~~. These observed effects of prunes on appetite control are consistent with previous studies. Furchner-Evanson et al (2010) have demonstrated reduced hunger ratings following consumption of a prune-based snack. They are also consistent with results of the acute study (phase 1) ~~in~~ which ~~a significant effect of condition on AUC fullness was identified with post-hoc t-tests revealing that this was due to~~showed significantly greater AUC fullness in the 140g prune condition.

In the acute (phase 1) study, the highest dose of prunes (140g) produced clear reductions in weight of food consumed and energy intake. However, no significant effects on these measures were observed on probe days at weeks 4 and 8 during the active weight management study (phase 2). Initial effect size may be relevant in determining the likelihood of an acute intervention effect being sustained following repeated exposure (Dalton 2013; Halford et al. 2018). As such, the 9.9% reduction in weight of food consumed and the 8.6% reduction in energy intake across the study day observed in the acute study may not be sufficiently robust to support maintenance of impact over the longer term. Alt~~T~~hough there were no significant effects on amount of food consumed or energy intake on probe days at weeks 4 and 8, appetite was not dysregulated such that food intake was not increased by dried fruit consumption.

The dietary fibre content of prunes may at least partly explain the observed effects on appetite in the acute study. Whether dietary fibre reduces subjective appetite, energy intake and body weight has been the subject of considerable research (Wanders et al. 2011). A systematic review (Clark & Slavin 2013) found that over 60% of fibre studies examining appetite failed to show any effect, with only 6 of the 38 fibre sources examined producing such effects. This reveals the difficulty in isolating the potentially beneficial effects of fibre manipulations on appetite using appropriate standardised designs.

The high daily intake of prunes by a habitual low fibre consuming population in the intervention study resulted in some differences between the groups in ratings of gastro-intestinal effects in the intervention study, but these differences were small, did not translate into any adverse events and did not result in any withdrawals from the study. Data from the Bristol Stool Chart (Lewis et al, 1997) confirmed that normal bowel function was maintained during the course of the study. Together, these data support tolerability of the high intake of prunes.

A further consideration is that some countries, such as the UK, advise that snacking on dried fruit might have detrimental effects on the teeth (PHE 2017; NHS 2018). This is based on the premise that dried fruit is a concentrated source of sugars and may stick to the teeth and should therefore be eaten as part of meals. However, the evidence to support this is limited (Sadler 2016; Sadler 2017; Sadler et al. 2019). Nevertheless, this advice may have contributed to dried fruit not previously being recommended in healthy weight management programmes, in addition to the perception that dried fruit provides more calories than fresh fruit, although the energy content per individual fruit piece remains the same. These recommendations may in part explain why research to date has been limited. Yet, since dried fruit is a convenient and economical means to incorporate fruit in the diet, and is both satiating (Furchner-Evanson et al. 2010) and palatable, studying potential benefits is worthwhile, as corroborated by the present studies.

Strengths of the Studies

The key strength of this research was the application of robust methodology in a two-stage programme to examine the effects of prunes on weight loss. Phase 1 used gold-standard pre-load methodology to assess the potential for traditional dried fruits (prunes and raisins) to impact on satiety, before embarking on the intervention study. It also enabled two dried fruits and appropriate daily intakes to be assessed, for application in phase 2. Combining this approach with a small pilot study ensured that the intake of prunes was maximised for optimal effect.

A strength of the intervention study (phase 2 - structured weight loss programme) was close matching of the control and prune conditions, allowing a specific comparison of advice to eat prunes as a snack or advice to switch to healthier snacks (control group).

Limitations of the Studies

Adopting the prune intervention in the context of a structured, active weight loss programme does not allow for generalisability of the results to adults following unsupervised weight loss diets. A less intensive study design that is more representative of usual consumer weight loss approaches remains to be investigated. Due to budgetary restraints, the intervention study did not include dietary intake data to assess differences in food intake between groups, and dietary analysis was only undertaken for energy intake. The lack of self-reported measures of habitual intake meant that it was not possible to quantify any change in snack use in the active control group. With no restriction on the healthy snacks consumed by this group their fibre intake may have equally increased. In future, studies limiting intake in the control group to a defined selection of low-fibre snacks may provide a better understanding of equivalence between conditions.

The study was designed to investigate an experimental change in appetite that potentially drives a change in body weight. As change in body weight is more difficult to detect than changes in appetite, the study was powered (primary endpoint) on the ~~2nd~~ second of these two primary objectives. However, the generation of power calculations was limited by a lack of reports for dried fruits in comparable interventions. As a compromise, published studies reporting related strategies and fibre manipulations were used (Jenkins et al. 1993; Reyna-Villasmil et al. 2007). With this approach the study was powered to achieve a weight loss of 3-6kg but weight loss in the prune group was lower than this (-1.99kg). Consequently, although both groups demonstrated a significant reduction in body weight compared with baseline, the between-group differences failed to reach statistical significance.

Variability introduced through examination of both genders within a relatively broad weight-status range also reduced the statistical power of the design. Nevertheless, the reduction in weight and waist circumference reported for this study are comparable with reported reductions following an intervention based on current dietary guidelines (Reidlinger et al. 2015).

A further limitation is that the trial was not registered, although it closely followed CONSORT guidelines. At the time the protocols were written (2010), it wasn't standard practice to register trials, as it took a few years for the CONSORT guidelines to become established.

Whilst considered comprehensive, the pre-planned statistical analyses could have included more powerful approaches. Only VAS scores for individual time points were corrected for multiple comparisons in order to reduce the risk of type 1 error. Testing for adverse effects followed a structure of (i) an effect of time, (ii) interaction between time and condition, and (iii) testing for differences between condition as post-hoc t-tests within each time. A more powerful approach would have been a factorial analysis including the main effect of condition, or a structured contrast in the treatment structure Time/(Condition_wk4 + Condition_wk8) to test for a main effect of time, an effect of condition at week 4 and an effect of condition at week 8 in a single ANOVA, thus benefiting from the full set of residual degrees of freedom.

Recommendations for future research

The findings require corroboration in further intervention studies that address the limitations of the current study. Future studies should focus on the intervention period beyond 8-weeks, the point of divergence in weight loss, in order to investigate longer-term benefits of prune consumption in place of usual snacks. As weight loss is generally more difficult over time, it would be worthwhile to investigate specific difficulties around weight control including liking and wanting for specific foods and food cravings. Reductions in desire for specific problem foods may result from the general effects of prunes on appetite potentially benefitting long-term weight management. DEXA (dual energy X-ray absorption) could also be ~~a valuable additional endpoint~~used for assessing changes in body composition, a valuable additional endpoint, following weight loss interventions with dried fruits, particularly in longer term studies with the potential for enhanced weight loss.

More powerful statistical analyses could be pre-planned in future acute studies. For example, viewing all analyses as an example of multi-strata ANOVA where the random effects (blocks) have particular structure as well as the fixed effects (treatments), and considering either a multiplicity correction to pairwise tests, or using the structure of the study to set up orthogonal informative contrasts within the ANOVA. Individual comparisons to control could be adjusted for multiplicity corrections, and a change in treatment structure would help to elicit patterns. Specifically, a treatment structure of *Type/(Fruit x Weight*) would partition the 4 degrees of freedom available to test for treatment differences into 4 separate 1 degree of freedom tests corresponding to (i) difference between control and (any) fruit treatment, (ii) difference in prunes vs raisins, (iii) difference in equal weight vs equal calorie, and (iv) interaction between fruit and weight. This could also include a factorial term to test for the effect of time with a treatment structure *Time*[Type/(Fruit x Weight)]* with a block structure *Person\Visit\Time of Day.*

Conclusions

The current research has demonstrated that the instruction to participants to replace usual snacks with a high intake of prunes in conjunction with a structured dietary weight loss intervention resulted in comparable weight loss to that of the control group. Controls were following the same structured programme and replaced usual snacks with healthier alternatives. Attempts to control appetite and body weight in the prune group were not undermined, in line with our hypothesis. Similarly, compared with the ~~baseline~~control group, weight management, reduction in central adiposity (as measured by waist circumference) and increase in satiety (by enhancing long term fullness) were not undermined. Based on these results, advice to exclude prunes, and potentially dried fruit more widely, from weight management programmes appears unjustified. Additionally, a high daily intake of prunes over the long term was tolerated by participants in the prune group. These results suggest that the inclusion of prunes in a structured weight management programme in place of usual snacks is compatible with weight loss. Further studies are needed to investigate the effect of prunes in a more generalised setting.

Declaration of Interests

Michele Sadler works as a consultant nutritionist and receives consulting fees from a wide range of industry clients and trade associations, including funding from the Californian Prune Board for various ad hoc projects and independent advice. Jennette Higgs provides nutritional consultancy services to the dried fruit industry and is consultant Nutritionist & Dietitian to the California Prune Board.

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Table 1. Study Foods for phase 1 (acute) and phase 2 (weight loss) studies

Condition	Control		Dried Fruit			
	Jelly babies		Prunes		Raisins	
Phase 1 - Acute Study						
			Weight Matched	Energy Matched	Weight Matched	Energy Matched
Weight (g)	100		100	140	100	111
Energy (kcal)	335		240	336	300	333
Fibre (g)	0.1		6.6	9.2	5.3	5.9
Phase 2 – Intervention Study						
	Male	Female	Male	Female		
Weight (g)	122	100	171	140	N/A	N/A
Energy (kcal)	409	335	410	336	N/A	N/A
Fibre (g)	0.1	0.1	11.2	9.2	N/A	N/A

N/A: Not applicable

Table 2a. Macronutrient and energy composition of lunch food items (phase 1 acute study)

Food	Protein (g/100g)	Protein (total g)	Fat (g/100g)	Fat (total g)	CHO (g/100g)	CHO (total g)	Kcal (/100g)	Kcal (total)
White Bread	8.20	17.71	1.50	3.24	47.80	103.25	240	518
Light Margarine	Trace	Trace	59.00	23.60	Trace	Trace	531	212
Ham Slices	18.40	13.80	2.20	1.65	0.70	0.53	100	75
Cheddar Cheese	24.40	24.40	34.40	34.40	1.40	1.40	415	415
Cucumber	Trace	Trace	Trace	Trace	Trace	Trace	10	8
Salted Crisps	5.90	2.04	34.10	11.76	49.70	17.15	529	183
Snack a Jacks	7.00	1.82	7.40	1.92	77.40	20.12	404	105
Fruit Cocktail	0.40	1.64	0.10	0.41	12.70	52.20	53	218
Choc Cookies	6.20	6.20	23.90	23.90	68.00	68.00	511	511
TOTAL	70.50	67.61	162.60	100.89	257.70	262.64	2793	2245

The same food items were provided for probe days in phase 2, females provided with a total of 2225 kcal, and males with a total of 2865 kcal.

Table 2b. Macronutrient and energy composition of dinner food items

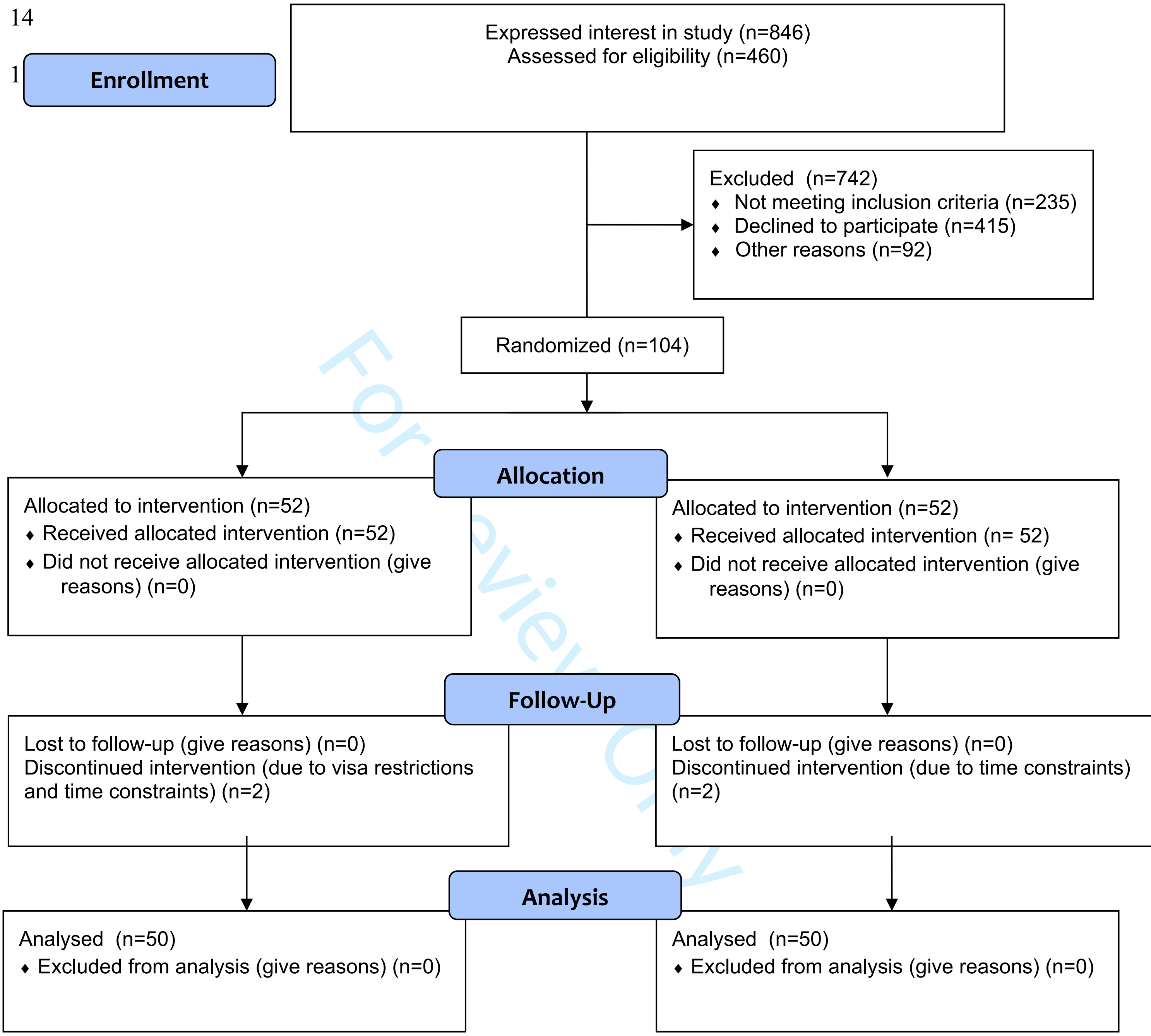
Food	Protein (g/100g)	Protein (total g)	Fat (g/100g)	Fat (total g)	CHO (g/100g)	CHO (total g)	Kcal (/100g)	Kcal (total)
Fusilli Pasta	12.50	62.50	1.40	7.00	73.00	365.00	355	1775
Garlic Bread	8.20	4.10	14.40	7.20	46.60	23.30	350	175
Pasta Sauce	1.60	7.36	0.10	0.46	8.70	40.02	43	198
Cheddar Cheese	24.40	12.20	34.40	17.20	1.40	0.70	415	208
Dark Choc Ice	2.80	1.20	21.00	9.03	30.20	12.99	325	140
TOTAL	49.50	**87.36**	71.30	**40.89**	159.90	**442.01**	1488	**2495**

The same food items were provided for probe days in phase 2, females provided with a total of 2450 kcal, and males with a total of 3225 kcal.

Table 3. Macronutrient and energy composition of snack box items (phase 1 acute study and phase 2 intervention study)

Food	Protein (g/100g)	Protein (total g)	Fat (g/100 g)	Fat (total g)	CHO (g/100 g)	CHO (total g g)	Kcal (/100 g)	Kcal (total)
Twix Twin Fingers	4.70	2.73	23.70	13.75	64.50	37.41	490	284
Ryvita Minis Cream Cheese & chive	8.00	2.40	2.90	0.87	71.00	21.30	342	103
Medium Banana*¶	1.20	1.80	0.30	0.50	23.20	34.80	100	150
Marshmallows	3.10	6.20	0.10	0.20	80.20	160.40	335	670
Mini Cheddars	10.38	2.70	28.80	7.49	48.80	12.69	496	129
Total	27.38	15.83	55.80	22.81	287.70	266.60	1763	1336
*or apple					14.00	21.00	47.00	71
Total	26.18	14.03	55.5	22.31	278.5	252.8	1710	1256
¶In phase 2 study								
Medium Banana	1.20	1.80	0.30	0.50	23.20	34.80	70	105
Total	27.38	15.83	55.80	22.81	287.70	266.60	1735	1292

Table 4. CONSORT flow diagram of intervention study



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17 **Table 5. Baseline participant characteristics for the acute study (phase 1)**

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Measure	All participants (n=40) Mean ± SEM
Age (years)	35 ± 15
Weight (kg)	76.0 ± 8.6
Height (m)	1.6 ± 0.1
BMI (kg/m^2)	28.3 ± 0.7
DEBQ Restraint Scale	2.6 ± 0.7

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20 DEBQ: Dutch Eating Behaviour Questionnaire

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Table 6. Energy intake at the ad-libitum study meals and across the study day (phase 1 acute study)

Condition	Intake (kcal) from ad libitum meal/study day (mean ± SD)			
	Lunch	**Dinner**	**Snack**	**Total intake†**
100g Jelly babies (control)	728 ± 267	1134 ± 391	402 ± 259	2598 ± 601
100g prunes	669 ± 247	1102 ± 449	463 ± 284	2474 ± 704.
100g raisins	706 ± 267	1092 ± 369	388 ± 248	**2486 ± 591***
140g prunes	689 ± 252	**971 ± 391****	377 ± 303	**2379 ± 621****
111g raisins	712 ± 289	**990 ± 356****	386 ± 310	**2420 ± 666****

†Lunch dinner and snacks, excluding breakfast; *Significant reduction from control (p<0.05); **Significant reduction from control (p<0.01)

Table 7. Baseline participant characteristics (phase 2 – weight loss study)

Measure	**All participants (n =100) Mean ± SEM**	**Control (n = 50) Mean ± SEM**	**Prunes (n= 50) Mean ± SEM**
Male	26	12	14
Female	74	38	36
Age (years)	43 ± 1.27	43 ± 1.82	43 ± 1.82
Height (m)	1.67 ± 0.008	1.68 ± 0.01	1.67 ± 0.01
Weight (kg)	83.58 ± 1.20	84.13±1.7	82.59 ±1.70
Waist (cm)	101.28 ± 1.10	101.85 ± 1.78	99.91 ±1.34
BMI (kg/m^2)	29.82 ± 0.281	30.04 ± 0.43	29.37 ± 0.36
DEBQ Restraint Scale	2.6 ± 0.06	2.59 ± 0.09	2.66 0.09

DEBQ: Dutch Eating Behaviour Questionnaire

Table 8. Mean body weight and waist circumference pre and post weight control programme over 12 weeks and mean percentage change (phase 2 – weight loss study)

Measure	Prune Group (n= 50)		Active Control (n= 50)	
	Baseline (Week 0)	**Week 12**	**Baseline** (Week 0)	**Week 12**
Body Weight (kg±SEM)	82.59 (±1.70)	80.60* (±1.70)	84.13 (±1.70)	82.6* (±1.72)
Change (kg)		-1.99		-1.53
Change (% kg)		-2.41		-1.82
Waist (cm±SEM)	99.91 (±1.18)	97.51* (±1.10)	101.84 (±1.79)	100.10* (±1.23)
Change (cm)		-2.40		-1.74
Change (% cm)		-2.29		-1.62

*Significant reduction from baseline (p<0.001)

Table 9. Weight of food consumed and energy intake across the study day (mean ± SD) following consumption of mid-morning and mid-afternoon snacks (phase 2 weight loss study)

Measure	Day 1 (Baseline)[†]		Day 29 (4 weeks)[‡]		Day 57 (8 weeks)[‡]	
	Active Control Group (n= 50)	**Prune Group** (n= 50)	**Active Control Group** (n= 50)	**Prune Group** (n= 50)	**Active Control Group** (n= 50)	**Prune Group** (n= 50)
Gram intake (g; mean±SD)	1780.73 ±58.22	1759.15 ±54.52	1692.05 ±54.38	1634.85 ±57.46	1628.52 ±53.55	1613.03 ±56.85
Energy intake (kcal; mean±SD)	3686 ±156	3635 ±119	3422 ±138	3186 ±122	3217 ±123	3067 ±111

[†]Both groups consumed the control snack (males 122g & females 100g jelly babies); [‡]Active control group consumed the control snack (jelly babies); prune group consumed the prune snack (males 171g & females 140g prunes)

Supplementary Table. Outline of structured weight loss plan

Week	Topics covered & take-home resources
Week 1 Session 1 HOW	**Eating well video 1:** Outline of the Eatwell plate, including portion control. **Eating well Summary session** Supply with the eating well leaflet (additional leaflet to be sent week 2) **What did you eat yesterday?:** Provide subjects with a blank Eatwell plate resource; show slide outlining how many items are required from each food group to achieve weight loss (consider portion sizes later – point 5); Discuss how subjects could improve the balance & then ask them to edit their original **Eating well video 2:** Demonstration of using the Eatwell plate when creating a meal. Shows how a typical family meal can be improved to make a healthier option and contain fewer calories; provide subjects with examples of unbalanced & balanced Eatwell plate resources. **Create a typical day menu utilising Portion Size booklet**: Show on the Eatwell plate resource how it could be improved to ensure a full balance is achieved in a NEW eating plan to fit personal diet **Guideline Daily Amounts (GDAs):** Presentation (with notes for trainers). Summary for subjects with GDA examples plus GDA cards (credit card size). Provide to take home: • 1 day menus in the food diary format - as example of how the food diaries can be used • 30 blank food diaries so that they can fill in their daily diet (separate copies for men & women) • Food swaps document and BHF booklet • Shopping list, and SMART goals – briefly discuss
Week 2	Post copy of **Healthy weight loss tips** document as a refresher to week 1: separate copies for prune group & active control (non-prune group)
Week 4 Session 2 WHY	**Discuss healthy weight loss tips** document (week 2) using the following prompts: • How are you getting on with checking food labels? • Are you still counting your portions? • What new things have you learnt? What habits have you changed? • Give an example of what you have put into practice from the leaflets over the last 4 weeks • What are you finding difficult? • SMART goals set at home **Fat & Sugar** **True & false** (interactive) **Traffic lights & Back of pack labelling** **What did you eat yesterday?:** repeat blank Eat well plate resource; then compare with original created in session 1 **1 week meal plan: p**rovide to subjects - contains menu ideas to help achieve a balanced weight loss **BHF weekly menu template** (p66). Use Eat well resource to help create a menu of the foods that you are going to eat for dinner each week and from this create your shopping list. This will help you to only buy the foods that you need; helps reduce food wastage; and if you stick to your shopping list stops you impulse buying those high fat and sugar snacks and treats. Never shop when you are hungry. This will also save you money! Use this approach every week before you go shopping. Provide subjects with 30 Blank food diaries to take home:
Week 5 phone call	**Still eating breakfast??** Reinforce benefits of eating breakfast • Post list of 'have foods ready that you can eat on the go'
Week 7 phone call	**How are you getting on with the eating plan? Are you having something substantial for lunch? Are you still counting your portions?** • Post recipes which include sandwiches & packed lunch ideas
Week 8 Session 3	**Discussion using the following prompts:** • How getting on with weight loss plan • Are you using GDAs on pack • Are you still filling out the blank food diaries? • Are you still counting your portions? • Has weight loss slowed? If so, refer back to portion control, and remember as our weight reduces, we need less energy & it is equally important that weight gain hasn't occurred • Have you noticed any health benefits with your weight loss? Has weight loss slowed? If so, refer back to portion control, and remember as our weight reduces, we need less energy & it is equally important that weight gain hasn't occurred. Weight loss of ½ lb per week is more likely to stay off in the long term so don't be disheartened • Any concerns? **Another example of an improved daily menu:** balanced day and unbalanced day shown on the Eatwell Plate resource; balanced day shown on the diary template **Eating out tips:** discuss better choices using eating out tips document; use takeaway menus as a practical task, allowing subjects to pick some better choices **Treats** and **Alcohol** – sensible swaps **Health benefits of losing weight and Motivational tips** **SMART goals** (refer back to session 1 – remember that goals are small achievable changes) • Review goals set out in week 4 – can these be added to and improved further? • Set new goals for the last section of the study
Week 9 phone call	**Are you using GDAs to pick healthier options when you are shopping?** **Are you adding vegetables/salad to your dinner?** **Discuss evening meal recipe ideas that are easy to prepare**

Week 11 phone call	**Are you still sticking to the eating plan?** **Encourage to stay on eating plan** **Explain why weight loss may have slowed down** (refer to week 8 session)
Post study	You have lost weight, now also focus on high fibre foods & increasing physical activity levels to add further boost to weight loss &/or maintain lost weight permanently (refer to BDA info). Send home with Waist & hip measurement wheel, high fibre document & physical activity document

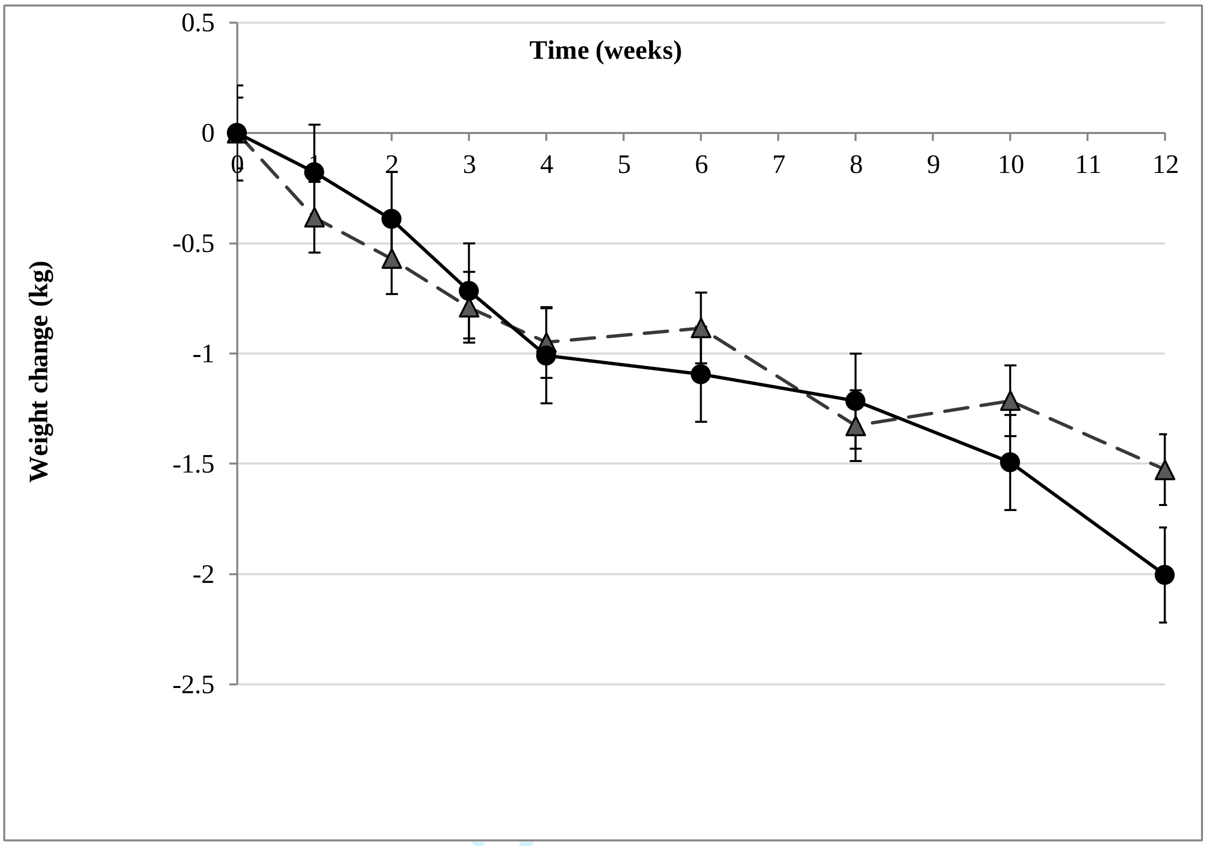

Figure 1: Cumulative mean weight loss (kg) over 12 weeks

Figure 2 (a)

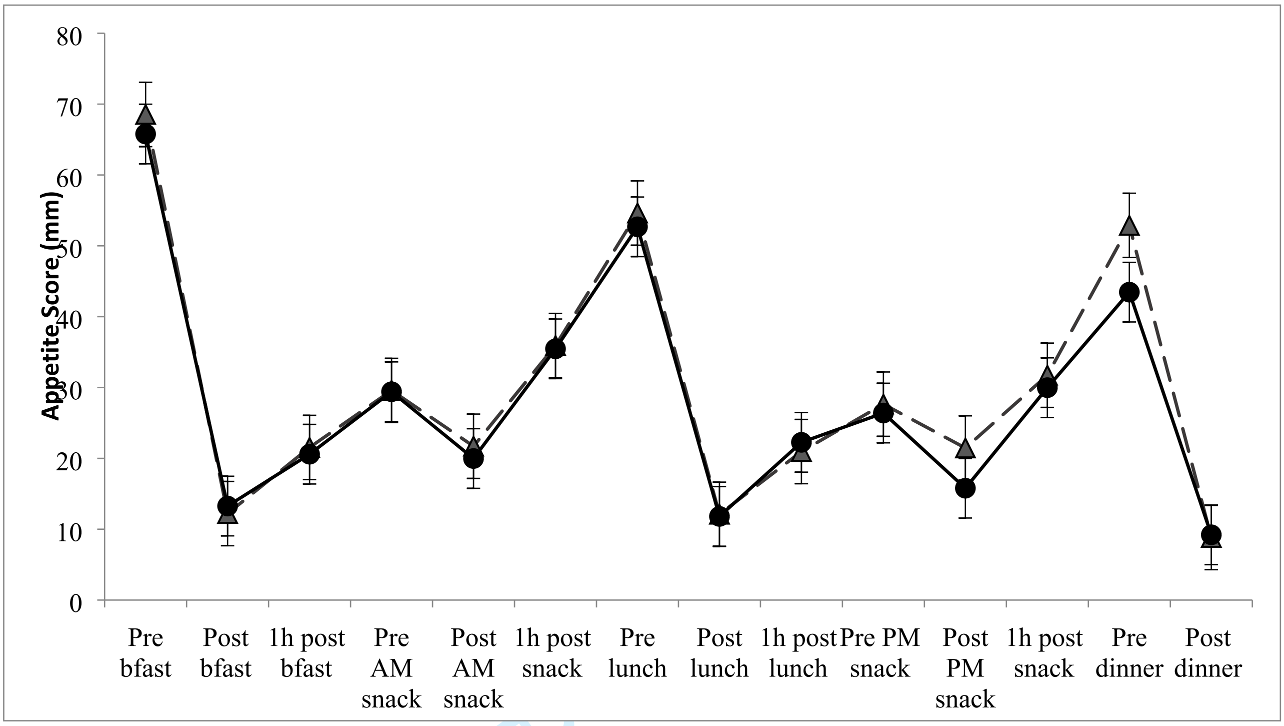

Figure 2 ((b)

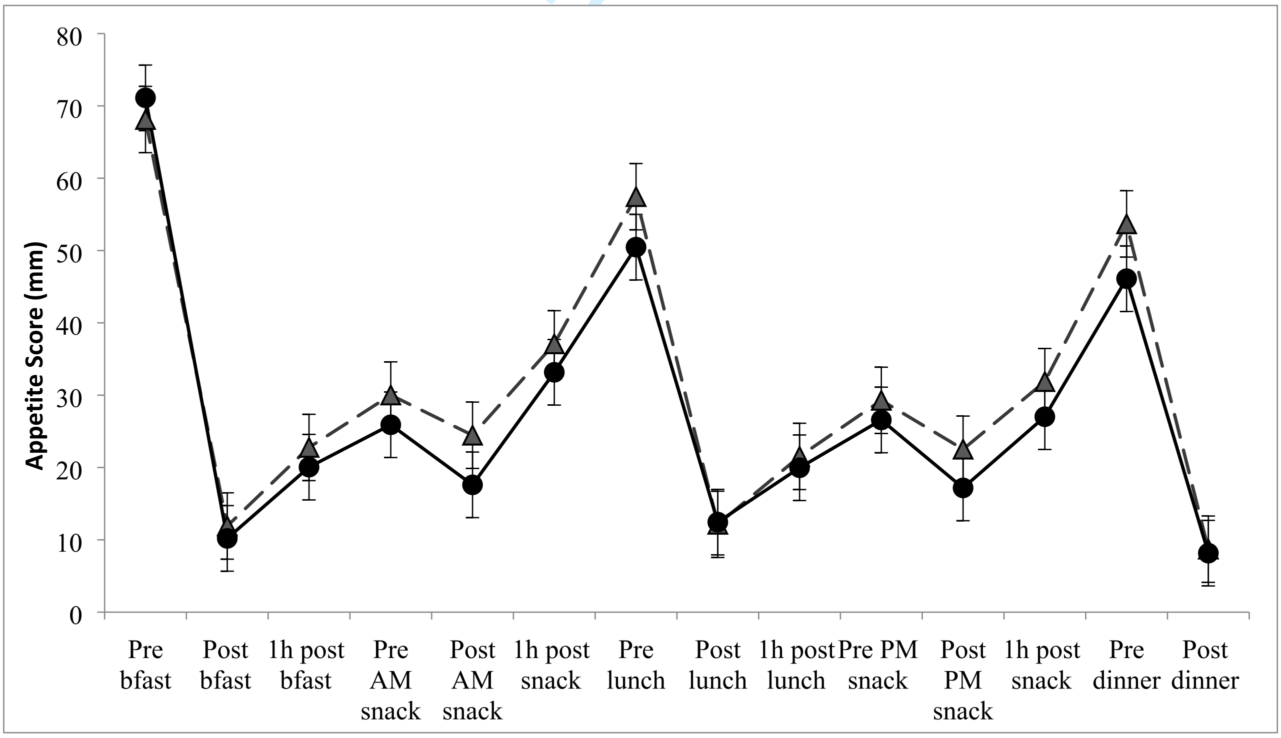

Figure 1: Cumulative mean weight loss (kg) over 12 weeks

Volunteers, 50 healthy, overweight adults in the control group (—▲—) and 50 healthy, overweight adults in the prunes group (—●—) participated in a 12-week free-living intervention study with a randomised, parallel-groups design. The prunes group ate 171g prunes/day (males) or 140g prunes/day (females) in place of usual snacks within a structured weight management programme. The control group followed the same structured weight management programme with instruction on inclusion of healthy snacks in their diet. Results are mean ± SEM.

Figure 2: Appetite score (mm change from baseline) throughout test days at (a) 4 weeks and at (b) 8 weeks.

Volunteers, 50 healthy, overweight adults in the control group (—▲—) and 50 healthy, overweight adults in the prunes group (—●—) participated in a 12-week free-living intervention study with a randomised, parallel-groups design. The prunes group ate 171g prunes/day (males) or 140g prunes/day (females) in place of usual snacks within a structured weight management programme. The control group followed the same structured weight management programme with instruction on inclusion of healthy snacks in their diet. Appetite was measured on 3 test days – day 1 (baseline measure, results not shown): both groups received a control snack of jelly babies (122g males; 100g females); on days 29 (4 weeks) and 57 (8 weeks) the prune group received prune snacks (171g males; 140g females) and the control group received jelly babies (122g males; 100g females). On each test day participants consumed a fixed-load breakfast, followed 2 hours from the start of breakfast by their mid-morning snack eaten over a 15-minute period, 2 hours later (four hours from the start of breakfast) by an ad-libitum lunch, 2 hours from the start of lunch by the afternoon snack and 2 hours later by an ad-libitum dinner (four hours from the start of lunch).

Participants marked their subjective ratings for hunger, desire to eat and fullness on Visual Analogue Scales (100 mm horizontal lines anchored by 'not at all' and 'extremely' at opposite ends), from which appetite score was calculated using the formula [(hunger + desire to eat) – fullness)]/3 for each full study day (14 time points) and for the periods between each snack and the next *ad-libitum* meal. Appetite scores were compared across study groups. Analysis was performed using mixed ANOVA with time as the within subjects' factors and study group as the between subjects' factors. Appropriate post-hoc independent t-tests were run at individual time points between study groups to identify where differences lay. Results are mean ± SD.