THE ROLE OF AUSTRALIAN PORK IN IMPROVING THIAMINE STATUS, HEART DISEASE RISK FACTORS AND GLUCOSE CONTROL IN PEOPLE WITH TYPE 2 DIABETES

Report prepared for the Co-operative Research Centre for an Internationally Competitive Pork Industry

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Executive Summary

Rationale for undertaking the project

With the increasing prevalence of obesity and type 2 diabetes there has been increasing interest in the use of higher protein, lower carbohydrate diets for weight and diabetes management. However, higher protein diets have been typically associated with increased consumption of red meat, of which there is some evidence, albeit not conclusive that higher consumption of red meat may increase the risk of developing cardiovascular disease and type 2 diabetes and iron intake may be related to the development of type 2 diabetes. Some preliminary evidence also exists suggesting that thiamine deficiency may be associated with micro-vascular complications and low thiamine concentrations have been reported in diabetes and thiamine intake is lower on low carbohydrate diets. Therefore, the incorporation of pork protein into a higher protein dietary plan maybe a valuable alternative option to optimise thiamine intake and status in type 2 diabetes. In addition, studies to date in type 2 diabetes have evaluated the effects of a higher protein diet without the incorporation of exercise training as a comprehensive lifestyle plan. This clinical trial assessed the efficacy of a comprehensive 16-week weight reduction program high in pork with resistance exercise in improving thiamine concentrations, diabetes control and markers of cardiovascular disease risk.

Outcomes of the project

Lifestyle programs incorporating a higher protein, high pork diet also had nutritional benefits for improving thiamine status. Relative to the high carbohydrate diet, the higher protein, high pork diet had a significantly greater thiamine intake and improvement in thiamine status.

This study showed preliminary evidence that a 16 week lifestyle program incorporating a higher protein, high pork diet and resistance exercise training was most effective for weight and fat loss compared to a lifestyle program without resistance exercise or with a high carbohydrate diet without resistance exercise. However, further research is required to confirm this result.

Weight loss following a higher protein, high pork diet or a high carbohydrate diet with or without resistance exercise had similar benefits on blood glucose control and biomarkers of heart health. There was also some preliminary evidence that a higher protein, high pork and resistance exercise program had the greatest improvements for improving fasting insulin levels (a marker of insulin sensitivity). This has important potential implications for improving metabolic health in patients with type 2 diabetes and warrants further investigation.

We found no adverse effects on markers of renal function, sodium or calcium excretion between the high protein, high pork or the high carbohydrate programs.

Relevance of the project's outcomes to the Australian Pig Industry

The work provides evidence that a higher intake of lean pork as part of a high protein lifestyle program, when combined with resistance exercise training may provide advantages for weight loss, improvements in body composition and insulin sensitivity in overweight and obese patients with type 2 diabetes. It also provides evidence that a lifestyle program that incorporates pork may offer additional nutritional advantages for promoting thiamine status over a high carbohydrate diet.

Collectively, this evidence suggests lean pork is valuable alternative source of protein within higher protein dietary patterns that can be used effectively for weight and diabetes

management in the community. Once published, it will support the case for the use of a higher protein diet which includes pork as part of comprehensive lifestyle program. These outcomes have relevance to the Australian Pig Industry for the development pork based food products consistent with the composition of this lifestyle program.

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1. Introduction

Nutritional Value of Pork Intake

Lean pork is a rich source of protein, niacin and thiamine. Thiamine concentration is uniquely high in pork relative to other animal based foods. In Australia thiamine levels in pork are approximately 0.8mg/100g raw weight and 1.2mg/100g cooked weight (Ausnut data). The Recommended Dietary Intake (RDI) for adults is 1.2mg per day (NHMRC) (1) demonstrating that a small serve of pork in human diets can easily meet the entire nutritional need for thiamine. Thiamine plays an important role in helping the body metabolize carbohydrates and fat to produce energy. It is essential for normal growth and development and helps to maintain proper functioning of the heart and the nervous and digestive systems. Thiamine is water-soluble and cannot be stored in the body; however, once absorbed, the vitamin is concentrated in muscle tissue.

A diet containing 200g/day of pork and ham will contain 2.4mg of thiamine/day and would well exceed the RDI. It is postulated that many people with diabetes have a deficiency of thiamine as assessed by a low plasma free thiamine (2). Treatment of animals with experimental diabetes with a high dose lipid soluble thiamine analogue can improve nephropathy and prevent diabetic nephropathy.

There is also data to indicate that higher consumption of red meat is associated with an increased cardiovascular (CVD) risk among women with type 2 diabetes (3), although the majority of studies do not show an association of ferritin levels with CVD. There is also some evidence that a high red meat diet, especially processed meats, is associated with increased risk of developing type 2 diabetes in women (4). Although this does not conclusively demonstrate cause and effect, it would seem prudent to ensure variety in sources of protein in diets for managing type 2 diabetes. Pork protein is a valuable alternative option.

Type 2 diabetes is a major public health problem driven largely by the increasing levels of obesity in Australia. Data from the Ausdiab study demonstrates continuing weight gain in the population of 2kg and a 2.1cm increase in waist circumference (Shaw et al 2006 unpublished data). It has been well established that moderate weight loss delays the progression from impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) to diabetes (5-7). The most recent study from the Ausdiab group suggests a strong association between abnormal glucose metabolism and mortality, with this condition contributing to a large number of CVD deaths in the general population (8).

Thiamine and Type 2 Diabetes

There is evidence of an increased prevalence of low thiamine concentration in diabetes (2) and that this is linked to one marker of macrovascular disease (heart disease and stroke). Correction of the low thiamine concentration with either thiamine supplements or a dietary pattern high in thiamine may potentially decrease the risk of microvascular complications in diabetes as has been shown in experimental animals with high dose supplements.

Lower Carbohydrate Diets And Thiamine

Thiamine requirements are largely dependant on carbohydrate intake. Theoretically the need for thiamine is lower on low carbohydrate diets as a high carbohydrate diet has been shown to cause a decrease in plasma and urine levels

of thiamine (9). Thiamine requirements have also been related to energy intake (10) with requirements expressed for adult humans as 0.40 mg of thiamine per 1000 kcal by FAO/WHO. An energy restricted high protein high pork low carbohydrate diet should achieve optimal thiamine status compared to higher carbohydrate diet which may provide similar thiamine but with which more thiamine would be required to metabolise a greater carbohydrate load. Hence net thiamine status would theoretically be better on a high protein high pork low carbohydrate diet compared to a high carbohydrate diet.

Physical Activity and Thiamine

Thiamine, as thiamine pyrophosphate, plays an important role in the metabolism of both carbohydrate and the branched-chain amino acids. It is a coenzyme for pyruvate dehydrogenase which catalyzes the conversion of pyruvate to acetyl CoA. Because exercise stresses metabolic pathways that use thiamine, the requirements for these vitamins may be elevated with increased physical activity. Theoretically, exercise increases the need for these nutrients because of an increased turnover, metabolism, or loss of nutrients and the need for tissue maintenance and repair. There is some biochemical evidence of poor vitamin status in active persons but studies examining these issues have been limited and equivocal (11, 12). There are no metabolic studies that have compared thiamine status in active and sedentary persons. Little research is available on the effect of the combination of diet and exercise on weight loss and thiamine status. Finally, no data are available on the effect of exercise or dieting plus exercise on the thiamine status of individuals with chronic health problems, such as diabetes. We propose to examine the role of dietary patterns in weight loss and physical activity in improving thiamine status, diabetes control and cardiovascular risk profiles in people with type 2 diabetes.

High Protein Diets And Resistance Exercise

Although both resistance training and high protein diets have both independently been linked to maintenance of resting energy expenditure and fat free mass during energy restriction, there is a growing suggestion that during weight loss with energy restriction, the consumption of a high protein diet compared to high carbohydrate diet may provide additive effects when combined with high-intensity exercise training for fat loss and the maintenance of lean body tissue and resting energy expenditure (13, 14). However, to date there has been limited research investigating this. Levenhagen et al. (15) found that supplementing with protein immediately following exercise increased whole body protein synthesis, whilst supplementing with carbohydrate or a placebo resulted in a reduction in whole body protein synthesis. Similarly, Andersen et al. (16) found that supplementing with protein vs. carbohydrate immediately pre and post exercise resulted in greater muscle function after 14 weeks.

Layman et al. (2005) (14) demonstrated a high protein diet combined with exercise training additively improved body composition during weight loss in healthy, overweight and obese women, such that fat tissue loss was greater in women undertaking exercise whilst consuming a high protein diet, compared to subjects consuming a high carbohydrate diet with or without exercise or the consumption of a high protein diet alone. Moreover, there was some evidence that subjects consuming a high protein diet lost less lean mass and had greater reductions in trunk fat than subjects consuming a high carbohydrate diet. However, no study to date has evaluated the interactive effects of diet composition and exercise training in patients with type 2 diabetes.

Aims and Hypotheses

The use of pork as a high thiamine source in the context of a high protein weight loss program in overweight/obese people with type 2 diabetes was investigated.
Our primary aim in this study was to determine if a weight reduction program high in pork (and therefore thiamine) both with or without high intensity, resistance exercise can be effective in

- correcting low whole blood thiamine pyrophosphate concentrations
- improving risk markers of cardiovascular disease

in overweight/obese people with type 2 diabetes

Our secondary aims were to

- to assess whole blood thiamine pyrophosphate concentrations in people with type 2 diabetes in Australia
- quantify thiamine intakes in this group

Hypotheses
Our primary hypothesis was that a weight loss diet high in thiamine from pork would improve thiamine status in people with type 2 diabetes relative to a conventional high carbohydrate diet with or without resistance exercise.
Improvement in thiamine status would be anticipated to be related to a higher dietary thiamine intake from a diet high in pork.

A secondary hypotheses was that compared with a conventional high carbohydrate diet a higher protein dietary pattern high in pork will

- improve diabetes control
- decrease medication requirements
- improve CVD risk markers

2. Methodology

Ethics Clearance
All experimental procedures were approved by the Human Research Ethics committee of the Commonwealth Scientific and Industrial Research Organisation (HREC 07/34). All subjects provided written informed consent prior to participation in the study.

Study Design
Randomised, parallel study design compromising a 16-week intensive weight loss intervention

Subjects
83 overweight and obese men and women with type 2 diabetes

Inclusion Criteria
- Age between 18-65 years
- BMI greater than 27 (weight (kg) divided by height (m) squared)
- Have type 2 diabetes (HbA1c $\geq$ 7.0% on screening or previously diagnosed and/or controlled with medication)
- Not have type 1 diabetes
- Participants must understand the procedures involved and agree to participate in the study by giving full informed, written consent
- No abnormality of clinical significance on medical history
- If female, not pregnant or breast feeding

Exclusion Criteria
- Lactose Intolerant
- Using Insulin
- Have been previously diagnosed with proteinuria, a malignancy, or metabolic disease such as liver, kidney, respiratory, gastrointestinal disease or stroke, or are pregnant or lactating
- Have been previously diagnosed with cardiac disease, including myocardial ischemia or major heart rhythm abnormalities.
- Have high uncontrolled hypertension (resting recumbent BP >160/100 mmHg)
- Have a musculoskeletal injury, joint or peripheral vascular disease sufficient to impede exercise (such as hip arthritis, foot, ankle problems or pain)
- History of smoking during 6 months prior to study
- History of heavy alcohol consumption (> 5 STD drinks/day)
- Participated in regular aerobic or resistance exercise program (greater than two 30-min sessions of moderate/vigorous aerobic exercise per week or greater than 1 moderate intensity resistance exercise session per week) during the 6 months prior to study
- Widely fluctuating exercise patterns
- Currently on a weight reducing diet
- Unwilling to cease thiamine or thiamine containing vitamin supplements
- Unwilling to consume pork and ham 4 times a week
- Unwilling to be randomized to either any of the experimental groups

- Extended absences due to travel or other commitments
- Unable to comprehend or cope with study requirements

Randomisation

Participants were block matched for age, gender, weight and diabetes medication and control; then randomised into one of four,16 week lifestyle interventions:

- **Group 1** (HC): High carbohydrate (CHO), low protein 0.8g/kg (PRO), low fat (LF), energy restricted diet (55% CHO, 20% PRO, 25% Fat)

- **Group 2** (HP): High protein, high pork, low fat energy restricted diet (40% CHO, 35% PRO, 25% Fat)

- **Group 3** (HC+EX): High carbohydrate, low protein 0.8g/kg, low fat, energy restricted diet (55% CHO, 20% PRO, 25% Fat) and a resistance exercise training program

- **Group 4** (HP+EX): High protein, high pork, low fat, energy restricted diet (40% CHO, 35% PRO, 25% Fat) and a resistance exercise training program

Outcome measurements:

- Weight
- Body composition as assessed by dual energy X-ray absorptiometry (DEXA)

Biochemistry

- Whole blood thiamine pyrophosphate
- Fasting lipids
- Fasting plasma creatinine
- Fasting plasma glucose and insulin concentrations
- HbA1C
- Blood pressure
- Urinary electrolytes, urea and creatinine
- Urine – micro albuminuria

Study Protocol

All participants were initially familiarised (2 wks prior to study commencement) with the dietary requirements/interventions and exercise protocols, that were to be carried out during the study. Participants were asked not to modify their lifestyle in any way during the intervention period, other than as advised in order to meet the dietary and exercise requirements of the study protocol.

At Weeks 0 and 16 of the study after an overnight fast, participants attended the CSIRO clinic for testing. Participants were instructed to refrain from exercise and alcohol consumption during the 24 hours prior to all testing sessions. At the clinic testing visits, height, body weight and blood pressure were measured, followed by the assessment of body composition via dual x-ray absorptiometry (DEXA) and an

electrocardiograph (Week 0 only) to check for any heart abnormalities. A venous blood sample was then drawn for the determination of lipids and insulin, plasma glucose, creatinine and C-reactive protein, glycoslyated hemoglobin (HbA_{1c}) and whole blood thiamine pyrophosphate. At Weeks 0 and 16, during the immediate 24-hours prior to the clinic testing visit, a 24-hour urine sample was collected for the measurement of sodium, potassium, calcium, urea, creatinine and albumin. On the day following the Week 0 visit participants commenced the dietary manipulations and resistance training program as appropriate.

Between Week 0 and Week 16 volunteers in the exercise groups attended the CSIRO gymnasium 3 times per week and performed the resistance exercise training program. Following the Week 0 visit and additionally at Weeks 2, 4, 6, 8, 10, 12 and 14 (in conjunction with one of the exercise training sessions for participants in the exercise groups), all participants attended the clinic and were provided with detailed dietary advice, meal planning and recipe information by a research dietician to ensure continued compliance with the dietary requirements throughout the study.

Medications and dosages were documented at baseline and lipid lowering and anti-hypertensive medication levels were encouraged to remain constant throughout the 16-week intervention. Blood glucose control of the participants was monitored by a clinician on a weekly basis by a research physician based on daily fasting blood glucose levels collected by the participants using a hand-held glucometer. All changes to medications and dosages and were documented.

Dietary Interventions
Participants in all groups followed one of two isocaloric, moderate energy restricted dietary plans with total energy contents of ~6000 kJ/day for women and ~7000 kJ/day for men which were presented in similar formats in booklet form and named as either Diet 1 or Diet 2.

The planned macronutrient profiles of the 2 diets were:

- Diet 1: High carbohydrate, low protein, low fat diet: 55% CHO, 20% PRO, 25% Fat
- Diet 2: High protein, high pork, low fat diet: 40% CHO, 35% PRO, 25% Fat

Some adjustments in kilojoules for individuals was necessary to achieve a deficit of 2000-4000KJ per day corresponding to 0.5-1.0kg weight loss per week.

Both dietary patterns were structured to include specific food quantities and weights to ensure the correct macronutrient and energy requirements were achieved (Table 1). These foods were listed in a quantitative food record which subjects completed daily. This provided participants with clear dietary targets and opportunity for dietary self-management. Key foods representative of each diet's macronutrient profile were also supplied fortnightly throughout the intervention to aid compliance (Table 2). These foods were generally uncooked but pre-weighed to provide about 50% of total energy.

Participants attended individual consultations with qualified dietitians whom they saw at baseline and every 2 weeks of the study for instruction on the dietary requirements, method for recording food intake and assessment of compliance. Participants were asked to weigh and measure their food daily and scales for weighing food were provided. Dietary composition was assessed using 3

days from the food records (2 weekdays and 1 weekend day) within each consecutive fortnightly period for the duration of the study using computerised dietary software (Foodworks Professional Edition, version 4 software, Xyris Software 1998, Highgate Hill, Australia). This was conducted in the presence of the volunteers to maximize accuracy and clarify any ambiguities. The fortnightly food records were then used to calculate the average nutrient intakes during the study. Thiamine intake at baseline was assessed by The Anti Cancer Council of Victoria food frequency questionnaire (FFQ) which as been validated by Hodge et al (17).

Exercise Intervention

In addition to the dietary intervention, participants in the exercise groups followed the same, supervised, progressive strength training program. The program was focused on muscle hypertrophy based on the American College of Sports Medicines Guidelines for Exercise Testing and Prescription (18), the American College of Sports Medicines position stand on Exercise and Type 2 diabetes (19) and resistance training reviews from Bird et al. (20) and Kraemer et al. (21). 8 separate exercises (Leg Press, Leg Extension, Bench Press, Shoulder Press, Lat Pull-down, Seated Row, Triceps and Abdominal Crunches) were performed using multi-station weight-stacked machines (Maxim Health Fitness, Adelaide, SA), except sit-ups, on 3 non-consecutive days per week. The weight loadings were approx 70-85% of 1RM to allow 8-12 reps to volitional fatigue with 2 sets per exercise and 1-2 minutes rest between sets. Lifts were performed at a slow to moderate 2:1:2 tempo, 2 seconds concentric: 1 second pause: 2 seconds eccentric. Once volunteers could successfully perform two sets of 12 repetitions the training weight load was increased. Each resistance training session lasted approximately 40 minutes. Before and after each strength training session participants performed a brief 5-10 minute warm-up and cool-down period consisting of low-intensity stationary cycling/light jogging and static stretching. To ensure compliance and that the exercises were performed with correct technique, participants performed the exercise training under the supervision of a qualified exercise professional at the Research Gymnasium at CSIRO, Human Nutrition, Adelaide).

Participants in all groups were asked to maintain their entry physical activity levels for the duration of the study other than required to follow the resistance exercise program as part of the study protocol if randomized to an exercise treatment group.

Table 1. Food profile and thiamine content of the treatment diets

HP (High Protein) Diet 6000kJ	Amount	Thiamin (mg)	HC (High Carbohydrate) Diet 6000kJ	Amount	Thiamin (mg)
Sanitarium Weetbix OR Uncle Toby's Plus Protein Mix	40g	0.52 (avg)	Uncle Toby's Oats OR Uncle Toby's Nut Feast	50g	0.04 (avg)
Noble Rise white with Oats	2 slices	0.52	Sunblest Wholemeal bread	2 slices	0.41
Skim milk	250ml	0.05	Ryvita Original	3 crispbreads	0.05
Diet yoghurt	200g	0.08	Skim milk	250ml	0.02
Devondale 7's cheese (low fat)	1 slice, 20g	0.11	Devondale Sandwich slices (reduced fat)	1 slice, 20g	0.05
High protein snack: skim milk + skim milk powder	250ml milk, 25g powder	0.16	High carbohydrate snack: Just Juice tetrapak (apple)	150ml	0.00
Fruit	200g	0.06	Fruit	300g	0.09
Mixed Vegetables/Salad	2.5 cups	0.23	Mixed Vegetables/Salad	2.5 cups	0.23
Hans Champagne Ham	50g, 4*/week	0.10	Beef, lean, raw	100g 2*/week	0.03
Tuna, tinned	50g, 2*/week	0.00	Chicken breast ,raw	100g 2*/week	0.03
Chicken breast, sliced	50g, 1*/week	0.00	Fish, raw	100g 2*/week	0.02
Pork, lean, raw	180g, 4*/week	0.84	Legumes, cooked	100g, 1*/week	0.01
Chicken breast ,raw	180g, 2*/week	0.05	Potato, cooked	300g, 1*/week	0.03
Fish, raw	180g, 1*/week	0.02	Rice, cooked	0.5 cup, 3*/week	0.01
			Pasta, cooked	1 cup, 3*/week	0.01
Poly/mono-unsaturated oil/margarine	15g (3 tsp)	0.00	Poly/mono-unsaturated oil/margarine	20g (4 tsp)	0.00
2 standard alcoholic drinks/week (optional), eg. wine	Max. 2 std drinks per week. Eg, wine max 300ml	0.00	2 standard alcoholic drinks/week (optional), eg. wine	Max. 2 std drinks per week. Eg, wine max 300ml	0.00
Total Average Thiamin/day (mg)		**2.75**			**1.06**

Table 2. Key foods provided to participants (weekly unless specified)

HP (High Protein) Diet 6000kJ	HC (High Carbohydrate) Diet 6000kJ
• 1*670g box Uncle Toby's Plus Protein Mix/6wks	• 1*1kgg box Uncle Toby's Oats/6wks
• 1*1.2kg box Sanitarium Weetbix/6wks	• 1*475g box Uncle Toby's Nut Feast/2wks
• 1*1kg bag Devondale skim milk powder/6wks	• 2*26-cripsbread boxes Ryvita/2wks
• 7*1L containers Devondale UHT skim milk/4wks	• 2*500g packets San Remo penne pasta/6wks
• 3*210g packets (10 slices) Devondale 7's/4wks	• 5*Just Juice tetrapaks (150ml*6)/4wks
• 1 loaf Noble Rise white with Oats	• 1*500g packet (24 slices) Devondale Sandwich Slices/4wks
•	• 1 loaf Tip Top Sunblest wholemeal bread
• 2*100g packets Hans Champagne leg ham	• 2*100g packets lean beef strips
• 4*180g portions of lean pork loin	• 2*100g packets lean chicken strips

Measurements

Height, body weight and body composition
Height was measured to the nearest 0.1cm using a stadiometer (SECA, Hamburg, Germany). Body mass was measured to the nearest 0.05 kg using calibrated electronic digital scales (Mercury, AMZ 14, Tokyo, Japan). Body composition was measured using dual energy x-ray absorptiometry (DXA; Lunar Prodigy; General Electric Corporation, Madison, WI, USA) to assess fat mass (FM) and fat free mass (FFM) at baseline and week 16.

Blood Pressure
Blood pressure was measured seated after a minimum 5-minutes rest using an automated sphygmomanometer (DYNAMAP^{TM} 8100, Criticon, Tampa, FL, USA). Three blood pressure measurements were performed, each separated by 2-minutes and an average of the 3 readings were used as the measured value.

Biochemical Analyses
Venous blood samples were collected into vacutainer tubes containing either no additives or sodium fluoride/ EDTA (1g/L) and the serum/plasma isolated by centrifugation for 10 min at 2000g, (5^{o}C) (Beckman GS-6R Centrifuge CA) and stored at -80^{o}C until study completion. Serum lipids (total cholesterol, HDL-cholesterol and triglycerides) and plasma glucose, C-reactive protein and creatinine were measured on a Hitachi 902 autoanalyzer (Roche Diagnostics, Indianapolis, IN) using commercial enzymatic kits (Roche Diagnostics, Basel, Switzerland). The Friedewald equation will be used to calculate LDL-C levels.(22)

HbA1c was measured using high-performance liquid chromatography at a commercial laboratory (IMVS, Adelaide, Australia). Insulin was measured in duplicate using Mercodia Insulin ELISA (Mercodia AB, Uppsala, Sweden). The Computerized Homeostatic Model Assessment 2 (HOMA2-IR) were used as a surrogate measure of insulin resistance based on fasting glucose and insulin concentrations (23). Whole blood thiamine pyrophosphate was measured at a commercial laboratory (IMVS, Adelaide, Australia).

24hr urine samples were collected into a 4L bottle without additives in the 24 hours immediately prior to the volunteer's visit at Week 0 and Week 16. Participants were instructed to keep the urine cool and bottles were returned to the clinic on the following day at their scheduled clinic visit. Analysis of 24-hour urinary sodium, potassium, calcium, urea, creatinine and albumin was performed in a single assay at a commercial laboratory (IMVS, Adelaide, Australia). In order to assess changes in renal function, calculated glomerular filtration rate (24) and the urinary albumin excretion rate was determined.

Statistical Analysis

All statistical analyses were performed using SPSS 14.0 for WINDOWS (SPSS Inc, Chicago, IL). Distribution was normal for all variables except insulin, C-reactive protein and urinary albumin. Data for these variables were normalised using logarithmic transformation prior to analysis, but the non-log transformed values are presented. Differences in baseline characteristics between groups and dietary data were compared using one-way ANOVA for continuous variables and Pearson Chi-square test (x^2) for categorical variables. To assess the effects of the treatment interventions between the groups over time on the dependant variables comparisons were made using a 4 (HC, HP, HC+Ex, HP+Ex) x 2 (Week 0 and Week 16) repeated measures ANOVA. Where there was a significant main effect (group x time interaction), post-hoc comparisons were performed on the within group change with Bonferroni's adjustment for multiple comparisons to determine differences between group means. Inclusion of age, gender and baseline BMI as covariates in the analysis model did not change the results. In addition, for an overall comparison of diet, a planned contrast was used to compare the 2 HC groups (HC, HC+EX) with the 2 HP groups (HP, HP+EX) to evaluate the magnitude of change between the 2 diets. Pearson correlation analyses were conducted to assess the association of change between variables. Statistical significance was set at $P \leq 0.05$. All data are presented as means ± SDs, unless otherwise stated.

This research investigation represents an efficacy trial and the analysis was based on participants who completed the intervention per protocol (i.e inclusion of volunteers who only completed the study and achieved compliance to the study protocols).

3. Outcomes

Participant attrition and baseline characteristics
Of the 85 participants initially enrolled in the study; 83 participants were randomly allocated to an intervention group and 82 participants commenced the study. The participant enrollment and attrition patterns in the study are shown in Figure 1. Four participants were unable to continue with the dietary protocols; 1 subject was unable to tolerate the exercise requirements; 3 withdrew due to family or personal reasons; 2 moved away, 2 had any injury unrelated to the study, 1 withdrew due to time constraints and a further 4 participants were lost to contact. Data for an additional 7 subjects were excluded from the analysis because they failed to comply with the dietary compliance and reporting requirements of the study. Overall, a total of 59 subjects (72%) completed the 16-week study per protocol. Baseline (week 0) characteristics of the participants who completed the study across treatment groups are shown in Table 1. No differences were observed between treatment groups in any of these characteristics.

Figure 1. Consort statement

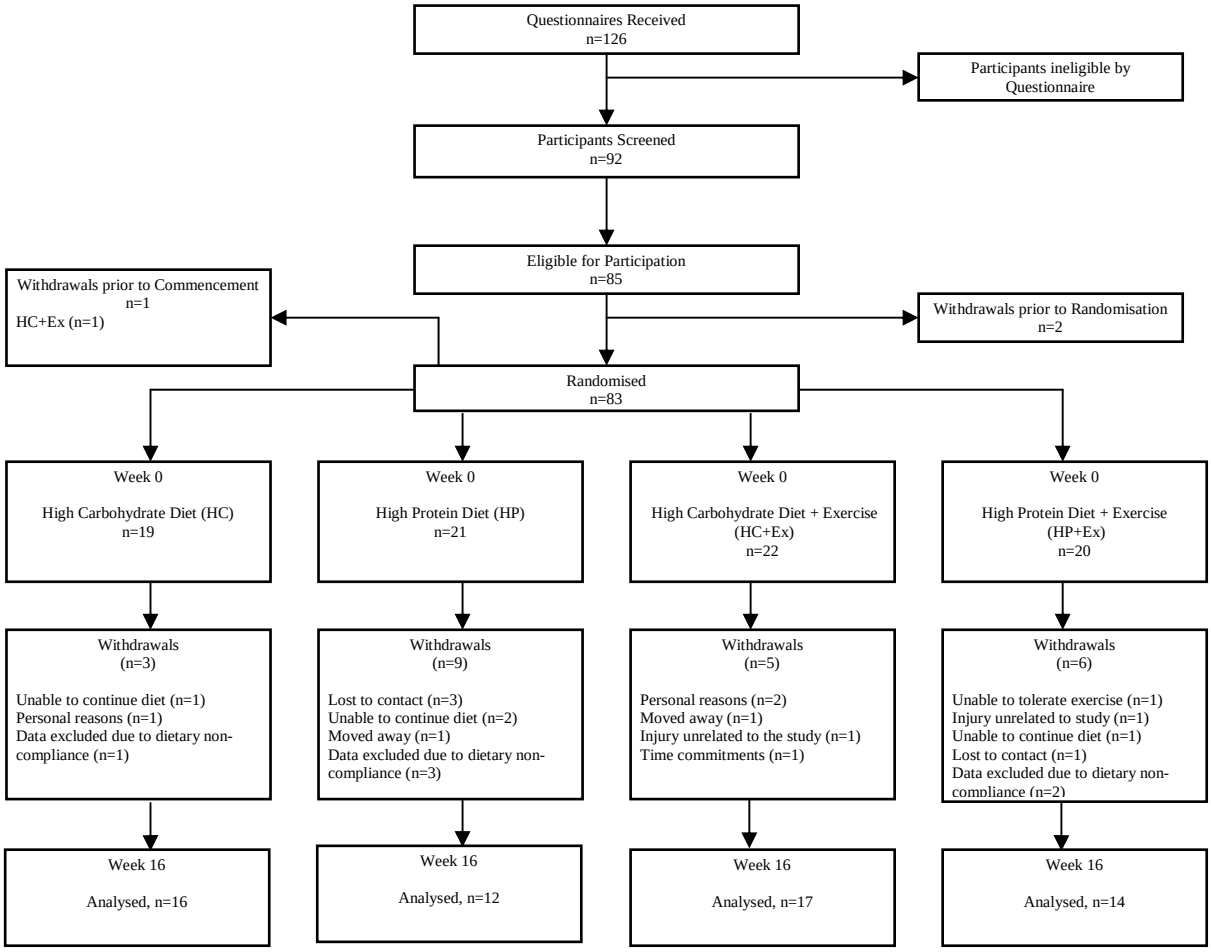

Table 1. Baseline participant characteristics of participants who completed the study across treatment groups: an energy restricted diet, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Characteristic	HC	HP	HC+EX	HP+EX
Age, years	58.0 ± 6.8	56.3 ± 7.6	53.9 ± 9.2	56.4 ± 6.1
Gender, male/female	8/8	7/5	12/5	8/6
Weight, kg	97.0 ± 10.7	102.3 ± 15.4	105.0 ± 15.3	107.6 ± 15.5
Body mass index, kg/m^2	34.8 ± 4.9	35.6 ± 3.8	34.9 ± 4.5	36.6 ± 5.0
Systolic Blood pressure, mmHg	137 ± 12	141 ± 11	137 ± 10	138 ± 9
Diastolic Blood pressure, mmHg	79 ± 8	83 ± 9	81 ± 8	79 ± 8
Fasting glucose, mmol	9.2 ± 2.7	9.5 ± 2.9	8.7 ± 3.2	8.2 ± 2.1
Fasting Insulin, mU/L	15.8 ± 10.0	12.4 ± 8.6	12.3 ± 4.8	15.2 ± 8.3
HbA1c, %	7.6 ± 1.0	8.0 ± 1.8	7.3 ± 1.4	6.8 ± 1.0
Triglycerides, mmol/L	2.3 ± 1.3	2.0 ± 1.1	1.6 ± 0.5	1.8 ±0.7
Cholesterol, mmol				
Total	4.8 ± 1.0	5.0 ± 1.1	4.3 ± 0.9	4.7 ± 0.9
High-density lipoprotein	1.2 ± 0.3	1.2 ± 0.3	1.1 ± 0.3	1.1 ± 0.3
Low-density lipoprotein	2.7 ± 0.9	2.7 ± 0.9	2.4 ± 0.8	2.7 ± 0.6
Anti-hypertensive medication, n (%)	11 (69)	7 (58)	10 (59)	5 (14)
Oral hypoglycemic medication, n (%)	9 (56)	4 (33)	14 (82)	9 (64)
Lipid-lowering medication, n (%)	9 (56)	5 (42)	9 (53)	6 (43)
Dietary Thiamine intake (mg/day)	1.6 ± 0.7	2.3 ± 1.3	2.0 ± 0.8	2.3 ± 1.2
Whole blood thiamine pyrophosphate (nmol/L)	209.8 ± 38.8	198.8 ± 59.0	231.2 ± 62.6	234.0 ± 45.5

Values are mean ± SD, unless otherwise specified.

Dietary analysis

Table 2. Dietary intake of the different treatments using daily weighted food checklists[1]

Variable	HC (N=16)	HP (N=12)	HC+Ex (N=17)	HP+Ex (N=14)
Total energy, kJ	6278 ± 648	6321 ± 763	6199 ± 696	6339 ± 649
Carbohydrate, g *	197 ± 16.3	176 ± 24	195 ± 22	170 ± 23
Carbohydrate, %E *	54 ± 3	47 ± 1.6	54 ± 4	46 ± 2
Protein, g *	69 ± 6	119 ± 8	68 ± 8	117 ± 7
Protein, %E *	19 ± 1	32 ± 3	19 ± 1	32 ± 2
Total fat, g †	39 ± 8	31 ± 8	38 ± 10	34 ± 6
Total fat, %E †	23 ± 3	18 ± 3	22 ± 5	20 ± 2
Saturated fat, %E *	7 ± 1	5 ± 1	6 ± 1	6 ± 1
Thiamine, mg	1.2 ± 0.2	2.8 ± 0.2	1.2 ± 0.2	2.8 ± 0.8

Values are mean ± SD.

[1]Participants completed daily semi-quantitative food records. Three days (2 weekdays and 1 weekend day) of dietary data were analysed at weeks 2, 4, 6, 8, 10, 12, 14 and 16.

* P<0.001, † P<0.05 significant group effect (HC vs HP)

Table 3. 24-hr urinary urea:creatinine ratio at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=15)	HP (N=12)	HC + EX (n=16)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	30.8 ± 8.6	31.1 ± 9.8	26.4 ± 4.7	28.3 ± 9.5	0.88	0.02	0.002
Week 16	26.7 ± 3.8	33.6 ± 11.3	24.3 ± 4.3	31.5 ± 7.7			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction
[3] test of significant diet comparison (HC: n=31; HP; n=26)

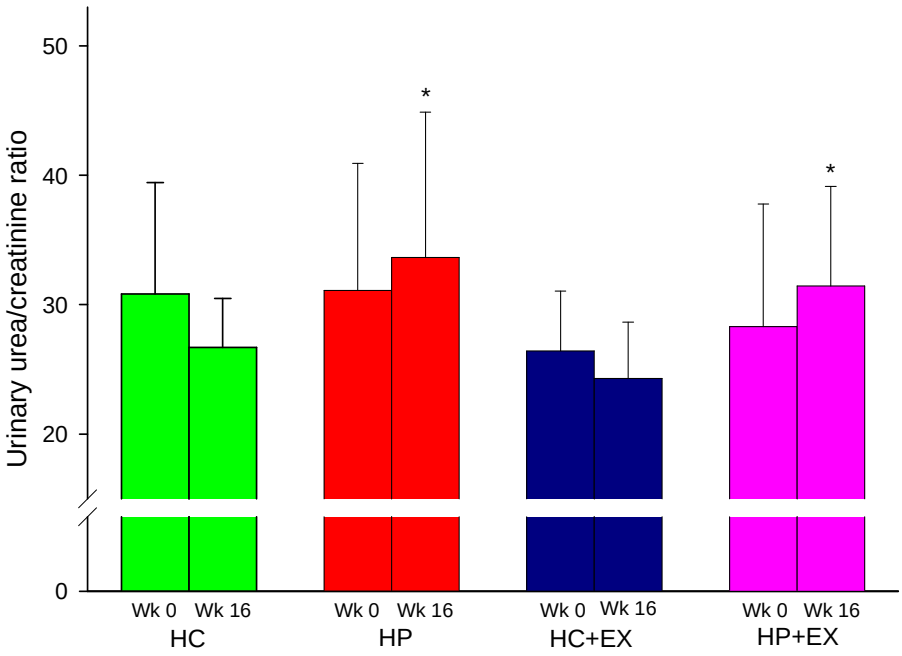

Figure 2. 24-hr urinary urea:creatinine ratio at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P=0.002 significant diet comparison compared to HC diet groups.

Based on the results of the food records, participants demonstrated good compliance with the prescribed diets. Total energy intake was similar across groups (Table 2). The intake of protein was significantly higher and the carbohydrate and fat intakes significantly lower in HP compared to HC. Urinary urea:creatinine ratio is an objective marker of protein intake and the significant diet comparison (P=0.002, Table 3, Figure 2), in which the ratio increased to a greater extent on HP (2.86±5.89: 10%) compared to HC (-3.09±7.73 (-10%) indicating adherence to a higher protein intake in the HP groups during the study.

For thiamine, the estimated average requirement (EAR) for adults is 1.0 mg/day (men) and 0.9 mg/day (women) (1). The recommended daily intake (RDI) for adults for thiamine is 1.2 mg/day/day for men and 1.1 mg/day for women (1). At baseline based on data obtained from the food frequency questionnaire participants met the EAR and RDI for thiamine intake with no difference between the treatment groups (HC 1.6 ± 0.7 mg/day, HP 2.3 ± 1.3 mg/day, HC+EX 2.0 ± 0.8 mg/day, HP+Ex 2.3 ± 1.0 mg/day; P=0.14 group difference). Based on the results of the food records, throughout the study, thiamine intakes were significantly greater in the HP diet intervention groups compared to the HC diet intervention groups (P=0.002), Table 2.

Body Weight

Table 4. Body weight (kg) at Week 0 and after 16 weeks of consuming an energy restricted diet, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet Comparison[3]
Week 0	97.0 ± 10.6	102.7 ± 15.4	105.0 ± 15.3	107.6 ± 15.5	<0.001	0.04	0.18
Week 16	88.4 ± 11.2	93.7 ± 13.8	94.5 ± 15.4	93.8 ± 13.5			

Values are mean ± SD.
[1] test for significant main effect of time
[2] test of significant group x time interaction: significant greater reduction in HP+EX compared to HC (P<0.05, post-hoc).
[3] test of significant diet comparison (HC: n=33; HP; n=26)

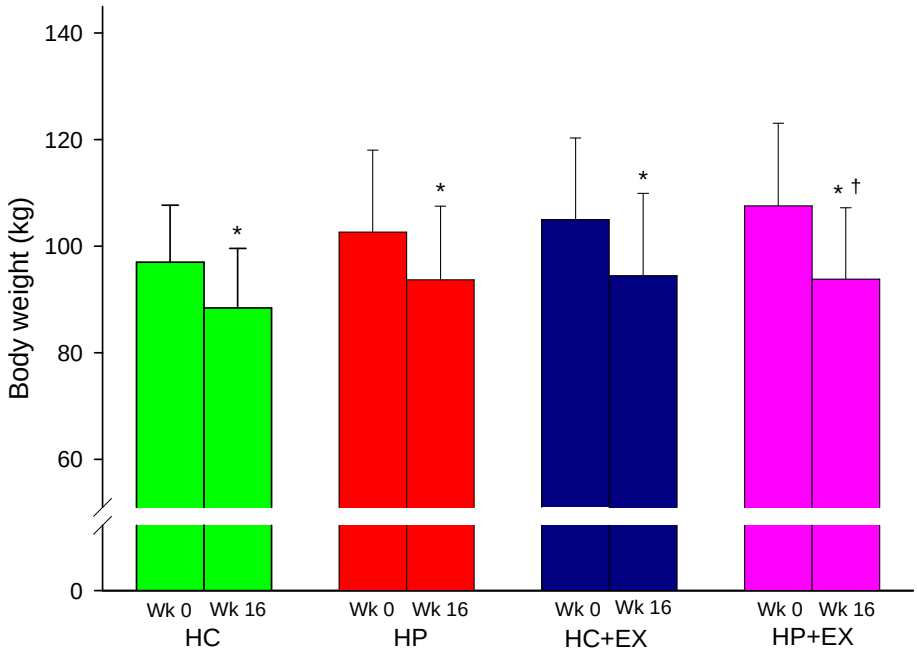

Figure 3. Body weight (kg) at Week 0 and after 16 weeks of consuming an energy restricted diet, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P<0.001 significant main effect of time; † P=0.04 significant group x time interaction: significant greater reduction in HP+EX compared to HC (P<0.05, post-hoc).

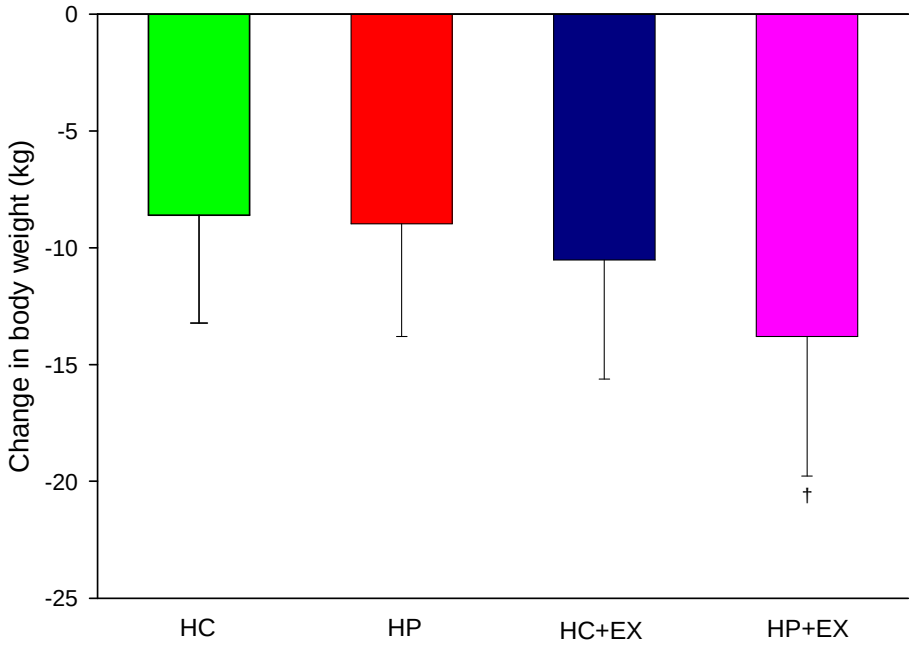

Figure 3.1. Change in body weight (kg) from Week 0 to after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
† P=0.04 significant main group effect: significant greater reduction in HP+EX compared to HC (P<0.05, post-hoc).

Table 4 and Figures 3 and 3.1 shows there was a significant reduction in body weight in all treatment groups. There was no significant diet comparison for body weight (P=0.18), however there was a significant time x group interaction (P = 0.04), such that weight loss was greatest in the HP + Ex group. Specifically, the combined effects of the HP diet and the EX produced a 12.8% weight loss; participants in the HC diet and EX group had a 10% weight loss; whilst participants in the HC and HP diet groups had a weight loss of 8.9% and 8.7%, respectively. Post-hoc analysis showed only differences in weight loss between the HP+EX and HC treatment groups reached statistical significance (P<0.05), whilst there was a trend for a greater reduction compared to HP but did not research statistical significance (P=0.13), HC+EX was not significant (P=0.50).

Body Composition

Total Fat Mass

Table 5. Total fat mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted diet, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value		
					Time effect[1]	Group x time effect[2]	Diet comparison[3]
Week 0	38.1 ± 7.6	39.7 ± 8.2	39.9 ± 9.7	42.3 ± 11.2	<0.001	0.005	0.08
Week 16	31.7 ± 9.1	33.0 ± 6.9	32.0 ± 10.4	31.2 ± 11.4			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction: significant greater reduction in HP+EX compared to HC (P=0.006, post-hoc) and HP (P=0.022, post-hoc).

[3] test of significant diet comparison (HC: n=33; HP; n=26)

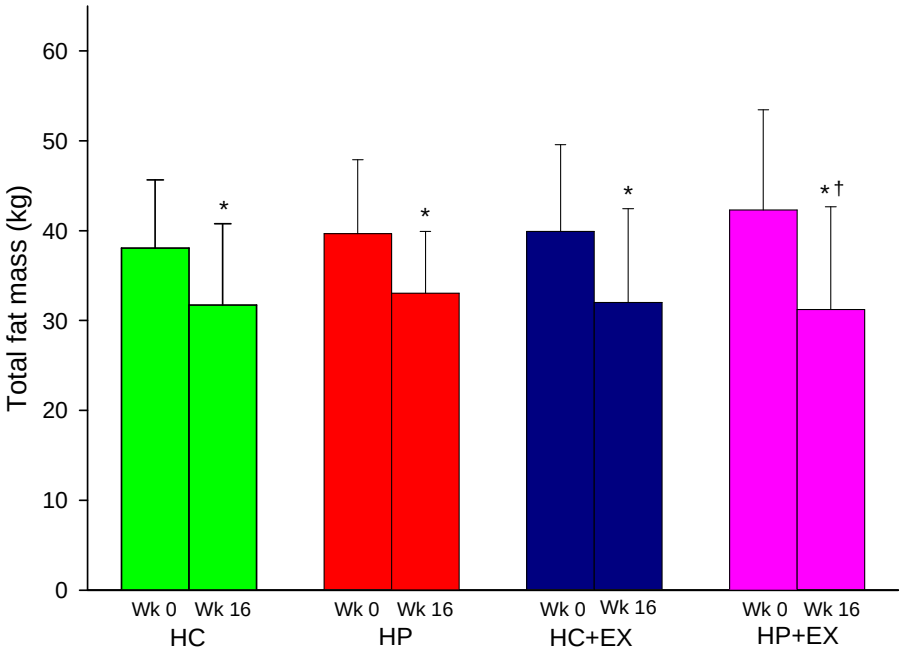

Figure 4. Total Fat mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted diet, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time; † P=0.005 significant group x time interaction: significant greater reduction in HP+EX compared to HC (P=0.006, post-hoc) and HP (P=0.022, post-hoc).

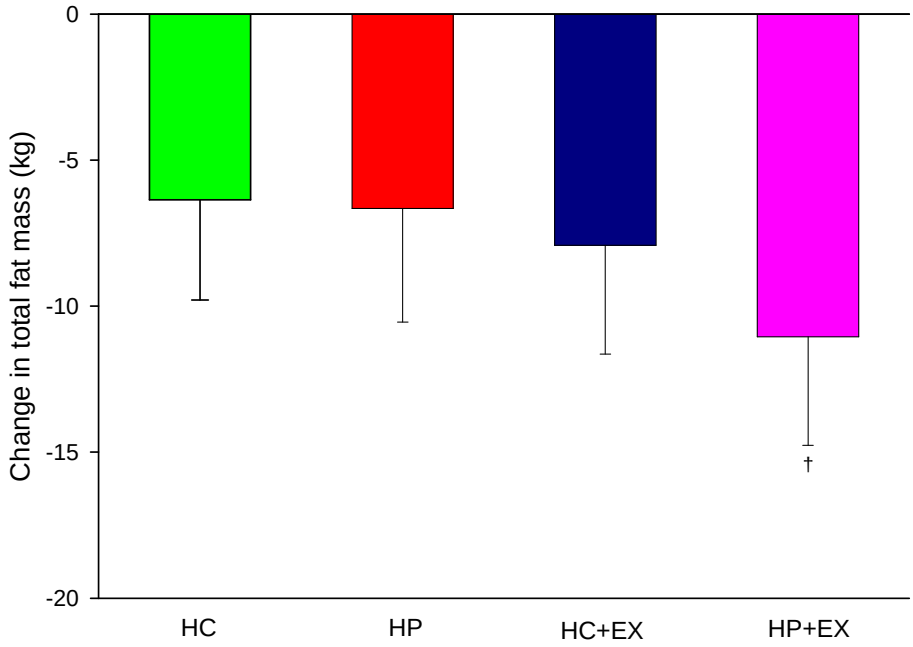

Figure 4.1. Change in total fat mass (kg) from Week 0 to after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
† P=0.005 significant main group effect: significant greater reduction in HP+EX compared to HC (P=0.006, post-hoc) and HP (P=0.022, post-hoc).

Table 5 and Figures 4 and 4.1 show there was a significant reduction in total fat mass in all treatment groups. There was trend for diet comparison for total fat mass (P=0.08); however there was a significant time x group interaction (P = 0.005), such that total fat loss was greatest in the HP + Ex group. Specifically, the combined effects of the HP diet and the EX produced a 26.1% reduction on total body fat; participants in the HC diet and EX group had a 19.8% reduction in total body fat; whilst participants in the HC and HP diet groups had a reduction in total body fat of 16.7% and 16.8%, respectively. Post-hoc analysis showed statistically significant differences in fat loss between the HP+EX and HC (P=0.006) and HP (P=0.022), whilst there was a trend for a greater reduction compared to HC+EX but did not reach statistical significance (P=0.131).

Percent Body Fat

Table 6. Percentage body fat (%) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	39.9 ± 7.5	39.5 ± 7.3	38.4 ± 7.6	39.7 ± 8.2	<0.001	0.04	0.18
Week 16	36.3 ± 9.2	35.8 ± 7.7	33.9 ± 9.0	33.2 ± 10.0			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction: significant greater reduction in HP+EX compared to HC (P=0.05, post-hoc).

[3] test of significant diet comparison (HC: n=33; HP; n=26)

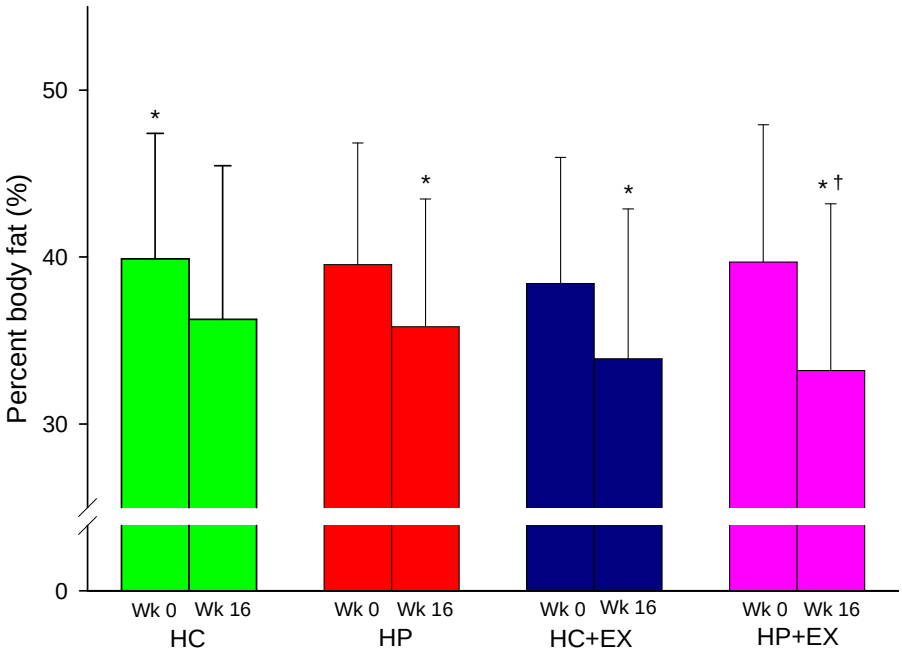

Figure 5. Percentage body fat (%) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time; † P=0.04 significant group x time interaction: significant greater reduction in HP+EX compared to HC (P=0.05, post-hoc).

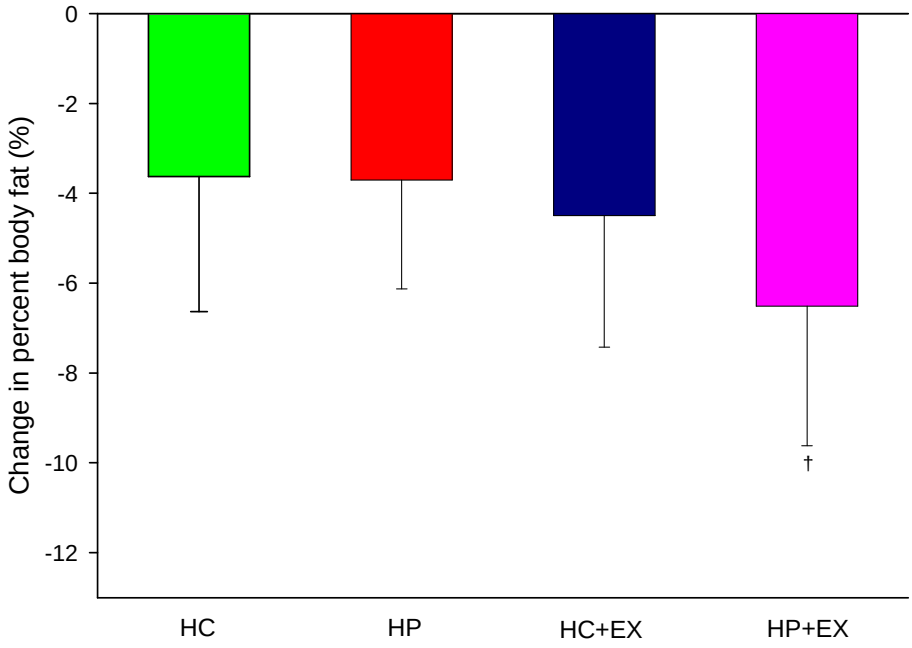

Figure 5.1. Change in percentage body fat (%) from Week 0 to after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
† P=0.04 significant main group effect: significant greater reduction in HP+EX compared to HC (P=0.05, post-hoc).

Table 6 and Figures 5 and 5.1 show there was a significant reduction in percentage body fat (%BF) in all treatment groups. There was no significant diet comparison for %BF (P=0.18); however there was a significant time x group interaction (P=0.04), such that the reduction in %BF was greatest in the HP + Ex group. Specifically, the combined effects of the HP diet and the EX produced a 6.5% (absolute) reduction in %BF; participants in the HC diet and EX group had a 4.5% (absolute) reduction in %BF; whilst participants in the HC and HP diet groups had a reduction in %BF of 3.6% (absolute) and 3.7% (absolute), respectively. Post-hoc analysis showed only differences in reductions in %BF between the HC and HP+EX treatment groups reached statistical significance (P=0.05). There was a trend for a greater reduction compared to HP but did not reach statistical significance (P=0.10), HC+EX was not significant (P=0.36).

Abdominal Fat Mass

Table 7. Abdominal fat mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	3.6 ± 0.8	3.8 ± 0.9	3.7 ± 0.7	3.9 ± 1.2	<0.001	0.12	0.15
Week 16	2.9 ± 0.9	3.0 ± 0.6	2.9 ± 0.9	2.8 ± 1.2			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

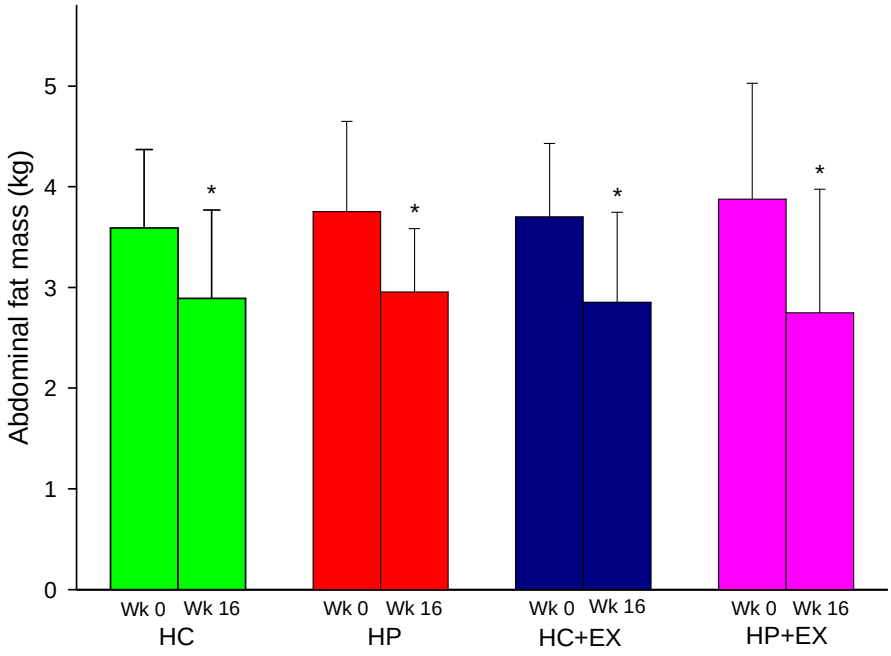

Figure 6. Abdominal fat mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 7 and Figure 6 show that there was a significant reduction in abdominal fat mass in all treatment groups (P<0.001). However, there was no significant diet comparison (P=0.15) or a time x group interaction (P=0.12).

Total Fat Free Mass

Table 8. Total fat free mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	57.9 ± 11.0	61.3 ± 13.2	64.0 ± 12.4	63.9 ± 11.3	<0.001	0.95	0.43
Week 16	55.9 ± 10.7	60.0 ± 13.1	61.9 ± 12.1	61.8 ± 10.9			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

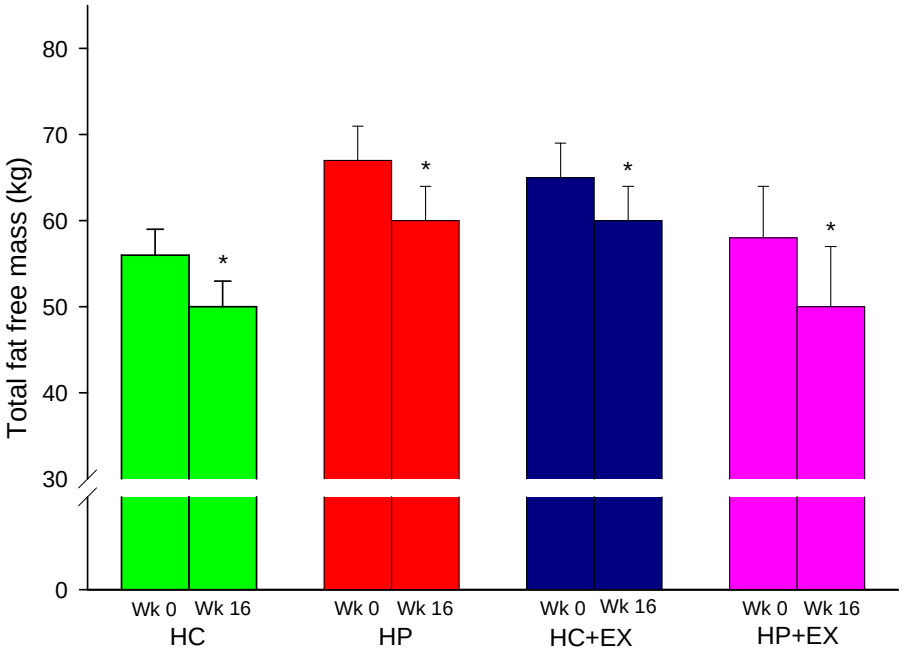

Table 7. Total fat free mass (kg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 8 and Figure 7 show that there was a significant reduction in total fat free mass in all treatment groups (P<0.001). However, there was no significant diet comparison (P=0.43) or time x group interaction (P=0.95).

Percentage fat free mass

Table 9. Percentage fat free mass (%) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	60.1 ± 7.5	60.5 ± 7.3	61.6 ± 7.6	60.3 ± 8.2	<0.001	0.04	0.18
Week 16	63.7 ± 9.2	64.2 ± 7.7	66.1 ± 9.0	66.8 ± 10.0			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction: significant greater increase in HP+EX compared to HC (P=0.05, post-hoc).

[3] test of significant diet comparison (HC: n=33; HP; n=26)

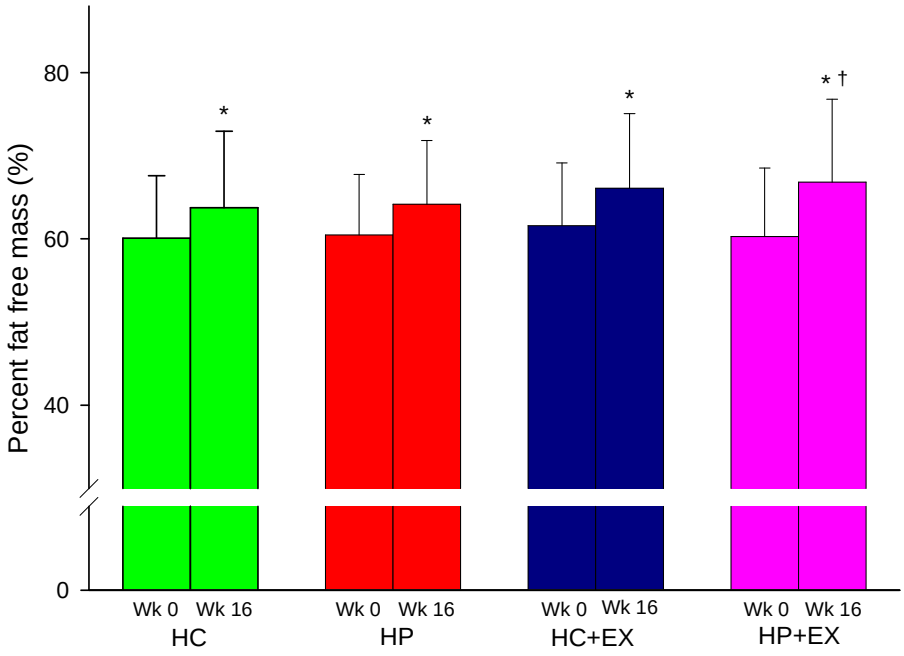

Figure 8. Percentage fat free mass (%) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time; † P=0.04 significant group x time interaction: significant greater increase in HP+EX compared to HC (P=0.05, post-hoc).

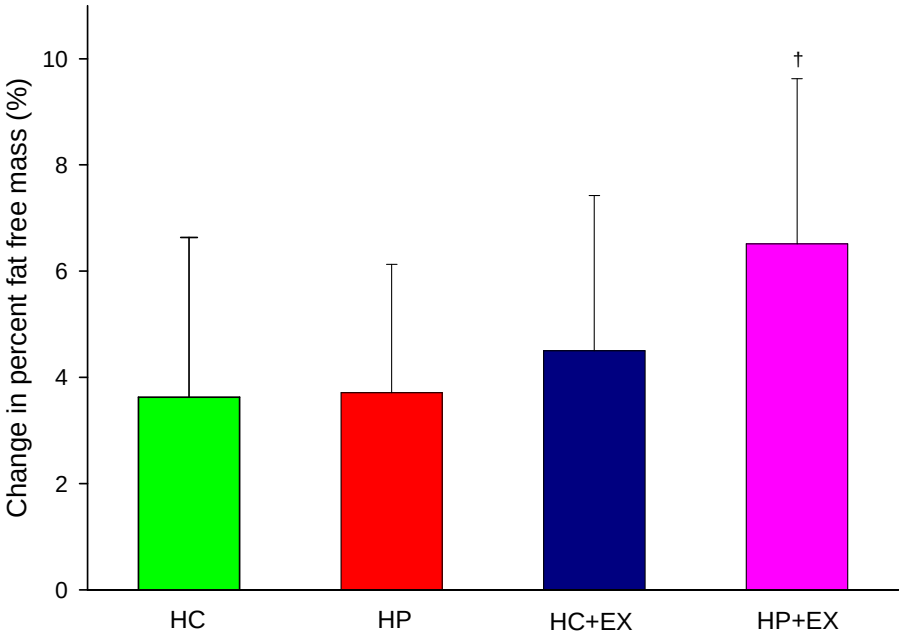

Figure 8.1. Change in percentage fat free mass (%) from Week 0 to after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
† P=0.04 significant main group effect: significant greater reduction in HP+EX compared to HC (P=0.05, post-hoc).

Table 9 and Figures 8 and 8.1 shows there was a significant increase in percentage fat free mass (%FFM) in all treatment groups. There was no significant diet comparison for %FFM (P=0.18); however there was a significant time x group interaction (P = 0.04), such that the increase in %FFM was greatest in the HP + Ex group. Specifically, the combined effects of the HP diet and the EX produced a 6.5% (absolute) increase in %FFM; participants in the HC diet and EX group had a 4.5% (absolute) increase in %FFM; whilst participants in the HC and HP diet groups had an increase in %FFM of 3.6% (absolute) and 3.7% (absolute), respectively. Post-hoc analysis showed only differences in reductions in %FFM between the HC and HP+EX treatment groups reached statistical significance (P=0.05). There was a trend for a greater reduction compared to HP but did not reach statistical significance (P=0.10), HC+EX was not significant (P=0.36).

Systolic Blood Pressure

Table 10. Systolic blood pressure (mmHg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	137 ± 12	141 ± 11	137 ± 10	138 ± 9	<0.001	0.90	0.86
Week 16	124 ± 11	125 ± 11	122 ± 9	124 ± 9			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

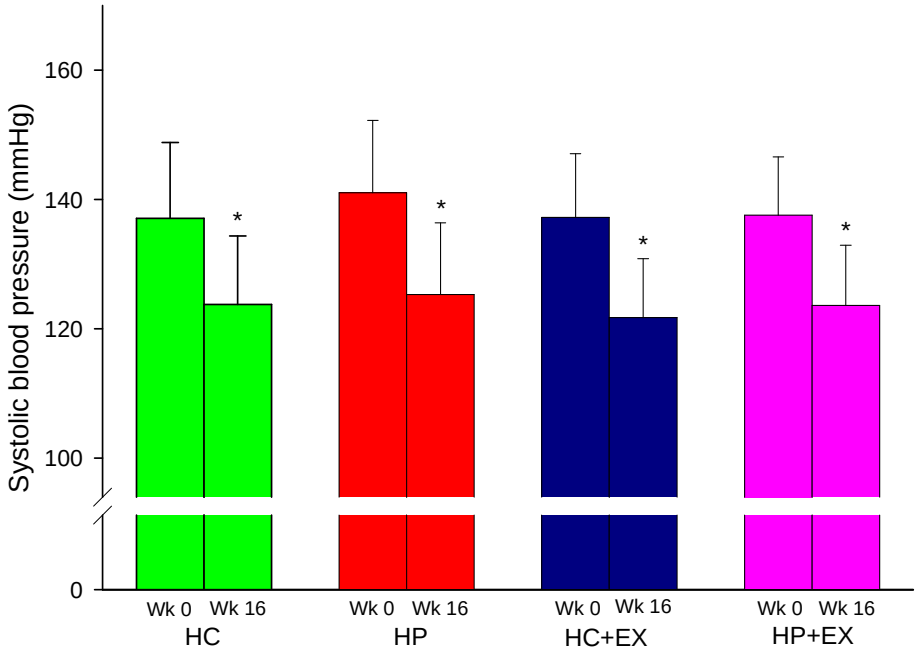

Table 9. Systolic blood pressure (mmHg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time;

Table 10 and Figure 9 show there was a significant reduction in systolic blood pressure in all treatment groups (P<0.001), with an overall reduction of 15 mmHg. However, there was no significant diet comparison (P=0.86) or time x group interaction effect (P=0.90).

Diastolic Blood Pressure

Table 11. Diastolic blood pressure (mmHg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	79 ± 9	83 ± 9	81 ± 8	79 ± 8	<0.001	0.49	0.56
Week 16	72 ± 6	74 ± 9	74 ± 6	72 ± 8			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

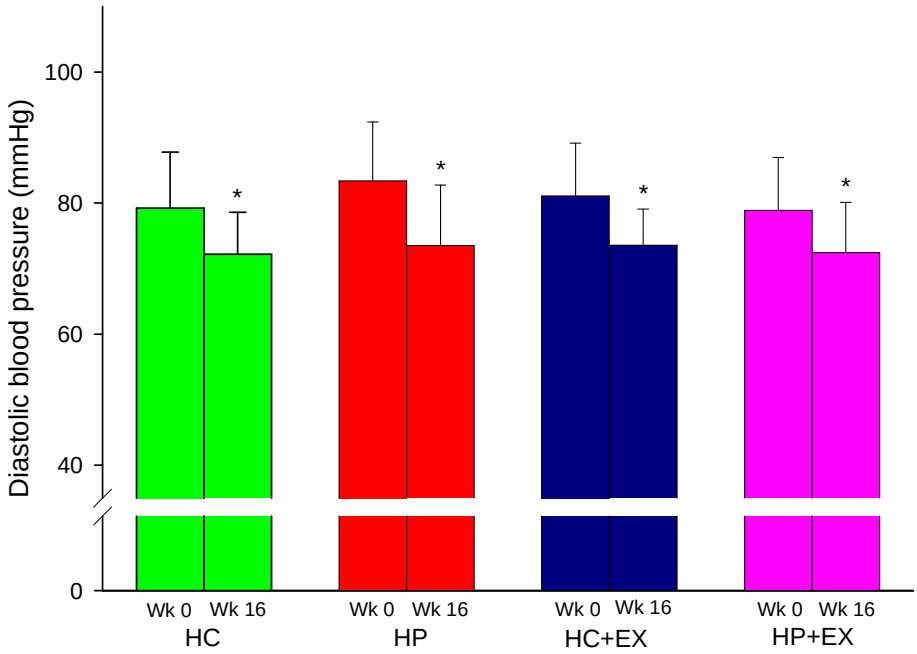

Figure 10. Diastolic blood pressure (mmHg) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 11 and Figure 10 show there was a significant reduction in diastolic blood pressure in all treatment groups (P<0.001), with an overall reduction of 6 mmHg. However, there was no significant diet comparison (P=0.56) or time x group interaction (P=0.49).

Plasma glucose

Table 12. Plasma glucose (mmol) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	9.2 ± 2.7	9.5 ± 2.9	8.7 ± 3.2	8.2 ± 2.1	<0.001	0.90	0.79
Week 16	7.1 ± 1.0	7.0 ± 1.0	6.8 ± 1.5	6.3 ± 1.0			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

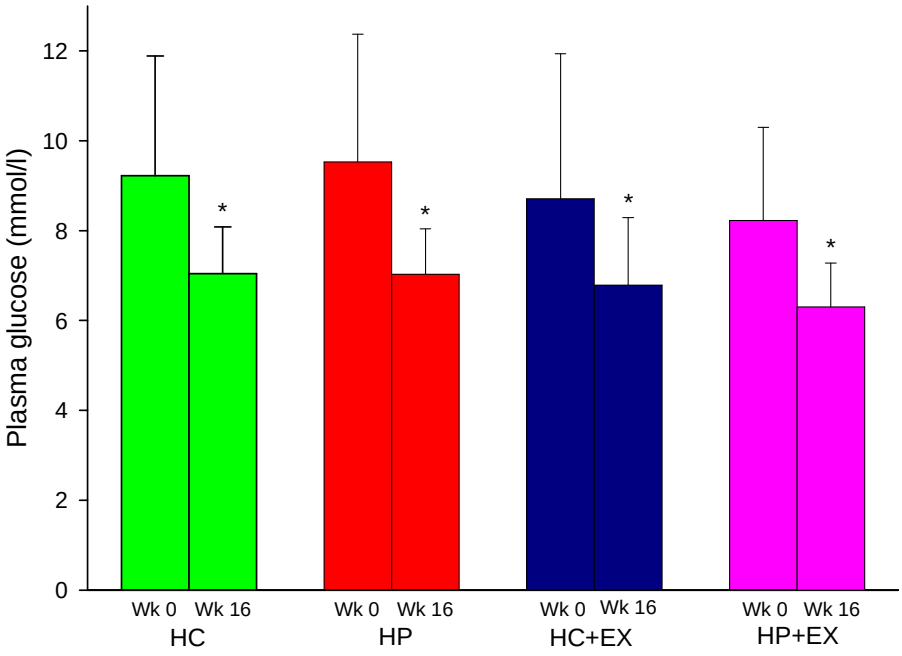

Figure 11. Plasma glucose (mmol) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 12 and Figure 11 show that there was a significant reduction in plasma glucose in all treatment groups (P=<0.001), with an overall reduction of 2.11 mmol/L. However, there was no significant diet comparison (P=0.79) or time x group interaction (P=0.90).

Glycosylated Hemoglobin (HbA1c)

Table 13. Glycosylated hemoglobin (%) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	7.6 ± 1.0	8.0 ± 1.8	7.3 ± 1.4	6.8 ± 1.0	<0.001	0.21	0.16
Week 16	6.4 ± 0.7	6.3 ± 0.9	6.2 ± 1.0	5.6 ± 0.6			

Values are mean ± SD.
[1] test for significant main effect of time
[2] test of significant group x time interaction
[3] test of significant diet comparison (HC: n=33; HP; n=26)

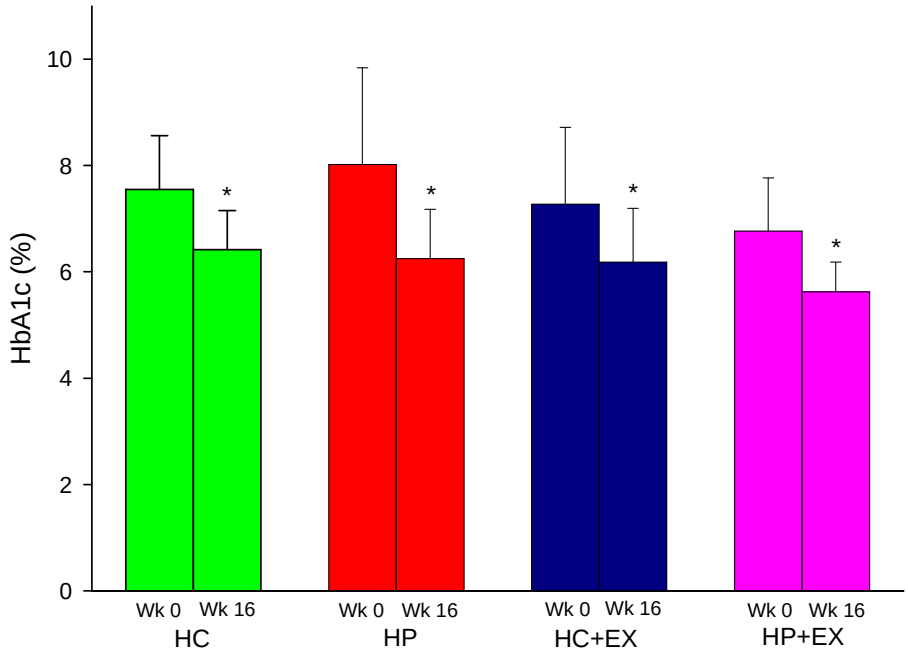

Figure 12. Glycosylated hemoglobin (mU/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P<0.001 significant main effect of time

Table 13 and Figure 12 show that there was a significant reduction in HbA1c in all treatment groups (P=<0.001), with an overall reduction of 1.25 % (absolute). However, there was no significant diet comparison (P=0.16) or time x group interaction (P=0.21).

Serum Insulin

Table 14. Serum Insulin (mU/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=16)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	15.8 ± 10.0	12.4 ± 8.6	12.3 ± 4.8	15.2 ± 8.3	<0.001	0.11	0.19
Week 16	11.8 ± 10.2	9.0 ± 8.0	8.8 ± 3.4	7.2 ± 3.6			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=32; HP; n=26)

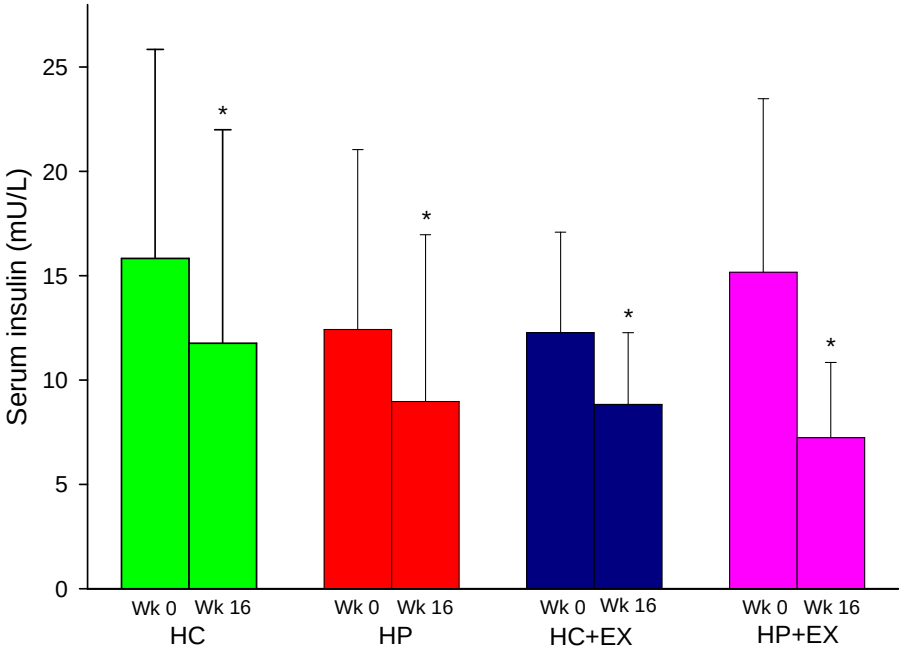

Figure 13. Serum Insulin (mU/L) at Week 0 and after 16 weeks of consuming a reduced-energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 14 and Figure 13 show there was a significant reduction in serum insulin in all treatment groups (P=<0.001), with an overall reduction of 4.7 mU/l. However, there was no significant diet comparison (P=0.19). There was a trend for a time x group interaction that did not reach statistical significance (P=0.11) by which the HP+EX had the greatest reduction in serum insulin (HC: -4.6±4.2 mU/L, HP: -3.5±2.8 mU/L, HC+EX -3.4±4.0 mU/L, HP+EX -7.9±8.1 mU/L).

Blood Lipids

Triglycerides

Table 15. Triglycerides (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	2.3 ± 1.3	2.0 ± 1.1	1.6 ± 0.5	1.8 ± 0.7	<0.001	0.70	0.91
Week 16	1.7 ± 1.5	1.6 ± 1.2	1.3 ± 0.5	1.2 ± 0.5			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=33; HP; n=26)

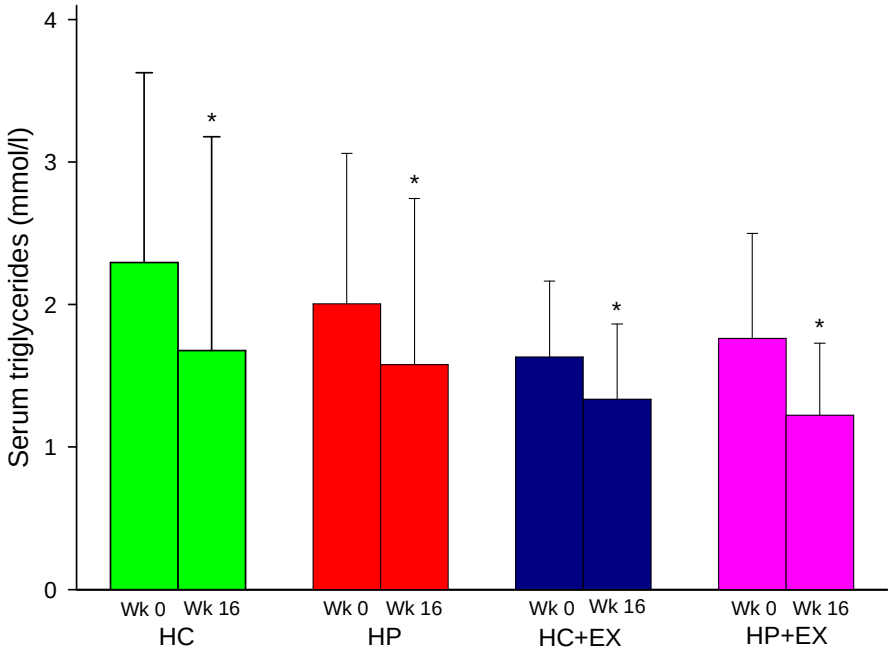

Figure 14. Triglycerides (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

Table 15 and Figure 14 show that there was a significant reduction in triglycerides in all treatment groups (P=<0.001), with an overall reduction of 0.47 mmol/l. However, there was no significant diet comparison (P=0.91) or time x group interaction (P=0.70).

Total Cholesterol

Table 16. Total cholesterol (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	4.8 ± 1.0	5.0 ± 1.1	4.3 ± 0.9	4.7 ± 0.9	<0.001	0.89	0.54
Week 16	4.1 ± 1.1	4.4 ± 1.4	3.5 ± 0.9	4.0 ± 0.8			

Values are mean ± SD.
[1] test for significant main effect of time
[2] test of significant group x time interaction
[3] test of significant diet comparison (HC: n=33; HP; n=26)

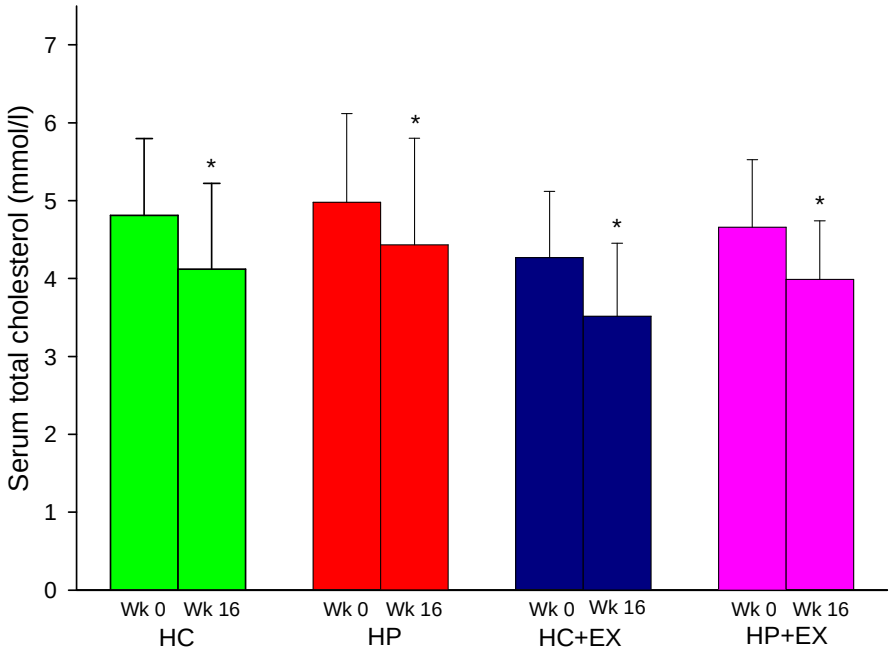

Figure 15. Total cholesterol (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P<0.001 significant main effect of time

Table 16 and Figure 15 show that there was a significant reduction in total cholesterol in all treatment groups (P=<0.001), with an overall reduction of 0.67 mmol/l. However, there was no significant diet comparison (P=0.54) or time x group interaction (P=0.89).

High-density lipoprotein cholesterol

Table 17. High-density lipoprotein cholesterol (mmol/L) at Week 0 and after 16 weeks of an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=11)	HC + EX (n=17)	HP + EX (n=13)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	1.2 ± 0.3	1.2 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.02	0.86	0.71
Week 16	1.1 ± 0.3	1.1 ± 0.3	1.0 ± 0.3	1.0 ± 0.2			

Values are mean ± SD.
[1] test for significant main effect of time
[2] test of significant group x time interaction
[3] test of significant diet comparison (HC: n=33; HP; n=24)

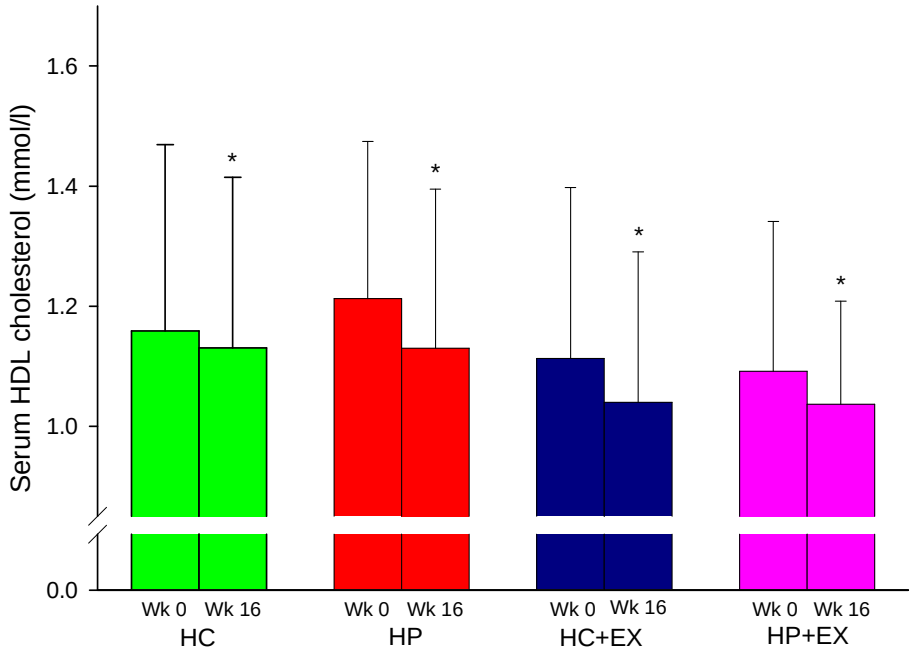

Figure 16. High-density lipoprotein cholesterol (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P<0.001 significant main effect of time

Table 17 and Figure 16 show that there was a significant reduction in high-density lipoprotein cholesterol in all treatment groups (P=0.02), with an overall reduction of 0.06 mmol/l. However, there was no significant diet comparison (P=0.71) or time x group interaction (P=0.86).

Low-density lipoprotein cholesterol

Table 18. Low-density lipoprotein cholesterol (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=13)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	2.7 ± 0.9	2.7 ± 0.9	2.4 ± 0.8	2.7 ± 0.6	<0.001	0.37	0.27
Week 16	2.4 ± 1.0	2.5 ± 1.2	1.9 ± 0.9	2.4 ± 0.6			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=30; HP; n=26)

NB. Low density lipoprotein cholesterol was not calculated in 2 persons because of a triglyceride level above 4.5 mmol/l.

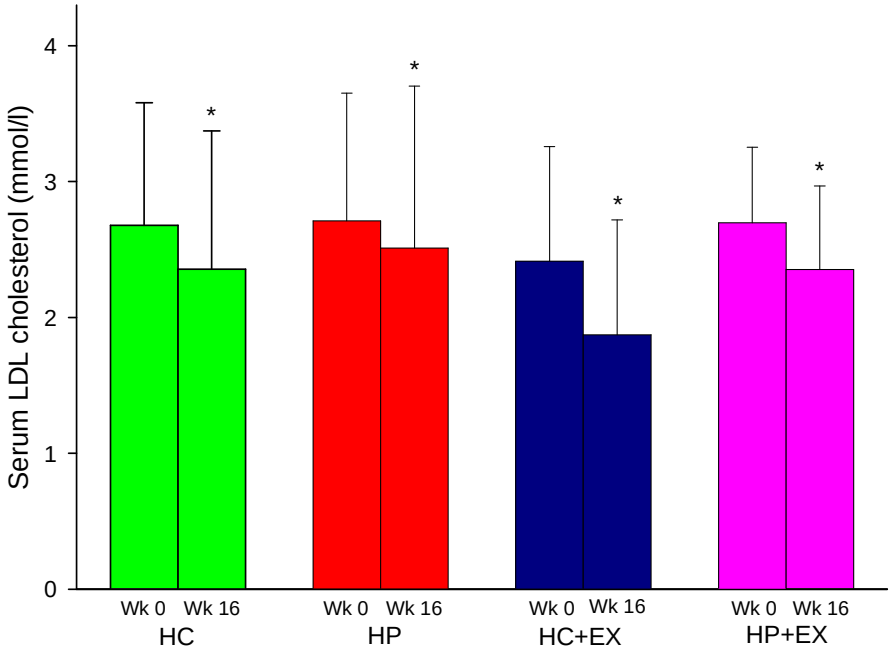

Table 17. Low-density lipoprotein cholesterol (mmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Figure 19 and Figure 17 show there was a significant reduction in low-density lipoprotein cholesterol in all treatment groups (P=<0.001), with an overall reduction of 0.37 mmol/l. However, there was no significant diet comparison (P=0.27) or time x group interaction (P=0.37).

C-reactive protein

Table 19. C-reactive protein (mg/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=10)	HC + EX (n=14)	HP + EX (n=12)	P value		
					Time effect[1]	Group x time effect[2]	Diet comparison[3]
Week 0	3.3 ± 2.4	4.5 ± 2.4	3.0 ± 2.6	4.0 ± 2.5	<0.001	0.55	>0.99
Week 16	2.6 ± 1.9	3.5 ± 1.1	1.8 ± 1.1	3.0 ± 2.5			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=30; HP; n=22)

NB. Participants with an isolated CRP concentration of >10.0 mg/L were excluded from the CRP analysis (HP,n=2;HC+Ex,n=3;HP+Ex, n=2) since concentrations above this level may be associated with the presence of infection or inflammation (25).

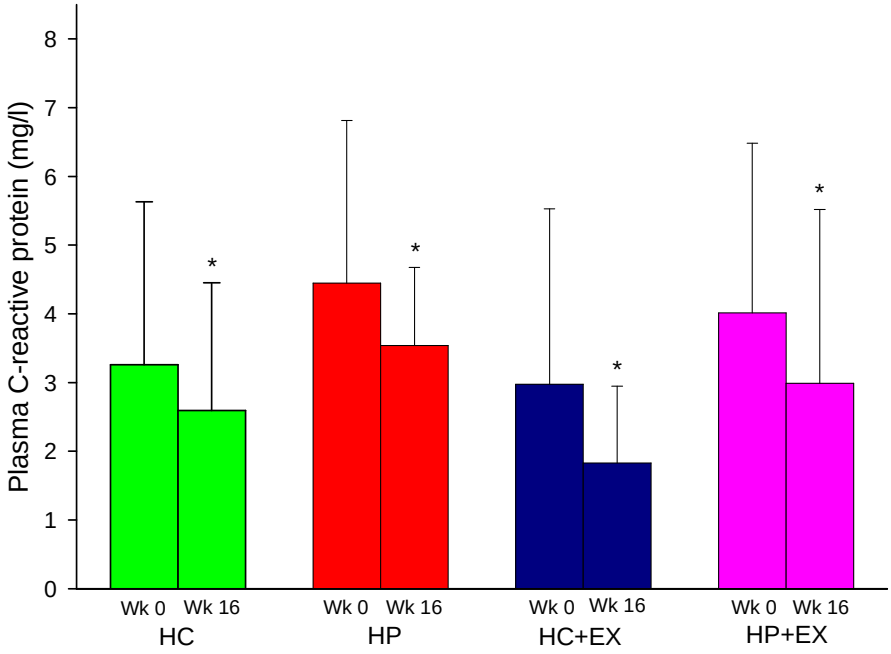

Figure 18. C-reactive protein (mg/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P<0.001 significant main effect of time

Table 19 and Figure 18 show that there was a significant reduction in C-reactive protein in all treatment groups (P=<0.001), with an overall reduction of 0.92 mg/L. However, there was no significant diet comparison (P>0.99) or time x group interaction (P=0.55).

Whole blood thiamine pyrophosphate

Table 20. Whole blood thiamine pyrophosphate (nmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	209.8 ± 38.8	198.8 ± 59.0	231.2 ± 62.6	234.0 ± 45.5	0.14	0.16	0.04
Week 16	176.7 ± 33.2	204.1 ± 38.0	213.7 ± 39.6	237.4 ± 46.0			

Values are mean ± SD.
[1] test for significant main effect of time
[2] test of significant group x time interaction
[3] test of significant diet comparison (HC: n=33; HP; n=26)

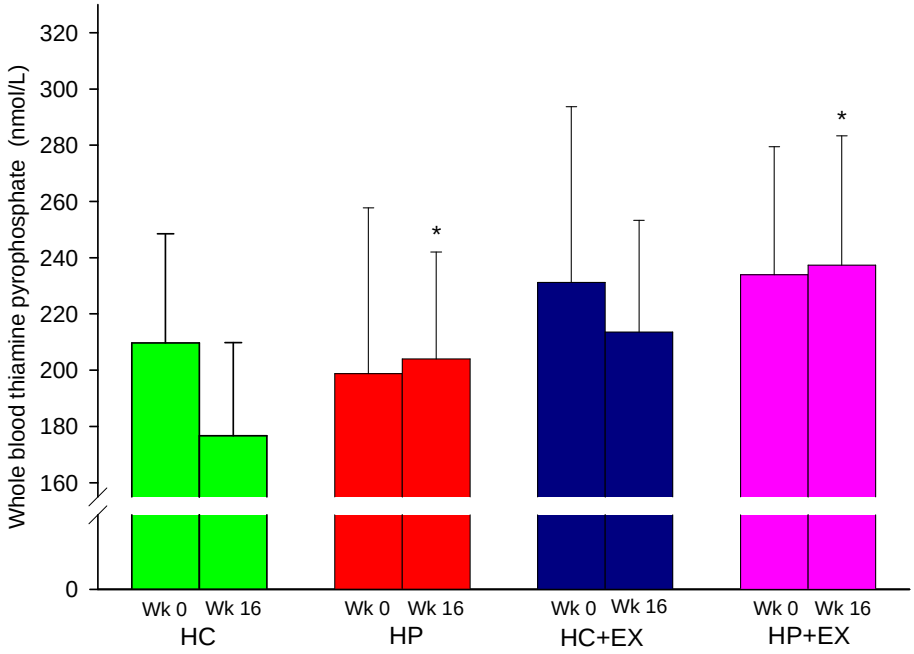

Figure 19. Whole blood thiamine pyrophosphate (nmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.
* P=0.04 significant diet comparison compared to HC diet groups

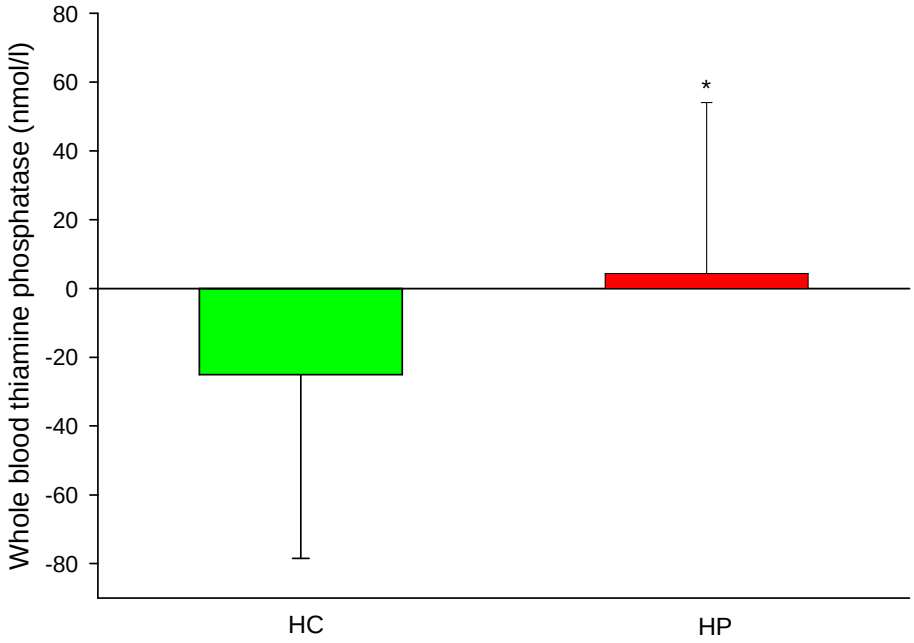

Figure 19.1. Change in whole blood thiamine pyrophosphate (nmol/L) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP), diet comparison. Values are mean ± SD.
* P=0.04 significant diet comparison

Table 20, Figure 19 and Figure 19.1 show for whole blood thiamine pyrophosphate there was a significant diet comparison (P=0.04), such that levels in the HP diet group increased by 4±50 nmol/L and decreased by 25±53 nmol/L in the HC diet group. However, there was no significant time x group interaction for this variable (P=0.16). There was no significant correlation between the change in whole blood thiamine pyrophosphate and the improvement in glycemic control (reduction in HbA1c) (r=-0.07, p=0.60). Dietary thiamine intake correlated significantly with the levels of whole blood thiamine pyrophosphate at Week 16 (r=0.26, p=0.049) and the change in whole blood thiamine pyrophosphate from Week 0 to 16 (r=0.28, p=0.03).

The reference range for whole blood thiamine pyrophosphate is between 70-200 nmol/L. In our patient population, at baseline whole blood thiamine pyrophosphate levels were in the upper limits of the normal reference range. By Week 16 in values in all participants remained ≥ 130 nmol/L which was above the lower limit for the normal reference range.

Urine Analysis

24-hr urinary sodium excretion (mmol/24 hr)

Table 21. 24-hr urinary sodium excretion (mmol/24 hr) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=15)	HP (N=12)	HC + EX (n=17)	HP + EX (n=12)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	185.9 ± 82.5	177.0 ± 90.6	232.9 ± 95.2	210.5 ± 79.3	0.013	0.37	0.95
Week 16	175.9 ± 95.1	169.4 ± 77.3	184.8 ± 67.8	162.3 ± 77.1			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=32; HP; n=24)

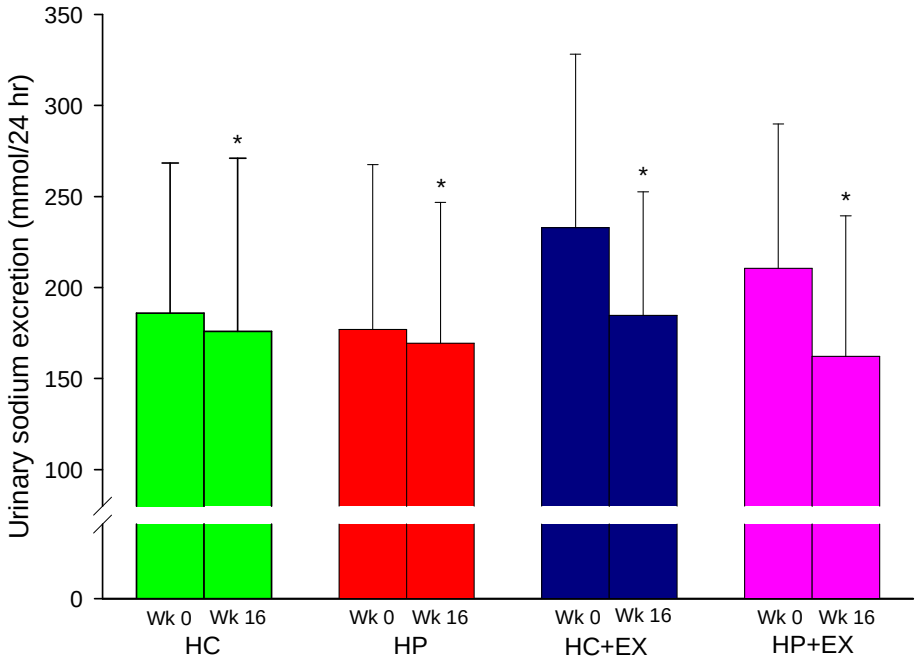

Figure 20. 24-hr urinary sodium excretion at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P=0.013 significant main effect of time

Table 21 and Figure 20 show was a significant reduction in 24-hr sodium excretion in all treatment groups (P<0.001), with an overall reduction of 28.7±80.6 mmol/24 hr. However, there was no significant diet comparison (P=0.95) or time x group interaction (P=0.37).

24-hr urinary potassium excretion (mmol/24 hr)

Table 22. 24-hr urinary potassium excretion (mmol/24 hr) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=15)	HP (N=12)	HC + EX (n=17)	HP + EX (n=12)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	87.3 ± 30.6	75.6 ± 34.1	99.6 ± 35.8	91.1 ± 33.3	0.008	0.26	0.049
Week 16	88.9 ± 31.9	95.6 ± 27.9	104.6 ± 33.8	123.3 ± 23.9			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=32; HP; n=24)

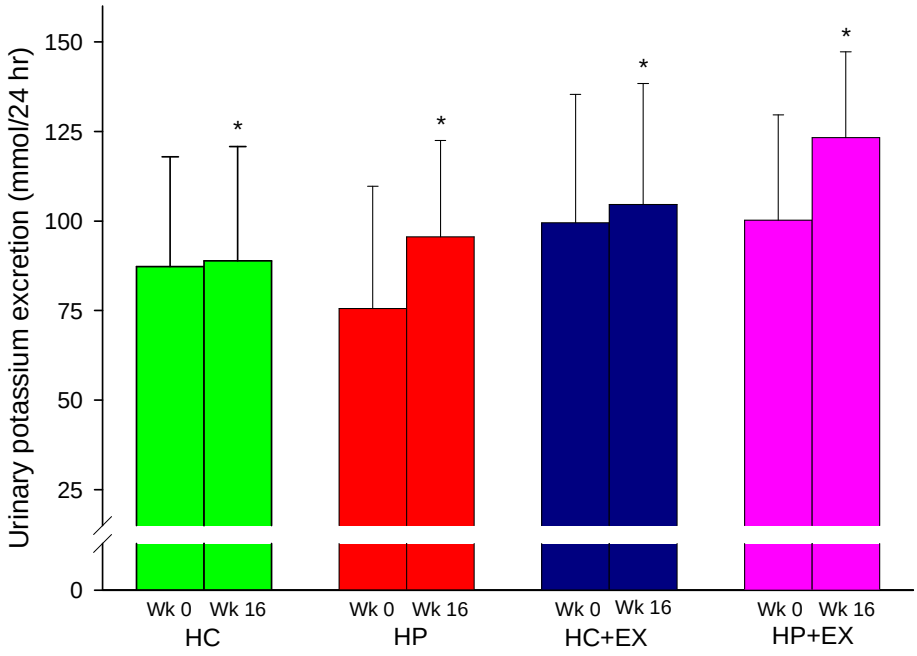

Figure 21. 24-hr urinary potassium excretion at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P=0.008 significant main effect of time

Table 22 and Figure 21 show was an overall significant increase in 24-hr potassium excretion across treatment groups (P=0.008). However, there was no significant main effect of a time x group interaction (P=0.26). However, there was a significant diet comparison (P=0.049), such that levels increased to a greater

extent in the HP diet group (21.6 ± 32.6 mmol/24hr) compared to the HC diet group (3.4 ± 32.6 mmol/24 hr).

24-hr urinary calcium excretion (mmol/24 hr)

Table 23. 24-hr urinary calcium excretion (mmol/24 hr) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX).

Group	HC (n=15)	HP (N=12)	HC + EX (n=17)	HP + EX (n=12)	Time effect[1]	P value Group x time effect[2]	Diet comparison[3]
Week 0	5.3 ± 2.8	5.0 ± 3.4	6.1 ± 3.2	4.5 ± 4.5	0.006	0.41	0.29
Week 16	4.6 ± 3.0	4.1 ± 2.3	4.4 ± 2.7	4.2 ± 2.5			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=32; HP; n=24)

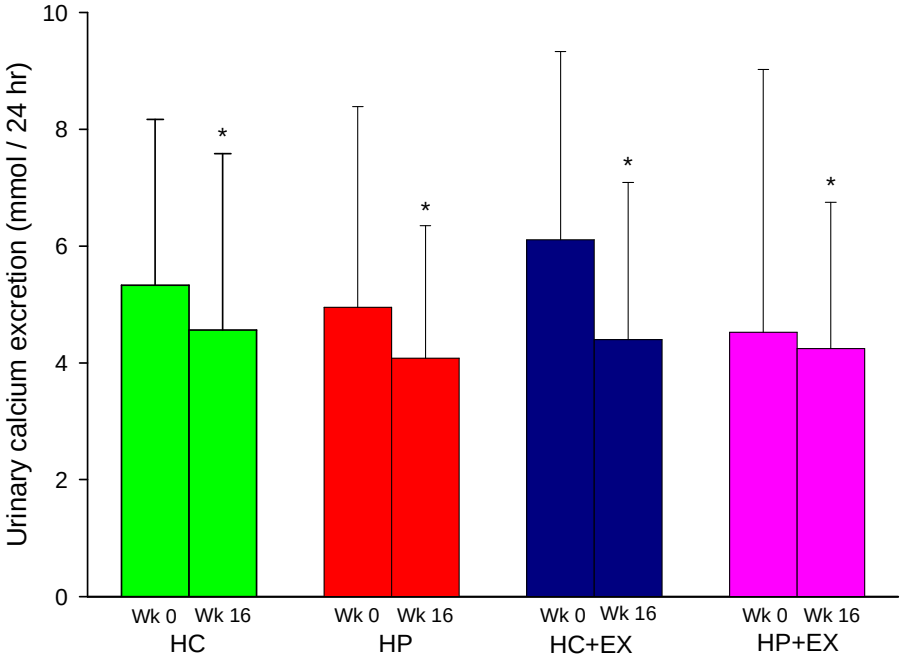

Figure 22. 24-hr urinary calcium excretion at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

* P=0.006 significant main effect of time

Table 23 and Figure 22 show that there was a significant reduction in urinary calcium in all treatment groups (P=0.006), with an overall reduction of 1.0±2.3 mmol/24 hr. However, there was no significant diet comparison (P=0.29) or time x group interaction (P=0.41).

Calculated Glomerular filtration rate

Table 24. Calculated glomerular filtration rate (ml/min^{-1}/1.73 m^2)(24) at Week 0 and after 16 weeks of consuming an energy restricted, high carbohydrate, low protein, low fat diet (HC) or an isocaloric high protein, low fat diet (HP) with or without resistance exercise training (EX). Values are mean ± SD.

Group	HC (n=16)	HP (N=12)	HC + EX (n=17)	HP + EX (n=14)	P value Time effect[1]	P value Group x time effect[2]	P value Diet comparison[3]
Week 0	81.3 ± 15.2	83.6 ± 18.9	79.1 ± 13.3	76.9 ± 11.2	<0.001	0.353	0.60
Week 16	94.2 ± 19.6	90.1 ± 21.6	84.1 ± 17.3	84.8 ± 14.7			

Values are mean ± SD.

[1] test for significant main effect of time

[2] test of significant group x time interaction

[3] test of significant diet comparison (HC: n=31; HP; n=25)

Table 24 show there was a significant increase in calculated glomerular filtration rate in all treatment groups (P<0.001). However, there was no significant main effect of time x group interaction (P=0.353) or diet comparison (P=0.60). There was no significant correlation between the change in whole blood thiamine pyrophosphate and the calculated glomerular filtration rate (marker of renal function) (r=-0.063, p=0.634).

Urinary albumin excretion rate

For the combined dietary groups, eight participants did not provide a complete 24-hr urinary sample at either Week 0 (HC=2; HP=4) or Week 16 (HP=2) and were exclude from the analysis for urinary albumin excretion rate.

At Week 0, for participants with a normoalbuminuria (≤19.9 μg/min) there was no significance difference in the urinary albumin excretion rate between the combined HC and HP diet groups (HP [n=14] 5.7 ± 4.1 μg/min vs HC [n=25] 5.5 ± 4.1 μg/min; P=0.49). Overall, there was no significant main effect of time for urinary albumin excretion rate (P=0.23); there was trend for a greater reduction for urinary albumin excretion rate in HP compared to HC, although this did not reach statistical significance (HP -2.9 ± 3.0 μg/min, HC 0.5 ± 7.8 μg/min; P=0.18 diet comparison). Of the participants classified as normoalbuminuric, only 1 participant in the HP diet group had an increase in urinary albumin excretion rate to a level of microalbuminuria classification.

Of the 12 participants (HC=4, HP=8) with microalbuminuria at Week 0, both diet groups had significant reductions in the urinary albumin excretion rate from Week 0 to Week 16 (HP: 48.9 ± 34.7 μg/min to 24.9 ± 27.2 μg/min, HC 56.1 ± 41.3 μg/min to 40.6 ± 52.4 ± 52.4 μg/min; P=0.005 for time). There was no differential effect of diet (P=0.62). Of the 8 and 4 participants in the HP and HC diet groups with microalbuminuria respectively, by Week 16 the urinary albumin excretion rate had decreased to values classified as normoalbuminuria in 6 and 2 participants in the HP and HC diet groups respectively; the remaining 4 participants maintained their microalbuminuria status.

Medication changes

Overall, for oral hypoglycemic medication, 9 participants (HC=2, HP=1, HC+Ex=4, HP+EX=2) had a reduction and 1 participant in the HC group had an increase in medication dosage. For antihypertensive medication, 4 participants in the HC+Ex group and 2 in the HP+Ex had decreases, whilst 1 participant in the HC had an increase in medication. For lipid-lowering medication, 1 participating in the HP+Ex group had a reduction. Overall, there was no significant difference in the proportion of participants that had changes in medications across the 4 treatment groups ($P \geq 0.08$, chi-square analysis); or between the combined HP diet and HC diet groups ($P \geq 0.26$, chi-square analysis).

Thiamine Food Analysis

Table 25. Thiamine values of provided foods

Food	Thiamine (mg/100g)
• Foodland beef strips, raw, trimmed, fresh	• 0.06
• Sunblest wholemeal bread	• 0.69
• Noble Rise white with oats, bread	• 0.62
• Uncle Toby's Nut Feast	• 0.13
• Uncle Toby's Traditional Oats	• 0.18
• Sanitarium Weet-bix	• 2.10
• Uncle Toby's Protein Plus Mix	• 0.25
• Ryvita crispbreads	• 0.16
• Hans, 97% fat free champagne leg ham, fresh *	• 0.68 ± 0.11 (0.60-0.75)
• Pork loin, cooked, trimmed (lean) *	• 0.70 ± 0.07 (0.65-0.75)

* Foods were measured at 2 separate time points throughout the intervention. Values represent mean ± standard deviation (range)

4. Results Summary

Overall, the results of this study showed that a 16 week weight loss intervention incorporating a higher protein, high pork diet and resistance exercise training was more effective for weight loss and improving body composition by enhancing fat loss compared to lifestyle interventions incorporating either a higher protein, high pork diet or a high carbohydrate, low protein diet without resistance exercise. There was also some evidence the higher protein, high pork diet and resistance exercise lifestyle plan was more effective for improving weight loss and body composition compared to a high carbohydrate, low protein and resistance exercise lifestyle plan; however due to relatively small participant numbers, statistical significance could not be determined and this cannot be concluded with absolute certainly and further research is require to confirm this result.

Weight loss following the lifestyle programs incorporating a higher protein, high pork diet or a high carbohydrate, low protein diet either with or without resistance exercise had similar benefits and substantially improved blood glucose control and biomarkers of heart health. There was also some preliminary evidence that a higher protein, high pork and resistance exercise program had the greatest improvement in improving fasting insulin levels (a marker of insulin sensitivity). This has important potential implications for improving metabolic health in patients with type 2 diabetes and warrants further investigation.

The lifestyle program incorporating a higher protein, high pork diet also had additional nutritional benefits for improving thiamine intake and status. Relative to the high carbohydrate, low protein weight loss programs, the higher protein, high pork lifestyle programs had significantly greater improvement in thiamine status. We found no adverse effects on markers of renal function, sodium or calcium excretion between the high protein, high pork or the high carbohydrate, low protein weight loss diet interventions.

5. Application of Research

The work provides evidence that a lifestyle program with a high protein intake from pork combined with resistance exercise may provide advantages for weight loss, improvements in body composition and some additional benefits for improving insulin sensitivity in overweight and obese patients with type 2 diabetes. It also provides additional evidence that a weight loss diet plan incorporating a high intake of pork protein may offer additional nutritional advantages for promoting thiamine status over a high carbohydrate diet.

Collectively, this evidence suggests that lean pork is a valuable source of protein within higher protein lifestyle patterns for weight management in type 2 diabetes. Once published, it will support the case for the choice of higher protein, high pork dietary patterns as a healthy option in clinical practice. These outcomes have relevance to the Australian Pig Industry for the development lean pork food products consistent with a high protein lifestyle program.

6. Conclusion

Collectively, this study provides preliminary evidence suggesting that a high protein diet that incorporates a high pork meat intake combined with resistance exercise training has greater efficacy as a lifestyle program for improving weight management, improving body composition, cardiovascular disease risk and thiamine status in overweight and obese patients with type 2 diabetes.

7. Limitations/Risks

Although significant time x group interaction effects were observed for weight and fat loss, with the high protein, high pork diet and resistance exercise lifestyle intervention having the greatest benefits for these outcomes, there was insufficient power to detect statistically significant differences between this treatment group and all the other lifestyle interventions. Therefore the conclusions drawn from these results should be taken with some caution and further research is required to confirm these results.

There was also insufficient power to detect a statistically significant treatment effect for fasting serum insulin (a marker of insulin resistance) with a suggestion that a lifestyle intervention combining a high protein, high pork diet with resistance exercise training may be most efficacious for improving insulin sensitivity. This has important potential implications for improving metabolic health in patients with type 2 diabetes and warrants further investigation.

8. Recommendations

As a result of the outcomes in this study the following recommendations have been made:

- Both an energy restricted higher protein diet incorporating high pork and a high carbohydrate, low protein diet can be used as effective weight loss strategies to improve glycemic control and cardiovascular disease risk markers, without any adverse effects on renal function in overweight and obese patients with type 2 diabetes.

- There is preliminary evidence suggesting that a higher protein, high pork diet may enhance weight loss and induce greater improvements in body composition by increasing fat loss compared to a high carbohydrate, low protein diet in overweight and obese patients with type 2 diabetes; and that these effects are further magnified with the addition of resistance exercise training. There was also preliminary evidence from this study that a lifestyle program of a higher protein, high pork diet combined with resistance exercise training may have greatest benefits for improving insulin sensitivity in this patient population. We recommend additional research to confirm these preliminary results.

- During energy restriction for weight loss, a higher protein, high pork diet may be a more appropriate dietary approach for improving thiamine status.

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