Title: Does Meal-based Enhancement of Protein Intake Augment Long-term Responses to Sarcopenic Obesity Reduction? – NPB #16-144

Investigator: Connie W. Bales, PhD, RD

Institution: Duke University Medical Center

Date Submitted: 12/4/18

Industry Summary:

This research (the SUPER-POWR trial: Sustained Use of Protein Extends Renewal: Protein Optimization in Women Enables Results) was conducted to explore the impact of a diet rich in high quality protein, including generous amounts of lean pork, on long-term outcomes related to physical function in obese older black and white women following an obesity reduction treatment. This was a small pilot study, enrolling 25 older (≥60 years of age) women who were obese and functionally limited; 64% of the women were African American, due to intentional over-sampling. The specific objectives of the study were to compare a Control (RDA-level protein) weight loss diet with a diet including generous high quality protein at every meal of the day (Protein group) and to follow changes in body weight, body composition and function, as well as markers of renal function and glucose levels, over 9 months in these two groups. The results of this study are pending a full statistical analysis but some descriptive information is available now. The average weight loss achieved during the trial was 5.7 kg (5.9%) at 6 months; however, mean weight loss was only 2.9% at 9 months. Most of weight loss was as fat, with body fat (on average) reduced by about 4 kg in controls and 5.2 kg in the protein group at the 6-month point. Lean mass effects were slight in both groups (loss of < 1 kg). No detrimental changes in renal function were encountered during the trial. To date, the main lessons of the trial to date are: (1) Following a higher protein diet with lean pork consumed twice daily is feasible, acceptable and beneficial for obese older women, both black and white. (2) Despite high motivation and strong dietitian support, many older women struggle in their efforts to reduce obesity. (3) Our hypothesis that extending the intervention duration would boost weight loss was not confirmed, at least not in this very small cohort. On average, weight loss did not improve between 6 and 9 months in either group. (4) Although amount of weight loss fell short of the goal for many participants, they nonetheless experienced strongly beneficial changes in their body composition (decrease in percent body fat). Additionally, this study allows us the opportunity to further investigate an important area of interest for the National Pork Board, namely racial disparities. An important next step is to combine the SUPER POWR data with data from POWR UP and analyze for racial disparities in a sample with greater power. This study, along with the parent study (POWR-UP) is the first trial of enhanced protein (30 grams protein per meal) using pork as the protein source to preserve muscle during a weight loss intervention. The successful confirmation of feasibility demonstrates the very high acceptance of pork in the diets of women following obesity reduction treatments, including the target population of African American women.

Connie W. Bales, PhD, RD
  Duke University School of Medicine
  bales001 @mc.duke.edu

Scientific Abstract: This should be a scientific description limited to one page in length to describe your project and its results.

This exploratory pilot trial extends the study of meal-based protein enhancement of weight reduction in participants with sarcopenic obesity by assessing the long-term (9-month) outcomes. The long-term impact of weight loss has rarely been studied in older adults. A total of 25 obese (BMI $\geq$30 kg/m^2) women $\geq$ 60 years with functional limitations were randomized in a 1:1 ratio to Control (C-WL) or Protein (P-WL) for a 9-month intervention**.** Assessments were conducted at 0, 3, 6, and 9 months for the primary outcomes of lean mass and function (6-minute walk) and secondary outcomes of Short Physical Performance Battery, body fat, waist circumference, 8 ft up and go, 30 sec chair stand, hand grip, and feasibility factors, with kidney function (GFR), glucose, and insulin assessed at 0, 6, and 9 months. The final results of the trial are pending full statistical analysis, so current findings must be considered very preliminary. Additionally, the very small size of this pilot project limits our power to detect group differences. The average weight loss achieved during the trial was 5.9% at 6 months; however, mean weight loss was only 2.9% at 9 months. Most of weight loss was as fat, with body fat (on average) reduced by about 4 kg in controls and 5.2 kg in the protein group at the 6-month point. Lean mass effects were slight in both groups (loss of < 1 kg). No detrimental changes in renal function were encountered during the trial. To summarize, the findings show that a higher protein diet with lean pork consumed twice daily is feasible, acceptable and beneficial for obese older women, both black and white. However, despite high motivation and strong dietitian support, many participants struggled in their efforts to reduce body weight. The hypothesis that a longer intervention duration would boost weight loss was not confirmed in this very small cohort. On a positive note, although amount of weight loss fell short of the goal, many participants nonetheless experienced strongly beneficial changes in their body composition. The results of this trial will contribute important knowledge to the field by establishing the efficacy, metabolic impact, and safety of increased amounts of high quality protein at every meal as a part of a long-term weight reduction intervention designed to improve physical function. Although larger trials are needed to confirm or refute our findings on weight loss success, these results bring recognition to African American women as a group with high rates of obesity and less robust response to traditional weight loss interventions.

Introduction:
    Recent research by our team and others indicates that quantity, quality and meal distribution of protein can be a major determinant of health in older adults. Age-related differences in muscle anabolism suggest protein intake recommendations for older adults need to be revised upwards and balanced protein at meals is being included in these recommendations. Beginning in middle age, most adults experience sarcopenia, likely related to age-associated blunting of the anabolic response to nutritional stimuli, as well as a low protein intake.
    This research targets protein-based interventions for sarcopenic obesity, a condition in which sarcopenia "co-occurs" with an elevated accumulation of body fat." Currently in the U.S., the obesity rate in women (42.3%) surpasses that of men (36.6%) with aging (>60 yrs). Indeed, the consequences of obesity are more severe in women compared to men, so that relatively small losses of muscle strength translate into serious limitations on mobility. Relative to men of the same age, women have more fat mass and less muscle strength and are more likely to develop functional limitations as a result
    Obesity treatments in older adults have been deemed controversial until recently, with

concerns that the benefits might be offset by the loss of lean mass and related functional declines over time. A growing body of research is giving encouragement that successful and safe weight loss can be achieved in obese older adults. However, the long-term effects of these interventions remain to be determined; very few studies to date have followed these interventions for intervals longer than 6 months.

Finding that strong health benefits accrue from regular inclusion of (pork) protein in the diet could lead to revolutionary changes in the way nutritionists, and consumers, think about meal planning and cause pork to be more commonly included. This study explored long-term feasibility and efficacy of a protein (pork)-supplemented weight loss diet for in a critically important demographic group—obese older women, including 64% African Americans.

Objectives:

This was a small pilot study designed to explore a long-term weight loss intervention in older women, with an over-sampling of African American participants. The objectives were:

1. To assess the long-term influence of an anabolic diet with regards to physical function and retention of lean mass during weight loss.

2. To assess the long-term influence of an anabolic diet on metabolic markers of glucose handling and kidney function during weight loss.

Materials & Methods:
Participants and Study Design

Participants were screened for eligibility; exclusion criteria included: body weight >495 lbs. (limits of BodPod); glomerular filtration rates (GFR) less than 60 mL/min; diagnosis of moderate/severe coronary artery disease; presence of unstable or symptomatic life- threatening illness; neurological causes of functional impairments. Study eligible obese (BMI $\geq$30 kg/m^2) women $\geq$60 years with functional limitations were randomized in a 1:1 ratio into one of two groups as shown below:

Study Design
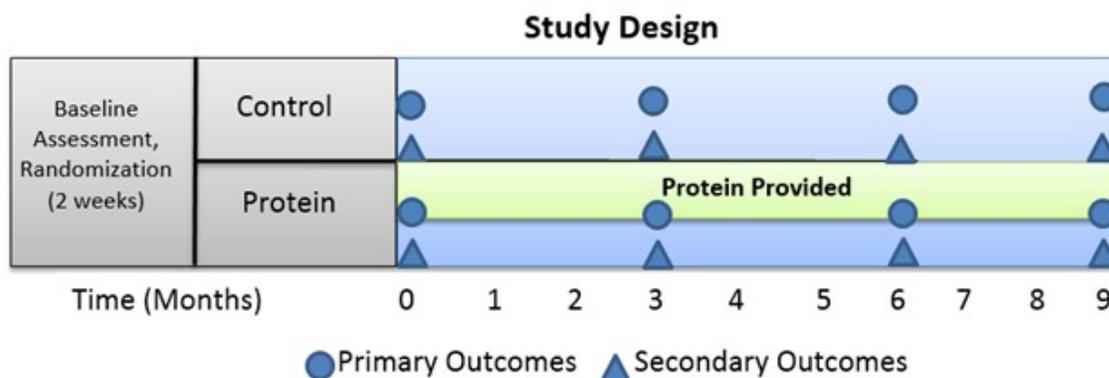
The Control group (C-WL) was prescribed a reduced kcal diet to produce a 10% weight loss from baseline and with a protein intake of 0.8 g/kg/day. The Protein group (P-WL) was prescribed a reduced kcal diet to produce a 10% weight loss from baseline and with a protein intake of 1.2 g/kg/day; the daily protein was distributed to provide 30 g high quality protein at each of 3 meals.

Interventions

Individualized calorie prescriptions were derived from estimated total energy expenditure (TEE) based on equations published by the Institute of Medicine:

TEE for OB Women: 387 – (7.31 x Age [y]) + PA x (10.9 x Weight [kg] + 660.7 x Height [m])

All subjects met twice with an interventionist and then began weekly group sessions designed to enhance diet compliance, including weekly weigh-ins as well as group support, goal setting, self-monitoring, stress management, problem solving, relapse prevention, daily diet journaling, email/phone reminders, and tutorials for on-line tools during the entire 9-month intervention. Participants were provided a low-dose multivitamin/mineral supplement (General Nutrition Center) and a calcium/vitamin D supplement (Glaxosmithkline Laboratories) that to complement the calculated levels of calcium/vitamin D in the diet and to standardize supplement intake (no other supplements were permitted). No formal exercise was included in the intervention; however, participants were encouraged to continue being active as tolerated.

Outcomes:

Primary (Lean mass (BodPod®) and function (6-minute walk) outcomes were assessed at 0, 3, 6, and 9 months. Secondary outcomes (Short Physical Performance Battery, body fat, waist circumference, 8 ft up and go, 30 sec chair stand, hand grip, mood and quality of life indicators, and feasibility factors were assessed at these same time points and glucose handling and kidney function were assessed at 0, 6, and 9 months. Adherence was monitored by weekly in–person weigh-ins and weekly food diaries monitored for calorie and protein intake. Additionally, a computerized nutrient analysis of 3-day food diaries was conducted every 3 months.

Results:

As illustrated in Figure 1, we screened 45 potential participants and enrolled 25 eligible women into the trial. (Because dropouts are common in this high-risk population, we enrolled 5 more participants than the n = 20 specified in the grant proposal). Table 1 provides baseline information and shows the very similar attributes of the two groups, including Class II level obesity and moderate functional impairment (score ~ 9 out of 12 on SPPB). Of total participants, 64% are African American, with randomization blocked so that they were equally represented, with 66.7% in C-WL and 61.5% in P-WL.

Physical function and retention of lean mass

The C-WL and P-WL groups achieved similar rates of weight loss. In the combined groups, the average weight loss achieved during the trial was 5.9% at 6 months; however, mean weight loss was only 2.9% at 9 months. Loss of body fat was substantial, reaching with losses of 3.6 kg and 3.2 kg at 6 and 9 months in C-WL and 5.2 kg and 4.5 kg at 6 and 9 months in the P-WL group. The loss of lean mass was minimal, less than 1 kg in either group.

Glucose handling and kidney function

Kidney function was assessed by GFR at baseline, 6 and 9 months. None of the 25 participants, including the 4 participants with enrollment GFRs between 45 and 60, experienced a deterioration of renal function markers during the trial. Analysis of blood glucose results during the trial is pending.
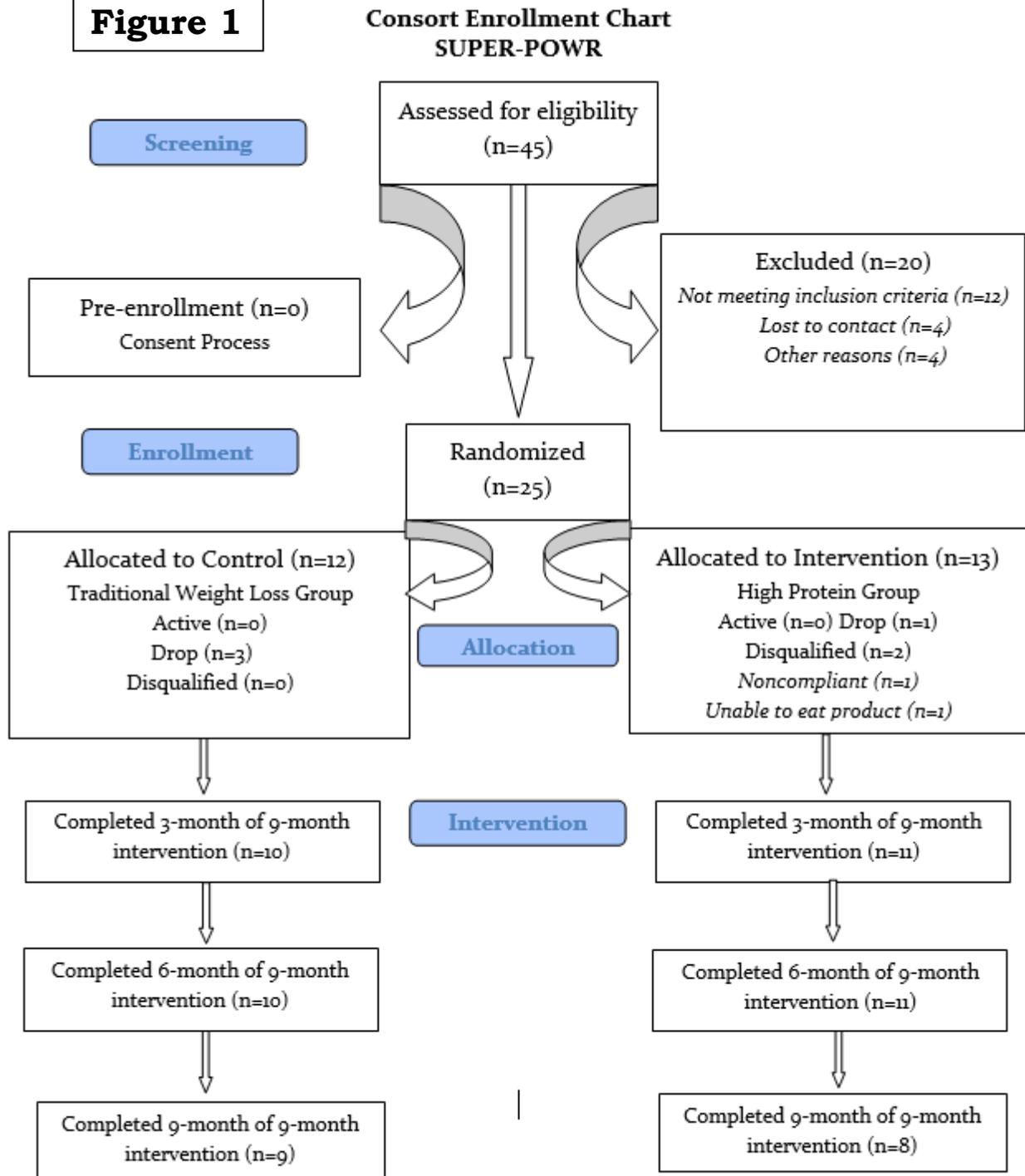
Discussion:

Now that the study is completed and the data are cleaned, the statistical work will be extended and confirmed. Upcoming analyses will consider an array of function test results and a large battery of information on mental health and quality of life attributes. Our plan for publishing the outcomes of this small pilot trial focuses on the rich amount of data collected on each participant and the unique opportunity to explore predictors and mediators of intervention success/failure in African American women. Ethnic disparities in intervention outcomes including weight loss, function, and body composition and predictors of intervention success and adherence will be explored. Although larger trials are needed to confirm or refute our findings on weight loss success, these results bring recognition to African American women as a group with high rates of obesity and less robust response to traditional weight loss interventions. An important next step will be for us to combine the SUPER POWR data with data from POWR UP and analyze for racial disparities in a sample with greater power.

Table 1. Mean baseline Characteristics, N = 25 participants		
	Control (n=12)	Protein (n=13)
Age (yrs)	66.9	62.6
BMI (kg/m^2)	38.8	36.05
Lean Mass (%)	48.2	50.2
Fat Mass (%)	51.8	49.8
SPPB (mean score)	9.25	9.69

Figure 1

Consort Enrollment Chart
SUPER-POWR

Screening

Assessed for eligibility
(n=45)

Pre-enrollment (n=0)
Consent Process

Excluded (n=20)
Not meeting inclusion criteria (n=12)
Lost to contact (n=4)
Other reasons (n=4)

Enrollment

Randomized
(n=25)

Allocated to Control (n=12)
Traditional Weight Loss Group
Active (n=0)
Drop (n=3)
Disqualified (n=0)

Allocation

Allocated to Intervention (n=13)
High Protein Group
Active (n=0) Drop (n=1)
Disqualified (n=2)
Noncompliant (n=1)
Unable to eat product (n=1)

Completed 3-month of 9-month
intervention (n=10)

Intervention

Completed 3-month of 9-month
intervention (n=11)

Completed 6-month of 9-month
intervention (n=10)

Completed 6-month of 9-month
intervention (n=11)

Completed 9-month of 9-month
intervention (n=9)

Completed 9-month of 9-month
intervention (n=8)

Figure 2:

Body Weight Change by Group

	Baseline	3 Month Midpoint	6 Month Endpoint	9 Month Endpoint
A: Control	0	-3.36	-4.24	-3.74
B: Protein	0	-4.1	-5.38	-5.26

Figure 3:

Body Fat Change by Group

	Baseline	3 Month Midpoint	6 Month Endpoint	9 Month Endpoint
A: Control	0	-2.92	-3.55	-3.19
B: Protein	0	-4.38	-5.23	-4.51

Figure 4:

Lean Body Mass Change by Group

	Baseline	3 Month Midpoint	6 Month Endpoint	9 Month Endpoint
A: Control	0	-0.45	-0.70	-0.55
B: Protein	0	0.28	-0.16	-0.75