## Study Protocol: Effects of Daily Prune Consumption on Lipid Profile, Inflammation, and Oxidative Stress

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**Objectives:** Cardiovascular disease (CVD) is the leading cause of death and disability worldwide. Atherosclerosis is recognized as a primary underlying cause of CVD resulting from oxidative stress, chronic inflammation, and excess low-density lipoprotein cholesterol (LDL). Prunes (Prunus domestica L.) are a nutritious food with components associated with improved cardiovascular health, including soluble fiber and polyphenolic compounds. The objective of this study is to investigate the cardioprotective benefits of prunes and determine the extent to which daily prune consumption effects blood lipids, oxidative stress, and chronic inflammation in men.

**Methods:** Healthy osteopenic men aged 55 to 80 years old with body mass index of <18 to >40 data were included in this 12-month, parallel design, randomized controlled trial. Participants were placed into one of three treatment groups: 50 g/day prune, 100 g/day prune, or control (multivitamin only) for 12 months. All groups consumed a multivitamin containing 450 mg calcium and 800 IU vitamin D. During each visit (baseline, 3, 6, and 12 months) height, body weight, waist and hip circumference, heart rate, and blood pressure were assessed. Fasting blood and urine samples were collected at each time point, and participants completed a 3-day food record and validated physical activity questionnaire. Blood total cholesterol (TC), LDL-C, triglycerides, and high-density lipoprotein cholesterol (HDL-C) and biomarkers of inflammation and oxidative stress including high-sensitivity C-reactive protein (hsCRP), Tumor necrosis factor alpha (TNF- $\alpha$ ), Interleukin 1 beta (IL-1 $\beta$ ), lipid peroxidation (LPO), and total antioxidant capacity (TAC) will be measured.

**Results:** Study recruitment and retention is complete. Data analysis has yet to begin.

**Conclusions:** Based on the literature, whole foods high in polyphenols and soluble fiber, such as prunes, are beneficial in reducing chronic inflammation and circulating LDL-C. In the current study, we expect that long-term daily consumption of prunes will improve CVD risk factors including reductions in LDL and TC and provide antioxidant and anti-inflammatory cardiovascular benefits in older men. Findings from this research will further our understanding of the role that prunes may have in improving cardiovascular health.

Funding Sources: USDA, California Prune Board, and Shaklee.