

Format: Abstract

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Effects of Fermented Papaya Preparation (FPP) on Safety Outcomes in Older Adults - A Short Report of a Placebo-Controlled Clinical Trial.

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Abstract

Fermented Papaya Preparation (FPP®) has shown antioxidative and anti-inflammatory effects in preclinical and clinical aging studies. However, clinical trials are needed to fully evaluate the safety of FPP® in moderate-functioning, generally healthy older adults. In this randomized (9g/day of FPP® or placebo), crossover design study, we enrolled 30 older moderate-functioning older adults (70-100 years old). The participants completed both a treatment and a placebo condition. After eight (8) weeks on each of these regimens (with a 4-week wash-out period in between), participants had their venous blood drawn for assessment of blood chemistries, metabolic outcomes and inflammatory biomarkers. Participants were asked to report any adverse events during the course of the study and complete post-treatment outcome assessments for anthropometric and metabolic outcomes. The major finding related to safety was that there were no adverse changes in blood chemistries and few adverse events in the FPP® condition, which did not differ from placebo ($p>0.05$). There were no serious adverse effects in either condition. Twenty-nine (29) participants (mean age 78.2±5.3 yrs) completed the study with 94% adherence to the dosing regimen. There were no significant effects of FPP® on anthropometric and metabolic outcomes. In addition, no effects on markers of inflammation were observed. Our trial demonstrates FPP® supplementation is safe and feasible in adults ages 70 years and older. Based on these findings and the positive effects FPP has demonstrated in previous trials, future trials should examine the effects of FPP® in older adults with impaired health status and/or older adults who may have insufficient anti-oxidant protection due to their genetic background.

KEYWORDS: Natural compound; immune; inflammation; lifestyle; nutrition; stress

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Conflict of interest statement