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FEASIBILITY, SAFETY AND ACCEPTABILITY OF SOY-BASED DIET FOR PREGNANT WOMEN: PRELIMINARY RESULTS FROM A PILOT RANDOMIZED CONTROLLED TRIAL

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Background: Previous evidence suggests that soy containing foods may have beneficial effects on lipid and glycemic metabolism. Pregnancy is associated with a progressive deterioration in glucose and lipid metabolism, partially attributable to elevated estrogen concentrations. Little is known about the effects of soy intake on cardiometabolic risk factors in pregnant women.

Methods: A pilot RCT was conducted in 30 pregnant women who were randomized to receive counseling to consume a high-soy or low-soy foods containing diet. Assessments (physical measurements, food frequency questionnaires, fasting blood samples) were conducted at 14 and 28 weeks of pregnancy, and 6 weeks' postpartum. Monthly follow-up calls were conducted to assess safety and encourage adherence.

Results: Both the high-soy and low-soy groups demonstrated high adherence (80-90%), defined as consuming soy foods ≥ 15 days in the past four weeks for high-soy group and ≤ 5 days for low-soy group. Five adverse events possibly associated with soy intake were reported (nausea, vomiting, diarrhea, itchy mouth); all were transient and resolved without sequelae. The high-soy group lost body fat between baseline and postpartum while the low-soy group gained body fat, as reflected by change in triceps skinfold thickness (-4.8 mm vs +3.6 mm, $p=0.04$). There was a trend towards an improvement in BMI in the high-soy group, both at 28 weeks (+1.4 vs. +3.6 kg/m², $p=0.15$) and postpartum (-1.2 vs. +0.6 kg/m², $p=0.14$). There were no differences between groups in fasting glucose, HDL-C, LDL-C, TG, or VLDL levels.

Conclusion: Initial results from this pilot RCT support the acceptability and safety of consuming soy-based whole foods during pregnancy. A larger-scale RCT is needed to further elucidate the effects of soy diet on cardiometabolic risk among pregnant women.

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