

La Frano Treatment Protocol

This was a secondary analysis using samples from the Healthy Beginnings/Comienzos Saludables Study, a randomized clinical trial (RCT) that is part of the Lifestyle Interventions for Expectant Moms (LIFE-Moms) Consortium (Phelan et al., 2018). This RCT focused on the outcomes of behavior lifestyle change on weight gain during gestation (Phelan et al., 2018). Samples were acquired from two study sites: California Polytechnic State University, San Luis Obispo, California and Miriam Hospital with Women and Infants Hospital in Providence, Rhode Island. This trial was registered as NCT01545934. Eligibility consisted of being 9-16 weeks gestational age, BMI (in kg/m²) ≥ 25 upon study entry height and weight, English or Spanish speaking, age ≥ 18 years old, and singleton pregnancy. Participants were excluded if glycosylated hemoglobin ≥ 6.5 , reported major health diseases, substance abuse, undergoing treatment for serious psychological disorders, had contradictions to aerobic exercise, or who had repeated no-shows or loss of contact during screening. Participants were randomly assigned to two different intervention methods. Group one received enhanced usual care, which represented the control group. Group two had a multi-component lifestyle intervention, which included diet, exercise, and behavioral change. Data was collected throughout pregnancy, including blood samples, diet assessment, and clinic measured GDM diagnosis. Blood samples were taken between gestational weeks 10-16. Since the multi-component lifestyle intervention showed no statistically significant effect on GDM occurrence ($p=0.7$) (Phelan et al., 2018), the samples used for this secondary analysis are from both the control and treatment groups. There were a total of 34 GDM cases that were collected from the California ($n=13$) and Rhode Island ($n=21$) study sites. Samples for 34 GDM cases were matched to 34 healthy controls prior to metabolomics analysis based on age, study entry body mass index (BMI), ethnicity, study site, and treatment. The two groups did not differ in weight gain from entry to 26 weeks.

Note: This is an excerpt from a manuscript in preparation (McMichael et al.)