



Preliminary Results Comparing Weight Loss and Metabolic Improvements Using a Low Starch Dietary Education Program vs. Traditional Treatment for Polycystic Ovary Syndrome (PCOS)

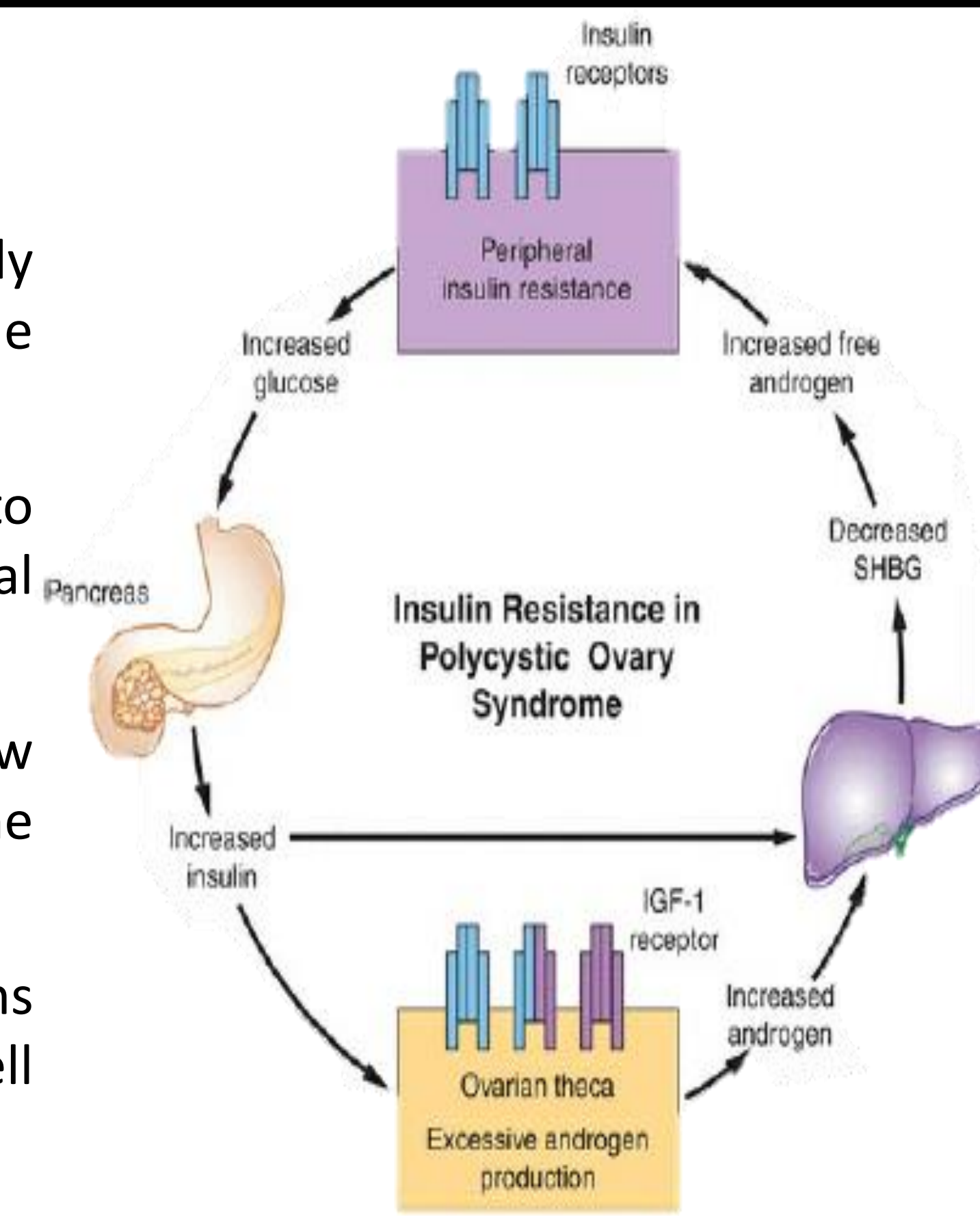
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Abstract

- Polycystic Ovary Syndrome (PCOS) affects roughly 10% of premenopausal women and correlates heavily with insulin resistance, type 2 diabetes, cardiovascular disease, cancer, and is suggested as one of the leading cause of infertility.
- Hyperinsulinemia seen in PCOS patients has been shown to play a synergistic role with elevated LH to create a vicious pathologic positive feedback producing the characteristic hyperandrogenic clinical presentation of PCOS.
- 56 participants who had previously been diagnosed with PCOS underwent an 8-week ad libitum low starch/low dairy diet. This dietary education was composed of a face-to-face (F2F) arm and an online education arm (WEB).
- Preliminary results from participants who underwent the dietary intervention through either of the arms experienced a statistically significant reduction in BMI, HbA1C, fasting serum glucose and insulin; as well as a notable reduction in free/total/and bioavailable serum testosterone.



Hypothesis

- Both arms of dietary interventions will experience reduced BMI, fasting glucose and insulin, as well as a reduction in free/total/and bioavailable testosterone.

Inclusion/Exclusion Criteria

Inclusion criteria:

- Women aged 18 to 45 years old
- Overweight (BMI >25 but <45)
- Have a diagnosis of PCOS according to the 2013 NIH Criteria.
- Have access to a computer/phone/electronic device with internet connection

Exclusion criteria:

- Pregnancy, abnormal thyroid stimulating hormone (TSH), hyperprolactinemia, adrenal hyperplasia, Cushing's disease or ovarian and adrenal tumors
- Previous diagnosis of diabetes
- History of eating disorder
- History of surgical weight loss procedure
- Persons with an inability to give informed consent
- Persons unable to exercise or to prepare their own food

The Diet

- Participants were instructed to eat lean animal protein (meat and poultry), fish and shellfish, eggs, non-starchy vegetables, low-sugar fruits (berries, apples, oranges, plums, etc.), avocado, olives, nuts and seeds, and oils (olive and coconut). Subjects older than 21 years were allowed 6 oz. of red wine per day, and all subjects were allowed up to 1oz of prepared or fresh, full-fat cheese per day. This diet was ad libitum without caloric restriction.
- The diet also did not call for an increase in physical activity, this was to minimize the effects of exercise on metabolic systems when measuring the effects of the diet.

Experimental Setup

- 56 participants with PCOS diagnosed within the last 2 years who met the inclusion and exclusion criteria were recruited for a dietary intervention study consisting of 2 clinical visits separated by an 8-week intervention.
- Visit 1: After consent was obtained, measurements of weight, body mass index, waist-to-hip ratio, HbA1C, fasting glucose and insulin, complete lipid panel, free and total testosterone, and hemoglobin A1c were obtained. They were then randomized 1:1:1 into one of three arms of the study; Control group, Face-to-face (F2F), and Webinar (WEB).
 - Control Group- Received Standard treatment of care as described by the NIH, consisting of recommendations for caloric restriction based on BMI, encouragement of increased daily exercise, and a prescription for metformin if initial fasting serum insulin was indicative.
 - Face-to-Face Group- Each participant spent 2 hours with a Registered Dietitian (AMP) for intensive diet education at the first clinical visit. Each participant was provided with written materials that included appropriate foods and products, example meal plans, a guide to eating out, and recipes.
 - Webinar Group- Each participant watched an online lecture covering all of the same information as the F2F group and is also provided with the same written materials.
- Visit 2: Post-intervention measurements of weight, body mass index, waist-to-hip ratio, HbA1C, fasting glucose and insulin, complete lipid panel, free and total testosterone, and hemoglobin A1c were obtained.

Results

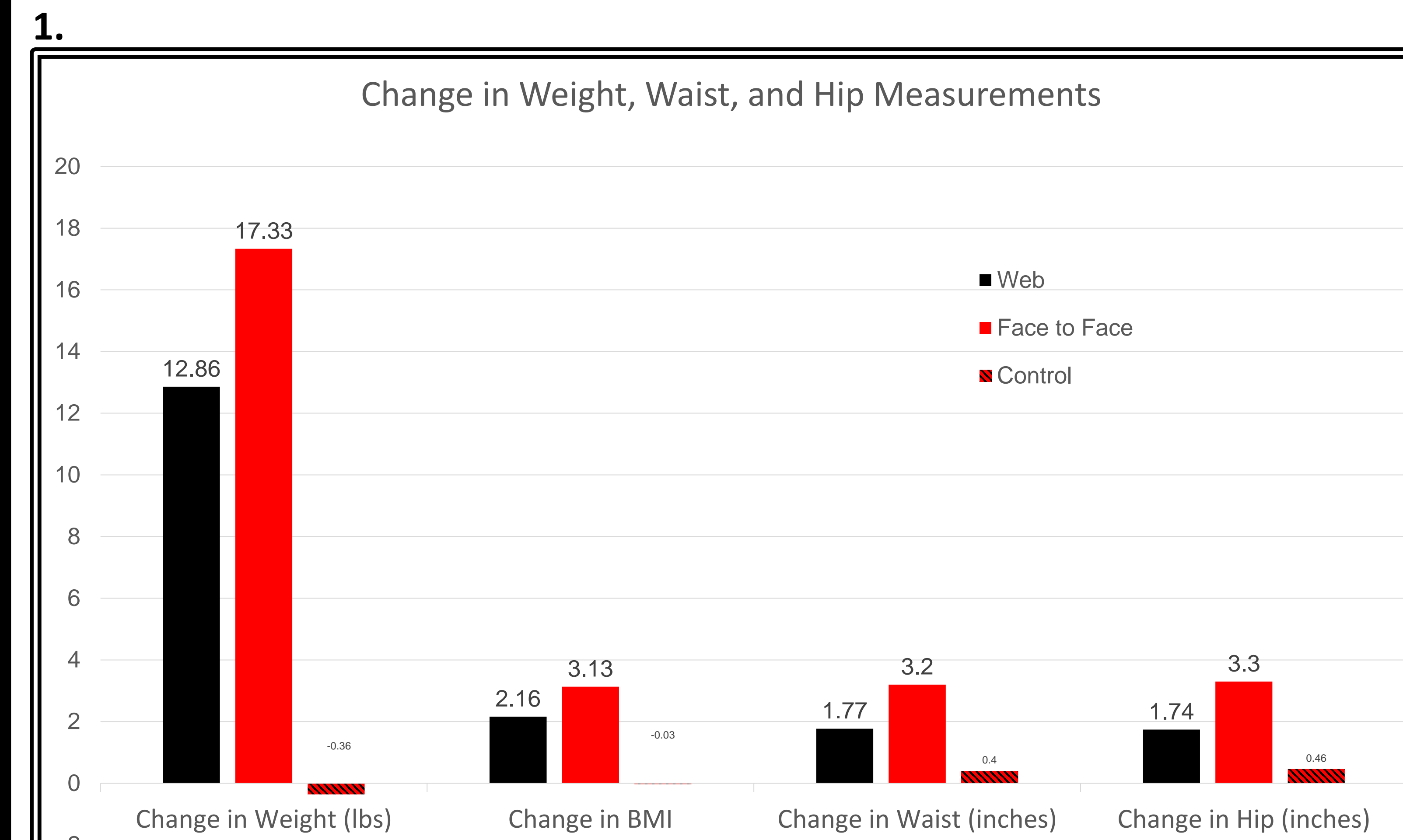


Figure 1: Significant decreases in weight in lbs (CP= -0.36; FTF= 17.3, p= 3.6e-10; WEB= 12.86, p=4e-6), BMI (CP= -0.039; FTF= 3.13, p= 4e-11; WEB= 2.16, p= 1e-6), waist circumference (CP= 0.4; FTF= 3.2, p= 1.5e-4; WEB= 1.77, p=.015), and hip circumference (CP= 0.46; FTF= 3.3, p= 1.3e-4; WEB= 1.74, p=.03) for both WEB and FTF vs CP.

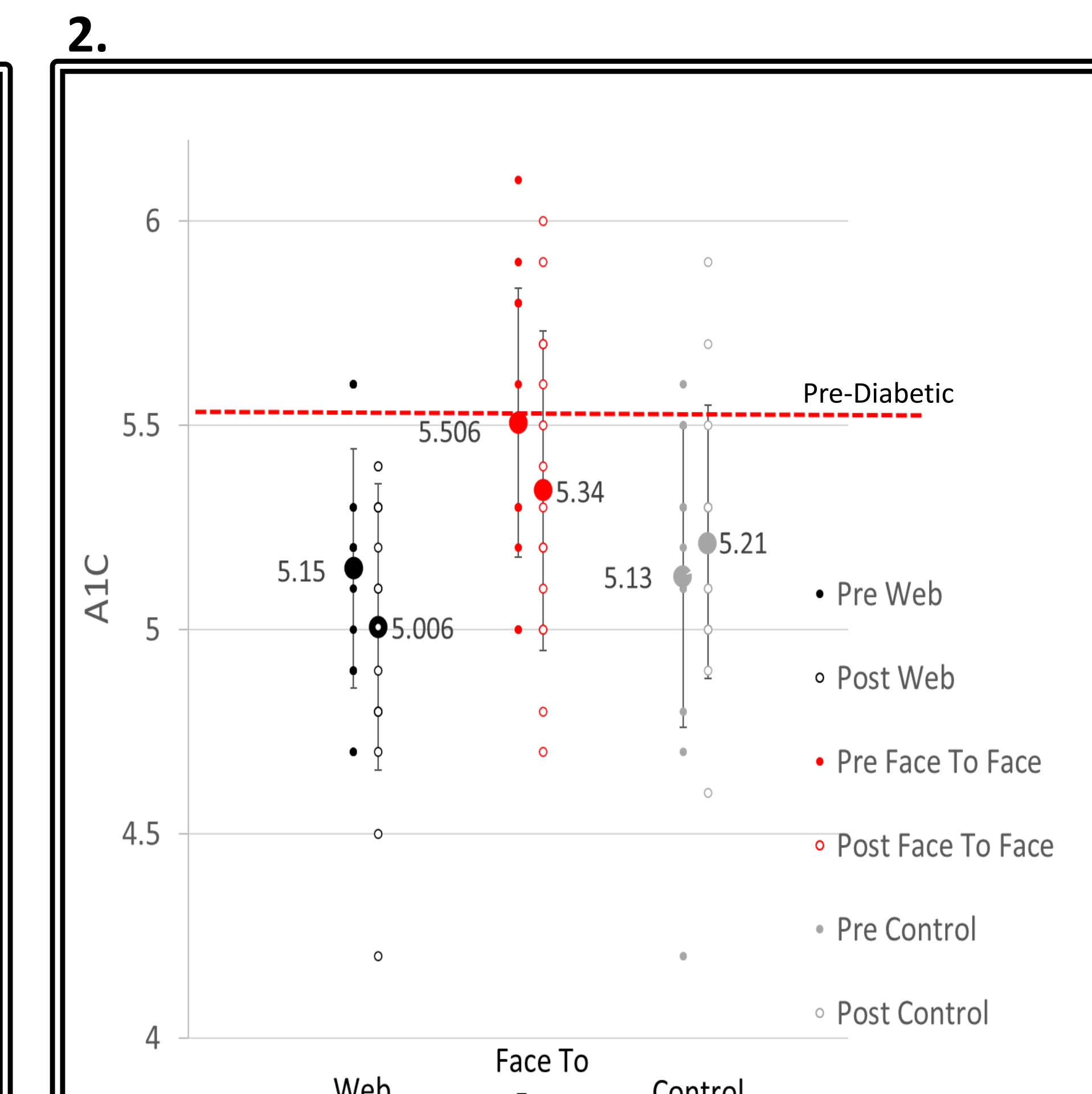


Figure 2: Significant decrease in average HbA1C for FTF vs CP. (CP= -.086; FTF= .166, p=.03; WEB= .14, p=.059)

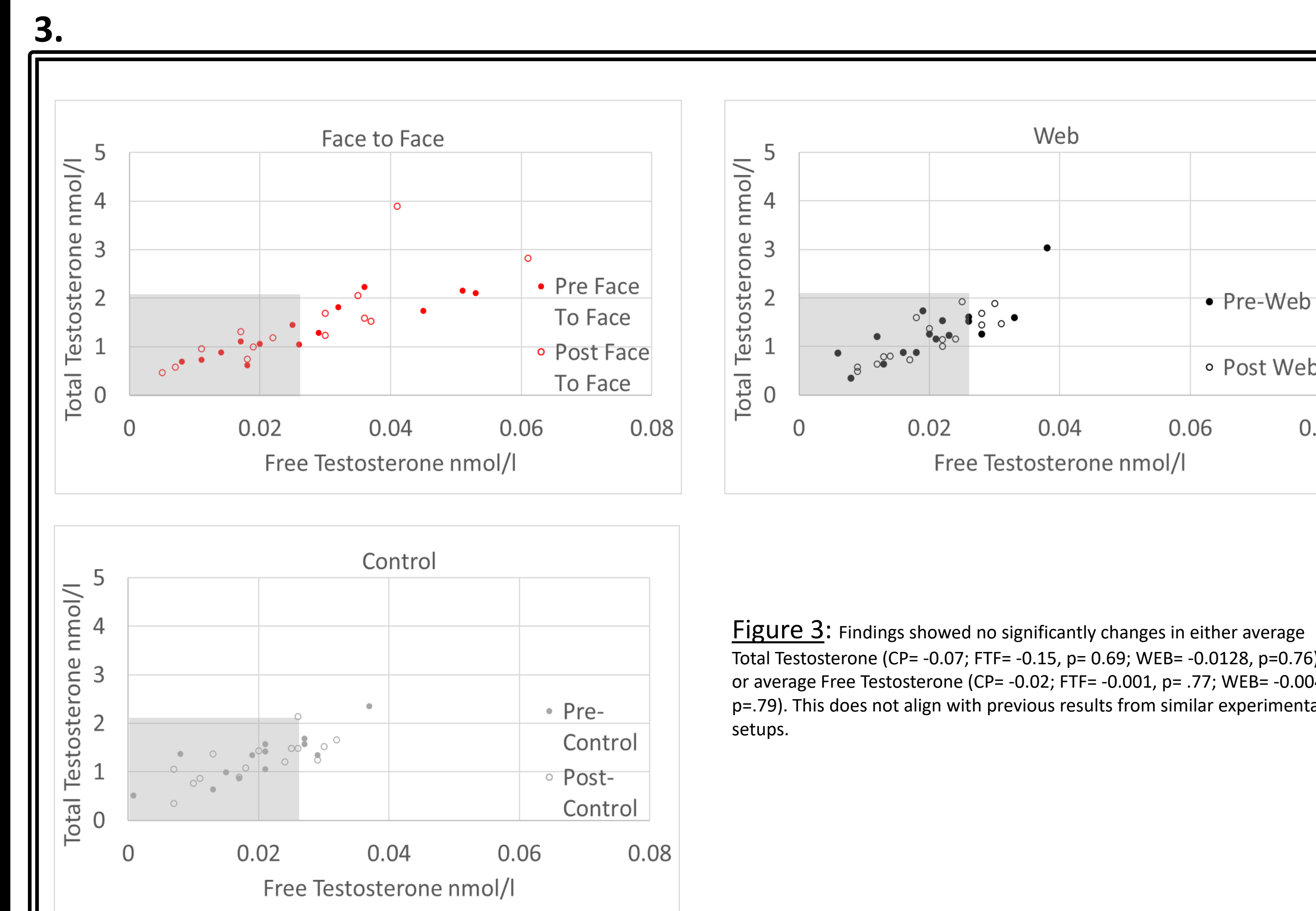


Figure 3: Findings showed no significantly changes in either average Total Testosterone (CP= -0.07; FTF= -0.15, p= 0.69; WEB= -0.0128, p=0.76) or average Free Testosterone (CP= -0.02; FTF= -0.001, p= .77; WEB= -0.004, p=.79). This does not align with previous results from similar experimental setups.

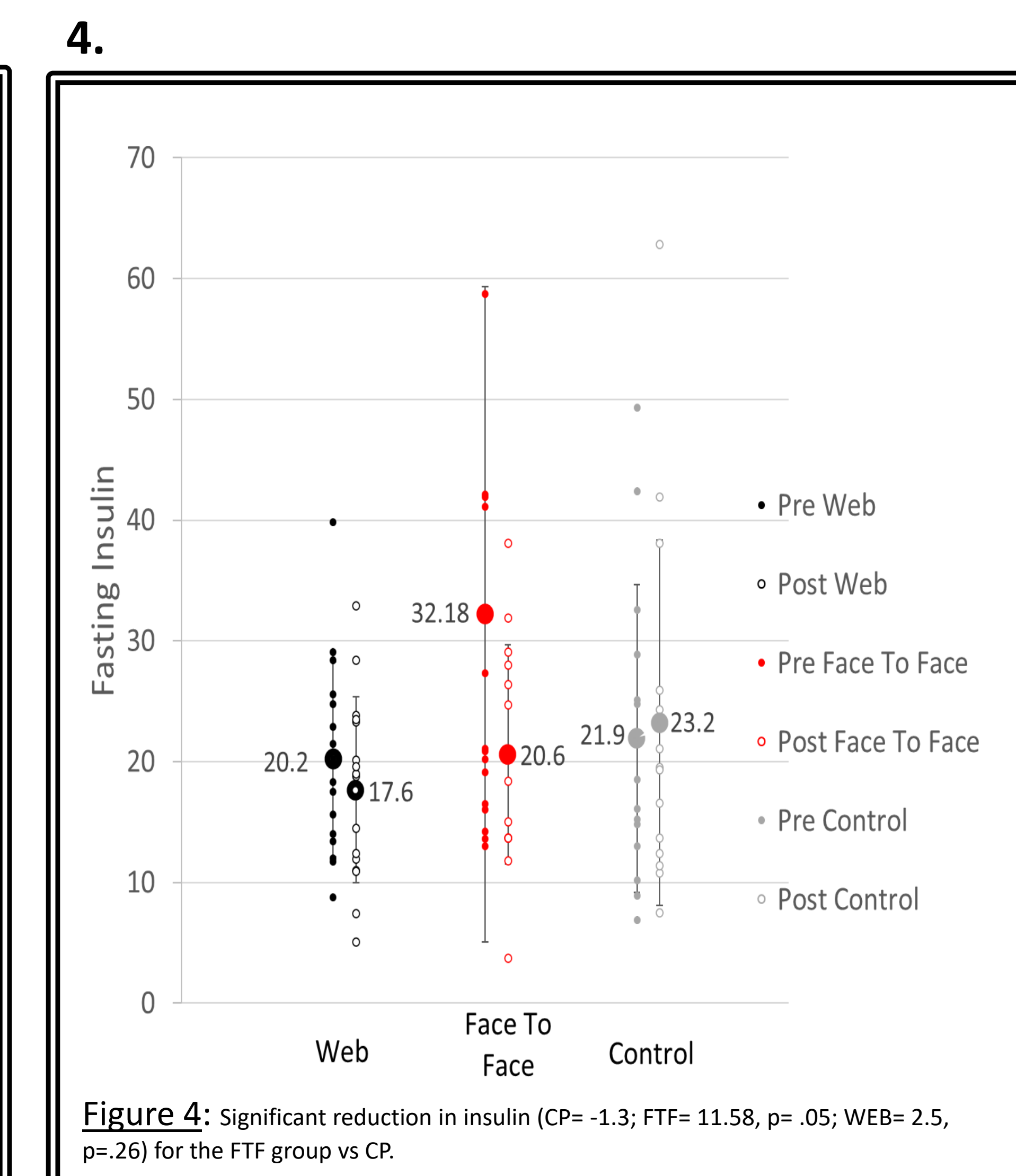


Figure 4: Significant reduction in insulin (CP= -1.3; FTF= 11.58, p= .05; WEB= 2.5, p=.26) for the FTF group vs CP.

Conclusions

- Both the Web based and face to face dietary interventions resulted in a greater reduction in BMI, HbA1C, and fasting insulin as compared to control.
- Neither of the dietary interventions resulted in a significant reduction in either Total or Free Testosterone, but further results may be necessary.
- Web-based dietary intervention outperformed the common clinical practice in all metabolic measurements but was not as efficacious as the Face-to-face intervention.

Acknowledgment

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