

SUPPLEMENT Appendix 1

This supplement is being provided to give readers additional information on ‘Procedures and Methods’.

SUBJECTS AND METHODS

Randomization

Women were randomly assigned at 1:1 ratio at the beginning of the second trimester to Lifestyle Intervention (LI) designed to control gestational weight gain (GWG) or to Usual Care (UC). The random allocation sequence was computer generated by the data manager. A randomly assigned number was generated at time of participant randomization. A printed copy was placed in the participant’s chart and the staff completing the randomization informed the participant immediately in person of group assignment. Staff involved in collection of measurements were blind to group assignment.

PARTICIPANTS

Exclusion criteria included diabetes (a glycosylated hemoglobin level of greater than 6.5%), fetal abnormality, planned termination of pregnancy, history of three or more consecutive first trimester miscarriages, current eating disorder, actively suicidal, prior or planned bariatric surgery, current use of metformin, systemic steroids, antipsychotic agents, anti-seizure medications, mood stabilizers, or ADHD medications, continued use of weight loss medications, contraindications to aerobic exercise in pregnancy, participation in another intervention study that influenced weight control, enrollment in this trial in a previous pregnancy, unwillingness or inability of the subject to commit to a one-year follow-up of herself or her child, smoking, history of drug and/or alcohol addiction, chronic health problems that prohibited regular exercise known to influence body composition, claustrophobia (for body composition

instrumentation reasons), lack of support from primary health care provider or family members, having another member of the household a study participant or staff member, any other medical, psychiatric, social or behavioral factor that in the judgment of the study principal investigators might interfere with study participation or ability to follow the intervention.

STUDY TREATMENTS

LI continued from randomization to delivery. Its goal was to maintain GWG during the second and third trimesters within IOM recommended limits of 0.32 kg/wk for women with overweight and 0.27 kg/wk for women with obesity [1]. LI focused on diet modification and increased physical activity along with behavioral and social support strategies delivered in individual sessions by study counselors. The intervention program was derived from the lifestyle intervention curriculum developed by the Diabetes Prevention Program [2] and Look AHEAD study [3], with the focus modified from an emphasis on weight loss to control of GWG as recommended by the 2009 IOM guidelines [1].

Individual Visits with Nutritionist: Immediately following randomization, women randomized to LI attended a 60-minute ‘Introduction’ session followed by individual visits every two weeks thereafter to delivery. At the first session, several “tools” were provided including a calorie book, food scale, set of measuring cups and spoons, a portable, insulated food pouch, and a pedometer. The website of the USDA’s Center for Nutrition and Policy Promotion (www.choosemyplate.gov) was used to develop the individualized meal plans for each participant, in addition to utilizing the nutrition guidelines from the Academy of Nutrition and Dietetics (www.nutritioncaremanual.org). Between visits, the participant was required to self-monitor her diet and exercise/physical activity, using methods most convenient for her, such as food logs, physical activity logs, smartphone based free-applications. Examples of those used

included “MyFitnessPal”, “SparkPeople”, “WeightWatchers” and “Lose It”. The individual sessions involved the measurement of body weight and review of the food/exercise logs, with appropriate recommendations made and tailoring of the intervention as needed. The program consisted of twenty modules that covered the following topics: nutrition, eating out, cooking, smart shopping, problem-solving, mindfulness, goal-setting, relapse prevention, cravings/hunger management, positive self-talk, and exercise. For participants unable to attend any individual session, the module was sent to her by email attachment or regular postal mail.

Additional contacts: During the weeks when the participant did not have an individual face-to-face meeting with the nutritionist, there were one-to-two contacts per week by telephone or email. These contacts served to reinforce positive behaviors and provide support for adherence to the intervention plan.

Group meetings: Voluntary group sessions open to all intervention participants were offered once every eight weeks during pregnancy. The topics covered related to health during pregnancy and included calcium and iron importance, portion control, and preparing for the holidays. A session on adapting physical activity to different seasons and related challenges during pregnancy was taught by a certified prenatal exercise specialist. A breastfeeding session was taught by a certified lactation consultant.

The UC program involved a single 20 to 30 minute ‘Introduction’ immediately following randomization. This session covered basic nutrition for pregnancy as set forth in www.choosemyplate.gov and in guidelines by the American Academy of Nutrition. Thereafter, participants were invited to attend UC group meetings once every 8 weeks through delivery. The topics covered related to health during pregnancy and were similar to those covered in the LI group sessions but with less focus on calorie counting.

REFERENCES

- [1] IOM (Institute of Medicine) and NRC (National research Council). Weight gain during pregnancy: reexamining the guidelines. 2009. Washington, DC: The National Academy Press.
- [2] Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. *Diabetes Care* 2002;25:2165-71.
- [3] Look AHEAD Research Group. The Look AHEAD study: a description of the lifestyle intervention and the evidence supporting it. *Obesity (Silver Spring)* 2006;14:737-52.

Supplemental Table 1. Maternal healthy eating index: between group comparison							
Outcomes	HEI-2010 Pregnancy 14 weeks^a			HEI-2010 Pregnancy 35 weeks			
	LI	UC	p-value^b	LI	UC	p-value^c	p-value^d within group
	N=89	N=80		N=85	N=80		
HEI, total score, range 0 to 100	56.34±14.26	56.76±16.52	0.8577	61.80±16.05	54.78±15.02	0.0043	0.0301
HEIX01-Total vegetables, range 0 to 5	3.22±1.73	3.03±1.80	0.4894	3.57±1.58	3.45±1.69	0.6303	0.5935
HEIX02-Dark-green and orange vegetables and legumes, range 0 to 5	2.02±2.25	2.00±2.25	0.9708	2.52±2.34	2.39±2.38	0.7354	0.9771
HEIX03-Total fruit, range 0 to 5	3.48±1.86	3.51±1.95	0.9263	3.79±1.69	3.00±1.93	0.0057	0.0466
HEIX04-Whole fruit, range 0 to 5	3.45±2.14	3.20±2.18	0.4562	3.82±2.01	3.02±2.22	0.0165	0.3327
HEIX05-Whole grains, range 0 to 5	3.66±3.79	4.00±3.72	0.5571	4.46±3.80	3.69±3.73	0.1905	0.2439
HEIX06-Total Dairy, range 0 to 10	7.16±3.01	6.04±3.14	0.0198	6.68±3.21	5.97±3.42	0.1734	0.4685
HEIX07-Total protein foods (meat and beans), range 0 to 10	3.79±1.63	4.00±1.33	0.3548	4.13±1.36	4.09±1.34	0.8611	0.3347
HEIX08-Seafood and plant protein, range 0 to 5	2.32±2.32	2.72±2.25	0.2681	2.94±2.22	2.81±2.24	0.7108	0.3602
HEIX09-Fatty acids, range 0 to 10	3.93±3.68	4.61±3.73	0.2297	4.19±3.86	4.18±3.59	0.9794	0.3440
Moderation							
HEIX10-Sodium, range 0 to 10	3.27±3.53	4.01±3.38	0.1714	4.25±3.43	3.68±3.57	0.2972	0.0306
HEIX11-Refined grains, range 0 to 10	6.30±3.45	5.82±3.85	0.3929	7.06±3.52	6.17±3.88	0.1251	0.5165
HEIX12-Calories from solid fats, alcohol and added sugar (SoFAAS), range 0 to 20	13.745±5.21	13.82±5.96	0.9280	14.52±5.73	12.33±5.76	0.0150	0.1823

^a Values are mean ± SD; p-value corresponds to differences: ^b between group at baseline; ^c between group at 35 week; and ^d between

group change from baseline.