

## Effect of Diet Composition on Weight Change and Metabolic Parameters

### INCLUSION – EXCLUSION CRITERIA

#### FOR PATIENT CHART

Patient selection will be according to inclusion and exclusion criteria listed in this study protocol.

#### **Inclusion Criteria:**

We plan to recruit and study 24 pre-menopausal women with the following inclusion criteria: All of these should be YES.

- a) Age range 20 yrs to 50 yrs,
- b) BMI  $\geq 30$  kg/m<sup>2</sup> to  $\leq 55$  kg/m<sup>2</sup>
- c) Fasting glucose  $\leq 110$ mg/dl and 120 minute OGTT  $\leq 170$  mg/dl glucose

#### **Exclusion criteria:**

All of these should be NO.

- a) Presence of proteinuria or elevated serum creatinine ( $> 1.5$  mg/dl),
- b) Surgical or premature menopause,
- c) History of liver disease or abnormal liver function tests,
- d) Diabetes mellitus
- e) Thyroid disease with abnormal TSH,
- f) Weight  $> 320$  lbs, (due to ability to fit on the DEXA scanner)
- g) Triglycerides  $> 400$  mg/dl or LDL cholesterol  $> 160$  mg/dl,
- h) SBP  $> 144$  or DBP  $> 90$  mm of Hg,
- i) Use of medications known to effect lipid or glucose metabolism (niacin, steroids),
- j) Pregnancy or the desire to become pregnant in the next 6 months,
- k) Weight loss of more than 5% of body weight in the last 6 months,
- l) History of cancer undergoing active treatment
- m) Food Allergies which might effect diet meals
- n) Being Treated for eating disorders
- o) Currently smoking

Interviewer \_\_\_\_\_

Date \_\_\_\_\_

SUPPLEMENTARY DATA

Effect of Diet Composition on Weight Change and Metabolic Parameters  
Telephone Questionnaire

“Thank you for calling about our weight loss study. If you are eligible for this study, you will be randomly assigned to one of two diets. One diet is based on the traditional recommendations of the American Diabetes Association where half of your calories come from carbohydrates (starches). The other diet is a modified Atkins diet that is higher in protein but still contains some carbohydrates such as bread, fruits and vegetables. The fat content will be the same in both diets, 30%. The study diet will last for 6 months and you will be required to visit the UT Clinical Research Unit (housed in Methodist University Hospital) weekly for the entire 6 months.”

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

1. Are you female? Yes \_\_\_\_\_ No \_\_\_\_\_  
If female, continue with questionnaire.

2. How old are you? \_\_\_\_\_  
If subject is between 20 and 50 years old, continue.

3. Date of Birth: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

4. What is your height? \_\_\_\_\_ What is your weight? \_\_\_\_\_  
BMI \_\_\_\_\_(Look up in BMI chart provided.)  
If weight is >320 pounds, subject is excluded.  
If BMI is <30 or > 55 subject is excluded.

5. Have you gained or lost any weight in the last 6 months? (circle relevant change)  
Yes \_\_\_\_\_ No \_\_\_\_\_

6. If yes to question number 5, how much weight have you gained or lost?  
\_\_\_\_\_(pounds)  
Calculate % of weight gained/lost (pounds gained/lost divided by original weight):  
\_\_\_\_\_ If greater than 5%, subject is excluded.

7. Have you ever been told that you have diabetes, high blood sugar or pre-diabetes?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, was this based on an Oral Glucose Tolerance Test?  
Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

SUPPLEMENTARY DATA

8. Do you have any other medical problems such as high blood pressure, high cholesterol, heart disease, liver disease, thyroid problems, cancer?

Yes \_\_\_\_\_ No \_\_\_\_\_ (Circle relevant conditions.)

9. Do you have any other medical conditions or have you had any surgeries? List:

\_\_\_\_\_  
\_\_\_\_\_

10. Do you have chronic N/V, constipation, diarrhea, GERD, IBS, ulcers or colitis?

Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

11. Have you had a total hysterectomy, that is one in which your ovaries been removed?

Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

12. Are you pregnant or do you plan to become pregnant in the next 6 months?

Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

13. Are you lactose intolerant?

Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

14. Have your menstrual cycles been regular over the past 12 months?

Yes \_\_\_\_\_ No \_\_\_\_\_

15. List any foods you are allergic to: \_\_\_\_\_

\_\_\_\_\_

16. Do you consume alcohol, if so how many drinks per week? \_\_\_\_\_

17. Do you smoke cigarettes, if so how many packs per week? \_\_\_\_\_

18. Do you abstain from any food for religious reasons, if so what food(s)?

\_\_\_\_\_

19. Do you fast, if so for how long? \_\_\_\_\_

20. Do you adhere to a special diet (such as low salt, vegan, vegetarian, etc.), if so what diet? \_\_\_\_\_

21. Do you have freezer space for 15 – 20 frozen entrees at one time?

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, subject is excluded.

SUPPLEMENTARY DATA

22. Do you have access to a microwave for all 3 meals, daily?

Yes \_\_\_\_\_ No \_\_\_\_\_ .

23. What medications are you on at this time? List all prescribed medications, over the counter medications, contraceptives, hormones and vitamin, mineral, herbal and other supplements.


25. Is subject on niacin (>500 mg/day) or any glucose altering medicine?

Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, subject is excluded.

Interviewer Name: \_\_\_\_\_ Date: \_\_\_\_\_

Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Subject meets inclusion/exclusion criteria for screening visit #1:

Yes \_\_\_\_\_ No \_\_\_\_\_