

(FS)² Framingham State Food Study

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Staff Introductions

Staff Training
July 25, 2016

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Staff Introductions BCH

- **PIs** Dr. Cara Ebbeling, Dr. David Ludwig
- **Study Director** Gloria Klein
- **Associate Director** Dr. Julia Wong
- **Nutrition Manager** Lisa Bielak
- **Data/Quality Manager** Sarah Steltz
- **Nutrition Coordinator** Megan Sandman
- **Research Coordinator** Courtenay Devlin
- **Diet Technician** Linda Seger-Shippee
- **Research Assistants** Jillian Fergione, Annie Nero, Adrienne Salisbury, Rachel Apone, Amanda Scott
- **Study Physician** Dr. Bridget Hron

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Staff Introductions FSU/Sodexo

- **Study Director** Dr. Patricia Luoto
- **Financial Coordinator** Denise Harney
- **Dining Services Director** Ralph Eddy
- **Program Manager** Lauren Stone
- **Study Dietitian** Carolyn Holland

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Protocol Overview

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Outline

- Specific Aims
- Study Participants
- Diets
- Study Outcomes
- Ancillary Studies
- Questions

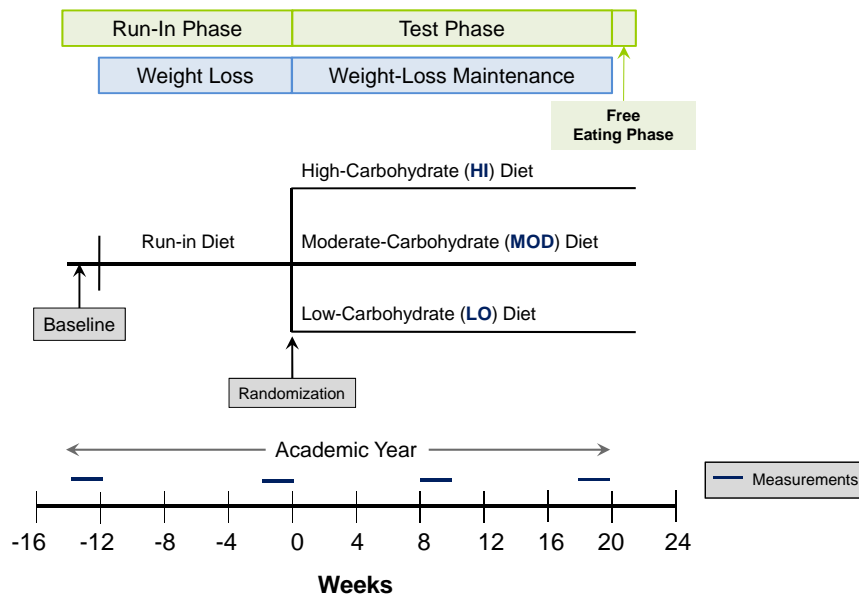
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What is the purpose of the study?

Many Americans currently follow popular weight-loss diets, but we do not know which diet is best for keeping weight off.

The purpose of this research study is to find out if one diet is better than the others for keeping weight off and decreasing risk for disease.

How will we answer these questions?



Specific Aims

- #1. To evaluate the effects of 3 diets varying widely in macronutrients – high-carbohydrate, moderate-carbohydrate, low-carbohydrate – on energy expenditure during weight-loss maintenance.
- #2. To evaluate the effects of 3 diets varying widely in macronutrients on chronic disease risk factors during weight-loss maintenance.
- #3. To evaluate physiological mechanisms potentially relating dietary composition to metabolism and risk for chronic disease.
- #4. To evaluate the effects of 3 diets varying widely in macronutrients on voluntary food intake and body weight during an *ad libitum* feeding phase.

Why did we contact FSU?

- Desire to conduct a “landmark” controlled nutrition study outside of a hospital setting
- Excellent reputation of the Food and Nutrition Department
- Proximity to Boston
- Possibility of working closely with a dining service, with access to a large and well-equipped commercial kitchen for production of high-quality controlled diets

What makes this project a “Landmark” Study?

- Designed to answer long-standing questions about calorie sources
- Widespread public health significance
- Research in a “real-life” setting
- Collaboration with a highly reputable dining service
- Novel infrastructure to accommodate a large number of study participants
- Longer duration than most controlled nutrition research studies
- Generous funding

Nobody has ever before done a study quite like this!

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(FS)² Study Participants

FSU Students, Faculty, and Staff; AV Faculty and Staff
FSU and AV Community Participants

- 18 to 65 years of age
- Interested in healthful weight loss
- Willing not to drink alcohol during the study
- Planning to be part of the FSU or AV community for the academic year

Enrollment (evaluation of eligibility criteria)

- Telephone conversation
- Informational visit
- Screening visit

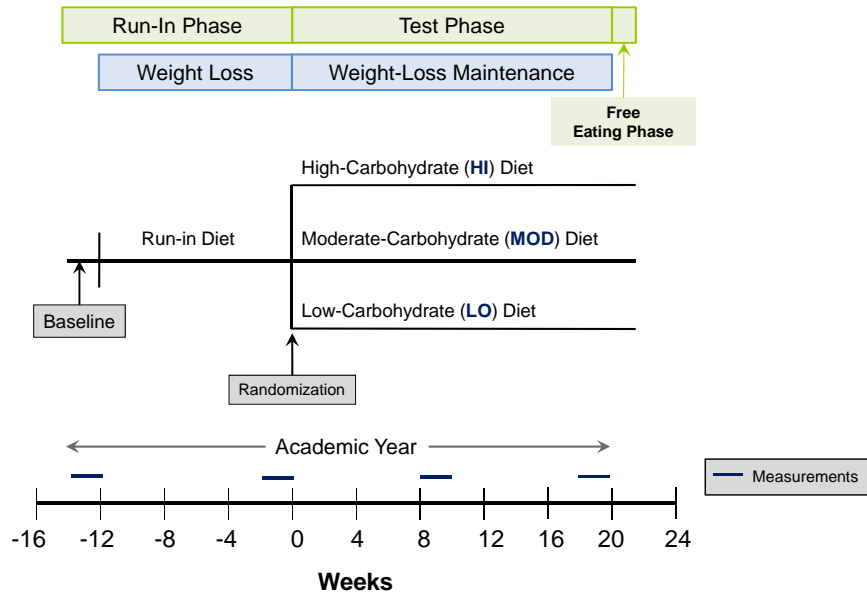
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How will we answer these questions?



What are the test diets?

LO Carb	MOD Carb	HI Carb
Dinner		
Herb Grilled Salmon Leaf Spinach Cheddar Cheese Cubes Peanuts Oranges Milk	Herb Grilled Salmon Leaf Spinach Long Grain & Wild Rice Cheddar Cheese Cubes Whole Wheat Bread Peanuts Oranges Milk	Herb Grilled Salmon Leaf Spinach Long Grain & Wild Rice Vanilla Greek Yogurt w/ Craisins Whole Wheat Bread Oranges Milk
Snack		
Falafel Lettuce Wrap w/ Lemon Tahini Sauce String Cheese	Falafel Lettuce Wrap w/ Lemon Tahini Sauce Apricot Greek Yogurt	Falafel Pita w/ Lemon Tahini Sauce Vanilla Greek Yogurt

Where do participants get their food?

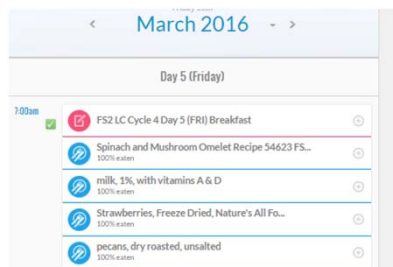
(FS)²K – McCarthy Center



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FS2 Portal

- Wi-Fi/Bluetooth-enabled scales for daily weights at home
- Integrated eating plans to report on food intake
- On-line scheduling and messaging functions
- On-demand videos and educational content to support weight loss and weight maintenance goals



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What do participants have to do for assessment of study outcomes?

- A series of measurements are completed during 4 assessment periods



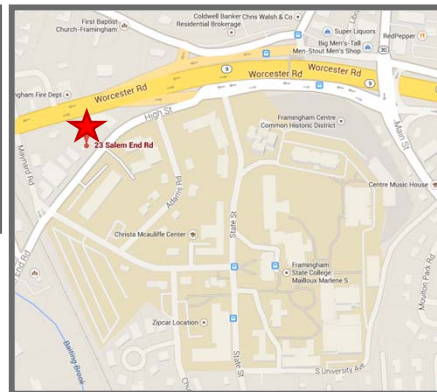
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Where will participants go for assessment of study outcomes?

“The (FS)² House”



23 Salem End Road



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Ancillary Studies

- Gut Microbiome (Intestinal Bacteria)
- Lipoprotein Particle Subfraction Distribution
- Cognitive Function
- Psychological Health
- Metabolic Fuels
- MRI
- Perceptions about Body Weight

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Questions

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SRA Roles and Functions

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(FS)² SRA Role and Function

- Involved in a wide range of day-to-day activities to support the study assessments and/or dietary intervention

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(FS)² Study Assessment Activities

- Greeting participants
- Collecting data
- Completing CRFs
- Processing of biological specimens
- Gathering materials & supplies for assessments
- Cleaning study equipment
- Completing data entry
- Filing study document
- Guiding participants from one assessment to the next
- Other activities vital to day-to-day study operations

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(FS)² Dietary Intervention Activities

- Printing and sorting weekly production sheets, and food & tray labels
- Assisting Intervention Support Dietitian with participant follow-up activities
- Assisting Sodexo Program Manager with tasks in the dining office and FS2K

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Questions

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