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# Study Designs

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## Cohort Studies

Observational studies - “real life”

Examine multiple exposures/multiple outcomes

Confounding/self report

## Clinical Trials

Allow investigators to test hypotheses using an experimental design in humans

Causal inference

Gold standard for medical treatments/medical practice

Very expensive, logistics, infrastructure, oversight

# Women's Health Initiative (WHI)

3 Controlled Trials

27,347

Hormone Therapy Trials:  
Coronary Heart Disease & Fractures.  
Adverse effect for Breast Cancer?

36,282

Calcium/Vitamin D Trial:  
Fractures & Colorectal Cancer

48,835

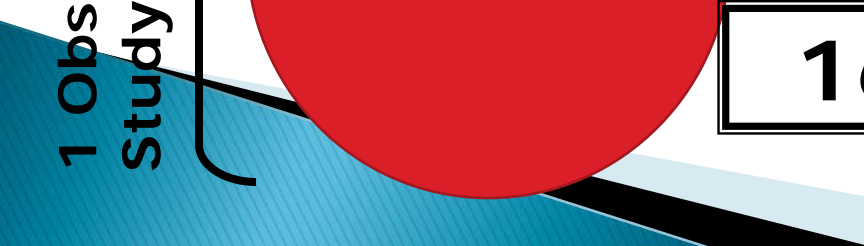
Dietary Modification Trial:  
Breast & Colorectal Cancers &  
Coronary Heart Disease

1 Observational Study

93,676

Observational Study

**161,808 women total**



# Dietary patterns

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- ▶ “ . . . the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed”

# Why study dietary patterns?

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- Complexity of diet
  - People eat foods (and meals), not nutrients
- Correlation among dietary constituents
  - Analysis of single nutrients may be confounded by the effect of dietary patterns
- Clinical trials show positive health outcomes with changes in “total diet”
  - Dietary Approaches to Stop Hypertension (DASH)
  - Lyon Diet Heart Study
- Relevance for policy and guidance



# Types of Dietary Indices

**FACTS ABOUT**

## The DASH Eating Plan

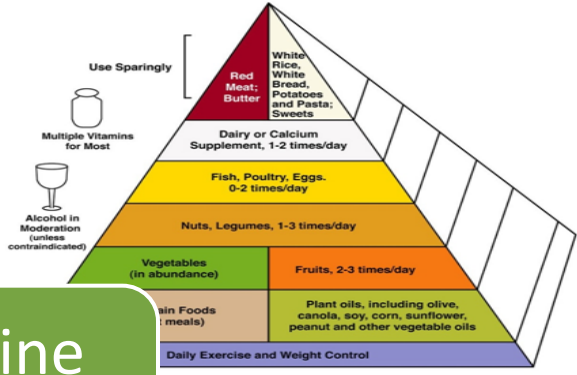
Research has found that diet affects the development of high blood pressure or hypertension (the medical term). Recently, two studies showed that blood pressure can be lowered by following a particular eating plan—called the Dietary Approaches to Stop Hypertension (DASH) eating plan—and reducing the amount of sodium consumed.

While each step alone lowers blood pressure, the combination of the eating plan and a reduced sodium intake gives the biggest benefit and may help prevent the development of high blood pressure.

This fact sheet, based on the DASH research findings, tells about high blood pressure and how to follow the DASH eating plan and reduce the amount of sodium you consume. It offers tips on how to start and stay on the eating plan, as well as a week of menus and some recipes. The menus and recipes are given five levels of daily sodium consumption—2,400 milligrams (the upper limit set by the Federal Government's National High Blood Pressure Program) and the amount used to figure food labels (2,300 milligrams).

Those with high blood pressure may especially benefit from reducing their sodium intake. But the combination of diet and exercise can help.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
National Institutes of Health  
National Heart, Lung, and Blood Institute



**Use Sparingly**

- White Rice, White Bread, Potatoes and Pasta; Sweets
- Red Meat; Butter

**Multiple Vitamins for Most**

- Dairy or Calcium Supplement, 1-2 times/day

**Fish, Poultry, Eggs.**  
0-2 times/day

**Nuts, Legumes,** 1-3 times/day

**Vegetables (in abundance)** and **Fruits,** 2-3 times/day

**Plant oils, including olive, canola, soy, corn, sunflower, peanut and other vegetable oils**

**Alcohol in Moderation (unless contraindicated)**

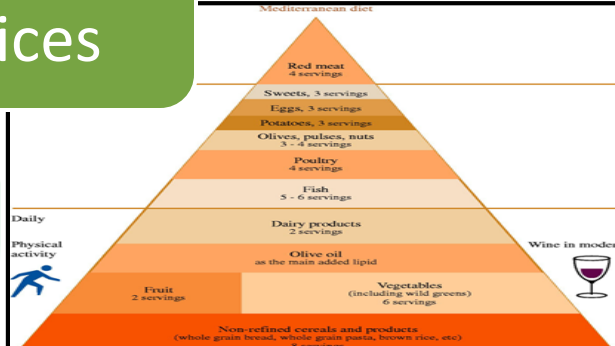
**Dairy Foods (meats)**

**Daily Exercise and Weight Control**

**Examine indices**

# Healthy Eating Index

**Mediterranean diet**



- Red meat 4 servings
- Sweets, 3 servings
- Eggs, 3 servings
- Potatoes, 3 servings
- Olives, pulses, nuts 3 - 4 servings
- Poultry 4 servings
- Fish 5 - 6 servings
- Dairy products 2 servings
- Olive oil as the main added lipid
- Wine in moderation
- Fruit 2 servings
- Vegetables (including wild greens) 6 servings
- Non-refined cereals and products (whole grain bread, whole grain pasta, brown rice, etc) 6 servings

One serving equals approximately half of the portions as defined in the Greek market regulations (portions served in restaurants)

Also remember to:

- Drink plenty of water
- Avoid salt and replace it by herbs (e.g. oregano, basil, thyme, etc)

Source: Supreme Scientific Health Council, Hellenic Ministry of Health, available at: [www.nut.uns.gr/dietary/DASH.html](http://www.nut.uns.gr/dietary/DASH.html)

# Controlled Feeding Interventions

# COMIDAS

## (Comparing Original Mexican Diets and Standard U.S. Diets)



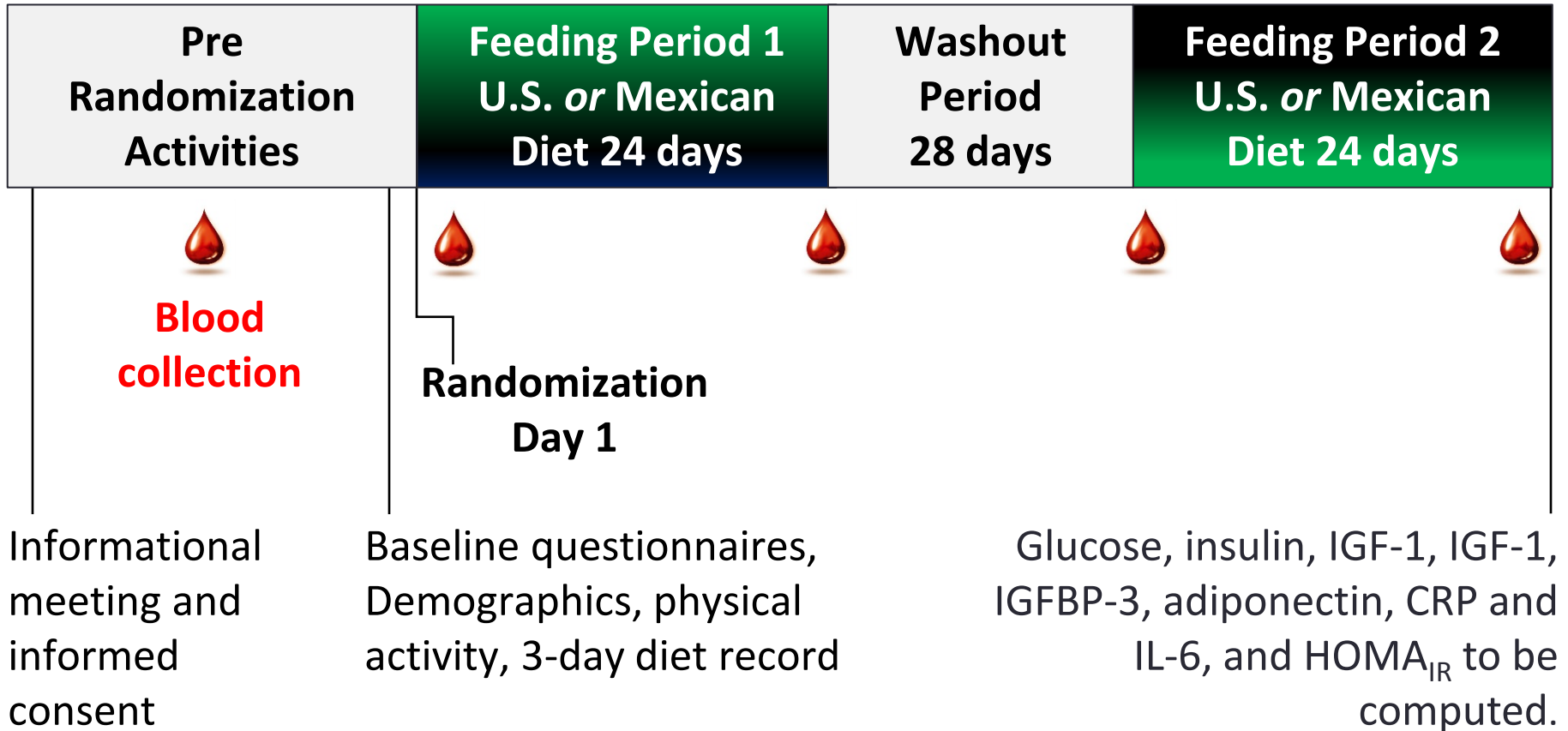


# HYPOTHESIS

Compared to a traditional Mexican diet, a U.S. diet produces detrimental metabolic profiles, including hyperinsulinemia, insulin resistance and inflammation, which leads to increased future risk of type 2 diabetes and breast cancer

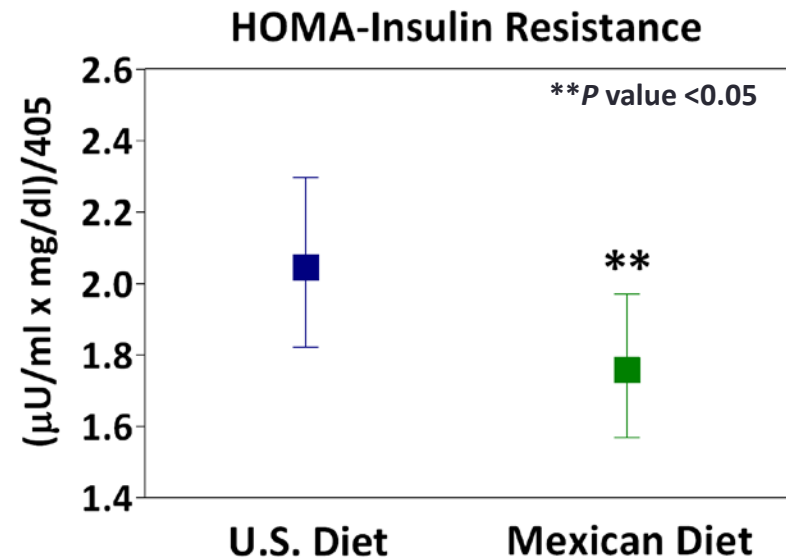
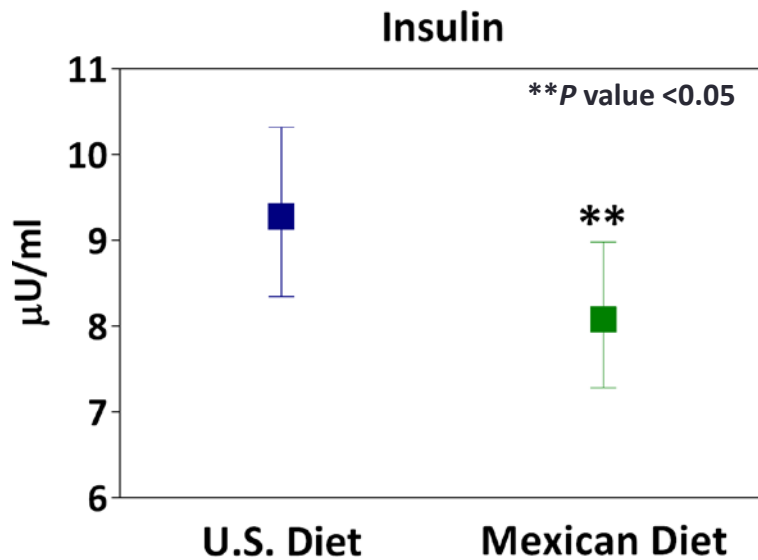
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# Study Design



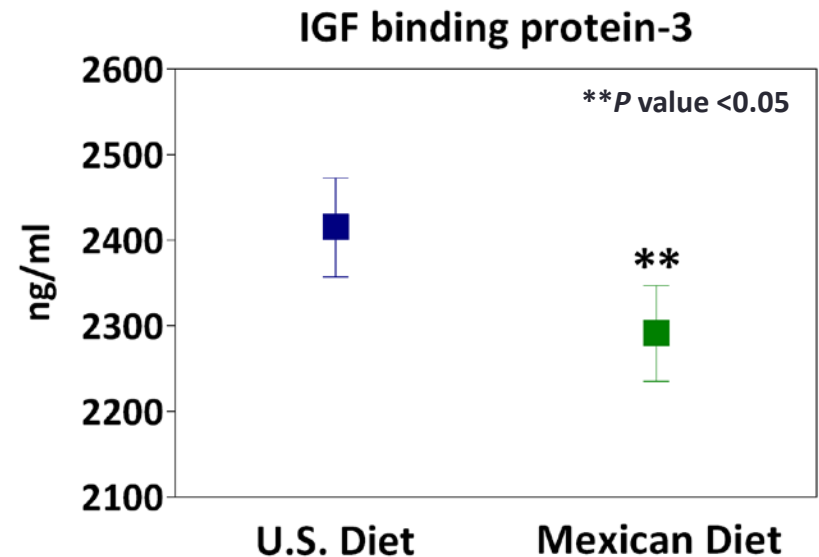
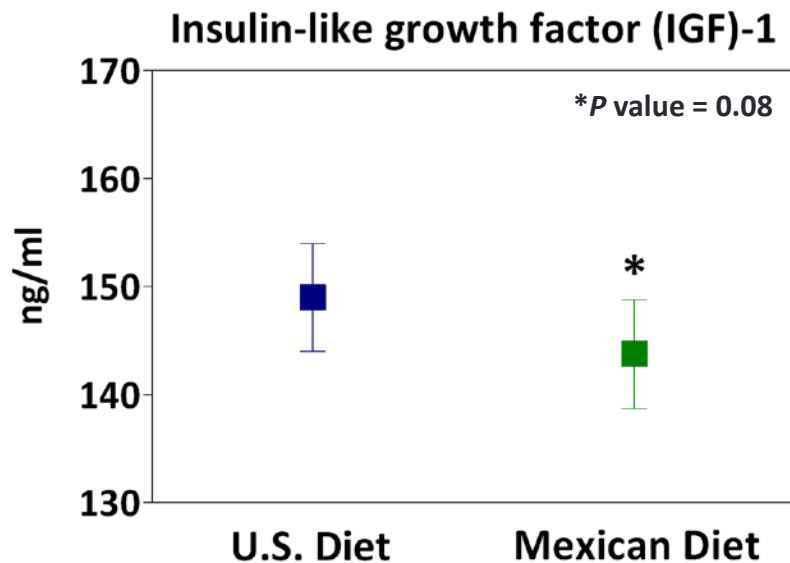
Weight was measured weekly, and energy intake was regulated to maintain participants' weight within 3% of baseline weight all throughout the trial

# Mexican diet improved insulin sensitivity



Linear mixed models were adjusted for diet sequence, feeding period, baseline and washout biomarker concentrations, age, acculturation and BMI. Values were log-transformed and means are presented as back-transformed geometric means.

# Mexican diet reduced circulating concentrations of IGF-1 and IGFBP-3



Linear mixed models were adjusted for diet sequence, feeding period, baseline and washout biomarker concentrations, age, acculturation and BMI.