Obesity is Not about Carbohydrates:

The POUNDS LOST Trial

Kathy McManus, M.S.,R.D.

Director

Department of Nutrition

Brigham and Women's Hospital

A Harvard teaching hospital affiliate

Outline

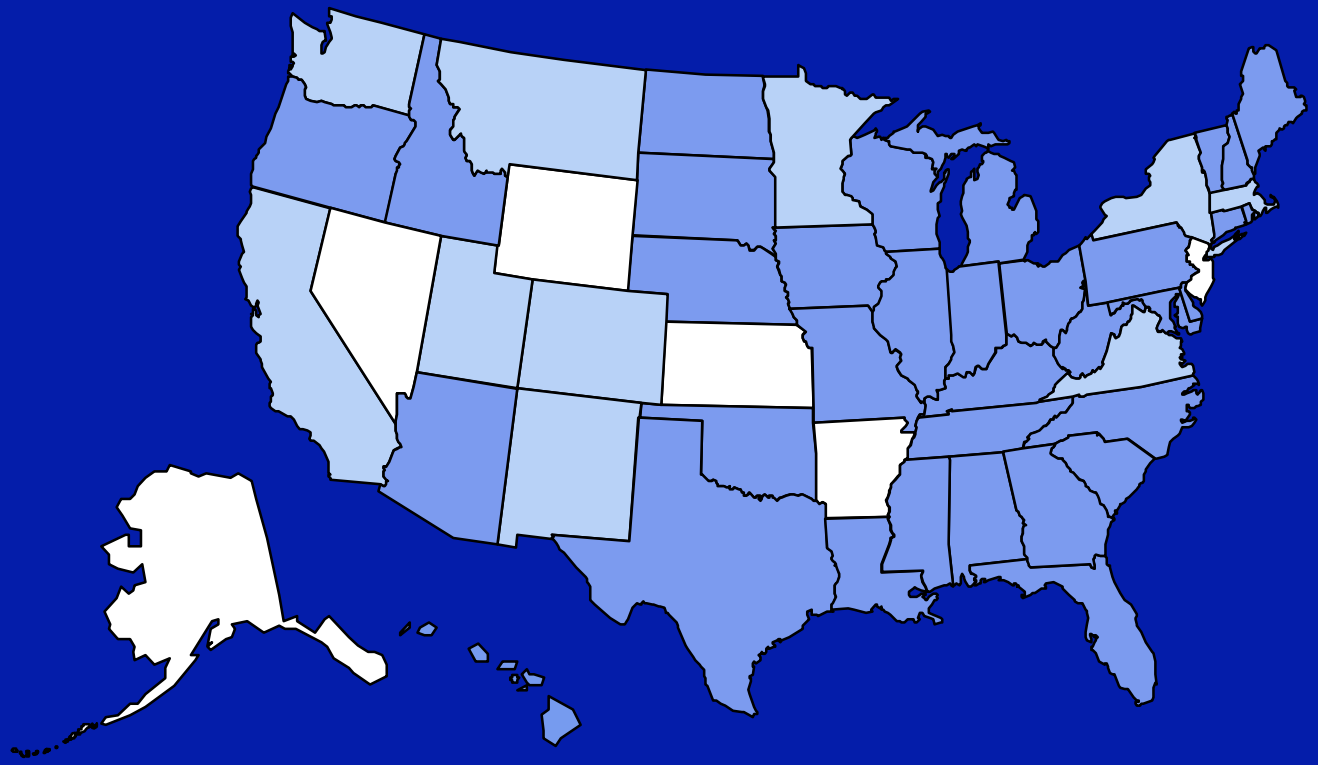
Overview of weight loss diet trials

Pounds Lost Trial

Pasta as part of healthy meals

Obesity Trends* Among U.S. Adults BRFSS, 1990

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



No Data | <10% | 10%–14%

Obesity Trends* Among U.S. Adults
BRFSS, 1995

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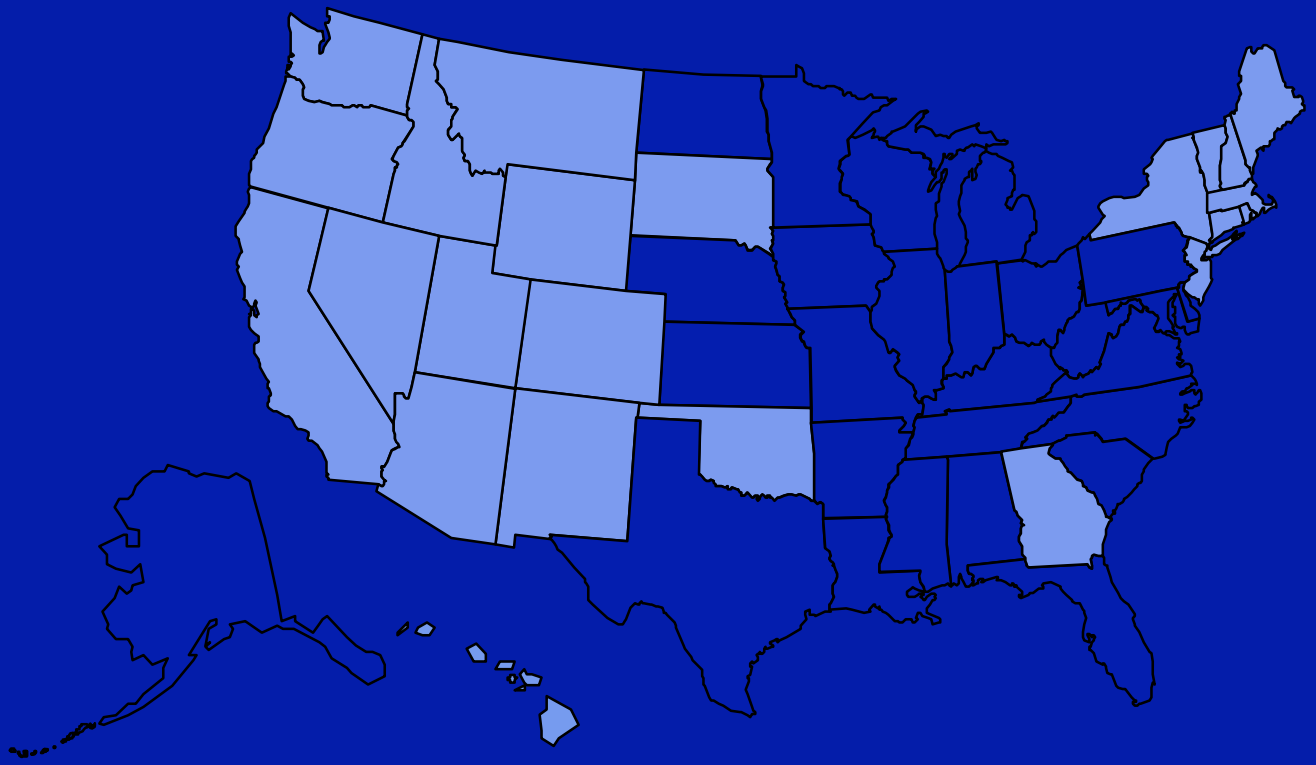
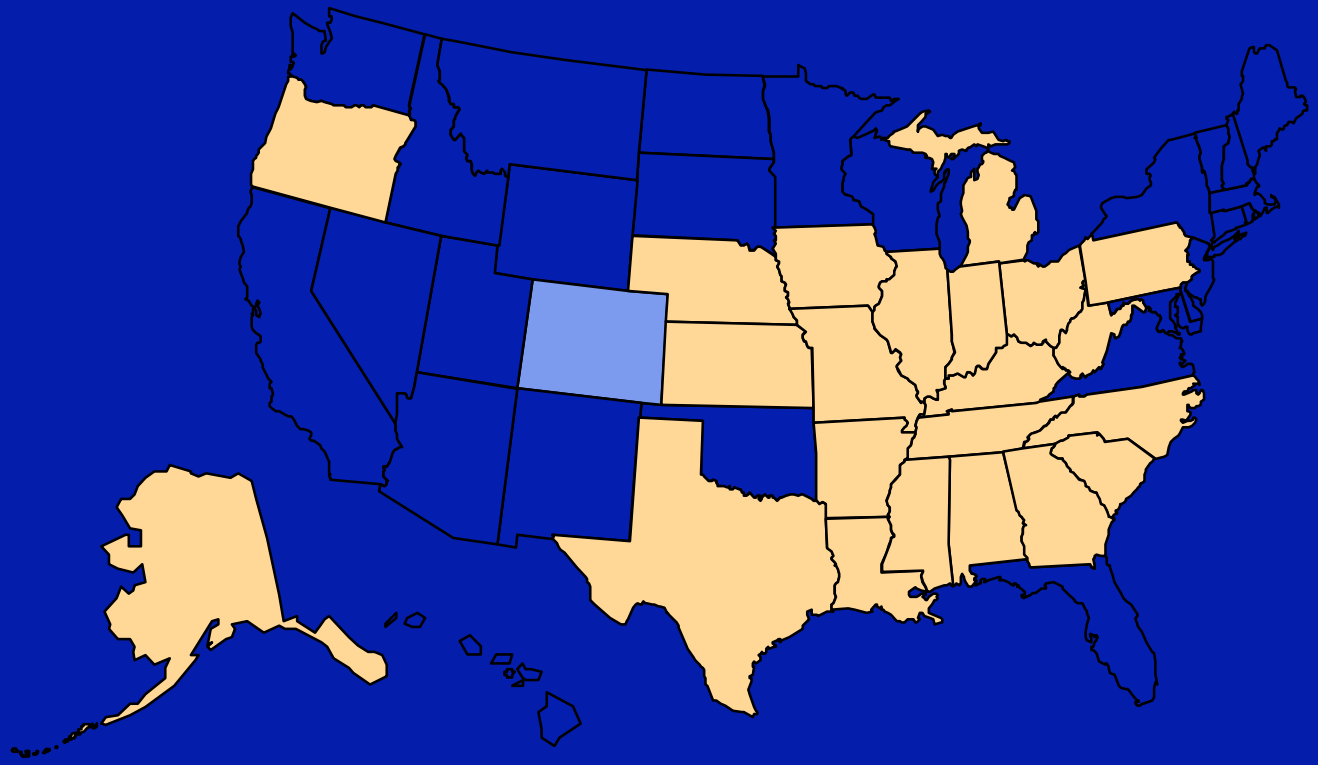


No Data | <10% | 10%–14% | 15%–19%

Obesity Trends* Among U.S. Adults BRFSS, 2000

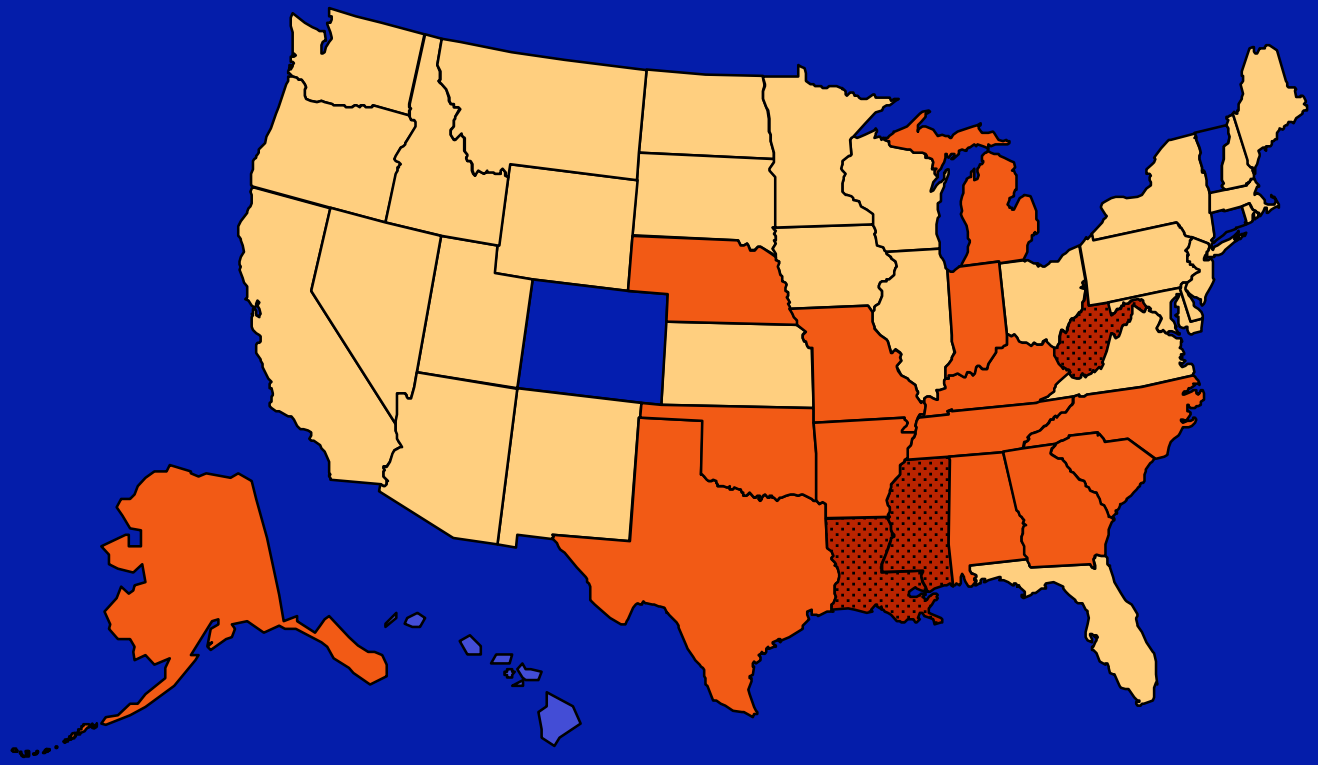
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



10% | 10%–14% | 15%–19% | ≥20%

Obesity Trends* Among U.S. Adults BRFSS, 2005

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)



Obesity Trends* Among U.S. Adults BRFSS, 2009

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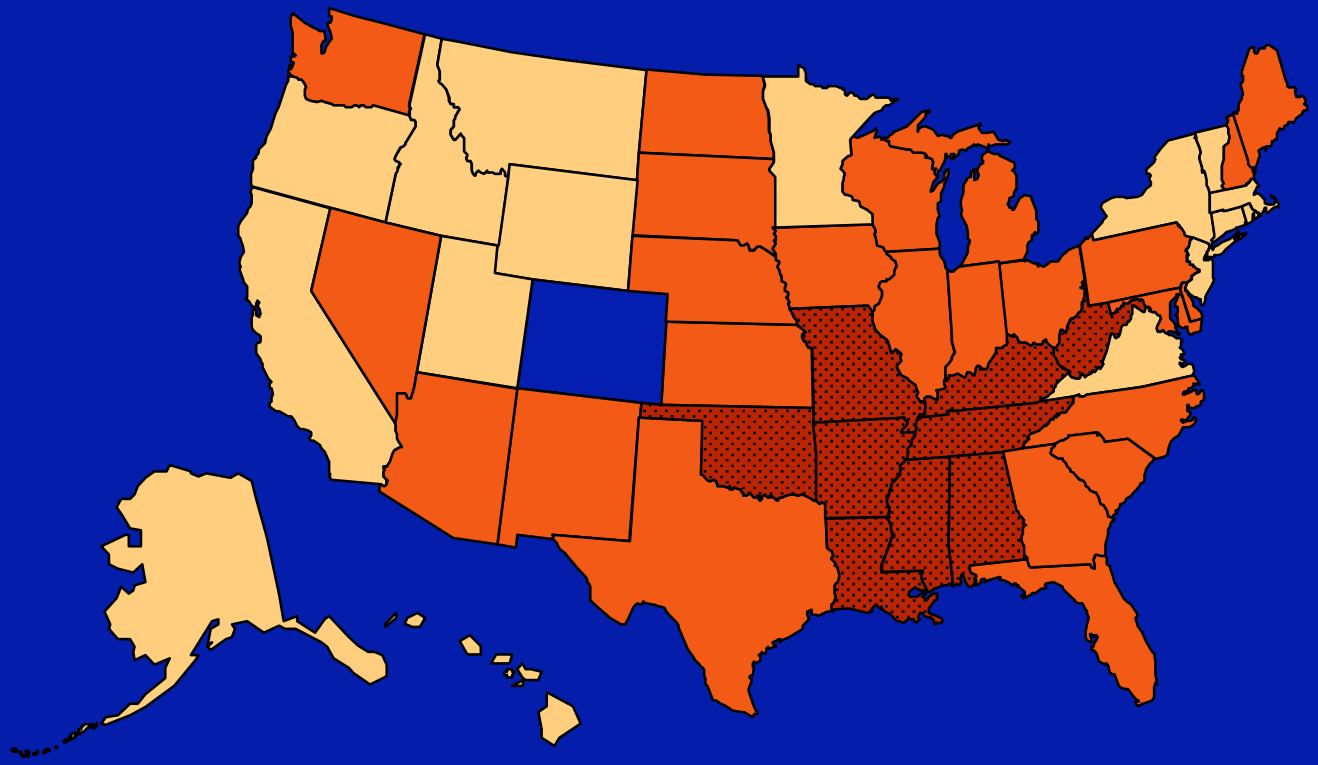
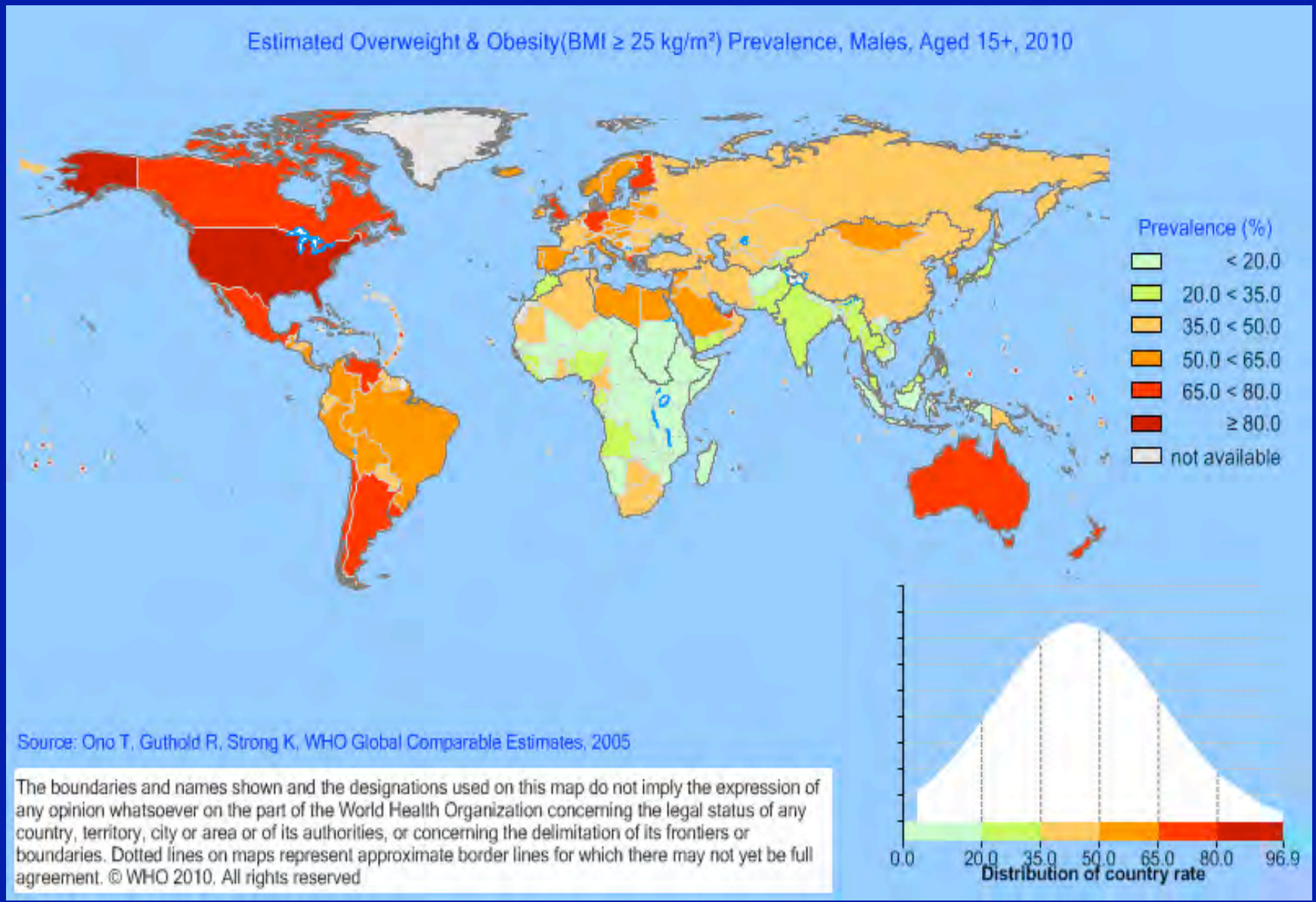
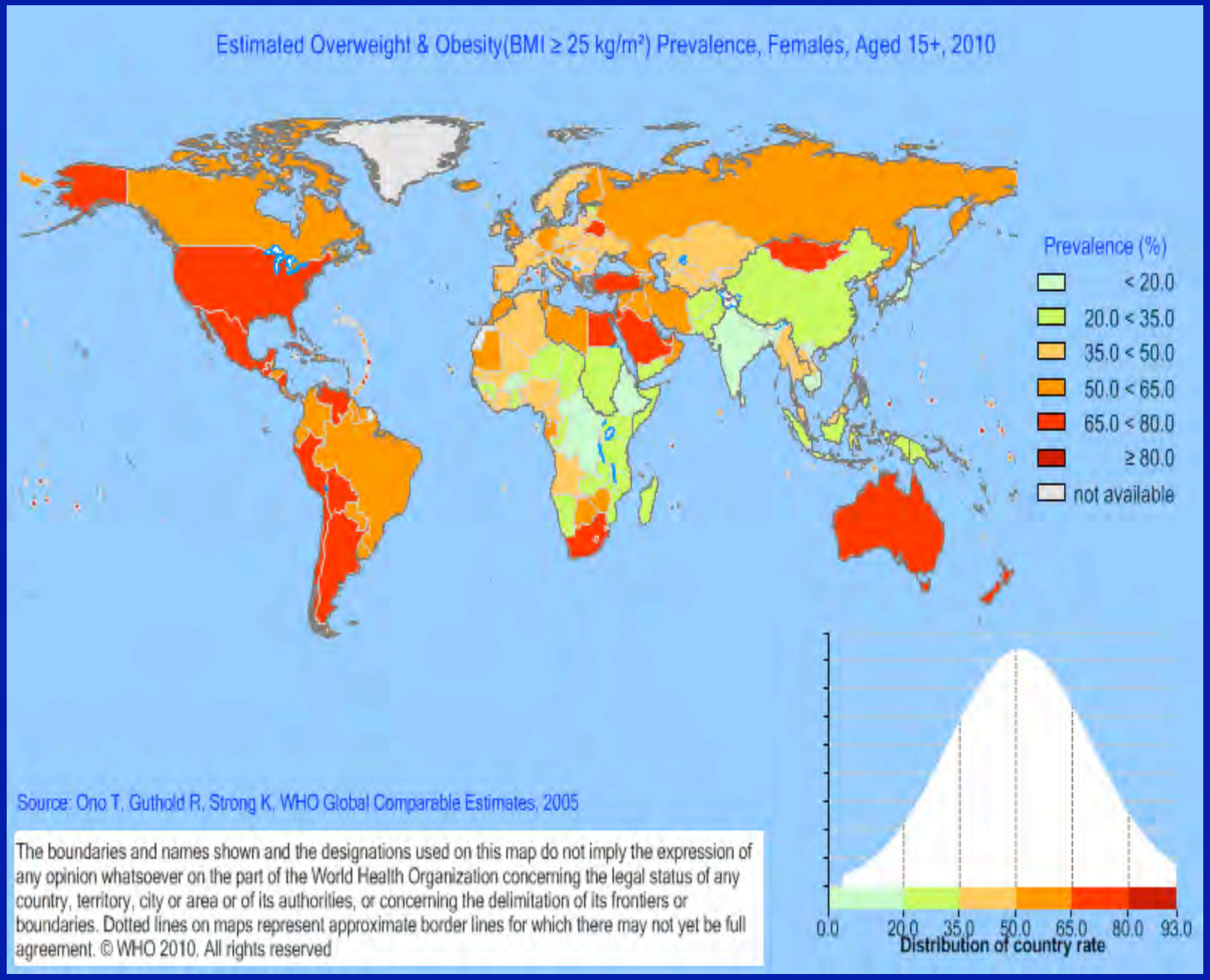



Estimated Overweight & Obesity(BMI ≥ 25 kg/m²) Prevalence, Males, Aged 15+, 2010
Prevalence (%)
< 20.0
20.0 < 35.0
35.0 < 50.0
50.0 < 65.0
65.0 < 80.0
≥ 80.0
not available
0.0
20.0
35.0
50.0
65.0
80.0
96.9
Distribution of country rate
Source: Ono T, Guthold R, Strong K, WHO Global Comparable Estimates, 2005
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. © WHO 2010. All rights reserved


Estimated Overweight & Obesity(BMI ≥ 25 kg/m²) Prevalence, Females, Aged 15+, 2010
Prevalence (%)
< 20.0
20.0 < 35.0
35.0 < 50.0
50.0 < 65.0
65.0 < 80.0
≥ 80.0
not available
0.0
20.0
35.0
50.0
65.0
80.0
93.0
Distribution of country rate
Source: Ono T, Guthold R, Strong K, WHO Global Comparable Estimates, 2005
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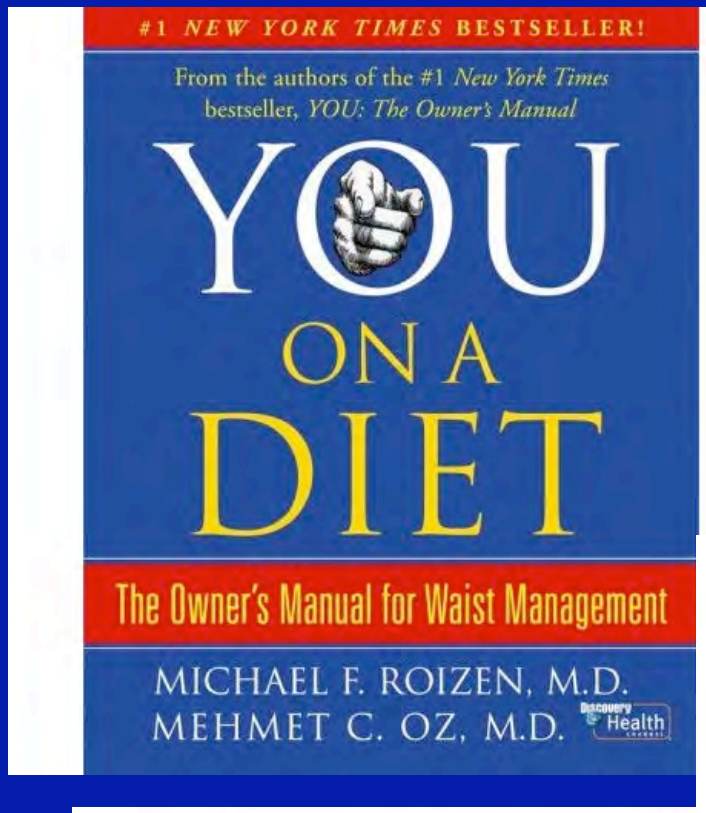
Fad or Real??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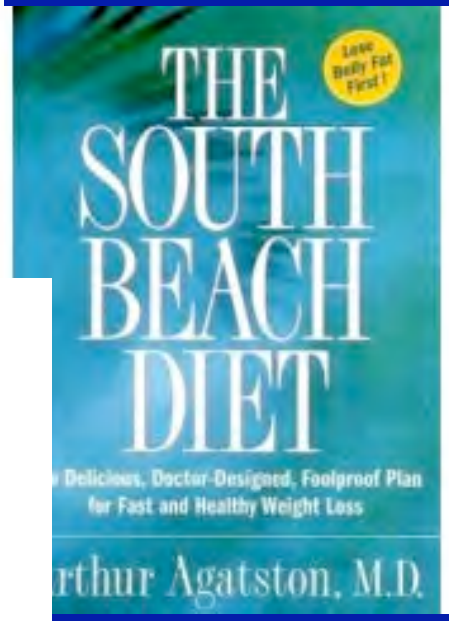
MICHAEL F. ROIZEN, M.D.
MEHMET C. OZ, M.D.
Discovery Health


Lose Belly Fat First!
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rthur Agatston, M.D.


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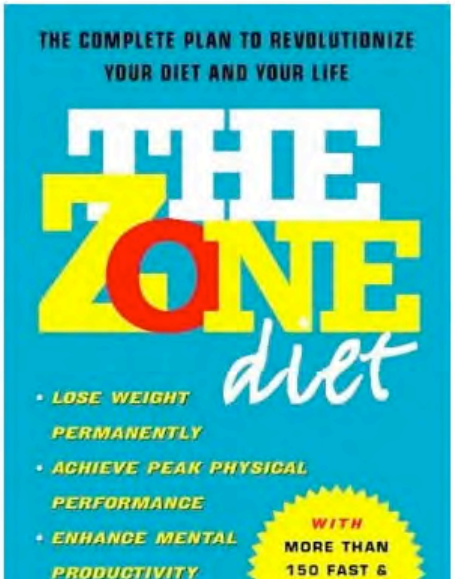
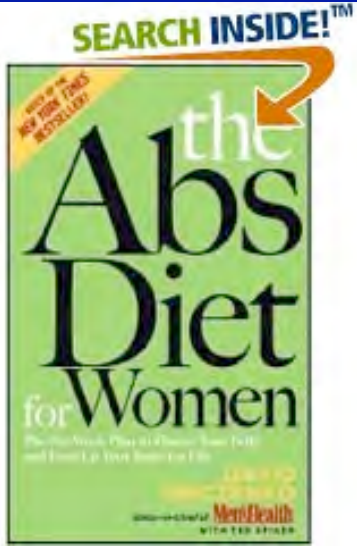
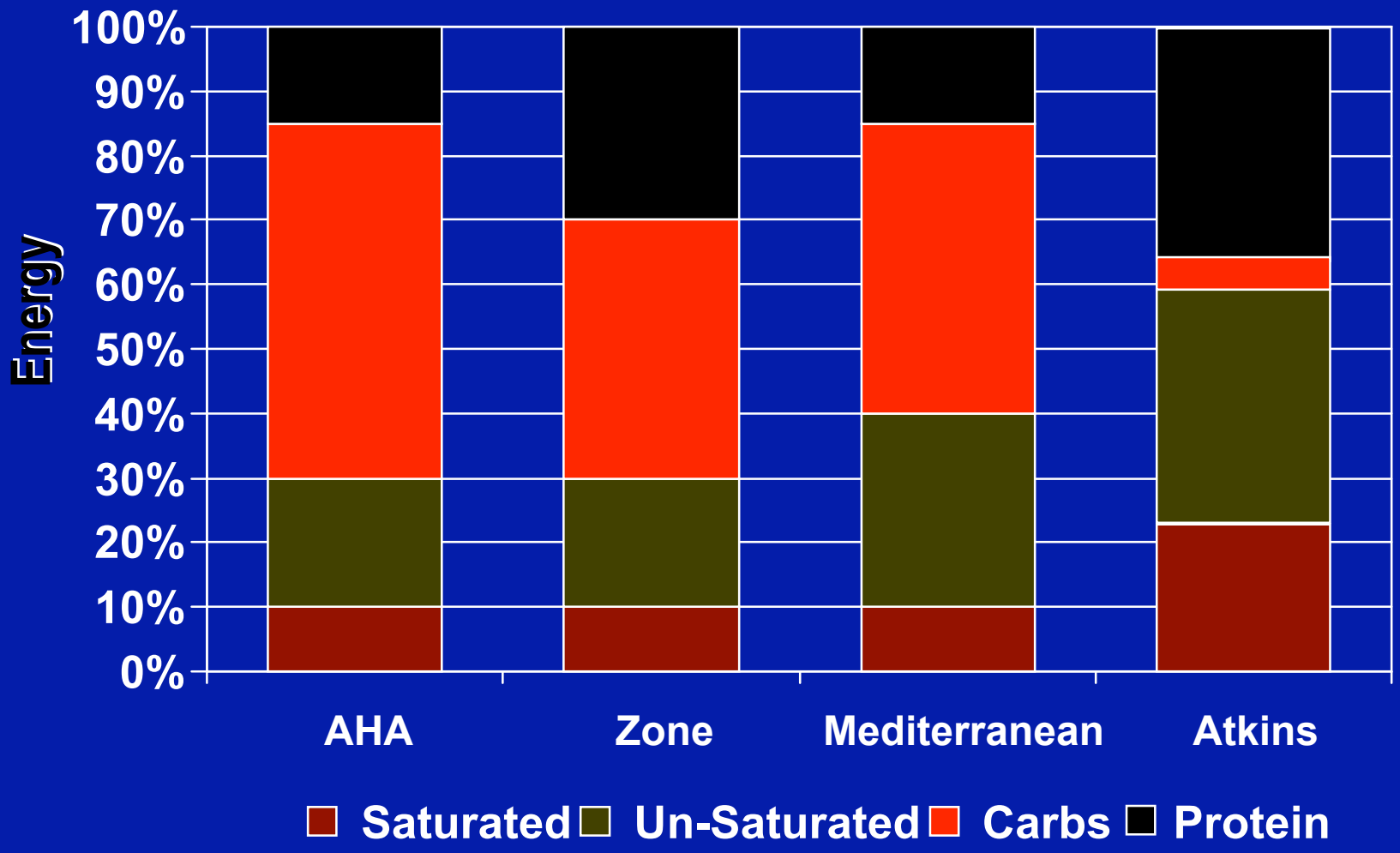
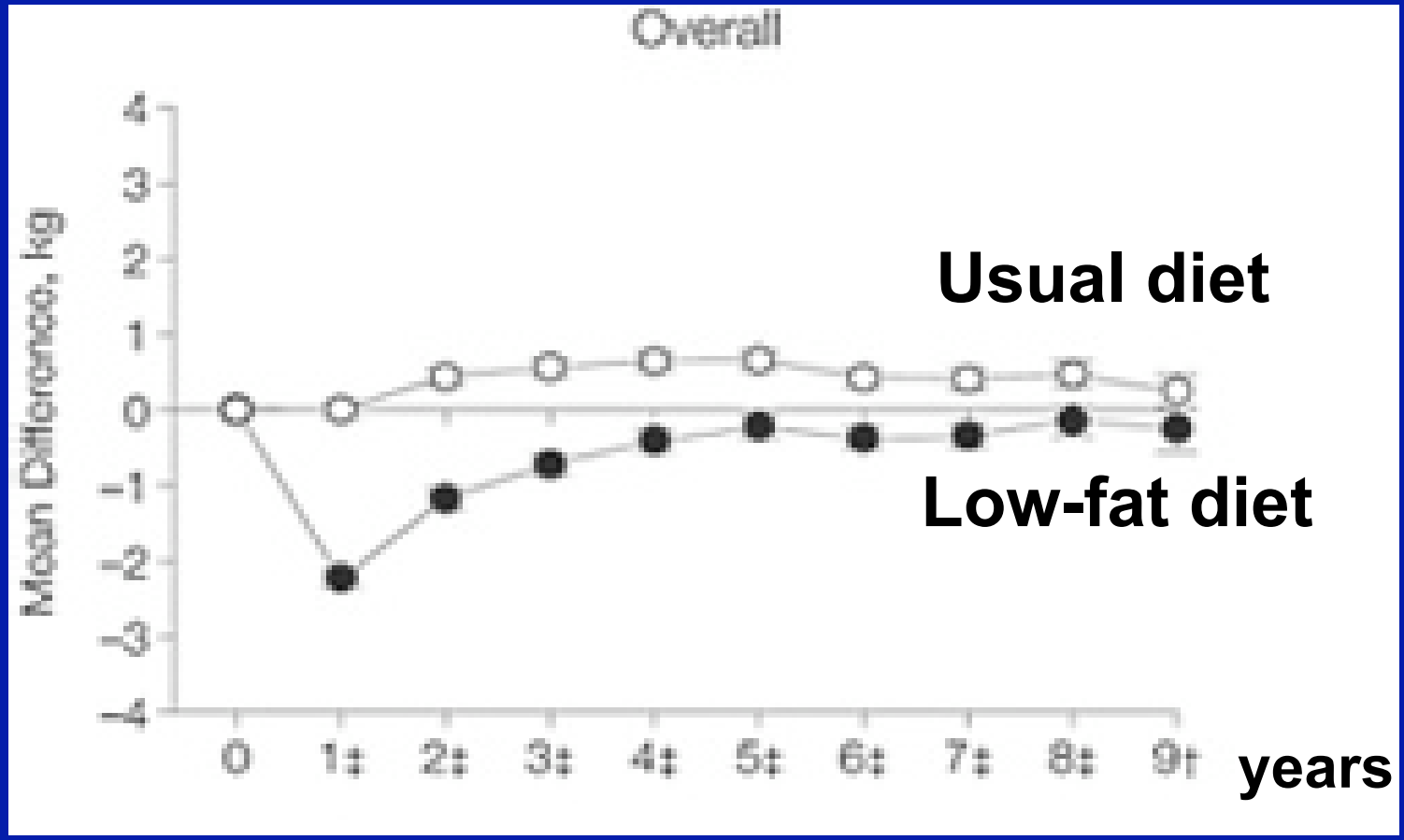

THE COMPLETE PLAN TO REVOLUTIONIZE YOUR DIET AND YOUR LIFE
THE ZONE diet
• LOSE WEIGHT PERMANENTLY
• ACHIEVE PEAK PHYSICAL PERFORMANCE
• ENHANCE MENTAL PRODUCTIVITY
WITH MORE THAN 150 FAST &


SEARCH INSIDE!™
the Abs Diet for Women
Men's Health

What's in a Diet ?



Low-Fat Dietary Pattern and Weight Change: Women's Health Initiative



Howard BV et al. JAMA, 2006

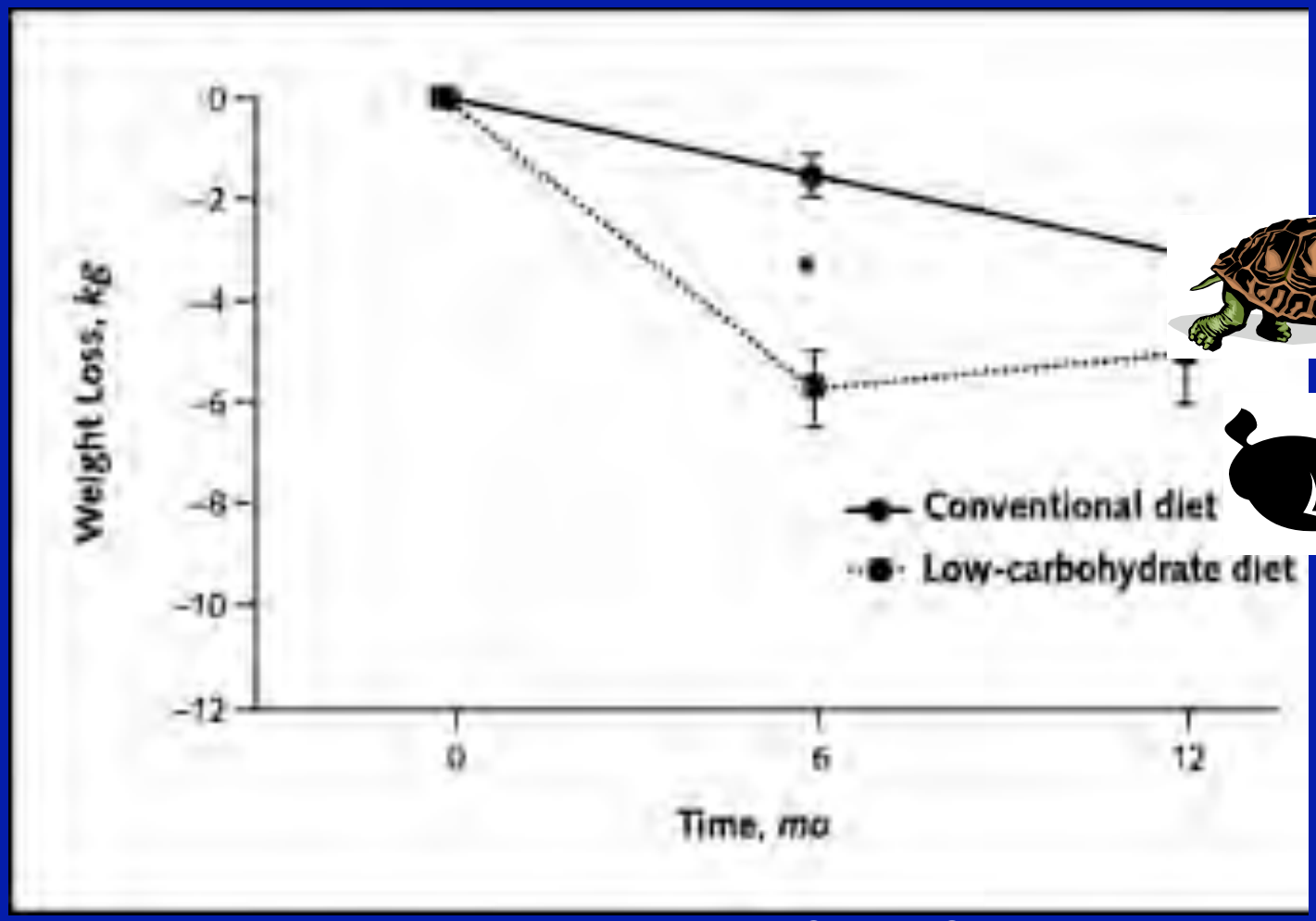
Superiority of Very Low Fat Vegan Diet Compared to Standard Low-fat in 2 yr: Effect of diet type and behavioral support

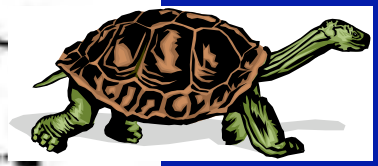
- **Vegan (n = 17)**
  - **With support after 3 months: - 5.3 kg**
  - **Without support: - 0.4 kg**
- **Standard low-fat (n = 14)**
  - **With support: - 2.7 kg**
  - **Without support: - 0.5 kg**

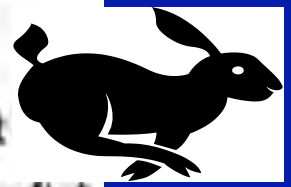
P<0.05 for diet type and support

Turner-McGrievy G, Barnard N, Scialli A. Obesity 2007

Low-Carb Diet vs Low-Fat Diet for Weight Loss

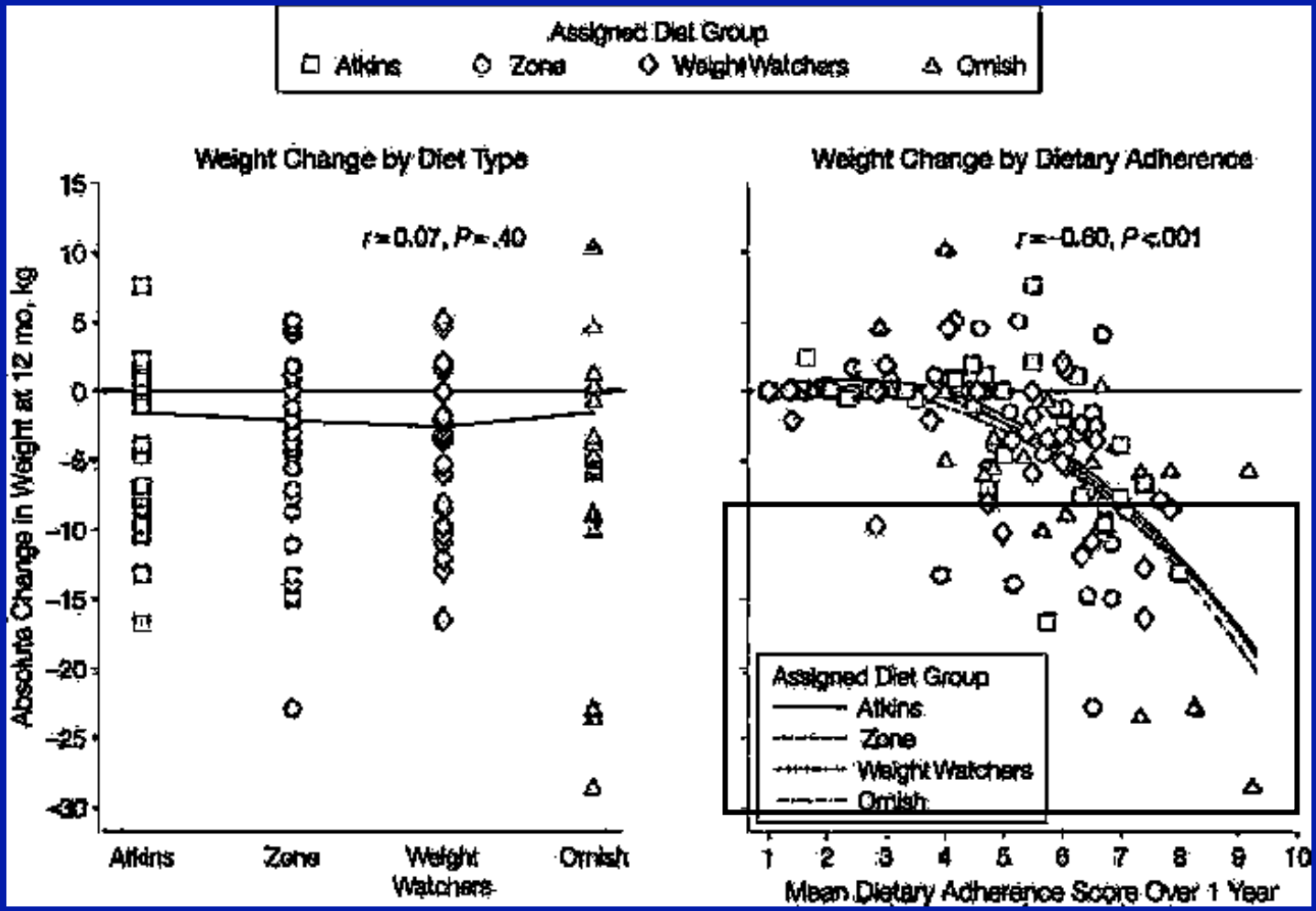




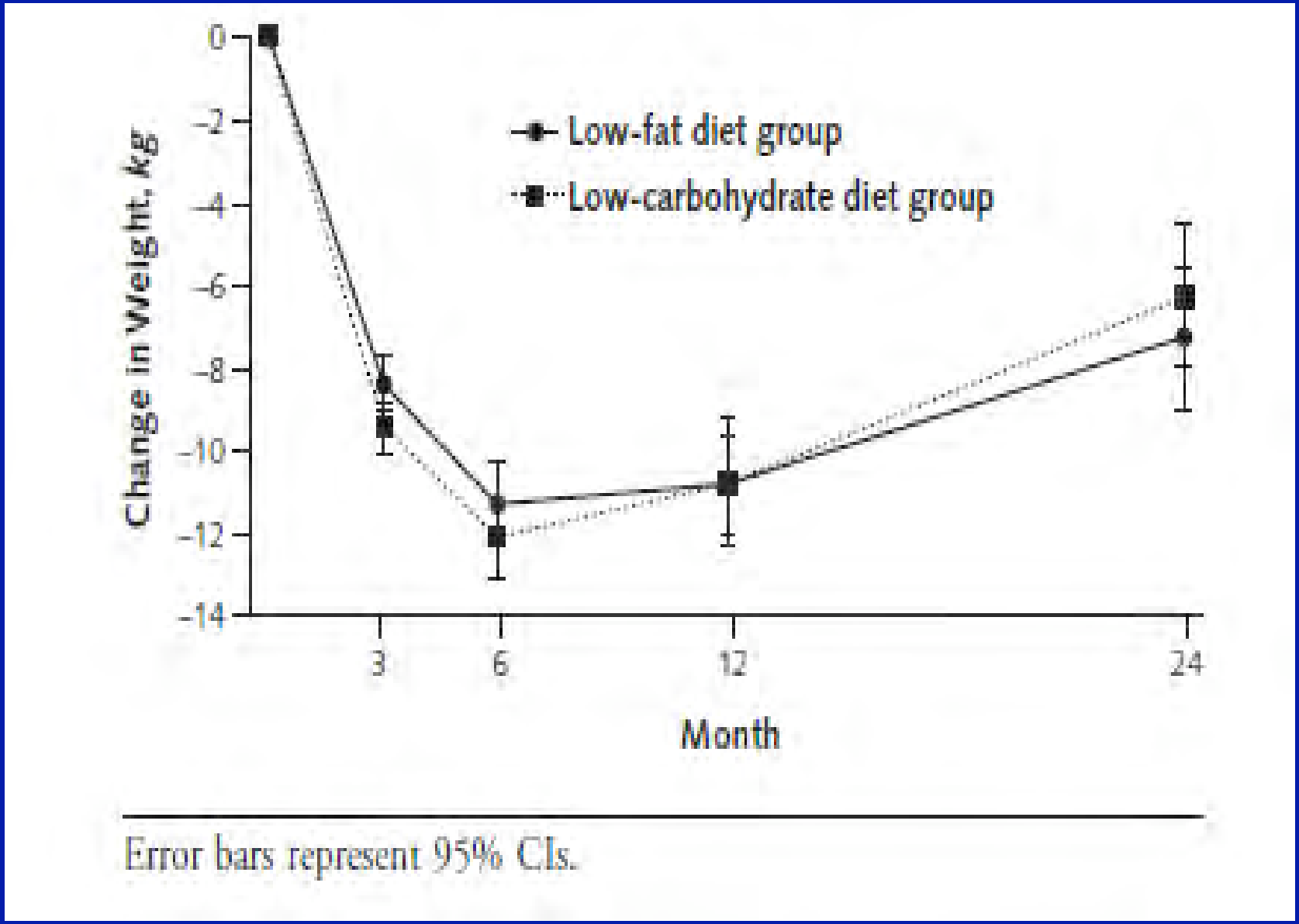


Stern L,Samaha F. Ann Intern Med, 2004

Similar Results with Low-Carb, Calorie Control or Very Low-Fat: Counseling by diet book

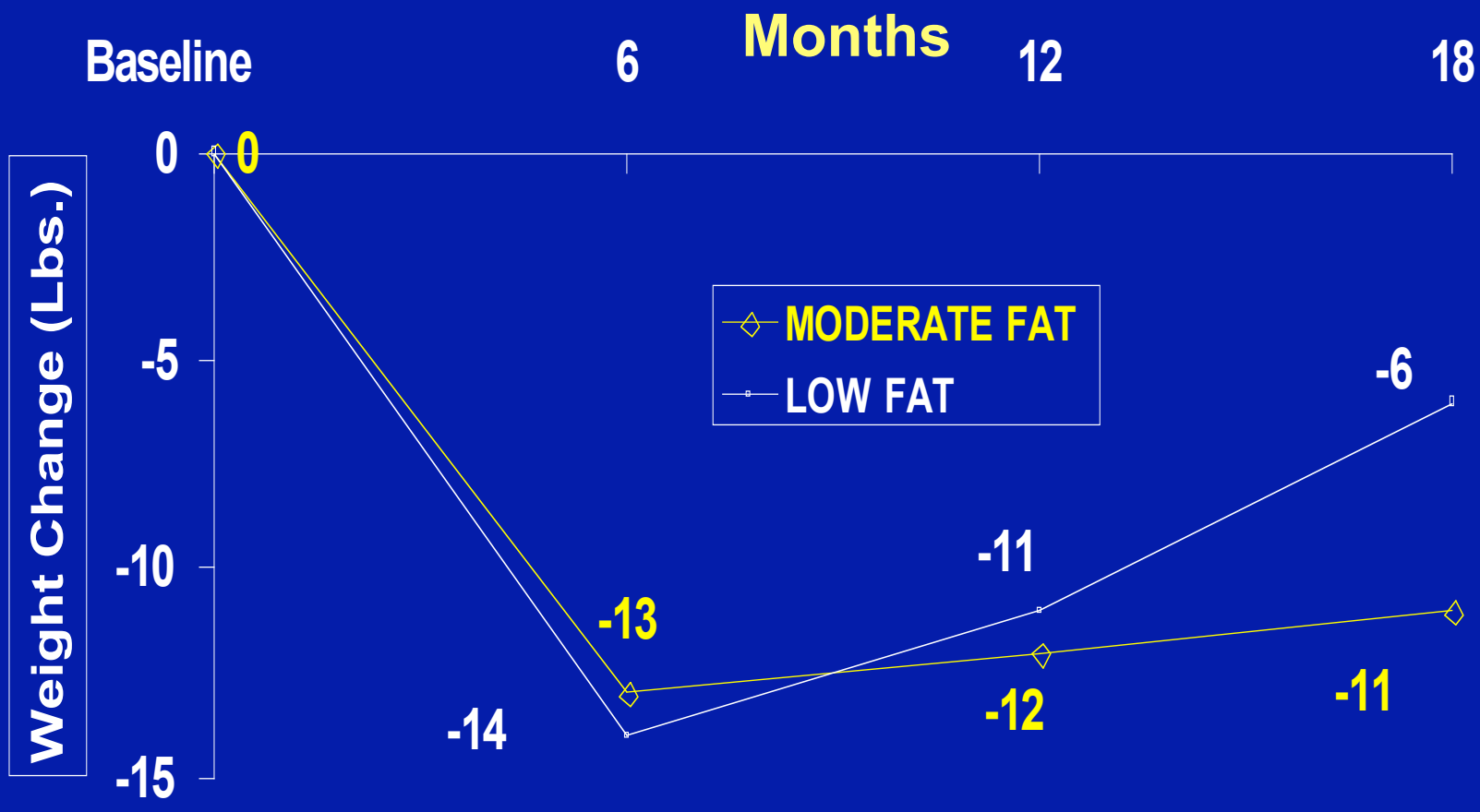


Dansinger..Schaefer. JAMA 2005



Foster et al, Ann Intern Med 2010; 153:147-157

Superiority of High-Unsaturated Fat, Mediterranean-style diet for weight loss



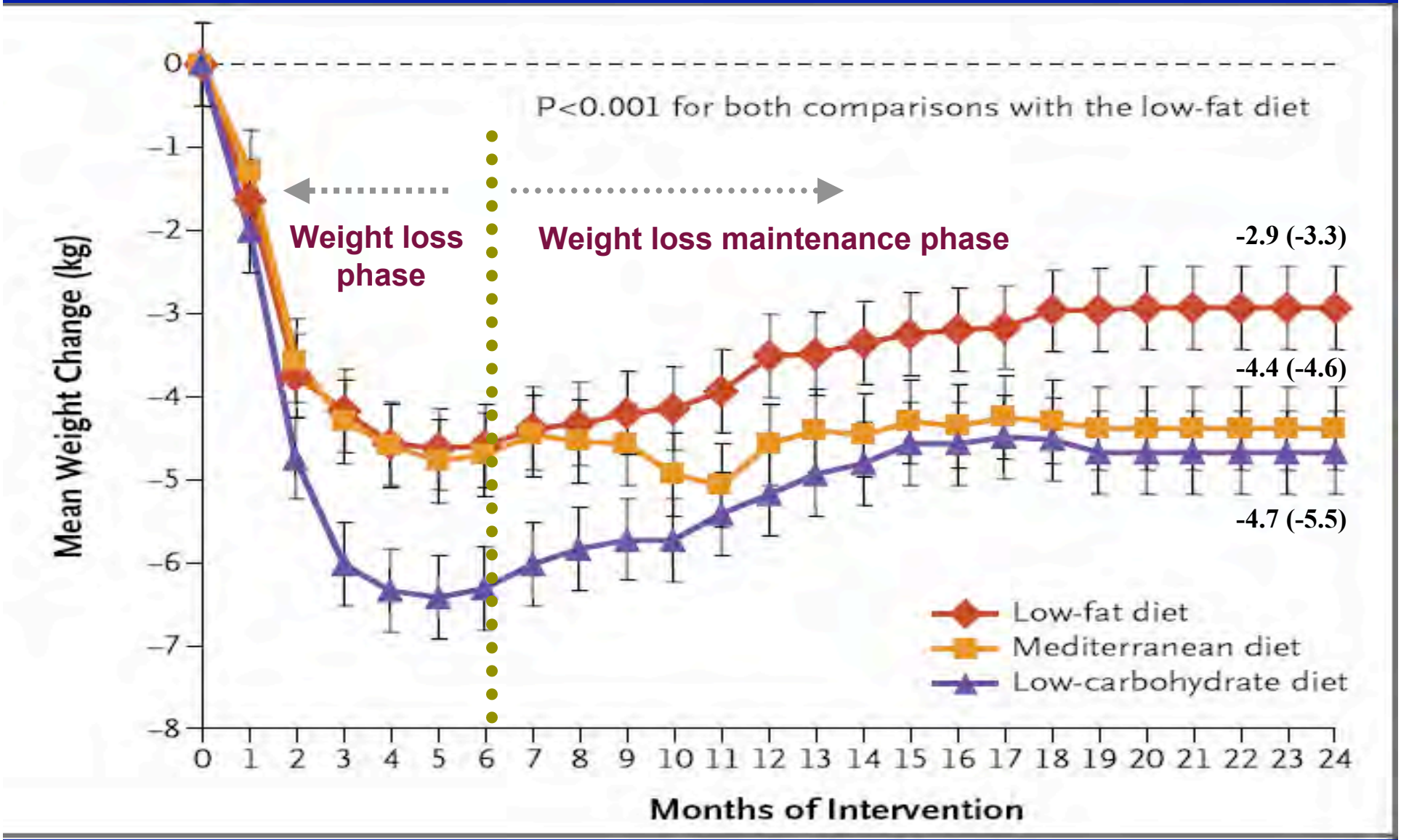
McManus, Antinoro, Sacks. Int J Obes 2001

Weight Gain in the Dropouts: Mediterranean and Low-Fat Groups Combined

- Dropouts had a net gain in weight of 9 pounds from the starting weight after 18 months.
- Those staying in the program lost 11 pounds.

McManus, Antinoro, Sacks. Int J Obes,2001

Mild Superiority of Mediterranean and Low-Carb Compared to Low-fat



Shai I, Stampfer M. N Eng J Med 2008

Limitations in Some Comparative Trials of Diet Types and Weight Loss

- Short duration, most lasted a few months.
- Some control groups had lower intensity of intervention
- Lack of blinded ascertainment of weight
- Underrepresentation of men
- Lack of information on adherence
- Large percentage of dropouts, up to 50%
- Novelty of one of the diets, media attention, and its marketing may have affected expectations of success.
- Researchers may have subtly favored a diet.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 26, 2009 VOL. 360 NO. 9

Comparison of Weight-Loss Diets with Different Compositions of Fat, Protein, and Carbohydrates

Frank M. Sacks, M.D., George A. Bray, M.D., Vincent J. Carey, Ph.D., Steven R. Smith, M.D., Donna H. Ryan, M.D., Stephen D. Anton, Ph.D., Katherine McManus, M.S., R.D., Catherine M. Champagne, Ph.D., Louise M. Bishop, M.S., R.D., Nancy Laranjo, B.A., Meryl S. Leboff, M.D., Jennifer C. Rood, Ph.D., Lilian de Jonge, Ph.D., Frank L. Greenway, M.D., Catherine M. Loria, Ph.D., Eva Obarzanek, Ph.D., and Donald A. Williamson, Ph.D.

ABSTRACT

BACKGROUND

The possible advantage for weight loss of a diet that emphasizes protein, fat, or carbohydrates has not been established, and there are few studies that extend beyond 1 year.

METHODS

We randomly assigned 811 overweight adults to one of four diets; the targeted percentages of energy derived from fat, protein, and carbohydrates in the four diets were 20, 15, and 65%; 20, 25, and 55%; 40, 15, and 45%; and 40, 25, and 35%. The diets consisted of similar foods and met guidelines for cardiovascular health. The participants were offered group and individual instructional sessions for 2 years. The primary outcome was the change in body weight after 2 years in two-by-two factorial

From the Department of Nutrition, Harvard School of Public Health (F.M.S., L.M.B.); the Channing Laboratory (F.M.S., V.J.C., N.L.) and the Endocrine Division (M.S.L.), Department of Medicine, Brigham and Women's Hospital and Harvard Medical School; and the Department of Nutrition, Brigham and Women's Hospital (K.M.) — all in Boston; Pennington Biomedical Research Center of the Louisiana State University System, Baton Rouge (G.A.B., S.R.S., D.H.R., S.D.A., C.M.C., J.C.R., L.J., F.L.G., D.A.W.); and the National Heart, Lung,

Pounds Lost Trial: Aims

- To determine whether fat, protein or carbohydrate contents affect weight-loss and its maintenance for 2 years.

- To determine the optimal proportions of fat, protein, and carbohydrate, if any, for weight loss and maintenance.

Sacks FM et al. N Eng J Med, 2009

Pounds Lost Trial Organization: Study Sites, Researchers, Funding

- Harvard School of Public Health and Brigham & Women's Hospital, Boston; F. Sacks, PI, Study Chairperson; Kathy McManus, Meryl LeBoff, Louise Bishop, Trisha Copeland, Jeremy Furtado, Jake Humpfreys, Cassandra Carrington, Jackie Gallagher, Audrey Shweky, Dawn Quintino, Marit Pywell, Mary Dinehart
- Pennington Biomedical Research Center, Louisiana State University System, Baton Rouge, G. Bray PI; Donna Ryan, Steven Smith, Steven Anton, Don Williamson, Cathy Champagne, Jennifer Rood
- Coordinating Center: Channing Laboratory, Brigham & Women's Hospital, V Carey Director; N Laranjo; BJ Harshfield, Melissa McEnery-Stonelake
- National Heart Lung and Blood Institute, NIH; Cay Loria, Eva Obarzanek, Project Officers
- Investigator Initiated proposal to NHLBI funded by cooperative agreement grant to Harvard School of Public Heath.

Pounds Lost Trial: Design

- 811 overweight or obese people
- Randomization among 4 diet types
- Duration of treatment 2 years
- Primary Outcome: Body weight, change from baseline to 2 years.
- Secondary Outcome: Waist Circumference
- Primary Analysis: Intention-to-treat with imputation of missing outcome data.
- Secondary Analysis: Completers (80%)

Pounds Lost Trial: Diets

The diets with target nutrient levels:

1. Low-fat (20%), average protein (15%), highest carbohydrate (65%)
2. Low-fat (20%), high protein (25%), carbohydrate (55%)
3. High fat (40%), average protein (15%), carbohydrate (45%)
4. High fat (40%), high protein (25%), lowest carbohydrate (35%)

Similar foods used in designing the meal plans for all diets but in different proportions. All dietary approaches adhered to healthful guidelines to prevent cardiovascular disease.

Dietary Program for Weight Loss

- Macronutrient targets were the main teaching objective.
- Specified menus for 2 week cycles for each group
- Participants taught to follow meal plans exactly
- Energy reduction goal was 750 Kcal daily
- Physical activity goal was 90 minutes per week
- Same technique and intensity for all groups

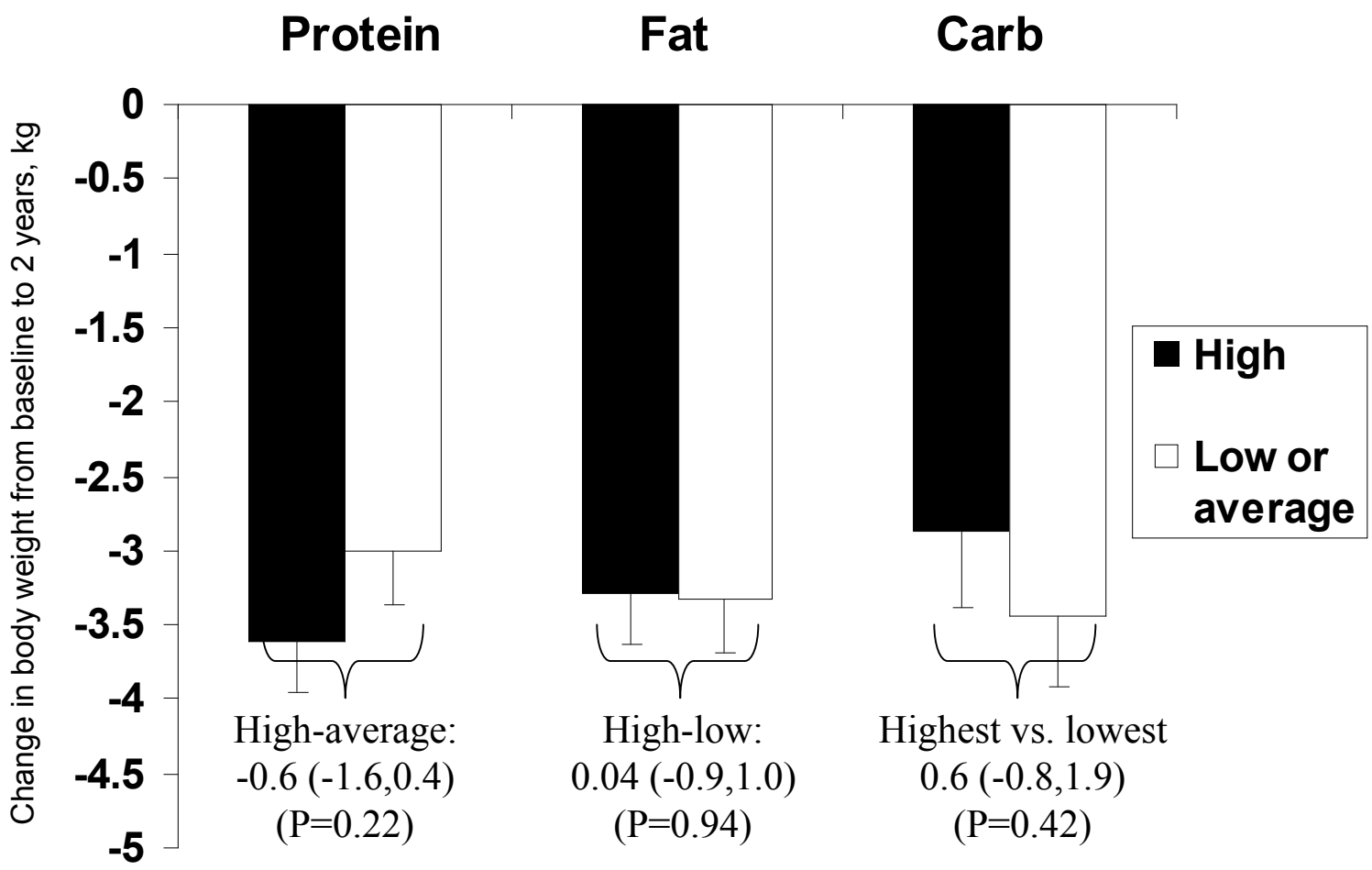
Dietary Program for Weight Loss

- Group sessions- 3 of every 4 weeks x 6 months, then 2 of every 4 weeks
- Individual counseling sessions: Every 8 wks for 2 yr
- Web-based system for participants to record diet and exercise to obtain feedback
- Contact among groups avoided
- Investigators and staff taught participants that each diet had an equal chance of success - goal was trial-wide “equipoise”.

Baseline Characteristics

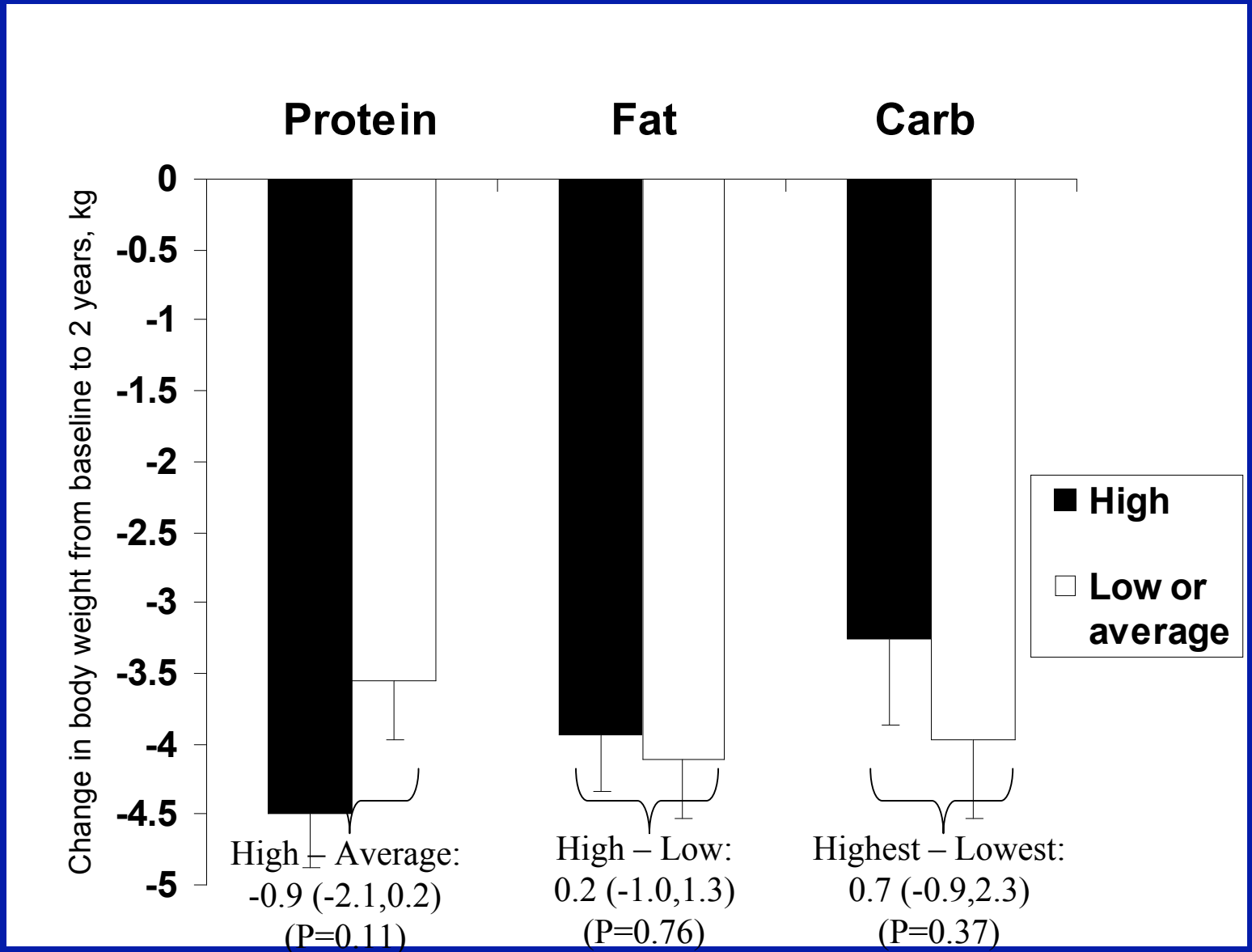
	All	Completers
• Number	811	645 (80%)
• Age	51	52
• Women	64%	62%
• White race	79%	81%
• BMI, kg (mean)	33	33
• BMI 25-30	27%	28%
• BMI ≥30	73%	72%
• Waist circumference	103 cm	104 cm
• Completed college	68%	69%
• Attended college	22%	20%
• Married	70%	69%

Pounds Lost: Primary Trial Outcome, 2 years
Body Weight Change: All randomized

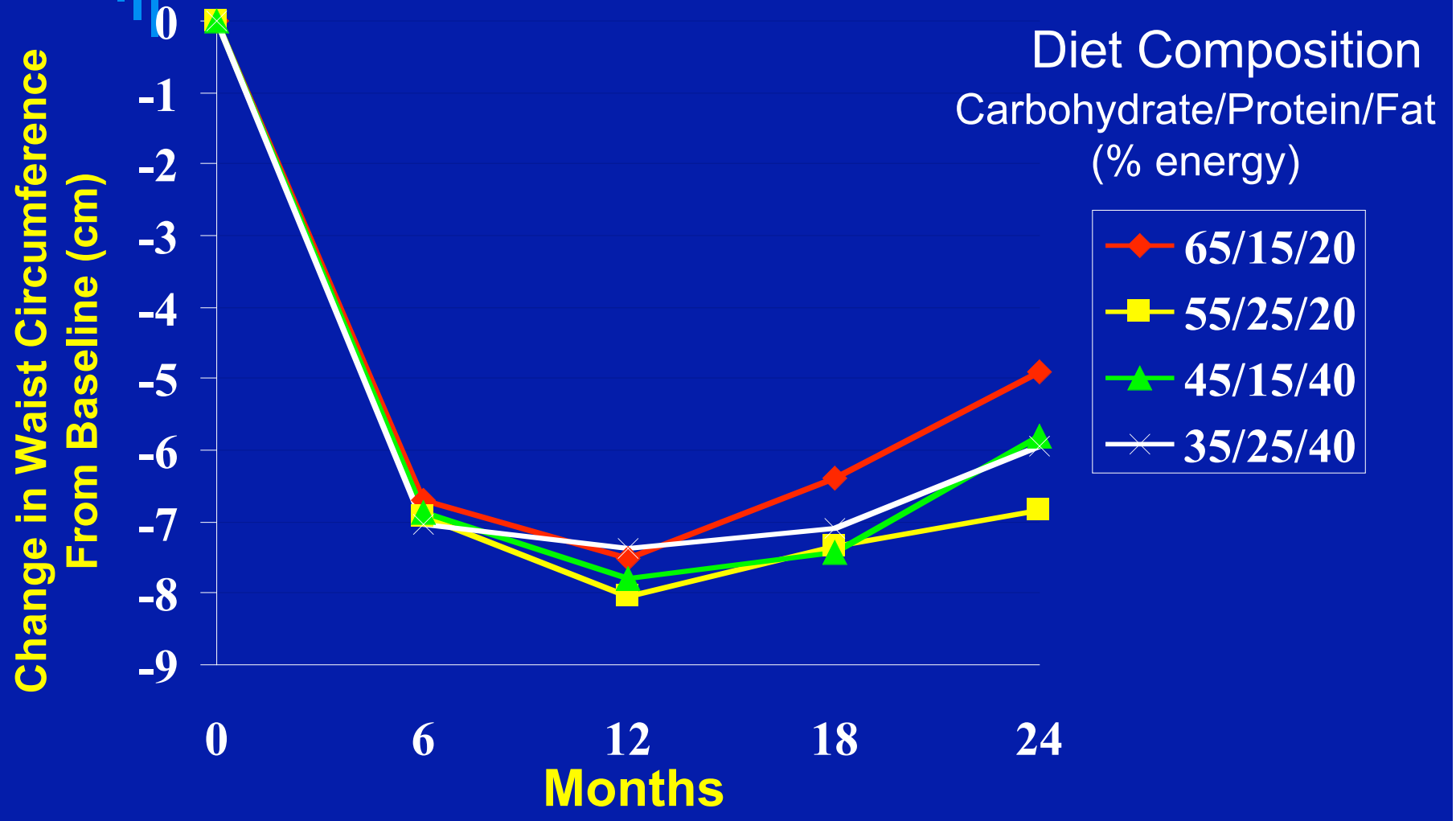


Sacks FM et al. N Eng J Med, 2009

Pounds Lost. Body Weight Change 2 years: Completers, N=645 (80%).



POUNDS LOST Waist Circumference in Completers



Achievement of Specific Weight Loss, 2 yr (Post-hoc Analysis)

	Carbohydrate/Protein/Fat, Target Intake, % Kcal			
	65/15/20	55/25/20	45/15/40	35/25/40
• Number	204	202	204	201
• ≥5% initial	30%	39%	31%	36%
• ≥10% initial	14%	15%	16%	14%
• ≥20 kg	4%	4%	2.5%	2%
• 90th p'tile	11.3 kg	12.3 kg	12.9 kg	10.9 kg

No significant differences by diet

Continued Weight Loss: from 6 months to 2 years

- 23% lost weight after 6 months
- Mean additional weight loss = 3.6 kg
- Total weight loss = 9.3 kg

No significant differences by diet group

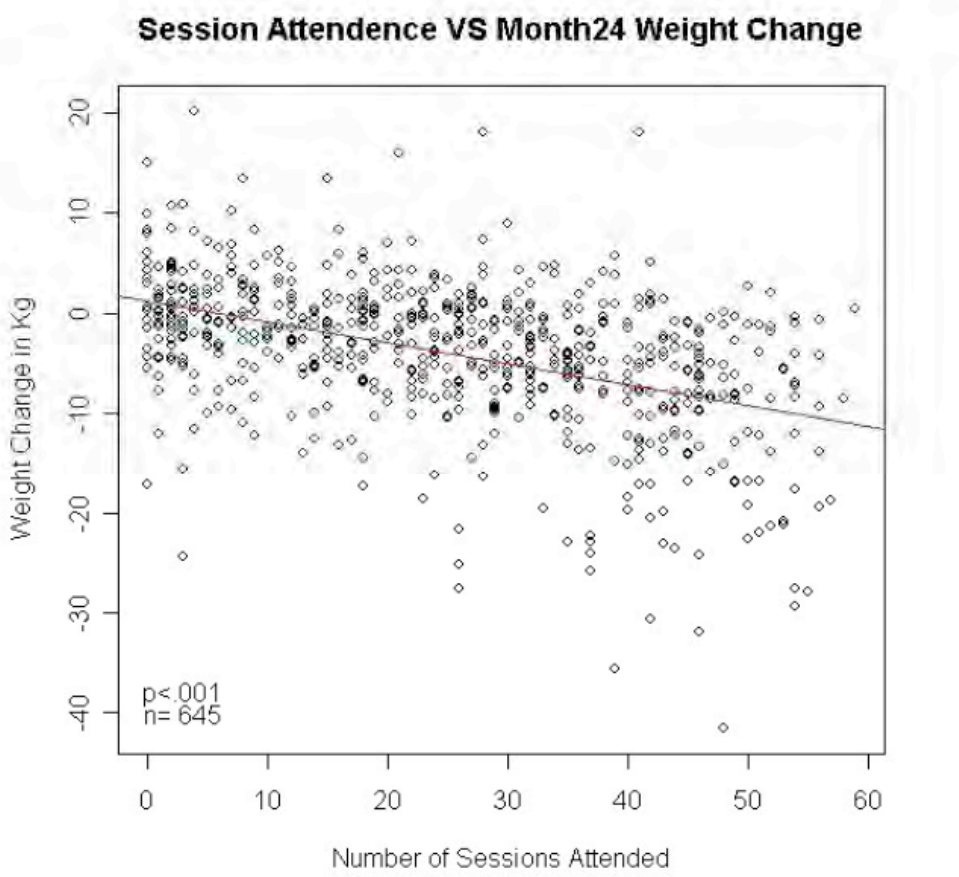
Satiety, Diet Satisfaction: Participants' reports at 6 months and 2 years

- Satiety by visual analogue scales
- Diet Satisfaction (Urban 1992)
- Food Craving: fats, sweets, carbohydrates, fast food fats, fruits & vegetables (FCI-II)
- Dietary restraint, dis-inhibition, hunger (Three Factor Eating Questionnaire, White M 2002)
- Quality of Life (SF-36)

No significant differences by diet group

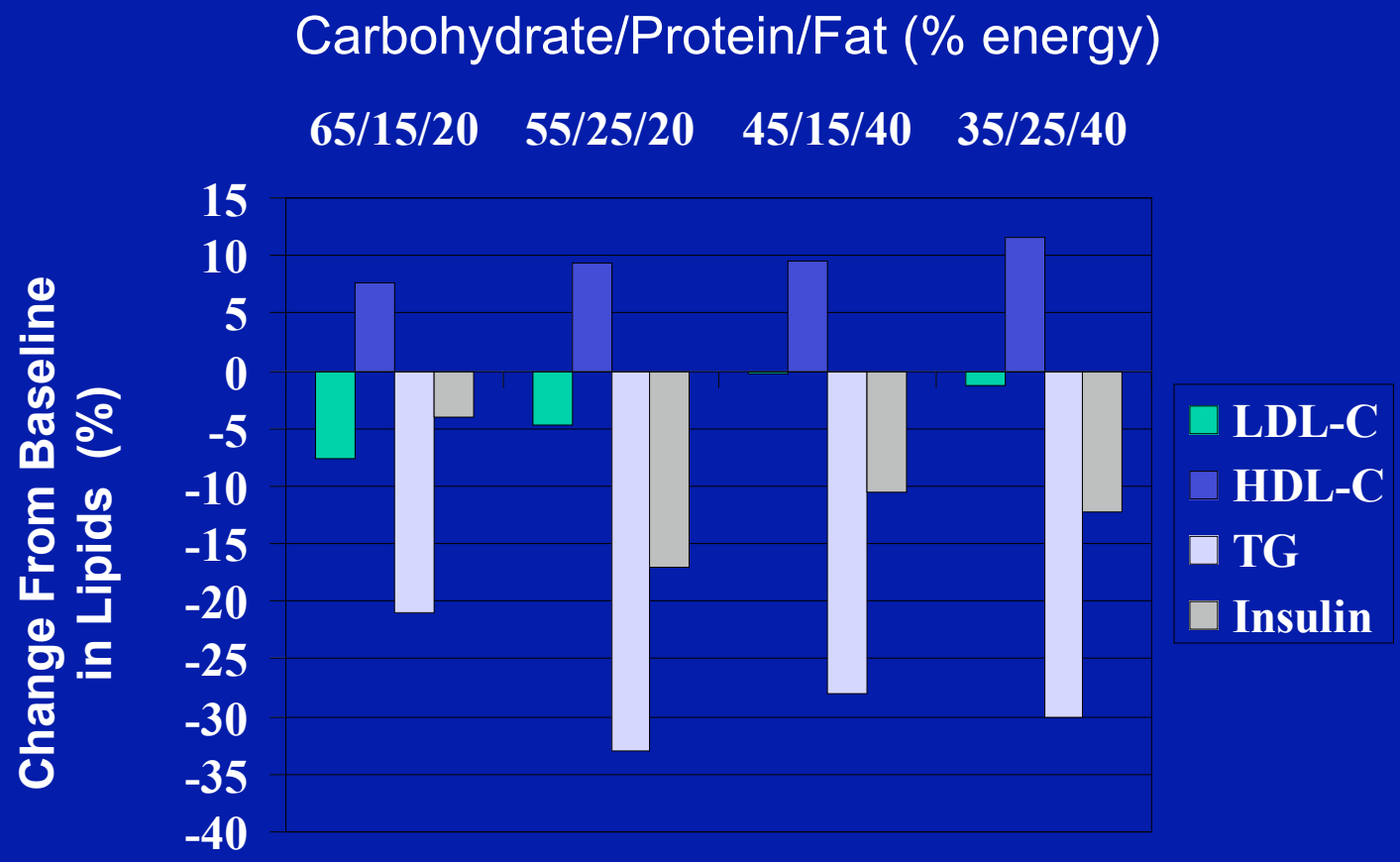
Group Session Attendance and Weight Loss at 2 years: Total Group

= *0.2 kg per session attended*



Sacks FM, N Eng J Med 2009

Serum lipid and insulin changes at 2 yr



Significant differences between diets:
↓LDL-C: Low-fat > high-fat; ↑HDL-C: Lowest carb > highest carb

Summary

- Reduced calorie diets achieve similar weight loss after 2 years regardless of emphasis on fat, carbohydrate or protein.
- Diet satisfaction, satiety, cravings similar with all approaches.
- Average weight loss: 9 pounds
- Average reduction in waist circumference: 2 inches
- Favorable changes in serum lipid risk factors and serum insulin

Conclusions

- Successful diets for weight loss can emphasize a large range of macronutrients
- These diets are made with foods that reduce risk of cardiovascular disease.
- Serum lipids and insulin are improved on all such diets. But low-fat may not be best for metabolic syndrome or diabetes.
- Ongoing counseling sessions are important to achieve and maintain weight loss.
- Successful diets for weight loss can be tailored to individual patients' personal and cultural preferences to achieve long-term success.

Pounds Lost Menus

- Five out of our 14 day menus included spaghetti or other forms of pasta
- All diet types enjoyed pasta – varying the amount eaten depending upon calorie level and macronutrient assignment
- We used both regular and whole grain pastas
- Pasta meals offered variety in our menus. We used different sauces (olive oil or tomato based) along with different vegetables and lean protein

1600 Calorie Meal Plan

Lunch

% Carbohydrate/Fat/Protein

Food	65/20/15	55/20/25	45/40/15	35/40/25
Whole wheat spaghetti	1 c	¾ c	½ c	½ c
Turkey, light meat	----	2 oz	---	2 oz
Summer squash, red peppers, mushrooms sauteed in Olive oil	1 ½ c 3 tsp	1 ½ c 3 tsp	1 ½ c 5 tsp	1 ½ c 4 tsp
Fruit- banana	1	1	1	½

1600 Calorie Meal Plan

Dinner

% Carbohydrate/Fat/Protein

Food	65/20/15	55/20/25	45/40/15	35/40/25
Salad Greens	2 c	2 c	2 c	1 c
Olive oil	1 Tbsp	1 Tbsp	5 tsp	2 Tbsp
Chicken breast-	----	4 ½ oz	----	6 oz
Pasta	1 c	¾ c	½ c	½ c
Spaghetti sauce w/	1 c	1 c	½ c	¼ c
Mushroom & garlic	½ c	½ c	¼ c	¼ c
Spinach	1 ½ c	1 c	½ c	½ c
Milk, skim	1 c	¾ c	¾ c	½ c

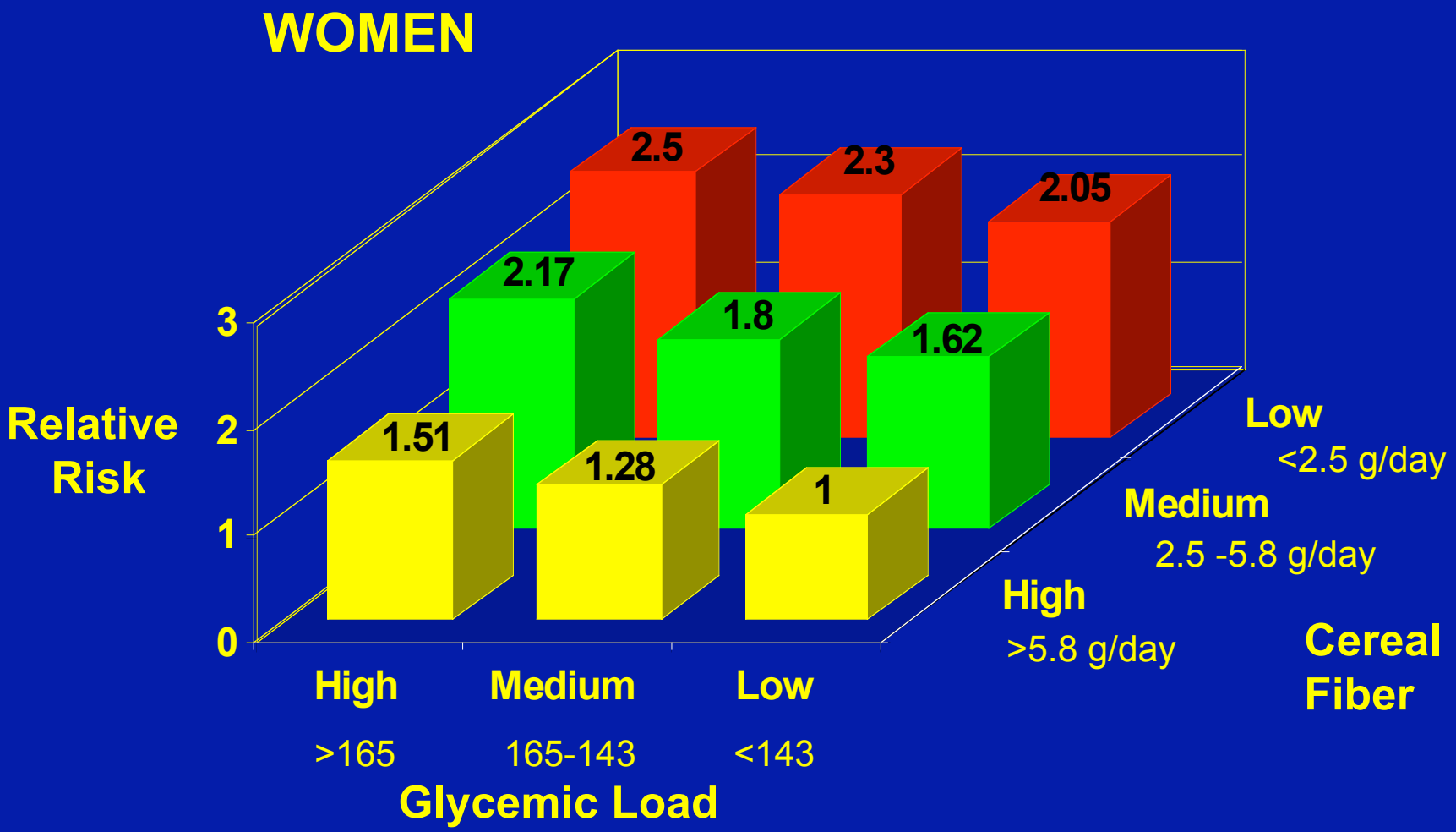
Food Name	GI	serve (g)	carb/serve (g)	GL
Spaghetti, white, boiled	42	180	48	20
Spaghetti, white, boiled (Vetta, Greens Foods, Glendenning, Australia)	49	180	44	22
Spaghetti, white, boiled (Canada)	50	180	48	24
Spaghetti, white, boiled	39	180	46	18
Spaghetti, white, durum wheat, boiled 20 min	58	180	44	26
Spaghetti, white, boiled (Nishin Shokuhin, Japan)	46	180	48	22
Spaghetti, white, boiled (Unico, Canada)	48	180	48	23
Spaghetti, white, durum wheat semolina (Panzani, Marseilles, France), boiled in 0.7% salted water for 11 min	59	180	48	28
Spaghetti, white, durum wheat semolina (Panzani, Marseilles, France), boiled in 0.7% salted water for 16.5 min	65	180	48	31
Spaghetti, white, durum wheat semolina (Panzani, Marseilles, France), boiled in 0.7% salted water for 22 min	46	180	48	22

Food Name	GI	serve (g)	carb/serve (g)	GL
Spaghetti, white, boiled, durum wheat (Catelli Ltd, Montreal, Canada)	34	180	48	16
Spaghetti, white, boiled	38	180	44	17
Spaghetti, white, boiled	42	180	48	20
Spaghetti, white, boiled	42	180	46	19
Spaghetti, white, boiled	45	180	48	22
Spaghetti, white, boiled	48	180	48	23
Spaghetti, wholemeal, boiled	32	180	44	14
Spaghetti, gluten-free, rice and Hi-Maize (high-amlyose) flour (Freedom Foods, Australia)	51	180	49	25
Wholemeal **spaghetti**, boiled	42	180	40	17
Spaghetti bolognaise, home made	52	360	48	25

Food Name	GI	serve (g)	carb/serve (g)	GL
Spaghetti, white, boiled 5 min	44	180	48	21
Spaghetti, white, durum wheat, boiled 12 min	34	180	48	16
Spaghetti, white, boiled 15 min (Lancia-Bravo Foods Ltd., Canada)	32	180	48	15
Spaghetti, white, boiled 15 min (Lancia-Bravo Foods Ltd., Canada)	36	180	48	17
Spaghetti, white, boiled 15 min	41	180	48	20
Spaghetti, Durum wheat, boiled 20 min	64	180	43	27
Spaghetti, white, boiled	33	180	48	16
Spaghetti, white, boiled, durum wheat (Catelli Ltd, Montreal, Canada)	34	180	48	16
Spaghetti, white, boiled	38	180	44	17
Spaghetti, white, boiled	42	180	48	20

University of Sydney, 2010

Relative Risk of Type 2 DM by Different Levels of Cereal Fiber and Glycemic Load



Salmeron, Willett. JAMA 1997;277:472