Empire Medical Training

ESTABLISHED IN 1998
OVER 45,000 GRADUATES TRAINED

Training for Physicians and Other Healthcare Professionals

WEIGHT MANAGEMENT & MEDICAL FITNESS

1-DAY PROGRAM

1 (866) 366-1576
www.EmpireMedicalTraining.com

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"Seminar Etiquette"

Do's

1. Learn a lot
2. Enjoy the program
3. Ask questions
4. Make new friends
5. Eat/drink during the event (non alcoholic please)
6. Stretch and take breaks as needed

Don'ts

1. Interrupt the speakers
2. Create a conversation/monologue with the instructor
3. Talk on your cell phone in the classroom during the seminar
4. Be disruptive or argumentative with any staff member, instructor or attendee during the program. (Sorry, we must enforce this "DON'T". Our primary concern is to ensure all attendees have maximally benefited from our event). **Hotel security will escort from the seminar (without refund) anyone who is deemed by any Empire staff member to be disruptive**, argumentative or a distraction to other attendees.

Thank you in advance for your cooperation. Please enjoy the program.

Physician Medical Weight Loss Training

AGENDA

8:00am–8:30am • Registration.

8:30am–9:30am • Epidemiology of Obesity in the USA. Lifestyle & Environmental factors behind the epidemic of obesity. Effects of adrenal, thyroid and gonadal hormone imbalance on obesity.

9:30am--11:00am • hCG Diet Plan, protocols, contraindications, delivery methods, and compliance issues. MIC Injections, Vitamin B-12, meal replacements, and other supplements. Exercise and Weight Loss Compliance.

11:00am–11:15am • Break.

11:15am–12:30pm • Metabolic Syndrome (Syndrome X), Hypothyroidism, Why most adults are overweight, Diagnosis, Testing, and Treatment; Protocols for prescribing.

12:30pm–1:30pm • Lunch (on your own).

1:30pm–3:15pm • Medical Weight Loss Patient, Pre-existing conditions, Pharmacologics and drug interaction. Customizing a Personal Weight Loss Plan with medical at risk patients. Weight Loss Supplements – when and how to use them. Interaction & Precautions. Prescription and OTC Protocols will be discussed.

3:15pm–3:30pm • Break.

3:30pm–4:30pm • Implementing weight loss into your practice and after weight loss maintenance programs. Insurance, Testing, Follow up, and special considerations. How to startup your weight loss practice and incorporate it to your existing patients and community.

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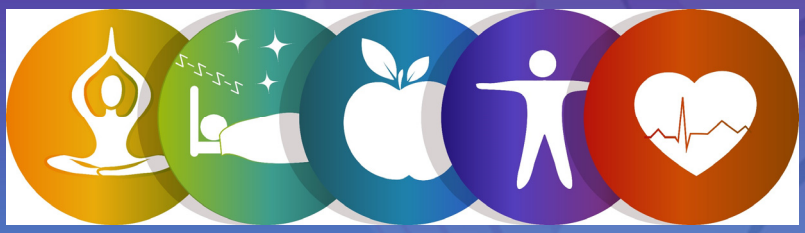
PHYSICIAN MEDICAL WEIGHT LOSS TRAINING

Modern Weight Loss Treatment in the Physician Practice



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Speaker Introduction

about.me

It's all about you.

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CME Information

Disclosure Statement

- In compliance with the Accreditation Council for Continuing Medical Education (ACCME) it is the policy of Empire Medical Training that faculty disclose all financial relationships with commercial interests **within the past 12 months.**

Program Evaluation/CME Credits

- A completed **Participant Demographic & Evaluation Form** is required in order to receive your CME/CE certificate

- Upon completion of these forms you will be issued a certificate of continuing education credit.

Obesity is nothing new…

- But the EPIDEMIC of obesity is

Stone Buddha
Temple of Xian, China
+/- 3,000BC

Reality of Obesity Treatment

- How much did you learn in med school?
- Biochemistry of the obese is different
  - Even after weight loss, the biochemistry of the formerly obese person is different from the person who never gained weight
- No longer an issue of "willpower"
- Many genetic factors still undiscovered
- The "Disease of Diseases"
  - Far-reaching pathophysiology and insidious comorbidities.

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Reality of Obesity Treatment

- Money Spent on Weight Loss Treatments

$60 BILLION PER YEAR

Geoff Williams, **The Heavy Price of Losing Weight,** US News & World Report/Money January 2013

- Cost of Obesity to Society

$147 - $210 BILLION PER YEAR

Cawley J and Meyerhoefer C. **The Medical Care Costs of Obesity: An Instrumental Variables Approach**. Journal of Health Economics, 31(1): 219-230, 2012

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Reality of Obesity Treatment

- Only **2%** of diets are successful.
- If 20% of Americans diet each year, and only 2% are successful, we are spending **$33,000** per successful dieter!

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Centers for Disease Control and Prevention
National Center for Health Statistics

During the past 24 years there has been a dramatic increase in obesity in the United States. In 1985 only a few states were participating in CDC's BRFSS and providing obesity data. In 1991, four states had obesity prevalence rates of 15-19 percent and no states had rates at or above 20 percent.

- Today, no state had a prevalence of obesity less than 20%.
  - 6 states and the District of Columbia had a prevalence of obesity between 20% and <25%.
  - 19 states and Puerto Rico had a prevalence of obesity between 25% and <30%.
  - 21 states and Guam had a prevalence of obesity between 30% and <35%.
  - 4 states (Alabama, Louisiana, Mississippi, and West Virginia) had a prevalence of obesity of 35% or greater.

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Obesity in the United States

- Prevalence of Self-Reported Obesity Among U.S. Adults by State and Territory
  - Obesity: Body Mass Index (BMI) of 30 or higher. Body Mass Index (BMI): A measure of an adult's weight in relation to his or her height, calculated by using the adult's weight in kilograms divided by the square of his or her height in meters.
  - The data were collected through the Behavioral Risk Factor Surveillance System (BRFSS), an ongoing, state-based, telephone interview survey conducted by state health departments with assistance from CDC. Height and weight data used in the BMI calculations were self-reported.

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Obesity in the United States (Contd.)

- Prevalence of Self-Reported Obesity Among U.S. Adults by State and Territory
  - BRFSS Methodological Changes Started in 2011 which now includes new exclusion criteria beginning with 2011 Chart Data. Older charts no longer have a correlation to the newer chart data.
  - New sampling frame that included both landline and cell phone households and new weighting methodology used to provide a closer match between the sample and the population.

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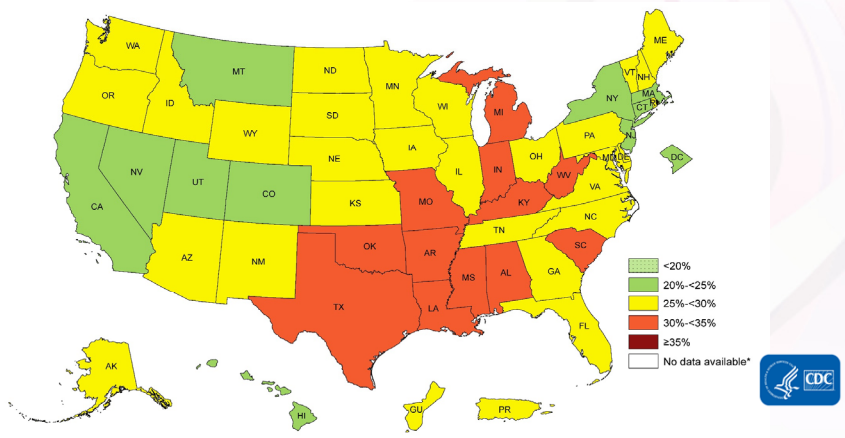
Self-Reported Obesity By Adults

BRFSS Data: 2011



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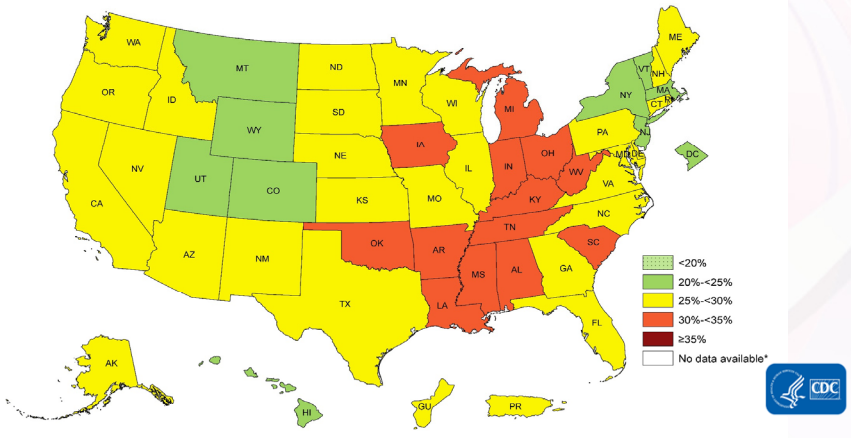
Self-Reported Obesity By Adults

BRFSS Data: 2012



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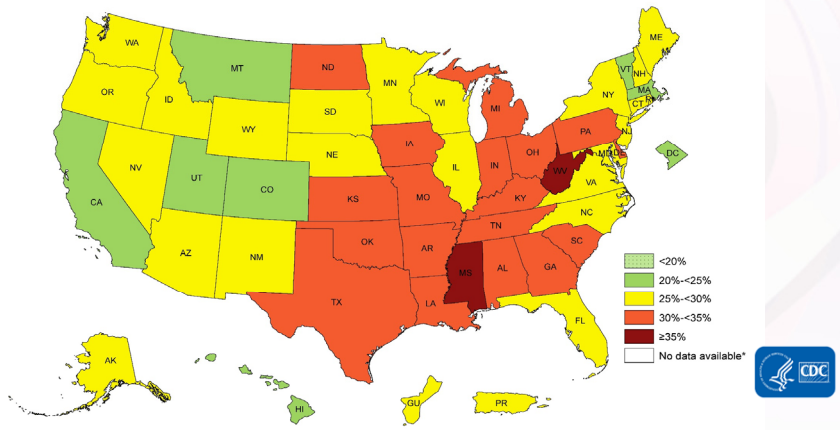
Self-Reported Obesity By Adults

BRFSS Data: 2013



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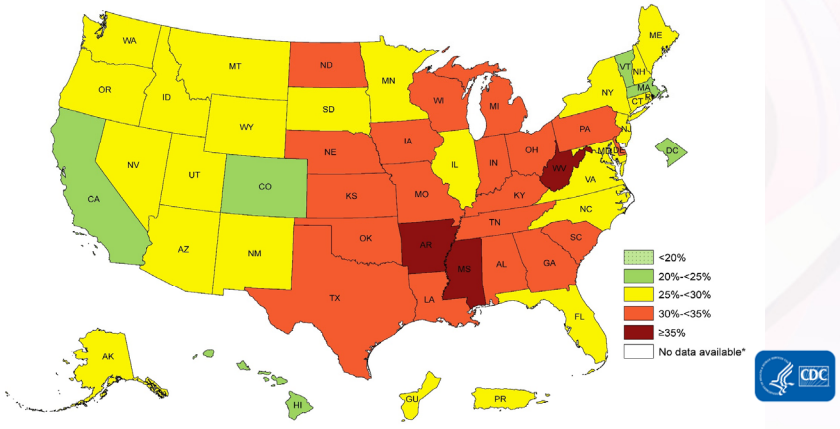
Self-Reported Obesity By Adults

BRFSS Data: 2014



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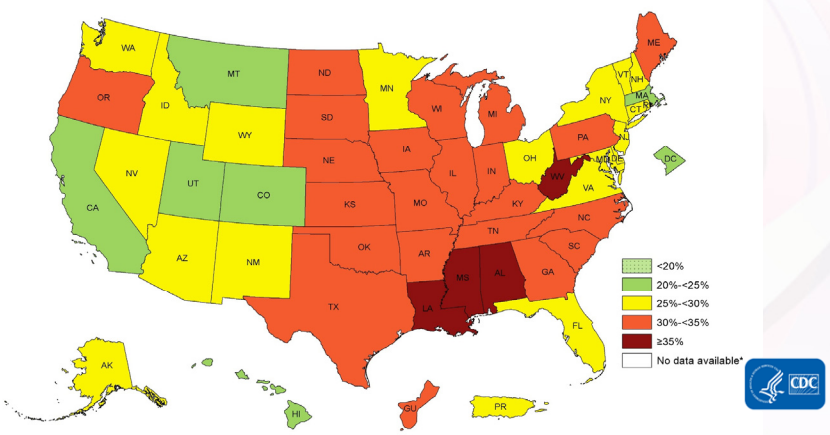
Self-Reported Obesity By Adults

BRFSS Data: 2015



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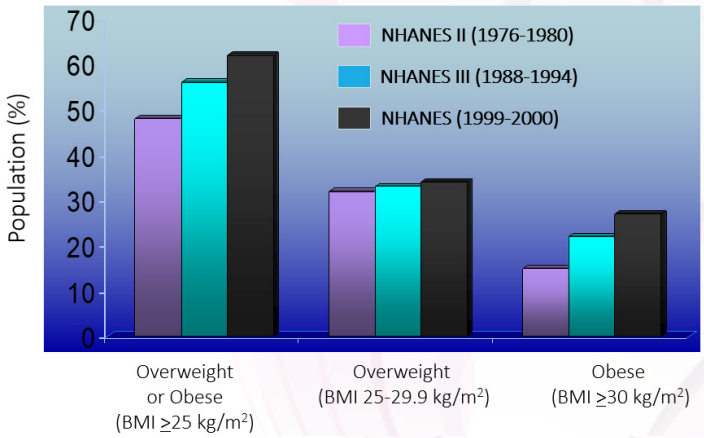
Age-Adjusted Prevalence

Overweight or Obesity in Adults



National Center for Health Statistics Website.

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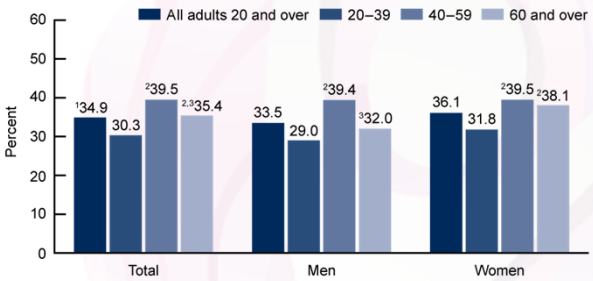
Age-Adjusted Prevalence

Overweight or Obesity in Adults

2011-2012

- Significant difference from ages 20-39
- Significant difference from ages 40-59
- Estimates are age-adjusted for all adults 20 and over.



Source: CDC/NHS National Health & Nutrition Sudy 2011-2012

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Prevention: How are we doing?

- From 1991-1998 prevalence of obesity increased by 50%
- Most insurance companies still do not pay for treatment of obesity itself, just the sequelae.
  - Most don't cover pharmacotherapy for obesity
- For every $1 spent on promotion of healthy eating, $45 is spent on consumer advertising by the food industry.

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Stigmatization of the Obese

- Negative attitudes toward obese Seen even in young children (age 3+)
  - Disadvantage in college admissions
  - Lower likelihood of hiring, raise, or promotion
  - Less likely to get help or favors

"The more pressure there is to be fit and thin in pop culture, the fatter we get as a group!"

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Perception of Quality of Life

- BRFSS (N=109,076)
  - BMI>30 associated with impaired physical well-being when all other factors controlled.
  - Observed in all age and ethnic groups
- Higher level of perception of impaired well-being in women.
- Overall perception of poor health increases with BMI

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National Consumption Averages

- Average American Male (Estimated)
  - 2,800 cal per day consumption
- Average American Female (Estimated)
  - 2,000 cal per day consumption
- The average person estimates that they consume 30-40% less than they really do

Gender	Sedentary	Moderately Active	Active
Male	2000-2600 cal	2200-2800 cal	2400-3000 cal
Female	1600-2000 cal	1800-2200 cal	2000-2400 cal

U.S. Department of Agriculture, 2014

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The Epidemic in Calories

50 kcal per day

- Extra consumption per person leads to entire obesity epidemic over past 15 years.
  - Average adult weight gain of .5-2 kg/yr over the past 15 years. *(51)*
- Over last few decades
  - Decrease in consumption foods higher in fat
    - Increase in consumption of added fat (butter, fried foods)
  - Increased fruit and vegetable servings
    - 17.5% of all vegetables is potato in French Fries
  - Cheese consumption increased 2.5 times
    - The increase is completely used in pizza and cheeseburgers

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Portion Size / High Energy Foods

- The more food on the plate, the more we eat!
  - Larger plate sizes
  - Larger portions in restaurants
- UNC Study – consumption from 1977 to 1996
  - Salty snacks increased by 93 calories or 0.6 ounces
  - Soft drinks by 49 calories or 6.8 ounces.
  - Hamburgers by 97 calories or 1.3 ounces
  - French fries by 68 calories or 0.5 ounces.
  - Mexican food by 133 calories, or 1.7 ounces

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Eating Out

- Increased 200% from 1985 to 2010
  - Higher fat and sugar content in fast foods
    - May lead to larger sizes at home
- Even at home, people who do not eat as a family consume more fat and carbs

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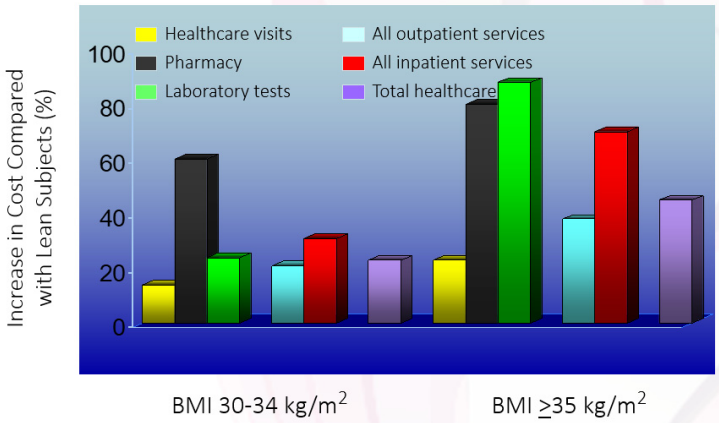
Increase in Healthcare Costs Among Obese Compared with Lean (BMI <25 kg/m2) Patients*



*HMO Setting: Northern California Kaiser Permanente.

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Quesenberry CP Jr et al. **Obesity, Health Services Use, and Health Care Costs Among Members of a Health Maintenance Organization,** *Arch Intern Med.* 1998;158:466-472.

Annual Medical Expenditures

Attributable to Obesity in US

- 6% total adult medical expenditures are attributable to obesity
  - Range: 4% (AZ, CT) – 7% (AK)
- 7% Medicare expenditures
  - Range: 4% (AZ) – 10% (DE)
- 11% adult Medicaid expenditures
  - Range: 8% (RI) – 16% (IN)

Finkelstein, et al **State-Level Estimates of Annual Medical Expenditures Attributable to Obesity**. *Obes Res.* 2004; 12:18-24.

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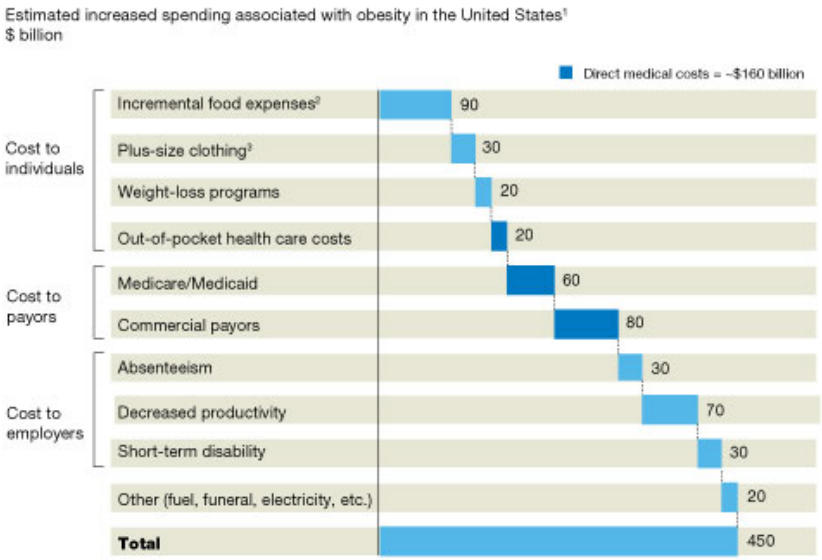

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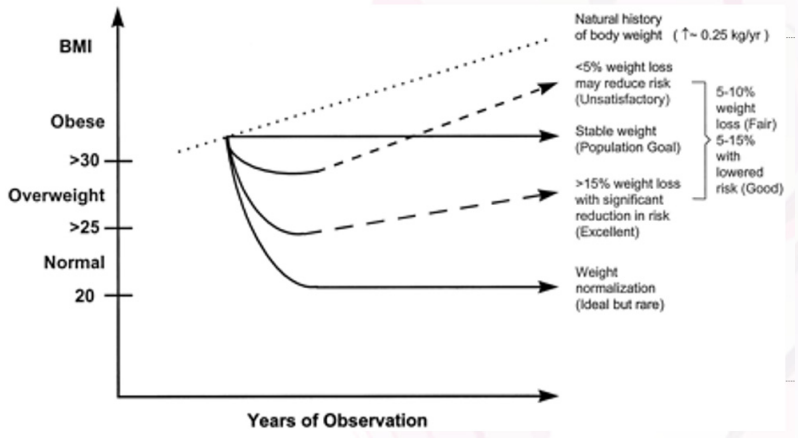
Natural History of Weight Gain



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Gradual Weight Gain

- Survival Instinct (52)
  - Our body has stronger resistance against weight loss than defense against weight gain.
  - Constant food supply
  - We need little need for physical activity to survive.
  - We are limited now by our conscious cessation of eating, not by supply of food running out
  - Our resting energy expenditure is not keeping up with our intake– need for voluntary exercise.

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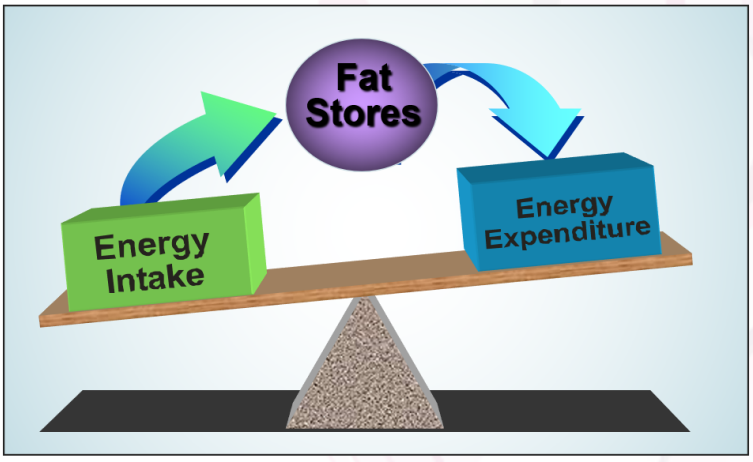
Obesity is Caused by Long-Term

Positive Energy Balance



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Maximizing Energy Expenditure

- Exercise
- Youthful Hormone Levels
- Regular meals-skipping breakfast increases obesity by 450%
- Stop yo-yo dieting-lose muscle, decrease metabolic rate, increase numbers of fat cells each cycle
- Adequate protein intake

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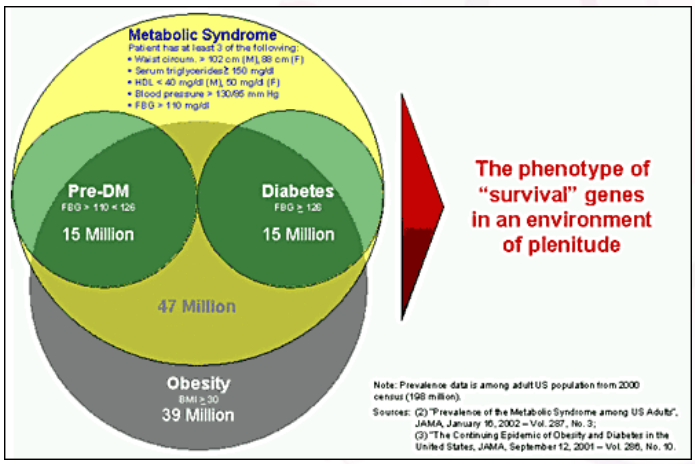
Definition of Obesity

Excessive accumulation of stored energy in the form of body fat.



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Measuring Obesity Medical Complications

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Obesity as a Risk Factor

- Coronary Artery Disease
  - Dyslipidemia
- Type II DM
- Hypertension
- Stroke
- Breast Cancer
- Endometrial Cancer
- Prostate Cancer
- Colon Cancer

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Death From Obesity

- Framingham Heart Study
  - 1% increase in risk of death in the next 26 years for every extra pound of weight gain from age 30-42.
  - 2% increase for each pound for ages 50-62
  - Of 4,246 healthy men without liver disease over 5 years 622 developed fatty liver disease. Just 5 lb weight gain increased risk.

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Weight Loss Reverses Disease

- Framingham Heart Study (13)
  - Lower BP and Improved Lipid Profiles
- Weight Loss lowers the risk factors in obese people with…
  - Hypertension
  - Dyslipidemia
  - Insulin Resistance
  - Type II Diabetes

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Body Mass Index (BMI)

- Most accepted and simple single measure to define obesity.
  - Most accurate for adults.
  - Accuracy decreases for muscular individuals.

$$BMI = \frac{\text{Weight in Kg}}{\text{Height in m}^2}$$

OR

$$\left[BMI = \frac{\text{Weight in pounds}}{\text{Height in inches}} \right] \times 703$$

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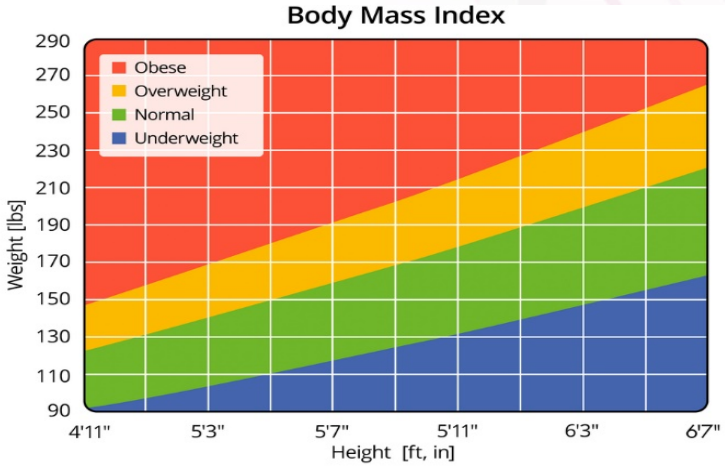
Body Mass Index Chart



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BMI Chart Key

- Underweight (BMI <18 kg/m^2, blue area)
- Normal weight (BMI 18.5–24.9 kg/m^2, light green area)
- Overweight (BMI 25–29.9 kg/m^2, yellow area)
- Obese (BMI ≥30 kg/m^2, orange area)

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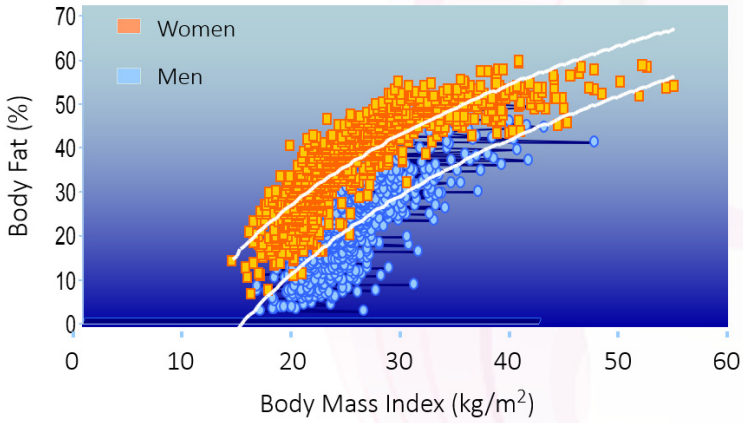
Relationship Between BMI Percent

Body Fat in Men and Women



Adapted from: Gallagher et al. **Healthy percentage body fat ranges: an approach for developing guidelines based on body mass index,** Am J Clin Nutr 2000;72:694.

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BMI – Associated Disease Risk

Men and Women

Classification		BMI (kg/m^2)	Risk
Underweight		<18.5	Increased
Normal		18.5-24.9	Normal
Overweight		25.0-29.9	Increased
Obese	I	30.0-34.9	High
	II	35.0-39.9	Very High
	III	≥40	Extremely high

Additional risks:
- Large waist circumference (men>40 in; women >35 in)
- 5 kg or more weight gain since age 18-20 yrs
- Poor aerobic fitness
- Specific races and ethnic groups

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults—The Evidence Report. *Obes Res* 1998;6(suppl 2).

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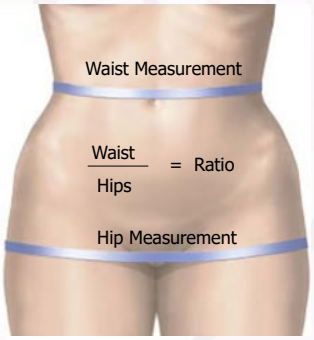
Waist-Hip Ratio (WHR)

- Predictor of Abdominal Fat
  - >1.0 for Men (trend toward 0.9)
  - >0.85 for Women (trend toward 0.8)
- Correlates best with increased cardiovascular disease risk.
- Waist Measurement: Measure in cm or inches at midpoint between the lower border of the rib cage and the upper border of the pelvis.
- Hip Measurement: Measure in cm or inches from widest point of the buttocks and hips.



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Waist-Hip Ratio (WHR)

Chart: Adjusted for Age

Waist to Hip Circumference Ratio Standards for Men and Women

		Disease Risk Related to Obesity			
	Age (years)	Low	Moderate	High	Very High
MEN	20-29	<0.83	0.83-0.88	0.89-0.94	>0.94
	30-39	<0.84	0.84-0.91	0.92-0.96	>0.96
	40-49	<0.88	0.88-0.95	0.96-1.00	>1.00
	50-59	<0.90	0.90-0.96	0.97-1.02	>1.02
	60-69	<0.91	0.91-0.98	0.99-1.03	>1.03
WOMEN	20-29	<0.71	0.71-0.77	0.78-0.82	>0.82
	30-39	<0.72	0.72-0.78	0.79-0.84	>0.84
	40-49	<0.73	0.73-0.79	0.80-0.87	>0.87
	50-59	<0.74	0.74-0.81	0.82-0.88	>0.88
	60-69	<0.76	0.76-0.83	0.84-0.90	>0.90

(Adapted from Heyward VH, Stolarcyzk LM: Applied Body Composition Assessment. Champaign IL, Human Kinetics, 1996, p82.)

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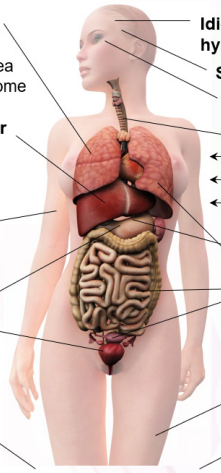
Medical Complications of Obesity



Pulmonary disease
abnormal function
obstructive sleep apnea
hypoventilation syndrome

Nonalcoholic fatty liver disease
steatosis
steatohepatitis
cirrhosis

Skin

Gall bladder disease

Gynecologic abnormalities
abnormal menses, infertility
polycystic ovarian syndrome

Osteoarthritis

Idiopathic intracranial hypertension

Stroke

Cataracts

Coronary heart disease
Diabetes
Dyslipidemia
Hypertension

Severe pancreatitis

Cancer
breast, uterus, cervix
colon, esophagus, pancreas
kidney, prostate

Phlebitis
venous stasis

Gout

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Obesity Associated Health Problems

- **Metabolic**: Type 2 diabetes, insulin resistance, hypertension, high triglyceride levels, low HDL levels
- **Psychosocial**: Depression, anxiety, social stigmatization, reduced quality of life, sick leave, early retirement
- **Cardiovascular**: Coronary artery disease, stroke, heart failure, atrial fibrillation
- **Gynecological**: Infertility, polycystic ovary syndrome, obstetrical risks
- **Gastrointestinal**: Gastroesophageal reflux, gallbladder disease, liver steatosis, non-alcoholic steatohepatitis
- **Respiratory**: Sleep apnea, asthma, pulmonary embolism
- **Bone and joints**: Osteoarthritis, gout, back pain
- **Dermatological**: Striae, acanthosis nigricans, hirsutism, fungal infection
- **Cancer**: Malignancies in the breast, endometrium, colon and rectum, esophagus, pancreas, kidney, thyroid gland, gallbladder, hematopoietic system, malignant melanoma

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Genetics of Obesity

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Genetics and Obesity

- Weight is the ultimate polygenic trait.
  - No evidence of Mendelian inheritance
- Adoption studies
  - Adoptees show more correlation with biological parents' BMI than adoptive parents BMI. (63)
  - Strong correlation with biological siblings versus adoptive half-siblings (64)
- 30 known (rare) genetic obesity syndromes
  - Prader-Willi (1:25,000) most common
    - Autosomal Dominant

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Genetics and Obesity

- Polygenic Obesity
  - Leptin Receptor
  - Proopiomelanocortin
  - Ghrelin
  - Melanocortin-4 receptor
  - Beta-2 adrenergic receptor
  - Glucocorticoid receptor

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Is there a Genetic Fat Set Point?

- Overfed identical twins (50)
  - Much variability between the unrelated twin pairs
    - Differences show tremendous variation in energy expenditure increases with feeding (energy expenditure at rest) "Adaptive Thermogenesis"
  - Little variability among the related siblings
  - Genetic predisposition to resistance to weight gain after overfeeding.

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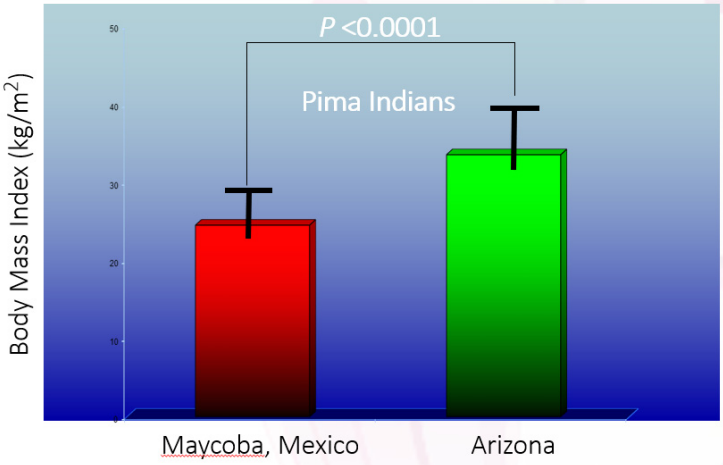
Gene-Environment Interaction

in the Pathogenesis of Obesity



Ravussin E et al. **Effects of Traditional and Western Environments on Prevalence of Type 2 Diabetes in Pima Indians in Mexico and the U.S.** *Diabetes Care* 1994;17:1067-1074.

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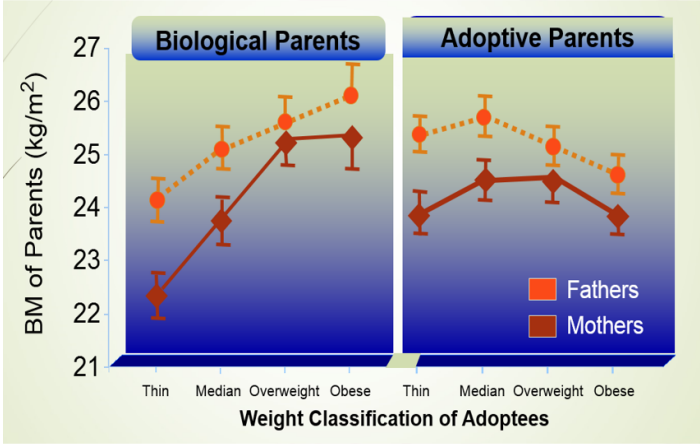
Relationship: Adoptee Weight

and Weight of Biological or Adoptive Parents



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Stunkard et al. **An Adoption Study of Human Obesity,** *N Engl J Med* 1986;314:193.

Sleep and Weight

- Less Sleep = More Obesity
- NHANES I Study (1980's)
  - Less than 7 Hours sleep resulted in significantly more obesity
  - 6 hours of sleep = 27% increased rate of obesity
  - 5 hours of sleep = 73% increased rate

Upated 2006 Study, **NHANES I Epidemiologic Followup Study (NHEFS),** June 14, 2016, CDC/National Center for Health Statistics

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Sleep and Weight

- Children (Age 6-12)
  - Less than 10 hours of sleep a night
    - 3.5 times greater incidence of obesity compared to 12 hours of sleep.
  - Sleep deprivation at 30 months of age can predict obesity at age 6
- Night Shift work
  - Averages 42 minutes less sleep per 24-hour period.

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Sleep and Weight

- Less Growth Hormone
- Increased Insulin
- Increased Cortisol
- Decreased Leptin
- Increased Ghrelin
- More daytime fatigue
- Less physical activity

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Sleep and Weight

- An extra 20 minutes of sleep a night can reduce BMI
- Recommend a minimum of 7 hours
- Prefer 8 hours of sleep on average.

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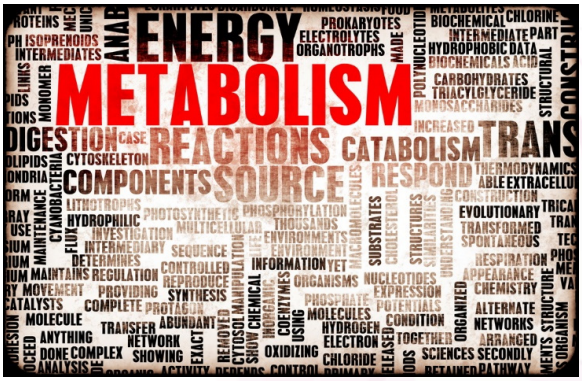

Metabolic Syndrome

Other Biochemical Factors Behind Obesity

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Evolution of Metabolic Syndrome

AKA: Insulin Resistance Syndrome; Syndrome X; Dysmetabolic Syndrome; Multiple Metabolic Syndrome

1923: Kylin describes clustering of hypertension, gout, and hyperglycemia

1988: Reaven describes "Syndrome X" – hypertension, hyperglycemia, glucose intolerance, elevated triglycerides, and low HDL cholesterol

1998: World Health Organization defines "metabolic syndrome" as clustering of hypertension, low HDL, hypertriglyceridemia, insulin resistance, glucose intolerance or type 2 diabetes, high waist-to-hip ratio, and microalbuminuria

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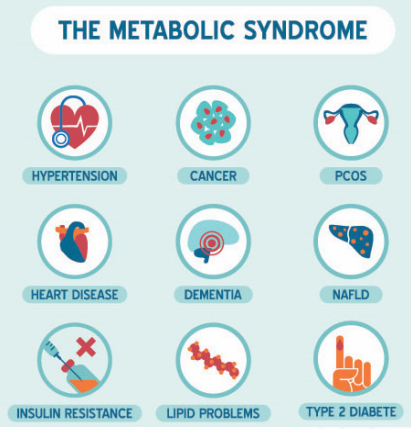
Isomaa B et al. **Cardiovascular Morbidity and Mortality Associated With the Metabolic Syndrome.** *Diabetes Care.* 2001;24:683-689.

Metabolic Syndrome



- Abdominal obesity
- Hyperinsulinemia
- High fasting plasma glucose
- Impaired glucose tolerance
- Hypertriglyceridemia
- Low HDL-cholesterol
- Hypertension

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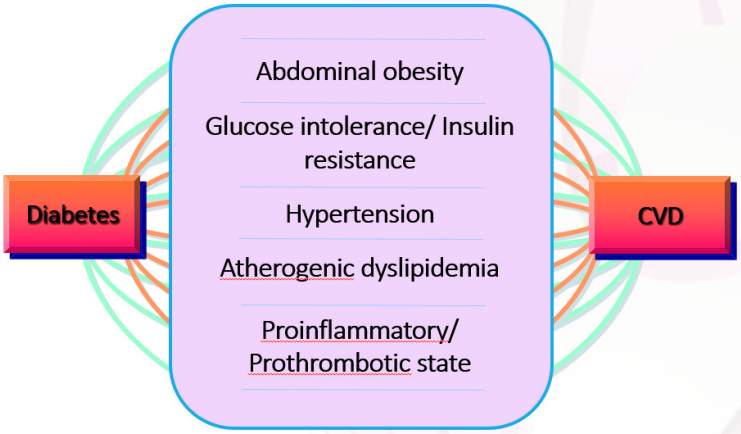
Characteristics: Metabolic Syndrome

NCEP-ATP III



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National Cholesterol Educational Program (NCEP), Adult Treatment Panel (ATP) III; 2001.

NCEP-ATP III *

***Diagnosis is established when ≥3 of these risk factors are present**

Risk Factor	Defining Level
Abdominal obesity	
(Waist circumference)	
Men	>102 cm (>40 in)
Women	>88 cm (>35 in)
TG	≥150 mg/dL
HDL-C	
Men	<40 mg/dL
Women	<50 mg/dL
Blood pressure	≥130 / ≥85 mm Hg
Fasting glucose	≥100 mg/dL

Expert Panel on Detection, **Evaluation, and Treatment of High Blood Cholesterol in Adults**. *JAMA*. 2001;285:2486-2497

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**** 2010 New ADA IFG criteria (Diabetes Care)** American Diabetes Association, Diabetes Care 2010 Jan; 33(Supplement 1): S62-S69.

IRS: AACE Criteria

Diagnosing Insulin Resistance Syndrome
Is as Simple as 1 plus 2

Choose:

One Risk
+
Two Parameters

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IRS: AACE Criteria – Risks (Choose 1)

- BMI ≥25 kg/m^2
- Waist circumference
  - Men >40"
  - Women >35"
- Sedentary Lifestyle
- Age >40
- Non-Caucasian ethnicity
- Family History of DM, HTM, or CVD
- History of glucose intolerance or gestational diabetes
- Personal Dx of HTN, TGL, low HDL or CVD
- Acanthosis nigricans
- Polycystic ovarian syndrome (PCOS)
- Nonalcoholic fatty liver disease (NAFLD)
- Cancer (obesity related)

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IRS: AACE Criteria – Parameters

(Choose 2)

- Triglycerides >150 mg/dl
- HDL cholesterol
  - Men <40 mg/dl
  - Women <50 mg/dl
- Blood pressure ≥135/85
- Blood glucose
  - 2-hour >140 mg/dl, **OR**
  - Fasting 110 – 125 mg/dlb

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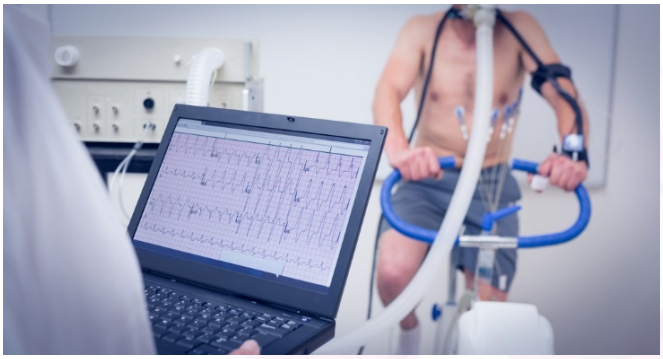

The Science of Exercise

Popular Diets

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Benefits of Regular Physical Activity

Obese Persons

- Decreases loss of fat-free mass associated with weight loss
- Improves maintenance of weight loss
- Improves cardiovascular and metabolic health, independent of weight loss

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Exercise

- Do we really need proof?
  - Energy Expenditure Breakdown
    - BMR is 60-70% (1 kcal/kg/hr)
    - Thermal Effect of a Meal is about 10%
    - We can't change either of the above
  - Exercise energy expenditure
    - 10-40% of total energy expenditure
    - Depends on activity

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Exercise (contd.)

- Sample energy expenditure (90kg person)
  - Reclining 90 kcal/hr
  - Studying 160 kcal/hr
  - Standing in Line 180 kcal/hr
  - Cycling 5-10/14mph 360/720 kcal/hr
  - Low Impact Aerobics 450 kcal/hr
  - Walking 360/450 kcal/hr
  - Scrubbing Floors 495 kcal/hr
  - Chopping Wood 540 kcal/hr

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Energy Expenditure: Physical Activity

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Nutrition: energy and protein. American Gastroenterological Association, 1998.

Exercise

- More beneficial for weight loss maintenance than for initial weight loss.
- No advantage shown for supervised activity in long-term weight loss (103-104)
- No difference in weight loss for resistance training vs. aerobic exercise (105-106)
- Initial exercise goal should be 120 minutes per week
  - More weight loss proven at 200 min per week

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The Problem With Exercise Alone

- As the obese person loses weight, it takes more and more exercise just to maintain the weight loss. (58-60)
  - 30 minutes a day to start losing weight
  - 60-90 minutes a day to maintain the goal weight
- It likely takes less exercise to prevent the initial weight gain in the first place.
- Exercise can make up for a bad diet and prevent weight gain (61)

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Exercise

- A single bout of exercise can increase the BMR by 5-15% for up to 48 hours. (146)
  - Possible mechanism– increased norepinepherine systemically
- For a 70 kg person
  - Extra 160 kcal/day burned daily
  - Extra pound of fat lost every 20 days

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Exercise

Muscle and Fat Oxidation

- With increase in exercise: (149)
  - Muscle mass increases
    - Allows for more prolonged stamina
    - Allows for more intense workouts
  - Muscle becomes more efficient at oxidation of fats
    - Amount of fat burned per unit of exercise is greater
- Improvement in fat metabolism begins quickly (150-151)
  - Within 10 days of exercise 1 hour per day
  - Within 3 weeks of exercise 3x/week

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Studies on Exercise Alone

- Weight loss is the same short-term (152)
  - Calorie restriction versus equivalent increase in calories burned from exercise
  - Resistance exercise not as effective as aerobic exercise at translating work into immediate weight loss. (153)
  - Resistance training better at increasing lean body mass, therefore resting metabolic rate

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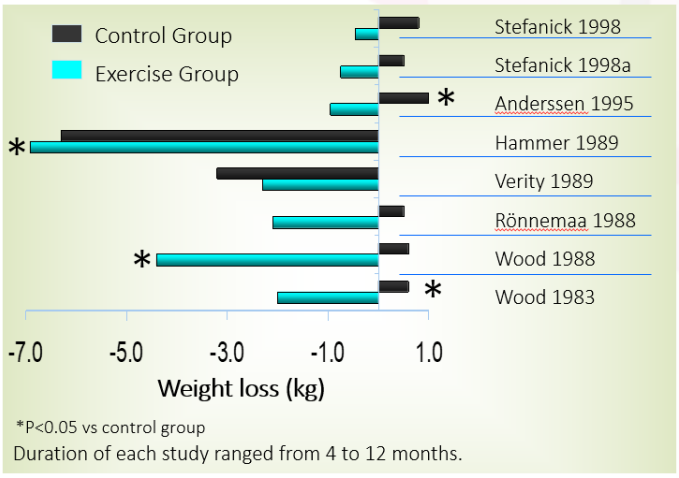
Physical Activity Alone

Results in Minimal Weight Loss



*P<0.05 vs control group

Duration of each study ranged from 4 to 12 months.

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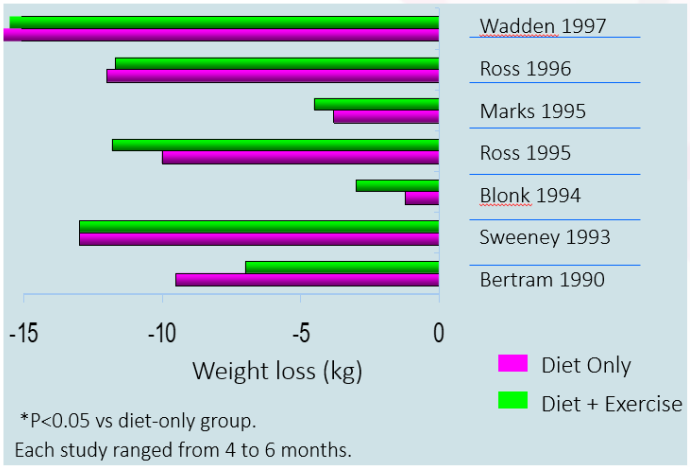
Wing RR. **Physical Activity in the Treatment of the Adulthood Overweight and Obesity: Current Evidence and Research Issues,** Med Sci Sports Exerc 1999;31(suppl):S547.

Physical Activity

Usually Does Not Increase ST Diet-Induced Weight Loss



*P<0.05 vs diet-only group.
Each study ranged from 4 to 6 months.

Wing RR. **Physical Activity and Long-Term Maintenance of Weight Loss** *Med Sci Sports Exerc.* 1999;31(suppl):S547-S552.

Diet plus Exercise

- Lose slightly more weight than diet alone (152)
- Body Composition Changes
  - More fat loss with combined diet/exercise
  - Less lean tissue loss (154)
    - 2.9kg muscle lost with diet alone 10kg total loss
    - 1.7kg muscle lost with diet/exercise
  - Decrease in visceral fat (153)
- Exercise is the top determining factor in maintenance of weight loss.

Exercise for Maintenance

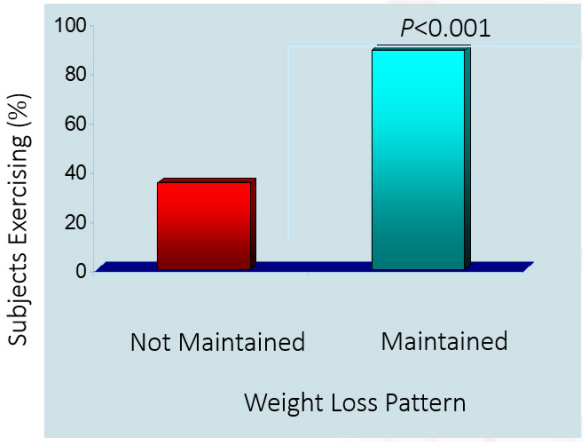
- Only 9% of people can maintain the lost weight without continuing or increasing their exercise energy expenditure. (155)

ALL STRATEGIES TO DECREASE INTAKE WILL FAIL OVER TIME IF EXERCISE DECREASES

MANY WILL PLATEAU UNTIL EXERCISE INCREASES

Relationship: Physical Activity

Maintenance of Weight Loss



Exercise for Maintenance

- 2,000 kcal/week expenditure is optimal to for peak fitness and to sustain a significant weight loss.
  - 420 minutes of brisk walking per week
- Exercise sessions generally recommended to be at least 20 minutes in duration to trigger the metabolic response.
  - Increased fat burning, muscle development, short-term appetite suppression.

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Exercise for Maintenance

Other Considerations

- Duration and Intensity of Exercise Session
  - Let patient choose what best allows for compliance.
- Short, Intense Sessions
  - Better for appetite suppression and to increase BMR
- Long Sessions, Moderate Intensity
  - Better to increase fat burning

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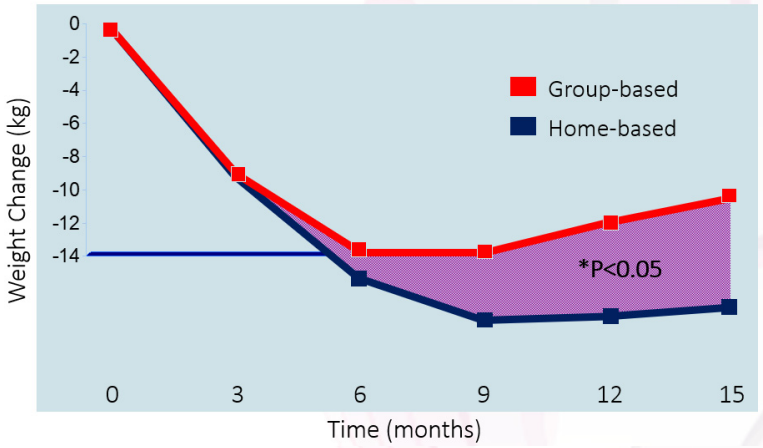
Effect: Group-Based vs Home-Based

Physical Activity on Body Weight



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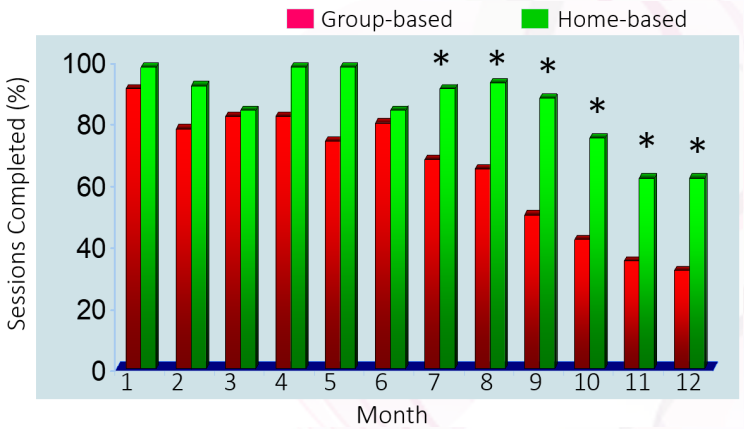
Greater Compliance

Home-Based versus Group-Based Activity



* P<0.05 group-based vs home-based.

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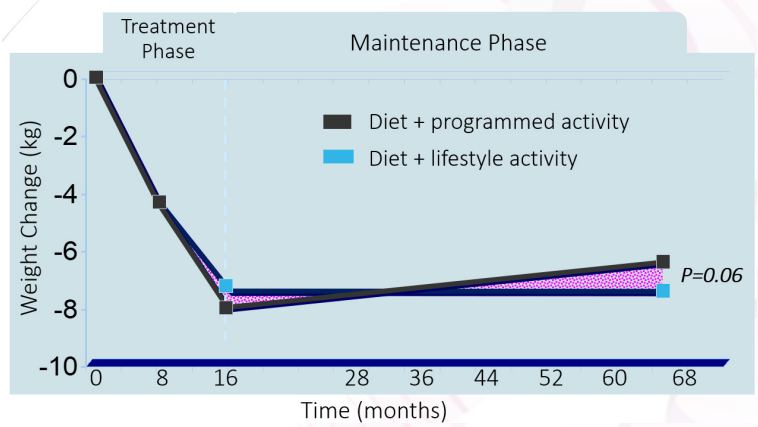
Weight Maintenance:

Programmed or Lifestyle Activity



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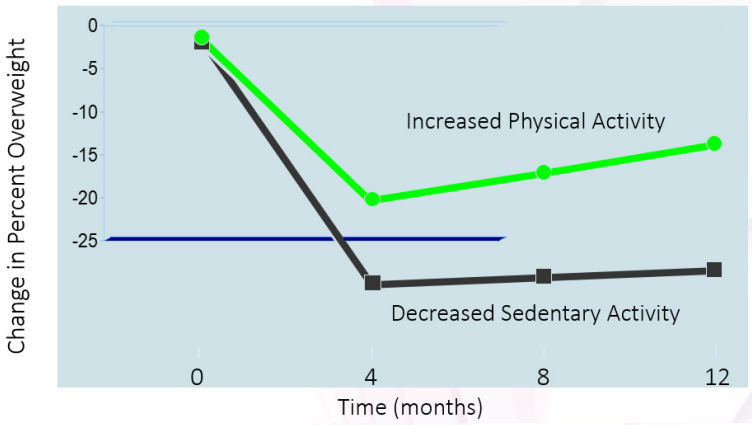
Andersen et al. **Lifestyle and Structured Interventions to Increase Physical Activity,** JAMA 1999;281:335.

Decreasing Sedentary Activities

Increasing Physical Activities on Body Weight: Children 6-12 y/o



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Epstein et al. **Effects of decreasing sedentary behavior and increasing activity on weight change in obese children,** Health Psychol 1995;14:109.

Summary of Exercise Guidelines

- Assessment
  1) Medical and psychological readiness
  2) Physical limitations
  3) Current activities
  4) Barriers to activity
- Develop physical activity plan
- Start activity slowly and gradually increase planned aerobic activity to 200 min/week
- Enhance compliance
  - Programmed vs lifestyle activity
  - At-home vs onsite activity
  - Multiple short bouts vs single long bout of activity

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Water Intake

- Must be higher on any diet
- Loss of 2% of body water associated with
  - Decreased mental function
  - Decreased physical performance
  - Impaired thermoregulation
- Universal recommendation is a minimum of 64oz of water daily
  - More if sweating or significant physical activity

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Diet & Exercise

Walking

- Here's how you can shape your body the way you want, by walking:

  1. Flat Stomach - Walk downhill with small, fast steps, stomach in, shoulders straight. Make your steps as small as possible and very fast.

  2. Shapely Thighs - Walk uphill with long steps, without bending your knees, stomach in, shoulders straight. This will shape your hips as well.

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Diet & Exercise

Walking

3. **Slimmer Arms** - Swing your arms freely as you walk. Feel the pressure in your upper arms as you stretch your arms back and forth.

4. **Slim Waistline** - Walk at a medium pace with your hands held high in the air above your head. Keep your hands straight and maintain a perfect posture as you walk.

Continued exercising in the correct way will bring you desired results. Continuing any kind of exercise regularly for at least 40 days before expecting results.

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Energy Content:

Alcoholic Beverages

Alcohol contains 7 kcal/g		
Beer	12 oz	160 calories
Wine	5 oz	100 calories
Margarita	8 oz	270 calories
Gin and Tonic	8 oz (contains 1.7 oz gin)	190 calories
1 shot of liquor	2 oz	128 calories

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Intermittent Fasting

Aids in Weight Loss for almost any Diet

- Endorsed by most physicians, Intermittent fasting is an eating pattern where you cycle between periods of eating and fasting.
- There are many different types of intermittent fasting, such as the 16/8 and 5:2 methods.
- Numerous studies show that it can have powerful benefits for your body and brain. A systematic review of 40 studies found that intermittent fasting was effective for weight loss, with a typical loss of 7-11 pounds over 10 weeks.
- A randomized controlled trial that followed 100 obese individuals for one year did not find intermittent fasting to be more effective than daily calorie restriction.

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Harvard School of Public Health, The Nutrition Source > Healthy Weight > Diet Reviews > Diet Review: Intermittent Fasting for Weight Loss

Intermittent Fasting

Potential Benefits

1. When you fast, insulin levels drop and human growth hormone (HGH) increases. Your cells also initiate important cellular repair processes and change which genes they express.
   A. Higher levels of HGH facilitate fat burning and muscle gain, lower insulin blood levels also facilitate fat burning
2. Lowers calorie intake boosting metabolism slightly - effective to lose weight and visceral fat.
3. Beneficial for insulin resistance, fasting blood sugar has reduced by 3–6% over the course of 8–12 weeks in people with prediabetes. Fasting insulin has been reduced by 20–31% only in men.
4. Reduce oxidative damage and inflammation in the body.

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onlinelibrary.wiley.com/doi/epdf/10.1002/oby.22518

Intermittent Fasting

Potential Benefits (contd.)

5. Improve numerous risk factors for heart disease, such as blood pressure, cholesterol levels, triglycerides, and inflammatory markers.
6. Triggers autophagy, which removes waste material from cells.
7. Increases levels of a brain hormone called brain-derived neurotrophic factor (BDNF). A BDNF deficiency has been implicated in depression and various other brain related problems

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The American Journal of Clinical Nutrition, Volume 81, Issue 1, January 2005, Pages 69–73, https://doi.org/10.1093/ajcn/81.1.69

Intermittent Fasting

Methods

- **16/8 method**: In this diet, you fast for 16 hours a day and have an 8-hour window to eat. You can choose any 8-hour window to consume calories. Some people opt to skip breakfast, while others avoid eating late and stick to a 9 a.m. to 5 p.m. schedule.
- **5:2 diet:** Five days per week, you eat normally and don't restrict calories, the other two days of the week reduce your calorie intake to one-quarter. For a normal 2,000 calorie diet, reduce your calorie intake to 500 calories per day, two days per week. Any days of the week work.
- **Eat Stop Eat:** is an unconventional approach to fasting popularized by writer, Brad Pilon. It is not preferred as it may lead to binging and overconsumption later on. It may also lead to disordered eating patterns.

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Intermittent Fasting

Methods

- **Alternate-day fasting:** intermittent fasting plan where you fast every other day but can eat whatever you want on the non-fasting days. On fasting days consume 500 calories or for some individuals do not eat at all. **Not necessarily recommended**.
- **Warrior Diet:** encourages eating very little for 20 hours during the day, and then eating as much food as desired throughout a 4-hour window. Dieters consume small amounts of dairy products, hard-boiled eggs, raw fruits and vegetables and water during the 20-hour fast period.

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Intermittent Fasting

Absolute & Relative Contraindications

- Diabetes
- Eating disorders that involve unhealthy self-restriction (anorexia or bulimia nervosa)
- Use of medications that require food intake
- Active growth stage, such as in adolescents
- Pregnancy, breastfeeding
- Morbidly Obese Patients – no real benefit
- Other "at-risk" medical conditions

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Paleo Diet for Weight Loss

aka "Stone-Age" Diet

- The Paleo diet, also referred to as the caveman or Stone-Age diet, includes lean meats, fish, fruits, vegetables, nuts, and seeds.
- The diet is high in protein, moderate in fat (mainly from unsaturated fats), low-moderate in carbohydrate (specifically restricting high glycemic index carbohydrates), high in fiber, and low in sodium as well as refined sugars.
- The monounsaturated and polyunsaturated fats (including the omega-3 fats EPA and DHA) come from marine fish, avocado, olive oil, and nuts and seeds.
- There are many forms of the Paleo diet as there is debate over what foods existed where and the differences between 21st Century man and our predecessors.

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Paleo Diet
Foods

Allowed Foods

- Fresh lean meats
- Fish and shellfish
- Eggs, seeds, fruits, berries, vegetables, olive oil or coconut oil, and small amounts of honey.
- Root Vegetables such as sweet potatoes and cassava.

Disallowed Foods

- Whole grains, cereals, refined grains and sugars.
- Dairy products, white potatoes, legumes (peanuts, beans, lentils), alcohol, coffee, and salt.
- Refined vegetable oils such as canola, and most processed foods in general.

Calorie counting and portion sizes are not emphasized. Some plans allow a few non-Paleo meals a week, especially when first starting the diet, to improve overall compliance.

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Paleo Diet for Weight Loss
Does it Really Work?

- Paleo diet to produce greater short-term benefits than diets, including greater weight loss, reduced waist circumference, decreased blood pressure, increased insulin sensitivity, and improved cholesterol. However these studies were of short duration (6 months or less) with a small number of participants (less than 40).
- Conversely, Paleo diet does produce greater fat loss at 6 months but not at 24 months. Triglyceride levels decreased more significantly with the Paleo diet at 6 and 24 months than most diets.
- Bottom Line: Meal Planning, Cost of Fresh Foods, and deficiency of nutrients such as calcium, vitamin D, and B vitamins within in the allowed foods may make this unattractive. Was very popular years ago but lack of long-term results is a negative to patients.

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Mediterranean Diet

Heart Healthy Diet

- Endorsed by most physicians
- The Mediterranean diet incorporates the basics of healthy eating including fruits, vegetables, fish and whole grains, and limit unhealthy fats. While these parts of a healthy diet, subtle variations or differences in proportions of certain foods may make a difference in your risk of heart disease or ability to lose weight.
- Many physicians will promote the Mediterranean diet as a "maintenance diet" after successful weight loss or a type of diet for patients that may be contraindicated or medically predisposed from other weight loss programs.

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Mediterranean Diet

Benefits

- The diet has been associated with a lower level of oxidized low-density lipoprotein cholesterol in patients.
- Mediterranean diet was associated with a reduced risk of cardiovascular mortality as well as overall mortality (1.5M Study).

D.Giugliano, A. Ceriello, M. Maiorino Diabetes Research and Clinical Practice Vol 89, Issue 2, Aug 2010, Pages 97–102

- The Mediterranean diet is also associated with a reduced incidence of cancer, and Parkinson's and Alzheimer's diseases.
- Almost all healthcare organizations encourage healthy adults to adapt a style of eating like that of the Mediterranean diet for prevention of major chronic diseases.

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Mediterranean Diet

Key Components of the Diet

- Eating primarily plant-based foods, such as fruits and vegetables, whole grains, and nuts
- Replacing butter with healthy fats such as olive oil and canola oil
- Using herbs and spices instead of salt to flavor foods
- Limiting red meat to no more than a few times a month
- Eating fish and poultry at least 2x weekly
- May drink red wine in moderation (optional)
- Exercise daily and can be vigorous

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Mediterranean Diet

Drawbacks

- **Non-Compliance**: requires a change of eating habits to a healthy lifestyle which many patients cannot achieve.
- **Slow weight reduction (1-2 lbs) weekly and not guaranteed**.
- Exercise is a key component to losing weight.
- **Very difficult to create new revenue streams for physicians**.
- Education of Patients (time, nutritionist?)
- The Mediterranean diet may not be appropriate for those with multiple food allergies/intolerances or those with gastrointestinal difficulties which prevent them from consuming a normal diet.
- Cancer patients may have special nutritional needs and should be advised before changing to any type of diet.

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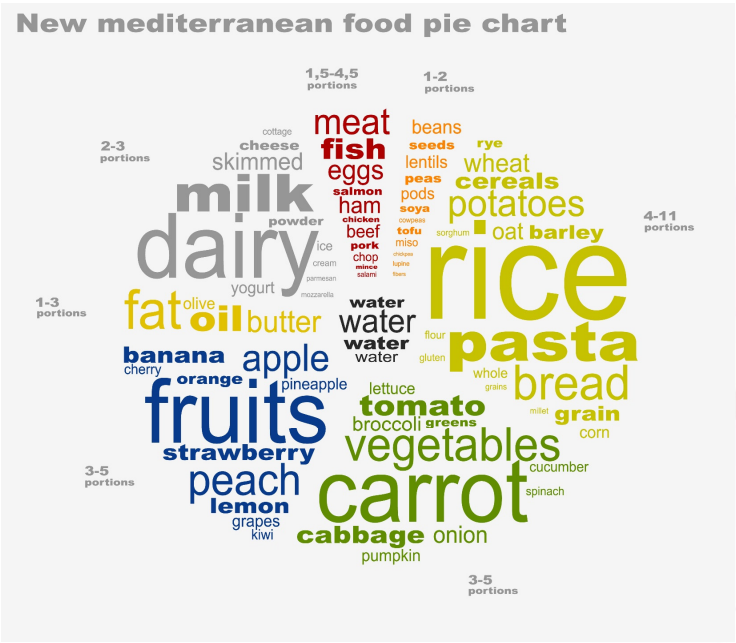

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Very Low Calorie Diets

- Less than 800 cal. per day
  - Health concerns with rapid weight loss
  - No more effective long term than 1200-1500 calorie diets although initial weight loss is faster.
  - Popular alternative in 1980's (liquid diets)
  - Now considered unsafe and unnecessary.
- The strength of these diets was in the absolute control of intake.
- Now, 1,000 -1600 calorie diets recommended

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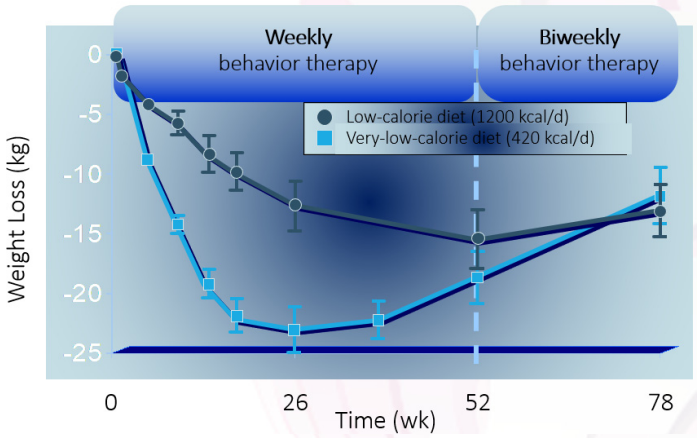
VLCDs

Do Not Produce Greater LT Weight Loss Than LCDs



Wadden et al. **One-year behavioral treatment of obesity: comparison of moderate and severe caloric restriction and the effects of weight maintenance therapy.** *J Consult Clin Psychol* 1994;62:165.

Medical Contraindications: VLCD

- Recent MI
- Cardiac Arrhythmia
- History of CV disease
- Renal disease
- Liver disease
- Pregnancy
- Psychiatric illness (Bulemia, Bipolar)
- Substance Abuse
- Other Medical at Risk Conditions (Be Conservative)

Ketosis Diets

- Low carb intake results in primary fat burning for energy
  - Bad breath from exhaled ketones
- Potential Risks
  - Kidney failure/stones, Gout, Osteoporosis
  - Low in fiber, vitamins, trace minerals, antioxidants
- Rapid weight loss initially
  - Dehydration
  - Loss of sodium
  - Depletion of glycogen stores
- Plateauing of weight loss is a concern

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Low-Fat Diets

- Recommendation
  - 20-30% calories from fat, <10% saturated fat
    - Average American eats 34% / 12% saturated
  - Endorsed by
    - National Cancer Institute
    - American Diabetic Association
    - American Heart Association
- Limit
  - Saturated Fats (meat, dairy)
  - PUFA (corn oil, sunflower oil)
  - trans-FA's (fried foods, margarines)

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Low-Fat Diets

- ADVANTAGES
  - Endorsed by most major authorities
  - Lowers lipid profiles, heart disease risk
- DRAWBACKS
  - Substitution of carbs for fats can create more body fat (i.e. corn syrup)
  - Hunger
  - No accounting for essential fatty acids
  - Lack of numerous vitamins and nutrients

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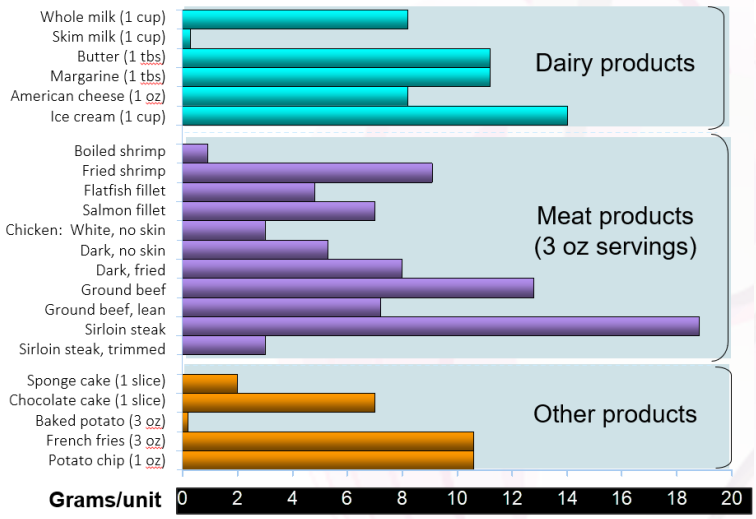
Fat Content of Selected Foods



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Adapted from Alpers et al. Manual of Nutritional Therapeutics (4th ed); Lippincott: Philadelphia, 2002.

Very Low Fat Diets

- Pritikin, Ornish
- Usually very high in carbohydrates and fiber (Ornish)
- Less than 20% calories from fat
- Most rapid improvement in cardiac risk indicators
- Nearly impossible to adhere to

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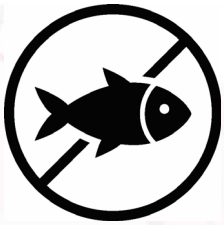
Ornish Diet



- ADVANTAGES
  - Improves BP and lipids, reverses angina
  - Reverses atherosclerosis
- DISADVANTAGES
  - Very difficult to follow
  - Excludes fish
  - Potential for deficiency of essential fatty acids

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Protein Consumption

- Average American
  - 15% of caloric intake
  - Can't afford to reduce this when dieting
- Protein needs rise above this during low calorie diets
- 1–1.5 gm of high-quality protein per kg of body weight is minimum while on a low calorie diet.

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Carbohydrate Requirements

- Less than 50 – 100 gm per day are ketogenic
- Leads to excessive protein breakdown unless protein intake is increased
- Water loss
  - For every gram of protein or glycogen broken down, 3 gm of water are released

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Very High Fat Diets

- Atkins, etc. (60%+ fat)
- Very low carbohydrate
- Ketosis – possible protein loss
- People lose weight because they consume less overall calories when allowed to eat unlimited fat vs. their usual eating habits
- High body water loss
- Require nutritional supplementation
- Increased cardiac risk

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Atkins Diet

- Unlimited consumption of fats and protein
- Reduces insulin production
  - Stimulates ketosis
  - Forces body to burn fat as a result
- ADVANTAGES
  - Easy to follow for the American
  - Little hunger since fats are very filling
  - Shown effective for weight loss in published studies
    - 12.8 lbs. lost vs. 4.2 pounds at 6 months

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Atkins Diet

- DRAWBACKS
  - Logic is flawed, other cultures (Asian) have high-carb, low fat diets
  - Diet is mainly diuretic in nature in the early phases
  - Potential deficiency of dietary fiber, vitamin C, folate
  - Increased risk of heart disease, atherosclerosis
  - Poor real-world results in retaining weight loss

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Higher Protein Diet

- Danish Study, 1999 (129)
  - 25 people in each group
  - Eat as much as you want, just maintain the ratios
    - 25% Protein, 45% Carb, 30% Fat
    - 12% Protein, 58% Carb, 30% Fat
    - Strict controls, DEXA body scans
  - High protein diet lost more
    - 16.7 lbs. vs 10 lbs. in 6 months
    - Slightly less lean body mass loss in protein group

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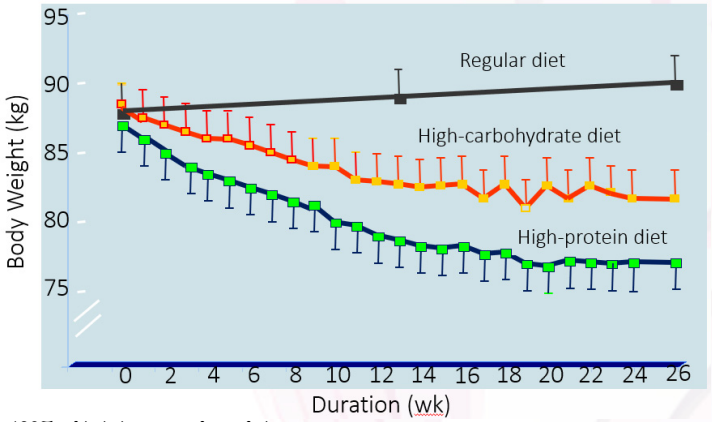
Effect: Ad Libitum High-Protein

Low-Fat* Diet on Body Weight



*30% of total energy from fat.

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Skov et al. **Protein intake during Energy Restriction: Effects on Body Composition and Markers of Metabolic and Cardiovascular Health,** Int J Obes Relat Metab Disord 1999;23:528.

Weight Loss at 6-Months in RCTs

Low-fat vs Low-Carbohydrate Diets

		Weight Loss (kg)		Difference
Study	n	Low-fat	Low-carb	(kg)
Samaha (2003)	132	-1.9	-5.8	3.9
Brehm (2003)	42	-3.9	-8.5	4.6
Foster (2003)	63	-5.3	-9.6	4.3
Yancy (2004)	120	-6.5	-12.0	5.5

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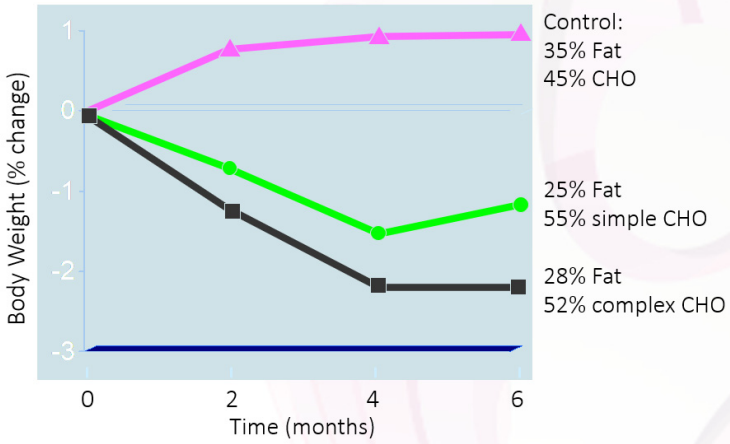
Relationship: Dietary Macronutrient

Composition and Body Weight



Saris WHM et al. **Randomized controlled trial of changes in dietary carbohydrate=fat ratio and simple vscomplex carbohydrates on body weight and blood lipids**, Int J Obes 24:1310,2000

Empire Medical Training

Glycemic Index – History

- First described in 1981 by Jenkins (109)
- Most studies dietary adaptation this century as a specific tx of metabolic syndrome (110-113)
  - Greater Satiety
  - Lower Glucose levels and peaks
  - Lower Insulin levels
  - Reduction in progression to Type 2 DM
- GI is new standard for Diabetes management in France, UK, Australia, Canada, NZ

Empire Medical Training

Glycemic Index (GI)

- Measure of how the quickly 50gm of carbohydrate in a particular food is converted to glucose
  - Does not take into account portion size and amount of carbohydrate in the food
  - 100=Glucose in most scales
    - 100 = white bread in other scales
  - Has nothing to do with calories

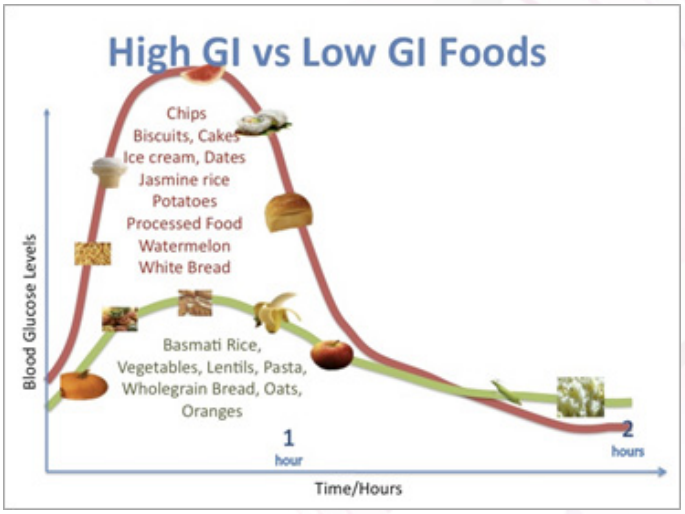
Empire Medical Training

Effects of High GI Diet

- Postprandial glucose surges lead to increased insulin secretion
  - Increased fat storage
  - Increased production of FFA's after meal
  - Inhibits fat oxidation
  - Increased glycogen storage
- 2 Hours later
  - The response continues, but the nutrients are gone
  - Drop in sugar triggering hunger

Empire Medical Training

Effects of High GI Diet



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Glycemic Index (GI)

- Low: up to 55
- Moderate: 56-70
- High: 71 and above

Glucose 100	Sweet Corn 54
Baked Potato 85	Banana 52
Cornflakes 81	Spaghetti 42
White Bread 71	All-Bran Cereal 42
White Rice 64	Kidney Beans 28
Pineapple 59	Peanuts 16

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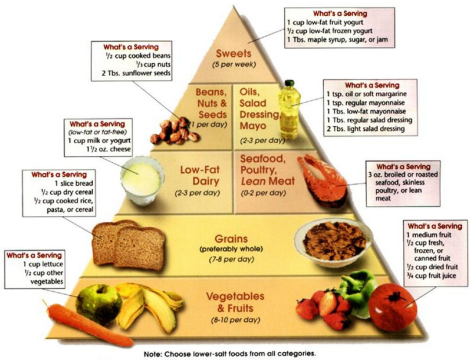
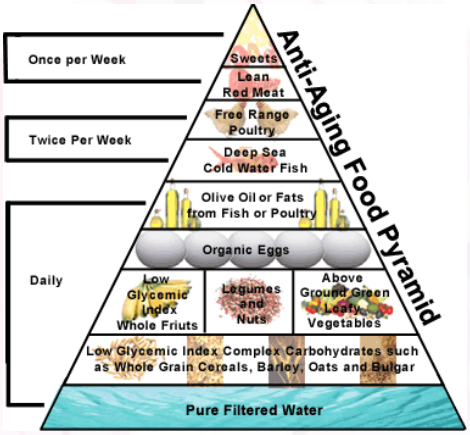
Low-GI pyramid



Traditional Model



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Glycemic Load (GL)

- Multiplies GI by how much carbohydrate is present in the particular food. (114)
  - Better overall indication of glucose-raising impact of a given food
  - Goes beyond the simple vs complex classifications
- 50gm of carbs for a given food may be more than a portion.
  - 1 ½ pounds of carrots has same net carbs as a baked potato

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GI and GL

This table uses white bread = 1.00

GLYCEMIC LOAD OF A SAMPLING OF FOODS

Food (one serving)	Carbohydrate content (in grams)	Glycemic Index* (percent expressed as decimal)	Glycemic Load (rounded to nearest tenth)
Potato (1 baked)	37	1.21	45
Carrots ($\frac{1}{2}$ cup cooked)	8	1.31	10
Lentils ($\frac{1}{2}$ cup cooked)	20	0.41	8
Dry beans ($\frac{1}{2}$ cup cooked)	27	0.60	16
White rice ($\frac{1}{2}$ cup cooked)	35	0.81	28
Wild rice ($\frac{1}{2}$ cup cooked)	18	0.78	14
White bread (2 slices)	24	1.00	22
Whole grain bread (2 slices)	24	0.64	15
Pasta (1 cup cooked)	40	0.71	28
Cheerios (1 cup)	22	1.06	23
All-Bran (1 cup)	24	0.60	14
Grape-Nuts ($\frac{1}{2}$ cup)	47	0.96	45
Corn flakes (1 cup)	26	1.19	31
Corn chips (1 oz)	15	1.05	16
Popcorn (air-popped, 1 cup)	5	0.79	4

* Standard reference for this table is white bread.

(Carbohydrate content and GI values derived from various sources, including the Division of Preventive Medicine, Brigham and Women's Hospital, Harvard Medical School; "International Tables of Glycemic Index," *American Journal of Clinical Nutrition* (1995): Vol. 62, 871S-93S; and *The Complete Book of Food Counts*, 5th Edition (Dell, 2000), by Corinne T. Netzer.)

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Advantages of Low-GI diet

- People dieting on a Low-GI diet had:
  - 4.5% decline in BMR compared to 10% decline in High-GI diet (120)
    - Both groups lost the same amount of weight
    - Low-GI people kept weight off better after calorie restriction was lifted.
    - Low-GI dieters lost more body fat
    - Low-GI dieters lost less muscle
- Low GI diet showed better satiety (121)

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Low GI vs High GI

- Two groups of men
- Crossover study (126)
  - Equal times on each diet with 5-week washout in between
- No difference in body weight
- Low GI period resulted in a 500 gm greater fat loss and lower waist circumference compared to high-GI
- Improved lipids after the Low-GI phase

Empire Medical Training

Low GI vs Balanced Low Calorie

- Two groups of Hyperinsulinemic women
- Case Control study (127)
- 12 weeks
  - Low GI
  - Balanced Low Fat
  - Same caloric intake
- Low GI group lost 2 kg more, had lower glucose and insulin levels, had better glucose tolerance compared to controls.

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Implementing Low GI Diets

SUBSTITUTION OF HIGH-GI FOR LOW-GI FOODS

High-GI-food	Low-GI-food
Bread, whole meal or white	Whole grain bread
Low amylose rice (sticky rice, waxy rice)	High-amylose rice (basmati, parboiled rices)
Processed breakfast cereals	Unrefined cereals (oats, muesli, porridge)
Potato	Pasta or legumes
Biscuits and crackers	Biscuits made with dried fruit or whole grains
Cakes and muffins	Muffins made with fruit, oats or whole grains
Tropical fruits (bananas)	Temperate climate fruits (apples, stone fruit)

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GI and Mixed Meals

- Most studies show that weighted average of GL for a mixed meal is valid. (117-119)
  - Independent of Fat and Protein content.
  - Adding a single low glycemic food to a meal reduces glucose and insulin response
    - Even slight changes such as adding whole apples vs processed apples was significant
    - Substituting whole grain breads
    - Substituting high fructose for high glucose foods.

Empire Medical Training

Schwarzbein Principle

- Balanced Diet
- No skipped meals
- Low Glycemic
- Protein is the main nutrient
- No processed foods
- No caffeine or artificial sweeteners
- Heal the adrenal glands and insulin resistance first
  - "You need to be healthy to lose weight, before you can lose weight to be healthy"

Empire Medical Training

Schwarzbein Principle

- Focus on "real carbohydrates"
  - Anything you can't pick, gather, or milk should be excluded from the diet
- Metabolism can be rebuilt with the right balance of hormones and foods
- Supplements are almost always necessary due to reduced nutrients in our food supply

Empire Medical Training

Glycemic Index of Foods

1 When you eat a processed carbohydrate such as white bread:

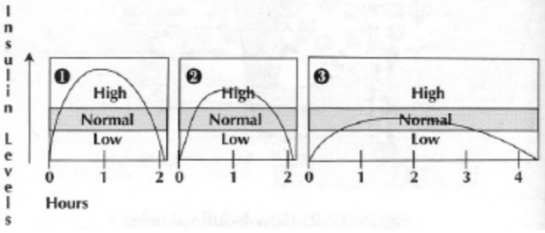
Refined carbohydrates are rapidly digested into sugar, which is quickly absorbed into the portal vein, causing a rapid rise in insulin.

2 When you eat a complex carbohydrate such as whole wheat bread:

Complex carbohydrates are digested at a slower rate so that less sugar arrives at the portal vein all at once. Less insulin is secreted in response, but it is still above a balanced level.

3 When you eat a balanced meal such as chicken, baked potato with butter and a nonstarchy vegetable such as broccoli:

Digestion is slowed down even further when you eat a balanced meal of proteins, fats, nonstarchy vegetables and carbohydrates. This results in a balanced level of insulin, which remains level for a longer period of time.



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High Fiber Diet

- Soluble
  - Beans, oats, fruit
- Insoluble
  - Grains and vegetables
- Recommends 25 to 40 gm fiber daily
  - Average American eats 10 gm per day

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Meal Replacement

- Improved Compliance vs Diet Alone
  - Greater weight loss in some studies (170,171)
    - 25-60% more weight loss at 3 mos. and 1 yr.
  - Higher levels of patient satisfaction
- Less of a sacrifice of convenience
  - "Fast food that's good for you"
- Great strategy to implement in the office setting.

Empire Medical Training

Pharmacologic Agents Supplements

Empire Medical Training

Pharmacologic Treatment

- Ultimate goal is simple

  PROMOTE NEGATIVE ENERGY BALANCE

- Obesity is the most understudied "disease" for pharmacologic management considering its number of victims

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Pharmacologic Mechanisms of Action

- Reduced Energy Intake
  - Reduced Hunger
  - Enhanced Satiety
  - Reduced preference for fat or carbohydrate
  - Reduced absorption
- Increased Energy Expenditure
  - Stimulation of Activity – fidgeting, exercise
  - Increased Metabolic Rate, Thermogenesis
- Increased Fat Oxidation

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Exclusions from Pharmacologic Tx

- Pregnancy
- Unstable Cardiac Disease
- Uncontrolled HTN
- Severe systemic illness
- Unstable Psychiatric history
  - History of anorexia
- Incompatible meds
  - MAO, Migraine drugs, Adrenergic agents
- Child under age 18
- Elderly – little data on use over age 50

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Centrally-Acting Agents

- Adrenergic
- Serotonergic

- NE, Serotonin, and Dopamine
  - Main neurotransmitters in the hypothalamus
  - Impulses
    - Altered energy intake, Energy Expenditure, Substrate utilization, Adipose Stores

Empire Medical Training

Adrenergic Agents

- Increase adrenergic (NE) neurotransmitter concentration in the hypothalamus
- DEA Schedule III
  - Benzphetamine, Phendimetrazine
- DEA Schedule IV
  - Diethylpropion, Phentermine

No use for Schedule II agents (amphetamine, methamphetamine)

Empire Medical Training

Phentermine

- Most commonly prescribed appetite suppressant
  - Resin form FDA approved 1959
    - Typical Doses: 15mg and 30mg (Ionamin)
  - HCl form FDA approved 1973
    - Typical Doses: 37.5mg immediate release (Adipex-P), or 15 or 30mg timed release (Fastin)
  - Generics of HCl form are readily available

Empire Medical Training

Phentermine

- Wholesale Cost
  - Generic 37.5 mg -- $150 per 1,000ct.
  - $0.15 each
- Typical Retail Price
  - Generic 37.5 mg -- $28-$30 for 30ct.
  - $0.96-$1.00 each
- 85% profit

Empire Medical Training

Phentermine

- Indications
  - BMI over 30
  - BMI over 27 with other medical risk factors
    - Diabetes
    - Hypertension
    - Hyperlipidemia

Empire Medical Training

Phentermine

- Contraindications
  - Severe Depression
  - Untreated Hyperthyroid
  - Renal of Liver Disease
  - Symptomatic Cardiovascular Disease
  - Use of MAO Inhibitor in last 2 weeks
  - Over age 60 or Under age 16
  - Pregnancy or Breastfeeding
- Suggestions
  - Do not take pseudoephedrine, Ritalin, caffeine, Tricyclic antidepressants, Alcohol

Empire Medical Training

Phentermine

- Common Side Effects
  - Nervousness, Dry Mouth, Sense of Well Being, Headache
- Less Common Side Effects
  - Heartburn, Unpleasant Taste, Skin Itching, Decreased Sex Drive, Insomnia

Empire Medical Training

Phentermine

- Has been tested in literature for up to 36 weeks of use (132-135)
  - Overall weight loss at the end of 36 weeks is 13% of body weight.
  - Most studies are short-term (3 months or less)
    - Show 5-10% loss of body weight
- Most effective agent according to the literature overall
- Never tested head-to-head against another agent.

Empire Medical Training

Phentermine

- Starting Dose
  - Often ½ of the 37.5mg tab will do well with few side effects
  - Increase to a whole tablet if tolerance reached.
  - Can use ½ tab BID for patients who need better night control.
  - Dose given before breakfast or 1-2 hours after breakfast.

Empire Medical Training

Phentermine

- Duration of Treatment
  - Manufacturer: "indicated for a few weeks"
  - Commonly used for 8-12 weeks straight
    - Most clinical trials show leveling off at that time.
  - Intermittent dosing
    - One month on, one month off, for 9 months compared to continuous therapy (128)
    - Intermittent group lost slightly more weight

Empire Medical Training

Diethylpropion

- Tenuate
  - Dose is 25mg TID one hour before meals
  - or 75mg sustained release in mid-morning
  - $1.50 to $2 per day
- Best Clinical Trial
  - 75mg/d vs placebo for 6 months (N=20) (130)
  - 12.3% loss vs. 2.8% for placebo
- Intermittent use (131)
  - Every other month for 24 weeks.
  - Placebo group lost more weight (!)
  - 82% dropped out due to poor results

Empire Medical Training

Orlistat

- Xenical
- FDA approved in 1998
- 120mg tablet taken with meals BID-TID
  - Cost= $1 per dose
- Works in your gut to reduce the amount of fat your body absorbs from the food you eat
- Binds to lipase in GI tract and inhibits absorption of 1/3 of dietary fat.
- No CV side effects
- Negligible systemic absorption
  - Possible decreased absorption of Vitamin A,E

Empire Medical Training

Orlistat

- First studies showed average weight loss of 8-11% of initial body weight at 6-8 months. (140)
- Later studies could not show more than 5% loss. (141)
- Independent improvement on lipids in addition to weight loss benefits. (140)

BLACK BOX WARNING

The most common side effects of orlistat relate to the extra fat being excreted instead of absorbed: gassiness, oily bowel movements and other bowel-related changes. Reports of severe liver damage in about a dozen people who used orlistat prompted a new warning label in 2010, though the FDA could not confirm that the drug caused the damage.

Empire Medical Training

Orlistat

- Side Effects
  - Abdominal Cramping
  - Flatus
  - Diarrhea
  - Passage of oily discharge

  - Improvement in side effects seen after a few months.
  - Reported side effects <10% at one year.

Orlistat

- Additional Warnings
  - Rare cases of severe liver injury have been reported
  - Avoid taking with cyclosporine
  - Suggested to take a multivitamin pill daily to make sure you get enough of certain vitamins that your body may not absorb from the food you eat

Bupropion

- FDA approved for depression and smoking cessation
- Weak reuptake inhibitor of Serotonin, NE, Dopamine
- 1999 Duke Study (127)
  - 50 patients started, 31 completed
  - All women with average BMI of 37
  - 1,600 cal diet plus 200mg BID vs Placebo
  - After 8 weeks:
    - 6.21% loss in Bupropion group vs. 1.56% Placebo
  - Theory that Bupropion may increase thermogenesis

Empire Medical Training

Bupropion

BLACK BOX WARNING

Boxed Warning for suicidal behavior in treating psychiatric disorders. FDA analysis revealed that some who have taken Bupropiun have reported experiencing unusual changes in behavior, become depressed, or had their depression worsen, and had thoughts of suicide or dying. In many cases, the problems began shortly after starting the medication and ended when the medication was stopped. However, some people continued to have symptoms after stopping the medication. Also, in a few cases, the problems began after the medication was stopped.

Empire Medical Training

SSRI's Alone

- Most studies show short-term weight loss comparable to adrenergic drugs (136)
- After 1 year, weight is usually gained back
- Possible success for use in combination with Phentermine…

Empire Medical Training

Phen-pro

- Combination of Phentermine and Prozac or other serotonergic agent
  - Prozac 20 mg po qd
  - Zoloft 50 mg po qd
  - Celexa 20 mg po qd
  - Luvox 50 mg po qd
  - Effexor XR 75 mg po qd
  - generic trazadone 50 mg po QHS.

Empire Medical Training

Phen-pro

- Starting Dose
  - 15mg Phentermine plus SSRI for 2 weeks
- Increase to 30mg phentermine thereafter
- Do NOT increase SSRI dose
- When hunger increases or weight loss levels off add
  - 5-HTP 50mg BID to regimen
- SSRI should be weaned off gradually.
- Some patients have continued the combo for over 8 years.

Empire Medical Training

Topiramate

- A mix of two medications: phentermine, which lessens your appetite, and topiramate, which is used to treat seizures or migraine headaches25-50 mg po qHS
- May make you less hungry or feel full sooner
- Common side effects dizziness, somnolence, cognitive dysfunction. Rare-nephrolithiasis, metabolic acidosis, glaucoma, hyperthermia, suicidality, constipation, trouble sleeping, taste changes
- May be combined with phentermine in AM

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Topiramate and Phentermine

- Combination of phentermine and topiramate

BLACK BOX WARNING

The drug combination can cause a birth defect called cleft palate in developing fetuses, so women of childbearing age taking it must use birth control and take a pregnancy test monthly. Another rare but serious side effect is the development of suicidal thoughts - about 1 in 500 people who take anti-seizure drugs like topiramate develop suicidal thoughts or behaviors.

Empire Medical Training

Metformin

- Approved for treatment of Type II diabetes
- Mechanisms
  - Reduces intestinal absorption of glucose
  - Reduces hepatic glucose production
  - Increases sensitivity to insulin
- Diabetics
  - 8 kg greater weight loss after 6 months (144)
- Insulin Resistance
  - French 1yr. Study showed greater weight loss in metformin-treated subjects (145)

Empire Medical Training

Metformin

- Starting Dose
  - 500mg BID, Increase to 875mg BID
- Greater weight loss than other oral hypoglycemics in diabetics
- Suggestion made that drug might prevent development of Type II diabetes (144)

Contrave

Naltrexone - bupropion

- Bupropion 360 mg/Naltrexone 32 mg - A mix of two medications: naltrexone, which is used to treat alcohol and drug dependence, and bupropion, which is used to treat depression or help people quit smoking
- Helpful for addictive eating/binge eating/emotional eating. May make you feel less hungry or full sooner
- Dopamine, NE ag, opioid antagonist: Side effects nausea, dizziness, BP stable, constipation, diarrhea, dry mouth, headache, increased heart rate, insomnia, liver damage, vomiting
- Phase III: 11.5% weight loss at 56 weeks
- FDA advisory panel asked for more study

Contrave

BLACK BOX WARNING

The drug also has a black box warning — the strictest of the FDA warning labels — because bupropion is associated with an increased risk of suicidal thoughts. The drug was previously approved as a smoking cessation aid and to treat depression. Naltrexone had been used to treat alcohol and opioid addiction. Doctors aren't entirely sure how the drug combination works to promote weight loss.

Empire Medical Training

Qsymia

- Phentermine/Topiramate
  - 3.75/23x14 days
  - 7.5/46, 11.25/69, 15/92 after 12 weeks or <5%
  - 14.7 % weight loss clinical trials
- Cognitive, mood disorders, potential for birth defects and CV morbidity.

Empire Medical Training

Qsymia

BLACK BOX WARNING

The drug combination can cause a birth defect called cleft palate in developing fetuses, so women of childbearing age taking it must use birth control and take a pregnancy test monthly. Another rare but serious side effect is the development of suicidal thoughts - about 1 in 500 people who take anti-seizure drugs like topiramate develop suicidal thoughts or behaviors.

Empire Medical Training

Lorcaserin

- Serotonergic 5-HT 2c agonist, appetite suppression in hypothalamus, FDA adv rec
- Weight loss average: 5.8% overall
- Cardiac valvulopathies-no excess 12 mos
- Other potential side effects mood changes due to inhibition of dopamine release
- HA, dizziness, nausea, breast & lung CA rodents
- Lorcaserin affects serotonin receptors, it can't be used alongside other drugs with the same target, such as selective serotonin reuptake inhibitors (SSRIs), which are used to treat depression.

Empire Medical Training

Victoza (liraglutide)

- Injectible GLP-1 agonist, improves glucose control but elevates insulin
- 5.5% weight loss seen as secondary outcome in Type II DM data
- 0.6-1.2 mg SQ injections qd
- Medullary thyroid carcinoma in animal studies

BLACK BOX WARNING

Victoza does come with a black-box label that warns of the risk of thyroid C-cell tumors and possible thyroid cancer. The black box warns that Victoza (liraglutide) "causes thyroid C-cell tumors at clinically relevant exposures in rodents," and goes on to state that it's unknown whether Victoza causes these tumors, including cancer (medullary thyroid carcinoma, or MTC), in humans.

Empire Medical Training

Victoza (liraglutide)

Saxenda

- Mimics a hormone called glucagon-like peptide-1 (GLP-1) that targets areas of the brain that regulate appetite and food intake
- At a lower dose under a different name, Victoza, this drug was FDA-approved to treat type 2 diabetes
- Side effects include: nausea, diarrhea, constipation, abdominal pain, headache, and increased heart rate.
- May increase the chance of developing pancreatitis.
- Has been found to cause a rare type of thyroid tumor in animals

Empire Medical Training

Wegovy (Semaglutide)

Injection Therapy

- Given weekly by injection
- Mimics a hormone called glucagon-like peptide-1 (GLP-1) that targets areas of the brain that regulate appetite and food intake
- Under different names and dosages, this drug was FDA-approved to treat type 2 diabetes as an injectable medication (Ozempic) and as an oral pill (Rybelsus)
- Do not use in combination with other semaglutide-containing products, other GLP-1 receptor agonists, or other products intended for weight loss, including prescription drugs, over-the-counter drugs, or herbal products
- May increase the chance of developing pancreatitis
- Has been found to cause a rare type of thyroid tumor in animals

Empire Medical Training

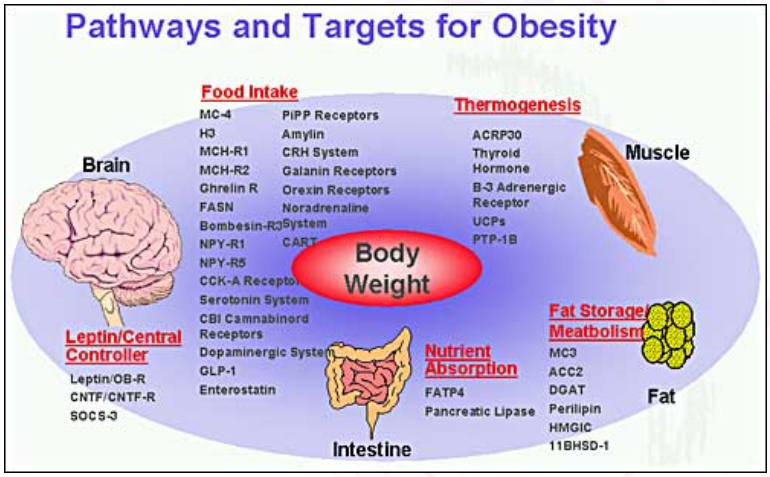
Wegovy (Semaglutide)

Side Effects

- nausea
- diarrhea
- vomiting
- constipation
- abdominal (stomach) pain
- headache
- fatigue

Empire Medical Training

Future Pharmacology



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Dispensing Controlled Substances

- Checklist
  - Current DEA registration
    - Must have rights to prescribe CIII and CIV
  - Call State Medical Society
    - Check on unique state laws regarding rx for weight loss controlled substances
      - Utah- can't use a CIII for weight loss
      - Must have documented complete physical and weight loss goal written in chart.
    - Some states restrict to 3 months of use.

Empire Medical Training

Record Keeping

- USC 21
  - Read this completely at www.dea.gov
  - Written inventory at least every 2 years of all controlled stock on hand
  - No written rx needed when drug dispensed directly by prescribing physician.
  - Keep drug locked up at all times
- Written record of patient's name and address, quantity and lot # of each rx dispensed

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Staying Under the DEA Radar

- Keep your licenses up to date
- Order only from reputable U.S. distributors
- Keep accurate records of dispensing
- Keep all paperwork that came with shipment of stock controlled substances
- Only use childproof containers
- Clear labels with date and patient name
- Don't fill any rx unless you have the basic patient encounter in the chart.

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Labeling

- Make 2 labels for each rx
  - Save one for records
- Have lot # on each rx
- Have patient sign second label and store by lot number.

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Non-Prescription Supplements

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Ephedra (ma huang)

- Removed from US market in 2004
- 64% of all herbal supplement adverse effect reports in 2001 (<1% of sales)
  - 10 deaths and 13 incidents of disability in two year period from 1997 to 1999
- Proven effective when combined with caffeine – similar to prescription stimulants
- Supplements circumvent ban by using Ephedrine with caffeine

Empire Medical Training

Chromium

- Combined with Picolinate to aid in absorption
- Thought to improve glucose tolerance
  - Aids Insulin mediated active transport of glucose into the cell
- Typical dose 200 – 400 mcg per day
- Mixed results in studies.
  - Better results in existing Type II diabetics than in MetS or insulin resistance

Empire Medical Training

Pyruvate

- End product of glucose metabolism
- Need to take in place of dietary carbs
- Some recommendations to take 22gm per day
  - Would cost $400 per month in capsule form
- One RCT of 6 gm per day (167)
  - 1.2 kg of weight loss vs placebo

Empire Medical Training

CLA (Conjugated Linoleic Acid)

- Trans Fatty Acid
- Studies in Mice show decreased fat deposition
  - Increased fatty acid oxidation (165)
  - Decreased triglyceride absorption
  - Increased programmed fat cell death
- 12-week RCT (166)
  - No improvement in BMI
  - Doses from 3.4 gm to 6.8 gm daily

Empire Medical Training

Cinnamon

- Clinical trials show improvement in blood sugar and lipid panels in diabetics
  - USDA actively studying
- Weight loss in rats seen, no human studies
- Dose 1-6 gm per day
  - To remove coumarin, place cinnamon sticks in hot water and drink the solution.

Empire Medical Training

Psyllium

- Plantago psyllium
- Dietary fiber (Metamucil)
- Improves satiety
- Will help decrease side effects of Orlistat
- N=125 study (160)
  - Improvement in glucose and lipid levels
  - No benefit for weight loss seen

Empire Medical Training

Guar Gum

- Cyamopsis tetragonolobus
- For promoting satiety
- Dietary fiber and thickening agent
  - Can swell to 10-20 times its size in GI tract
  - Relatively safe; obstruction at high doses
- Analysis of 11 RCT's show no benefit over placebo for weight loss (159)

Empire Medical Training

Glucomannan

- Amorphophallus Konjac root
- Functions as a dietary fiber and an inhibitor of glucose absorption in the gut
  - Reduced fat absorption as well
- 3 RCT's show benefit of 3-4 gm per day (156-158)
- Banned in some countries due to incidence of GI obstruction

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Ginseng

- Panax Ginseng
- Improvement of glucose tolerance (161)
- No studies showing independent contribution to weight loss

7-keto DHEA

- Version of DHEA that cannot be converted to androgens or estrogens
- Boosts basal metabolism and thermogenesis
  - Increase in thyroid hormone production (168)
  - Increase in lean body mass in women (168)
- No RCT showing weight loss yet
- Safety data lacking this early

5-HTP

- Intermediary between amino acid L-tryptophan and serotonin
  - Increases serotonin levels in CNS
  - 600mg per day decreased overall caloric intake
  - 900mg per day increases satiety and decreases carb cravings and results in weight loss in 2 trials (169)
- Concerns about EMS (Eosinophilia Myalgia)
  - Caused by contaminant or the 5-HTP
  - Reason for withdrawal of L-Tryptophan in 1990

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Hydroxycitric Acid

- Garcinia cambogia.
  - Tropical fruit from India (Tamarind)
- Typical dose = 750 mg daily
- Inhibits mitochondrial citrate lyase (162)
  - Decreases Acetyl Co A production
  - Decreases fatty acid synthesis
- Mixed results in trials (163, 164)
  - One showed a 1.3 kg weight loss after 12 weeks.
  - Slows intestinal glucose absorption in rats.

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Irvingia Gabonensis

- Extract from West African plant, 150 bid over 10 weeks
- Increases leptin sensitivity, inhibits alpha-amylase which slows carb absorption
- Increases adiponectin which increases insulin sensitivity

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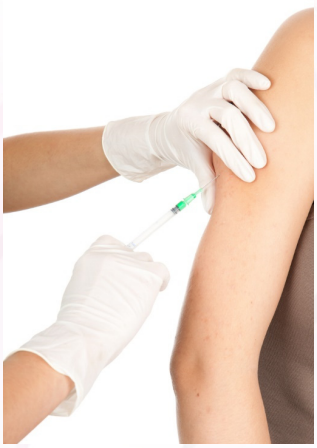
MIC Injections

- **Methionine (the M in MIC):** it assists in the lipolysis, as well as assisting with the digestive system and removing heavy metals from the body since it can be converted to cytosine, which is a precursor to glutathione, which is of prime importance in sulfation detoxification in the liver.



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MIC Injections

- **Inositol (the I in MIC):** part of B vitamin complex, helps to maintain proper electrical gradient and nutrient transfer across the cell membrane. It also acts as a cofactor in lipolysis. Inositol helps establish healthy cell membranes, which facilitate nerve impulses. It may also be helpful in preventing depression.

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MIC Injections

- **Choline (the C in MIC):** Choline is an emulsifier purported to assist in controlling weight, keeping cell membranes healthy in preventing gallstones, maintenance of the nervous system, and being studied to treat NASH. Choline is a component of cell membranes, critical for normal membrane structure and function.
- **Choline:** is the major precursor of betaine, and it is used by the kidneys to maintain water balance and by the liver as a source of methyl-groups for methionine formation. It is also used to produce the important neurotransmitter acetylcholine
- MIC injections popular though not significant positive data. Compounding pharmacies supply, 1-2 cc given IM weekly.

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Hoodia Gordonii

- South African appetite suppressant for bushmen
  - 2-3 inch piece of hoodia fruit would suppress appetite for days
  - P57 is code name for active molecule found in the plant

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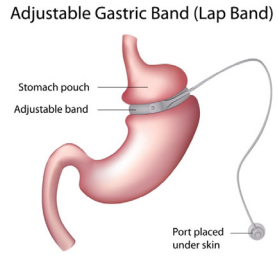
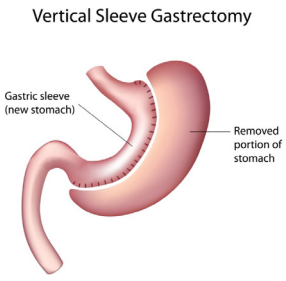
Referral for Surgery

- 100 lb. excess over ideal body weight
- BMI of 35-40+
- Failure of all other conservative measures

- Gastric Bypass
- Verticle Sleeve Gastrectomy
- Gastric Banding
- Adjustable Gastric Band





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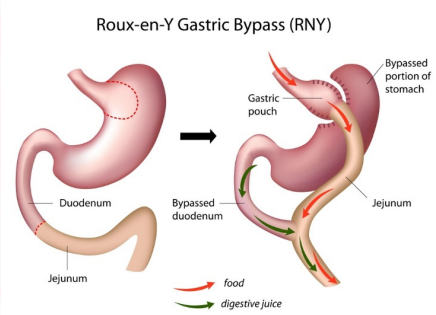
Surgery Long Term Outcomes

- Average weight losses 20-40 kg range 2-8 years after surgery.
  - Compared to conservative management
- Surgical Mortality = 1%
- Serious Morbidity = 10%



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END OF CME

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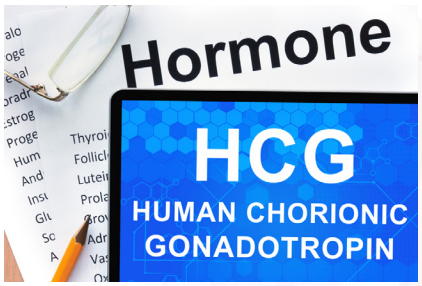

Appendix A: hCG Weight Loss

Latest News & Information

Protocols and Reference Guide

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hCG – Why does it work?

- Hypothalamic appetite suppressant
- Promotes leptin gene expression
- Stimulates LH receptor-produces T in men, P in women, increase BMR
- Spares and preserves lean muscle
- Adipocyte effects-"access abnormal fat stores"-enhance lipolysis if on VLCD

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hCG – Latest News

- Although the hCG (Human Chorionic Gonadotropin) diet has been very popular among physicians trying to help patients lose weight over the years, an update in 2020 by the FDA reclassified hCG as a biologic compound, which has been removed from the list of drugs that can be produced from 503B compounding pharmacy facilities.
- hCG, at this time, can still be purchased through 503A compounding facilities but it is becoming increasingly difficult to source:
  - Pharmacy Rx Solutions (Tampa, FL)
  - US HCG Shots (St. Petersburg, FL) – Since 2007
  - Invigor Medical (Kennewick, WA)
  - Tele hCG (Jupiter, FL)
- FDA warning to consumers https://www.fda.gov/consumers/consumer-updates/avoid-dangerous-hcg-diet-products

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Benefits of hCG

- Lose 1-2lbs per day with no hunger.
- hCG is natural hormone/protein substance.
- Exercise is not needed to reduce.
- Studies suggest may reduce rate of breast cancer.
- Helps reset hypothalamus which implies long last results.
- Safe for healthy women and most healthy males.
- Re-sculpts body so weight loss is proportional to all areas.
- Increases energy levels as compared to other low calorie diets.
- May improve sleep levels in patients, patients claim they are less irritable and without a sense of nervousness.

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Side Effects

- Irregular menses
- Migraine exacerbations
- Rare allergic reaction or edema
- Rare temporary hair loss
- Ganirelix (Antagon) drug interaction-HCG interferes with its inhibition of premature LH surges in fertility Tx

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Contraindications

- CHF
- Gout- or can rx with allopurinol
- Fibroids, endometriosis, breast cancer
- PCOS
- Severe systemic illness
- Respiratory disease-COPD, asthma
- Seizure disorder

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hCG Diet – History

- First developed by ATW Simeon in 1954 – "Pounds & Inches"
- His research on obesity, Dr. Simeon noticed lack of symptoms one would suspect from a low calorie diet when combined with hCG.
- Patients lost a considerable amount of weight as well as their own body reshaping naturally without the need for exercise.
- Patients lost more fat tissue directly from adipose tissue accumulations, causing visible contouring of the body.
- hCG regulated the metabolism, correcting that which initially caused the obesity.

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hCG Research

Craig Study 1963

- 20 overweight women
- 45 days
- placebo-controlled
- no advantage in weight lost due to diet

Asher Study 1973

- Asher and Harper
- 40 overweight women for 6 weeks
- Placebo group got saline injections
- Weight lost 19.96 lbs HCG v 11.05 placebo
- Well-being rated higher in HCG 86.5% vs 70% placebo

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hCG Research

Stein Study 1976

- 51 women
- 32 days
- HCG v saline placebo
- No difference in weight loss

Young Study 1976

- 202 people
- 6 weeks
- 6 days per week HCG v saline injections
- No difference in weight loss or maintenance

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hCG Research

Shetty/Kalkhoff Study 1977

- 6 hospitalized women
- Placebo controlled
- 30 days
- No difference between groups in weight lost

Greenway Study 1977

- 40 women
- 6 weeks
- Placebo-controlled
- No difference in weight lost

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Birmingham Meta-analysis

- 16 double-blind studies, 6 controlled studies reviewed
- 1 study positive, 5 negative for controlled studies
- Overall data negative

Birmingham CL, et al Br J Clin Pharmacol. **The effect of human chorionic gonadotropin (HCG) in the treatment of obesity by means of the Simeons therapy: a criteria-based meta-analysis,** 1995 Sep; 40(3): 237–243.

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Lijesen Meta-analysis

- 24 uncontrolled studies analyzed
- Overall negative results found

G K Lijesen, I Theeuwen, et al. **Human chorionic gonadotropin (HCG) in treatment of obesity,** 1987 May;47(5):297–307. [PubMed]

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2010 Bryman Study

- Sublingual preparation
- Modified HCG with 680 calories/day women, 750 calories/day men
- Compared to high protein, low carb meal replacements of 650 calories/day women, 800 calories/day men
- 6 week retrospect analysis study

David Bryman, et al. **Successful Weight Loss Intervention Using a Modified hCG Diet,**
THE BARIATRICIA - 2010, VOL. 25, NO. 2 • 9-11

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Bryman Results

- Weight loss 19.84 lbs HCG
- 14.75 lbs placebo
- BMI decreased 3.18 HCG v 2.48 placebo
- Conclusion was HCG sublingually was better for weight loss than meal replacements of similar composition

David Bryman, et al. **Successful Weight Loss Intervention Using a Modified hCG Diet,**
THE BARIATRICIA - 2010, VOL. 25, NO. 2 • 9-11

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FDA Disclaimer

- HCG has not been demonstrated to be an effective adjunct in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases hunger.

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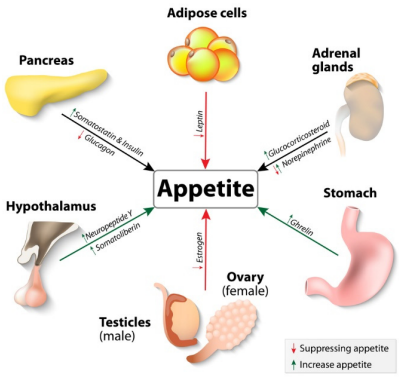
Compliance is the Key

- HCG enhances compliance
- Fewer side effects of VLCD
- Increased BMR
- Enhanced hormone levels



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Off-label use of hCG

- FDA cannot tell physicians how they can use approved drugs or devices.
- PDR: Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens that are not included in approved labeling.
- Off-label use is common
  - Courts have held that off-label use does not require special informed consent. Physician not required to discuss FDA regulatory status to comply with standards of informed consent.

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Off-label use is Legal

- Appellate court decision: Because the pace of medical discovery runs ahead of the FDA's regulatory machinery, the off-label use of some drugs is frequently considered to be "state of the art" treatment.
- US Supreme Court: Off-label prescribing is an accepted and necessary corollary to the FDA's mission to regulate.

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hCG Diet – Quick Overview

- 125 iu hCG administered daily by injection (except during menstruation)
- Until 3rd injection the patient eats excessively (24 total injections).
- After 3rd injection, the 500 calorie diet and personal care product restrictions are applied and continue through 72 hours after last injection.
- For continuing (3) weeks all foods are allowed except sugar and starch-including sweet fruits.
- After (3) weeks, starches are introduced into the diet in small quantities and weight maintenance program is established.
- This process can be repeated 1x.

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hCG Diet – Simeon Protocol

- **Day 1 and 2**
  Take the HCG as directed. These are your loading days. You can eat all you want and eat to capacity.
- **Day 3 - 23**
  Continue the HCG as directed. Begin the 500 calories diet; follow exactly for a minimum of 21 days for best results.
- **Day 24-26**
  Discontinue the HCG and continue eating 500 calories. It takes 72 hours for the HCG to leave your body.
- Program can be repeated after day 30 for only one additional period (same protocol).

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hCG Diet – Meal Planning

Breakfast:

- Tea or coffee in any quantity without sugar. Only one tablespoonful of milk allowed in 24 hours. Saccharin may be used as a sweetener.

Lunch:

- 100 grams (3.5 oz) of veal, beef, chicken breast, fresh white fish, lobster, crab, or shrimp. All visible fat must be carefully removed before cooking, and the meat must be weighed raw. It must be boiled or grilled without additional fat. Salmon, eel, tuna, herring, dried or pickled fish are not allowed. The chicken breast must be removed from the bird.

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hCG Diet – Meal Planning contd.

Lunch (contd.):

- One type of vegetable only to be chosen from the following: spinach, chard, chicory, beet-greens, green salad, tomatoes, celery, fennel, onions, red radishes, cucumbers, asparagus, cabbage.
- One breadstick (grissini) or one Melba toast.
- An apple, orange, or a handful of strawberries or one-half grapefruit.

Dinner:

- The same choices as lunch (above).

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Implementing Weight Loss into Your Practice

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Decide the Services You Want to Provide…

- Full medical/primary care
- Laboratory/EKG
- Dispensing of Controlled Substances
- Dispensing of Meal Replacements
- Supplements
- Nutritional counseling
  - In-house
  - Local Dietician (not popular)

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Decide if you want to Bill Insurance

- Virtually no coverage for "obesity" or "weight loss" treatment
- Must document that the patient's **medical sequelae** of their obesity was addressed
- Bill based on complexity of history/exam or based on time of consultation alone
- 99203– 30 minutes 99204– 40 minutes
- 99213– 15 minutes 99214– 25 minutes

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Call Your Competition

Pricing

- Other Weight Loss Centers
  - Fees for visits and pills
  - Availability
  - Frequency of follow-up visits
  - Insurance billing?
- Pharmacies
  - Costs of diet pills

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Extra Staff

- Train existing nurse for counseling
- Interview local dieticians to see if they are interested in partnership (not common)
  - Make sure your philosophies agree.
- Joint marketing ventures (i.e. referral)
  - Health Clubs, Curves
  - Personal Trainers

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Essential Counseling

- Exercise program
  - Anything that improves current activity level is a plus
- Water
- Sleep
- Other Wellness Strategies
- Reasonable Goals
- Endpoints Other than Weight
  - Moods, clothing size, self-image

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Set Reasonable Goals

- Remind the patient that the goals are:
  - Good Health
  - Improved Stamina
  - Improved Self-Image
  - Improved Testing
  - And…….weight loss
- Lose 10% of body weight over 6 months
  - A 500 calorie daily deficit should result in 26 pounds lost in 6 mos.
  - Period of maintenance after this level is reached
  - Real world: 8% loss over 3-12 months

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Obese Patients:

Have Unrealistic Weight Loss Goals

Outcome	Weight (lbs)	% Reduction
Initial	218	0
Dream	135	38
Happy	150	31
Acceptable	163	25
Disappointed	180	17

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Foster et al. J Consult Clin Psychol 1997;65:79.

The First Visit

- Weight, BP, BMI
- Medical History
- Dieting History
- Medications
- Eating Habits
- Exercise
- Sleep
- Stressors

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The First Visit

- Exam
- Laboratory
  - U/A
  - EKG
  - Comp. Metabolic, CBC, Fasting Glucose and Insulin, Fasting Lipids, Thyroid panel
  - Salivary Hormone Testing if indicated

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Taking a History

- Important History Questions
- History of use of hormones/herbals
- Caffeine intake per day
- Sleep Habits
- Use of sleep aids
- Time to fall asleep, Time of first awakening
- Meals per day

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Taking a History

- History should include:
  - Exercise Habits
  - Recent weight changes
  - Stress
  - GYN history
  - Diet

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Selling Options

- Consider doing Bio-Electric Impedance Analysis testing in the office.
  - Patients can see improvement in more areas that just on the scale.
  - Encourages long-term compliance
  - Is a test that they can't do at home…adds perceived value to the office visit.
  - Proven in a number of published studies.

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Selling Supplements

- Convenience for the Patient
- Profitable for You
- Can add $20 to $40 per encounter

- AMA is against physician sales in the office unless at selling price is at cost and a patient need is met.
  - Thousands of physicians sell products in their offices

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Sample Profitability

- Dispensing Phentermine
  - Adds $22 to each monthly visit
- Dispensing Meal Replacements
  - Adds $50-80 to each monthly visit
- Selling Supplements
  - Vitamins, Omega-3, Hormone-specific nutritionals, Melatonin
  - Adds $25-$75 monthly per visit

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Profitability – Labs

- Discuss with labs about doing "client billing"
  - Lab bills provider for tests at a deep discount
  - Provider marks up lab and bills patient or insurance
  - Must bill insurance with modifier -90 on all tests run at an outside lab.
    - Lipid panel or Chemistry for $3-4 each.
  - Not all insurance companies reimburse for -90 billing (HMO's, POS, Medicare, Medicaid)

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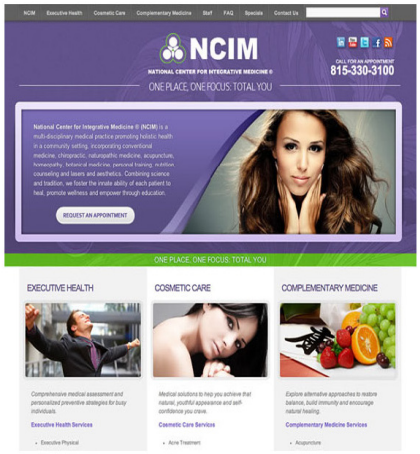
Website / SEO



RxMedicalweb
Physicians Rx for Success

Google AdWords

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Advertising

Digital Marketing

- Website
  - SEO keywords (i.e. Physician Weight Loss Program, Weight Loss – city name, etc.)
  - Website is for information and to make the phone ring.
  - Use words like; Medically supervised, physician's, doctor's, meal replacements
- Google Ad-Words
  - Regionalize a number of keywords for weight loss – advertising dollars will be less (10 mile radius of your practice if in a major municipality)
  - Guarantee yourself first page placement and 30-35% of the click through for your keywords – though only 30%, 70% of the people have the intention of buying.
- Social Media
  - Over 55% of all searches are on the phone; mobile website, facebook
  - Creates Branding (i.e. 45 Day Reset Diet)
  - Business Directory Listings (Yext: 200+ business directory listings – creates backlinks)

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Products

You will increase volume of people through your practice (10-15) per day so…

- Retail
  - Nutriceuticals with specific supplements – will compliment your medical practice as well)
  - Alcat Testing – sensitivity to certain foods (more for allergies)
  - Meal Replacements – (shakes, bars, drinks etc.)
  - Nutrition Services – does not necessarily need to be a nutritionist or dietician
  - Free Body Analysis (requires a bio-impedance scale – www.alibaba.com, www.dhgate.com
- Maintenance Diets
  - Recognize that most successful initial diets fail long-term – create a maintenance program to capture these patients.
- Referral Program
  - Leverage the 67% of people in your own practice that are obese or overweight with the 67% of society that is the same.
  - Be able to brand addtl services (Aesthetics – injectables etc.)

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Summary

- Initial Visit
- Counseling (i.e. Wellness/Longevity Program)
  - Exercise
  - Diet
- Consider Meal Replacement program
- Follow-Ups to ensure compliance
  - Package payment– give discounts for advance payment
- Maintenance Diet Program

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DISCLAIMER

The equipment and products mentioned or shown in this program, reflect the experience and preferences of the presenter and is not to be considered an endorsement. The presenter has not been given financial or product considerations with any manufacturer or medical distributor.

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EMPIRE MEDICAL TRAINING
WEIGHT LOSS LECTURES
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