Randomized Controlled Trial to Reduce Obesity in the Context of Primary Care

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Instructor of Medicine
How America got fat
By Matthew Engel
Outline

• Define and measure obesity
• Epidemiology of obesity
• Physiology of obesity
• Determinants of obesity
• Health consequences
• Clinical trial for obesity treatment
Obesity: a definition

- Excess adiposity (fat)
- Measured as excess weight:
  - Body Mass Index (BMI)
    - BMI = mass (kg) / height (m) $^2$
  - Used for adults over 18 years
    - Underweight $\leq$ 18.5
    - Normal range 18.6-24.9
    - Overweight 25-29.9
    - Obese $\geq$30
    - Class I: 30.0-34.9
    - Class II: 35.0-39.9
    - Class III: $\geq$ 40.0
Considerations: BMI

• Where might BMI be misleading?
• Less reliable with muscular individuals
• Need for different cut points for Asians and South Asians vs. European ancestry
  – Overweight = 23-27.4 kg/m$^2$
  – Obesity $\geq 27.5$ kg/m$^2$
• Height loss with aging or injury
• Anything that changes weight to height relationship
Body Fat Distribution

• Not just “how much” but WHERE the fat is deposited is important
• Men and women tend to increase body mass differently when developing overweight
• Two specific shapes are often characterized
  – “Pear” or gynoid = peripheral, subcutaneous
  – “Apple” or android = central
Body Fat Distribution

• Apple-shaped (male-like) fat pattern
  – Large waist, deposits of *intra-abdominal fat*
  – ↑ CHD and obesity-related CHD risk factors
    • ↑ blood pressure
    • ↑ type 2 diabetes
    • ↑ triglycerides
    • ↓ HDL cholesterol (“good” cholesterol)
  – ↑ gall bladder disease
  – ↑ obesity-related cancers

• Pear-shaped (female-like) fat pattern
  – *Subcutaneous fat* deposited on hips and thighs
Other Measurement Methods

• Waist circumference
• Skin fold thickness (standard locations for assessing subcutaneous fat)
  – Less accurate, particularly in the obese
• Underwater weighing (density measurement)
• Imaging
  – DEXA
  – MRI
  – CT Bioelectrical impedance
Outline

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Trends in Obesity

- Behavioral Risk Factor Surveillance System (BRFSS)
- Organized at a state level by the Centers for Disease Control and Prevention
- Began in 1984 with 15 states, now all 50
- Phone Interviews
- Self-reported height and weight
- About 200,000 adults surveyed annually
Obesity Trends Among U.S. Adults
BRFSS, 1985
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1986

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1987
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1988

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1989
(*BMI ≥ 30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1990

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1991

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1992
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1993
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1994
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1995

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1996
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1997

(*BMI ≥ 30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 1998

(*BMI \geq 30, or \sim 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 1999
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 2000

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 2001

(*BMI ≥30, or ~30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 2002

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 2003
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults
BRFSS, 2004
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

**BRFSS, 2005**

(*BMI ≥ 30, or ~ 30 lbs. overweight for 5’4” person)
Obesity Trends Among U.S. Adults

BRFSS, 2006

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends Among U.S. Adults

BRFSS, 2007

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends* Among U.S. Adults
BRFSS, 2008

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends* Among U.S. Adults
BRFSS, 2009
(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends* Among U.S. Adults
(*BMI ≥30, or about 30 lbs. overweight for 5’4” person)
Rising obesity

Obesity rates among the adult population in OECD countries

Note: For Australia, UK and US figures are based on health examination surveys, rather than health interview surveys.
Source: OECD Health Data 2003
Figure 1
Overweight and Obesity in Women 15 to 49 Years Old in Developing Countries and the United States

Source: See suggested readings at the end of this brief.
Note: CEE/CIS stands for Central Eastern Europe/Commonwealth of Independent States.
Prevalence of diabetes

The top 10 countries, in numbers of people with diabetes, are:

India
China
USA
Indonesia
Japan
Pakistan
Russia
Brazil
Italy
Bangladesh

Source: World Health Organization
Nutritional Status in Mexico

Figura 6.1
Comparativo de la prevalencia nacional de bajo peso, baja talla y emaciación en menores de cinco años por grupos de edad de la ENN 1988, ENN 1999 y ENSANUT 2006. México
Figura 6.10
Distribución del estado nutricio, de acuerdo con el IMC, por sexo ENSANUT 2006. México

[Bar chart showing the distribution of nutritional status by sex according to BMI (IMC) in Mexico, with categories for undernutrition, adequate, overweight, and obesity, indicating percentages for males and females.]
Figura 6.12
Comparación de la distribución de estado nutricio de acuerdo con el IMC, en mujeres de 20 a 49 años de edad de la ENN 1988, ENN 1999 y ENSANUT 2006. México
Evolution?
Outline

• Define and measure obesity
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• Physiology of obesity
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Physiology of Obesity

- Overweight/obesity is the result of **CALORIC IMBALANCE**
Energy Balance

- Weight Gain: Calories Consumed > Calories Used
- Weight Loss: Calories Consumed < Calories Used
- Maintenance: Calories Consumed = Calories Used

- 3500 Calories (kcal) = 1.0 pounds of body weight
- Walking 3 mph burns 240 kcal/hour (150 lb. person)
Potential for Weight Loss or Gain

• Typical resting metabolism: 24-26 kcal/day/kg
• Women slightly less than men
• 150 lb (68 kg) man = 1800 kCal/day

• Reduced Consumption or Increased Activity
• (-)300 kcal/day = loss of 2.5 lbs/month or 30 lbs/yr

• Increased Consumption or Decreased Activity
• (+)100 kcal/day = gain of 0.9 lbs/month or 10 lbs/yr
FRENCH FRIES

20 Years Ago

210 Calories
2.4 ounces

Today

How many calories are in today’s portion of fries?
FRENCH FRIES

20 Years Ago

210 Calories
2.4 ounces

Today

610 Calories
6.9 ounces

Calorie Difference: 400 Calories
Maintaining a Healthy Weight is a Balancing Act
Calories In = Calories Out

How long will you have to walk leisurely in order to burn those extra 400 calories?*

*Based on 150-pound person
Based on 150-pound person

If you walk leisurely for 1 hour and 40 minutes you will burn approximately 400 calories.*

*Based on 150-pound person
Outline

• Define and measure obesity
• Epidemiology of obesity
• Physiology of obesity
• **Determinants of obesity**
• Health consequences
• Clinical trial for obesity treatment
Factors that Affect BMI

- Increasing Age
- Gender
- Race/Ethnicity
  - Asian < White < Latino < Blacks and Native American
- Lower socioeconomic status
- Health behaviors
- Access to Health Care
- Environment
- For immigrants, length of time living in the US

*Note: Important to distinguish association from causation*
## Prevalence of obesity and diabetes by gender, BRFSS, 2001

<table>
<thead>
<tr>
<th>Gender</th>
<th>% Obese</th>
<th>% Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>21.0</td>
<td>6.8</td>
</tr>
<tr>
<td>Female</td>
<td>20.8</td>
<td>8.9</td>
</tr>
</tbody>
</table>

Mokdad et al. JAMA 2003;289:76-79.
Prevalence of obesity and diabetes by race/ethnicity, BRFSS, 2001

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>% Obese</th>
<th>% Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>19.6</td>
<td>7.2</td>
</tr>
<tr>
<td>African American</td>
<td>31.1</td>
<td>11.2</td>
</tr>
<tr>
<td>Latino</td>
<td>23.7</td>
<td>9.0</td>
</tr>
<tr>
<td>Other</td>
<td>15.7</td>
<td>8.2</td>
</tr>
</tbody>
</table>

Mokdad et al. JAMA 2003;289:76-79.
Prevalence of obesity and diabetes by education level, BRFSS, 2001

<table>
<thead>
<tr>
<th>Education Level</th>
<th>% Obese</th>
<th>% Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; High School</td>
<td>27.4</td>
<td>13.0</td>
</tr>
<tr>
<td>High School</td>
<td>23.2</td>
<td>8.2</td>
</tr>
<tr>
<td>Some College</td>
<td>21.0</td>
<td>7.5</td>
</tr>
<tr>
<td>College +</td>
<td>15.7</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Mokdad et al. JAMA 2003;289:76-79.
Trends in obesity prevalence (BMI ≥30), US adults, NHANES, 1971-2004

Prevalence (%) of overweight (BMI ≥25) and obesity (BMI ≥30) in different Asian-American groups, 1992–1995 National Health Interview Survey, United States

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overweight</td>
<td>Obesity</td>
</tr>
<tr>
<td>Total NHIS</td>
<td>60</td>
<td>15</td>
</tr>
<tr>
<td>Asian Indian</td>
<td>33</td>
<td>4</td>
</tr>
<tr>
<td>Chinese</td>
<td>26</td>
<td>3</td>
</tr>
<tr>
<td>Filipino</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>Japanese</td>
<td>42</td>
<td>7</td>
</tr>
<tr>
<td>Korean</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td>Vietnamese</td>
<td>17</td>
<td>0</td>
</tr>
</tbody>
</table>

Nature vs. Nurture

- Pima Indians today have a much more serious obesity problem and the highest incidence of diabetes in the world.
- “Thrifty gene” hypothesis
- Susceptible individuals in a permissive environment

Source: Marx J, Science 2002; 296:686-689
Genetic Influences on Obesity

- Known clustering of obesity in families
- Twin studies
  - greater concordance in MZ twins vs. DZ twins
- Statistical linkage studies suggest genetic associations
- Dramatic increase in obesity argues against a dominant influence of genetics
Outline

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Health Consequences of Obesity

- Mechanical: Increased fat mass leads to anatomical problem or increased stress
  - Osteoarthritis, Obstructive Sleep Apnea
- Metabolic: Altered physiology leads to abnormal cardiovascular complications
  - Diabetes Type 2, hypertension, elevated lipids
- Hormonal: Altered hormonal signals lead to increased cancer risk and reproductive problems
  - Breast cancer, fertility, pregnancy complications
- Social: Stigma associated with body size has negative consequences, potential relationship to depression
Figure 1. Estimated Hazard Ratios for Death from Any Cause According to Body-Mass Index for All Study Participants and for Healthy Subjects Who Never Smoked.

Hazard ratios and 95% confidence intervals are shown for white women (Panel A) and white men (Panel B). The hazard ratios were calculated with the use of age as the underlying time scale, were stratified by study, and were adjusted for alcohol intake (grams per day), educational level, marital status, and overall physical activity. Subjects were deemed healthy if they had no cancer or heart disease at baseline.
Pathogenesis of Health Problems Associated with Obesity

Environment

- Activity

Genes

- Food Intake

Excess Fat Stores

Diseases due to increased fat cell size
- Diabetes
- Dyslipidemia
- Hypertension
- CVD
- Cancer

Diseases due to increased fat mass
- Stigma
- Osteoarthritis
- Sleep Apnea

Bray, George A. J Clin Endocrinol Metab 2004; 89(6):2583
Other Health Consequences

- Depression
- Stroke
- Pulmonary disease
- Liver disease
- Gallbladder disease
- Gynecologic abnormalities
- Osteoarthritis

Protects against osteoporotic fx

- Idiopathic intracranial hypertension
- Cataracts
- Coronary heart disease
  - Diabetes
  - Dyslipidemia
  - Hypertension
- Cancer
- Urinary stress incontinence
- Phlebitis
  - Deep Venous Thrombosis
- Gout

Heart failure

Mortality from cancer for US women, 1982-98, by body mass index (BMI). For each relative risk, the comparison was between women in the highest BMI category and women in the reference category (18.5 to 24.9). Adapted from Calle et al.
Mortality from cancer for US men, 1982-98, by body mass index (BMI). For each relative risk, the comparison was between men in the highest BMI category and men in the reference category (18.5 to 24.9). Adapted from Calle et al.
Summary

• Although BMI dominates measurement, other strategies are very important.
• Obesity is a very prevalent condition and increasing in many populations.
• Obesity results from caloric imbalance.
• Obesity is associated with a number of metabolic, endocrine, and cardiovascular complications.
Outline

• Define and measure obesity
• Epidemiology of obesity
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What solutions exist?

• Prevention and treatment
• Interventions
  – Individual
    • Behavioral
    • Medical (meds, surgical)
  – Environmental
    • Built environment
    • Food environment
    • Health care systems
    • Public policy
Vivamos Activos: Obesity Management in a Low-income Latino Neighborhood

PI: Randall S. Stafford, MD, PhD

Program on Prevention Outcomes and Practices
Stanford Prevention Research Center
San Mateo County

2008 Population 713,000
Med. family Income $79K

- Urban / Suburban
- Rural / Open Space
- Fair Oaks Clinic
- South SF Clinic
- Willow Clinic
- Daly City Clinic
- San Mateo Med Ctr

Stanford Prevention Research Center
Rationale for Case-Management

• Medical care system not designed to provide chronic disease management services
• Physicians’ emphasizes acute health issues
• For many conditions, we do not apply known evidence to reduce risk of adverse outcomes
• Shortfalls disproportionately affect low-income populations
• Compelling need for new models of delivering disease management services
• Meager evidence for effectiveness of new models, esp. in low-income patients
What is Case Management

• Address the barriers to good chronic disease management services
• Nurses, dietitians, health educators may manage routine disease management with:
  – More continuity
  – Greater patient engagement
  – Appropriate focus on behavior change
  – Potential for greater cultural congruence
• Patient outreach
• Team-based approach including PCP
Obstacles to Case Management in Low Income Populations

• Most trials of CM for risk factors and obesity in employed populations, not low income

• Increased obstacles to prevention services:
  – Organizations with limited resources
  – Multiple non-health concerns (financial, legal)
  – Limited family resources for prevention
  – Neighborhoods less conducive to prevention: less access to fresh vegetables, less walkable
  – Increased cultural and language “barriers”
  – Problems with health literacy and numeracy
Opportunities for Success in Low Income Populations

• Challenges to CM in low income populations may be opportunities

• Value of CM in low income populations:
  – Greater preventable disease burden
  – Advantageous model for overcoming health literacy problems and cultural divisions
  – Receptivity to new prevention messages not effectively delivered in past
  – Health care organizations without incentives to maintain high cost acute services
Change in Risk of Heart Attack

Framingham Risk Probability

Before
After

p = 0.007
Vivamos Activos Objectives

• Use participatory methods to develop case management intervention for the Latino population of North Fair Oaks CA
• Integrate program into health care center
• Conduct RCT to evaluate effectiveness of two weight loss strategies vs. usual care
• Estimate intervention cost-effectiveness
• Transition to ongoing County program
**Vivamos Activos Design**

- **Recruitment (14 months)**
  - Case-Management Alone
  - CM PLUS Environmental Support
  - Usual Care

- **Baseline Measurement**
  - Usual Primary Care
  - CM: 12 group sessions, 5 individual sessions
  - ES: 5 home visits

- **12-month Measurement**
  - Usual Primary Care
  - CM: 3 group sessions, Phone as needed
  - ES: 2 home visits

- **24-month Measurement**
  - Usual Primary Care
  - 18-mo Phone Assessment

- **Intensive Intervention**
  - 0, 3, 6, 9 months (12 months)

- **Maintenance**
  - 12, 15, 18, 21 months (12 months)

- **Transition**
  - 24 months (9 months)

- **SMMC-financed Obesity Management Program**
Case-Management

• Four one-on-one counseling sessions:
  – Barriers to weight loss
  – Getting started with diet and activity

• 15 group health education sessions:
  – Shopping, cooking, portion control, physical activity, behavior change strategies
  – “Virtual Walking Tour” of N. and S. America
Environmental Support

• 7 home visits to participants
  – Cooking issues – demo and quick inventory
  – Physical activity – walking in neighborhood
  – Negotiations with family members

• “Photo voice” exercise with one-time use cameras – document and set goals
Randomized Controlled Trials

- Experimental design as opposed to observational (cohort case-control)
- Researcher randomly assigns treatment
- Balances treatment arms with respect to measured and UN-MEASURED confounders
Inclusion/Exclusion Criteria

Inclusion:
• 18 years +
• BMI > 30 & <40
• 1 + obesity-related CHD risk factors

Exclusion:
• Unwillingness to attempt weight loss
• Significant other co-morbidities
• Pregnant/lactating
• Family member enrolled in study
• Does not speak Spanish
• Others to limit loss to follow-up
Design issues

- Randomization strategy
- Avoiding contamination of the control group
- Limiting loss to follow-up
- Strategies for intervention fidelity and adherence
- Internal vs. external validity
- Primary and secondary outcome measures
- Blinding
Statistical analysis and hypothesis testing
Primary Hypothesis

• Patients managed through the CM + ES intervention will show greater reductions in BMI over 24 months than those in CM.
  – Depends on subsidiary hypotheses that CM and CM + ES will have higher BMI reductions compared to usual care

• Random effects regression on an intention-to-treat basis using SAS PROC GLIMMIX

$$BMI_{iklm} = \mu + \beta_1 Int_i + \beta_2 B\cdot BMI_{ikl} + \beta_3 T_m + \beta_4 (Int^*T)_{lm} + \beta_5 Sex_{ikl} + \beta_6 Eth_{ikl} + \beta_7 (Sex^*Eth)_{ikl} + \alpha_{(j)} + e_{iklm}$$
Secondary hypotheses

1. Patients in CM or CM +ES will experience reduced CHD risk through favorable changes in obesity-related risk factors relative to those in usual care

2. Patients in the CM + ES intervention will experience smaller increases in BMI from 12 months to 24 months than those in the CM

3. The change in BMI and other CHD risk factors attributable to the intervention arms will be cost-effective relative to usual primary care
Hypothesized Effects

Usual Care

CM+ES

Weight Change for 90 kg Person (kg)

Intensive Intervention

Maintenance Care

CM alone

CM+ES

Relative Change in BMI

Month
## Socio-demographic and Psychosocial Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male</th>
<th>Female</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Sex</td>
<td>48 (100)</td>
<td>159 (100)</td>
<td>207 (100)</td>
</tr>
<tr>
<td>&lt; high school education</td>
<td>31 (64.6)</td>
<td>122 (76.7)</td>
<td>153 (73.9)</td>
</tr>
<tr>
<td>Low food security</td>
<td>13 (27.1)</td>
<td>67 (42.1)</td>
<td>80 (38.7)</td>
</tr>
<tr>
<td>Very low food security</td>
<td>6 (12.5)</td>
<td>20 (12.6)</td>
<td>26 (12.6)</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Age</td>
<td>46.0 (11.5)</td>
<td>47.5 (11.1)</td>
<td>47.1 (11.1)</td>
</tr>
<tr>
<td>Age when came to USA</td>
<td>28.6 (12.4)</td>
<td>31.8 (11.9)</td>
<td>31.1 (12.1)</td>
</tr>
<tr>
<td>CESD</td>
<td>7.5 (3.4)</td>
<td>9.4 (3.8)</td>
<td>9.0 (3.8)</td>
</tr>
<tr>
<td>Annual Income ($)</td>
<td>19.4 (13.3)</td>
<td>15.3 (9.2)</td>
<td>16.2 (10.4)</td>
</tr>
<tr>
<td>Food sec.**</td>
<td>1.4 (1.9)</td>
<td>1.9 (1.9)</td>
<td>1.7 (1.9)</td>
</tr>
<tr>
<td>Steps per day*</td>
<td>7.4 (3.6)</td>
<td>6.0 (2.9)</td>
<td>6.3 (3.1)</td>
</tr>
<tr>
<td>Calories per day*</td>
<td>2.0 (5.9)</td>
<td>1.9 (6.8)</td>
<td>1.9 (6.6)</td>
</tr>
<tr>
<td>Dally fruit and vegetable servings</td>
<td>6.0 (3.6)</td>
<td>6.4 (3.2)</td>
<td>6.3 (3.3)</td>
</tr>
<tr>
<td>% calories from carbohydrates</td>
<td>49.2 (6.9)</td>
<td>49.4 (8.4)</td>
<td>49.4 (8.1)</td>
</tr>
<tr>
<td>% calories from fat</td>
<td>35.6 (7.1)</td>
<td>36.9 (7.6)</td>
<td>36.6 (7.5)</td>
</tr>
</tbody>
</table>

*Expressed in thousands **Food security score interpretation: 0 high, 1 marginal, 2-4 low, 5-6 very low
Baseline Characteristics

- 49% were depressed
- 41% low or very low food security
- 38% < 5,000 steps per day
- 41% < 5 fruits and vegetables per day
## Baseline Lab Values

<table>
<thead>
<tr>
<th>Measure</th>
<th>CM+ ES (N=82)</th>
<th>CM Alone (N=84)</th>
<th>Usual Care (N=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>35.5</td>
<td>36.0</td>
<td>34.9</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>114.8</td>
<td>114.5</td>
<td>117.2</td>
</tr>
<tr>
<td>Dystolic BP</td>
<td>74.1</td>
<td>73.0</td>
<td>73.8</td>
</tr>
<tr>
<td>LDL-Chol</td>
<td>107.8</td>
<td>100.6</td>
<td>107.8</td>
</tr>
<tr>
<td>HDL-Chol</td>
<td>47.2</td>
<td>44.3</td>
<td>44.9</td>
</tr>
<tr>
<td>TRG</td>
<td>147.1</td>
<td>175.4</td>
<td>176.2</td>
</tr>
<tr>
<td>Total-Chol</td>
<td>181.6</td>
<td>178.5</td>
<td>188.0</td>
</tr>
<tr>
<td>Fasting Gluc</td>
<td>111.9</td>
<td>116.6</td>
<td>110.0</td>
</tr>
<tr>
<td>HbA1c</td>
<td>6.4</td>
<td>6.5</td>
<td>6.4</td>
</tr>
<tr>
<td>CRP</td>
<td>0.8</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>
## Associations between Physical Activity and Predictive Factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male</th>
<th>Female</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change</td>
<td>95% CI</td>
<td>P-value</td>
</tr>
<tr>
<td>CESD</td>
<td>-6.6</td>
<td>-21.9, 11.7</td>
<td>0.45</td>
</tr>
<tr>
<td>Education</td>
<td>-27.9</td>
<td>-39.4, -14.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Income</td>
<td>1.9</td>
<td>-16.2, 23.8</td>
<td>0.68</td>
</tr>
</tbody>
</table>

*Estimated difference in steps per day from 25th percentile to 75th percentile presented as percent difference using log transformation of steps per day.

- CESD score of 6 vs. 12 associated with 692 (11.6%) fewer steps
- College education vs. less than 8th grade education associated with 2,222 (27.9%) few steps among males
### Associations between Dietary Habits and Predictive Factors

Estimated difference in dietary characteristics from 25th to 75th percentile: Linear regression results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male</th>
<th>Female</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change</td>
<td>95% CI</td>
<td>P-value</td>
</tr>
<tr>
<td>Dally fruit and vegetable servings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CESD</td>
<td>-1.1</td>
<td>-2.1, -0.1</td>
<td>0.04</td>
</tr>
<tr>
<td>Education</td>
<td>0.0</td>
<td>-1.1, 1.1</td>
<td>0.99</td>
</tr>
<tr>
<td>Food sec.</td>
<td>-0.3</td>
<td>-1.5, 0.8</td>
<td>0.56</td>
</tr>
<tr>
<td>Income</td>
<td>0.9</td>
<td>-0.5, 2.3</td>
<td>0.19</td>
</tr>
<tr>
<td>Percent of daily calories from carbohydrates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CESD</td>
<td>0.6</td>
<td>-1.8, 3.1</td>
<td>0.62</td>
</tr>
<tr>
<td>Education</td>
<td>-2.3</td>
<td>-4.5, -0.2</td>
<td>0.04</td>
</tr>
<tr>
<td>Food sec.</td>
<td>0.0</td>
<td>-1.1, 1.1</td>
<td>1.00</td>
</tr>
<tr>
<td>Income</td>
<td>0.3</td>
<td>-1.8, 2.3</td>
<td>0.80</td>
</tr>
<tr>
<td>Percent calories from fat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CESD</td>
<td>-1.9</td>
<td>-4.8, 0.9</td>
<td>0.18</td>
</tr>
<tr>
<td>Education</td>
<td>1.2</td>
<td>-1.4, 3.8</td>
<td>0.36</td>
</tr>
<tr>
<td>Food sec.</td>
<td>-0.2</td>
<td>-2.9, 2.5</td>
<td>0.87</td>
</tr>
<tr>
<td>Income</td>
<td>0.3</td>
<td>-2.1, 2.7</td>
<td>0.83</td>
</tr>
</tbody>
</table>

- Among males:
  - CESD score associated with fewer fruits and vegetables
  - More education associated with less energy from carbohydrates
Strategies in Community RCTs

- Recognize and confront valid community suspicion about experimentation
- Consultation and inclusion of community-based and governmental orgs as partners
- Integrate study within primary care setting
- All participants have primary care physician
- Incentives to participants for research aspects of program (not for intervention)
- “Delayed intervention” as model for control group, everybody receives benefits
Challenges of Community-Based Research

- Multiple logistical obstacles to success
- Less infrastructural resources available
- Including community organizations adds complexity & work to research development
- Difficult to overcome skepticism about the value of research & fear of experimentation
- Partner organizations will not have the same commitment to scientific rigor
- Turf wars over funding and people common
Charms of Community-Based Research

• Re-envision health from a community’s perspective (barriers vs. societal divisions)
• Work with populations in great need
• Work with grateful organizations that value the resources and expertise you contribute
• Committed organizations that serve their populations and want info to be successful
• If it works here, it can work anywhere
• Contribute to reducing health disparities
Final Thought

If our work is not directly addressing health care disparities, it contributes to their perpetuation. Not only do we inadvertently reinforce existing social inequities, we often make them worse.