Moving Toward Weight Centric Approaches to Better Diabetes Management: Results of the Look AHEAD Study

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Old Dogs, New Tricks

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Diabetes is a commonly encountered medical condition.

Total prevalence of diabetes in the United States, all ages, 2007

Total: 23.5 M people (10.7% of adults >20 yrs)

Diagnosed: 17.9 M
Undiagnosed: 5.7 M

Diabetes Prevalence Rises with Age

Source: NIDDK website
Diabetes Prevalence Rises with Age, Although Peak Age of Diagnosis is 45-60

Source: CDC website
There is a diabetes epidemic.

Crude and Age-Adjusted Prevalence of Diagnosed Diabetes per 100 Population, US, 1980-2005

Source: CDC website
Response to the Diabetes Epidemic

- Economic Costs of Diabetes
  - Disease Management programs by third party payors

- Research
  - A1c control and microvascular disease complications
  - ACE inhibitors and kidney complications

- Drug and Device Industry -
  - Monitor and manage diabetes
  - Prevention of diabetes comorbidities
Nine Classes of Diabetes Medications Are Available in the US

<table>
<thead>
<tr>
<th>Medication</th>
<th>Route</th>
<th>Year Approved</th>
<th>Efficacy*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Parenteral</td>
<td>1921</td>
<td>&gt;2.5</td>
</tr>
<tr>
<td>Inhaled Insulin</td>
<td>Pulmonary</td>
<td>2006</td>
<td>1.5</td>
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<tr>
<td>Sulfonylureas</td>
<td>Oral</td>
<td>1946</td>
<td>1.5</td>
</tr>
<tr>
<td>Biguanides</td>
<td>Oral</td>
<td>1957</td>
<td></td>
</tr>
<tr>
<td>Metformin</td>
<td>Oral</td>
<td>1995</td>
<td>1.5</td>
</tr>
<tr>
<td>Alpha-glucosidase inhibitors</td>
<td>Oral</td>
<td>1995</td>
<td>0.5-0.8</td>
</tr>
<tr>
<td>Thiazolidinediones</td>
<td>Oral</td>
<td>1995</td>
<td>0.8-1.0</td>
</tr>
<tr>
<td>Troglitazone</td>
<td>Oral</td>
<td>1997, withdrawn 1995</td>
<td></td>
</tr>
<tr>
<td>Rosiglitizone</td>
<td>Oral</td>
<td>1999</td>
<td></td>
</tr>
<tr>
<td>Pioglitazone</td>
<td>Oral</td>
<td>1999</td>
<td></td>
</tr>
<tr>
<td>Glinides</td>
<td>Oral</td>
<td>1997</td>
<td>1.0-1.5</td>
</tr>
<tr>
<td>GLP 1 analogues</td>
<td>Parenteral</td>
<td>2005</td>
<td>0.6</td>
</tr>
<tr>
<td>Amylin analogues</td>
<td>Parenteral</td>
<td>2005</td>
<td>0.6</td>
</tr>
<tr>
<td>DPP-IV inhibitors</td>
<td>Oral</td>
<td>2006</td>
<td>0.5-0.9</td>
</tr>
</tbody>
</table>

*Efficacy measured as reduction in A1c percentage points

How are we doing in achieving ADA goals for Diabetes Control?

- Hb A1c <7%
- Blood Pressure <130/80 mm Hg
- LDL <100mg/dL
Risk Factor Control: Adults with Diabetes

- HbA1c < 7%
  - NHANES III (n=1204): 44.3%
  - NHANES 1999-2000 (n=370): 37%
- BP < 130/80 mmHg
  - NHANES III (n=1204): 29%
  - NHANES 1999-2000 (n=370): 25.8%
- Total Cholesterol < 200 mg/dl
  - NHANES III (n=1204): 33.9%
  - NHANES 1999-2000 (n=370): 33.9%
- All in control
  - NHANES III (n=1204): 5.2%
  - NHANES 1999-2000 (n=370): 7.3%

Saydah JAMA 2004; 291 335
Clinical Sites

Seattle
Philadelphia
New York
Providence
Boston
Baltimore
Winston-Salem

Los Angeles
Phoenix
Denver
Minneapolis
Pittsburgh
Memphis
Birmingham
San Antonio
Houston
Baton Rouge

Clinical Sites

Coordinating Center
Primary Hypothesis

The incidence rate of the first post-randomization occurrence of a composite outcome, including

- cardiovascular death (fatal myocardial infarction and stroke)
- non-fatal myocardial infarction
- non-fatal stroke

over 11.5 yr. follow-up is reduced in the Lifestyle Intervention compared to Diabetes Support and Education.
Primary End Point
Composite

- Cardiovascular death (including fatal myocardial infarction and stroke)
- Non-fatal myocardial infarction
- Non-fatal stroke
Secondary End Point
Broad Composite

- Death
- Myocardial infarction
- Stroke
- Hospitalization for congestive heart failure
- Coronary artery bypass grafting and/or percutaneous coronary angioplasty
- Carotid endarterectomy or peripheral vascular disease (bypass procedure or angioplasty)
Other Outcomes

- Cardiovascular disease risk
- Costs and cost effectiveness
- Diabetes control and complications
- General health
- Hospitalizations
- Intervention and process factors
- Quality of life and psychological outcomes
Reduction in Weight and Cardiovascular Disease Risk Factors in Subjects With Type 2 Diabetes: One-Year Results of Look AHEAD

The Look AHEAD Research Group
Look AHEAD Trial

- Randomized controlled trial
- 5,145 participants
- 16 clinical centers in the USA
- Diabetes care provided by participant’s own physician
Look AHEAD Interventions

- Intensive Lifestyle Intervention (ILI)
- Diabetes Support & Education (DSE)
### Baseline Characteristics of Participants

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>ILI (N=2,570)</th>
<th>DSE (N=2,575)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>59%</td>
<td>60%</td>
</tr>
<tr>
<td>Minority</td>
<td>37%</td>
<td>37%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>58.6</td>
<td>58.9</td>
</tr>
<tr>
<td>Insulin Users</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>History of Prior CVD Event</td>
<td>14%</td>
<td>14%</td>
</tr>
</tbody>
</table>
## Baseline Characteristics of Participants

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>ILI Mean (N=2,570)</th>
<th>DSE Mean (N=2,575)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline BMI (kg/m²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>36.3</td>
<td>36.6</td>
</tr>
<tr>
<td>Males</td>
<td>35.3</td>
<td>35.1</td>
</tr>
<tr>
<td><strong>Baseline Weight (kg)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>94.8</td>
<td>95.4</td>
</tr>
<tr>
<td>Males</td>
<td>108.9</td>
<td>109.0</td>
</tr>
<tr>
<td><strong>Baseline Waist (cm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>110.5</td>
<td>111.2</td>
</tr>
<tr>
<td>Males</td>
<td>118.7</td>
<td>118.4</td>
</tr>
</tbody>
</table>
Lifestyle Intervention: Phase I, Weight Loss Induction

- Months 1-6
- Weekly contact
  - 3 group sessions/month
  - 1 individual session/month
- Personal weight loss goal = 10%
- Study weight loss goal > 7%
Lifestyle Intervention: Phase II, Weight Loss Maintenance

- Months 7-12
- Reduced contact
  - 2 group sessions/month
  - 1 individual session/month
  - 2 face-to-face contacts/month required; 3 recommended
- Individual weight loss goal
  - continue weight loss if < 10%
  - weight maintenance if ≥ 10%
Recommendations

- **Dietary Intake**
  - 1200-1500 kcal/day < 250 lb
  - 1500-1800 kcal/day ≥ 250 lb
  - < 30% calories from fat
  - meal replacements
  - menu plans

- **Physical Activity**
  - gradual increase
  - 175 min/wk
  - 10,000 steps/day
Diabetes Support and Education

- 3-4 meetings / year to promote retention
- Health education topics
  - Diet
  - Exercise
  - Social support
Attendance At Year 1 Examination

ILI Cohort: 97%

DSE Cohort: 96%

P=0.004
% Weight Loss at 1-Year

- **ILI**
  - 8.6%
  - *p < 0.0001*

- **DSE**
  - 0.7%
% Reduction in Initial Weight by Gender

- Men: N=1229, P<0.001
- Women: N=1197

Months
Weight Loss in Insulin Users vs. Non-Users within ILI Group

- Insulin: 7.6% weight loss, P=0.002
- No Insulin: 8.7% weight loss

Medication Use At Baseline
Fitness Change (%) at 1-Year

Mean % Fitness Change

- **DSE**
  - Unadjusted: 5.8
  - Adjusted: 10.8
  - P<0.001

- **ILI**
  - Unadjusted: 20.9
  - Adjusted: 15.9
  - P<0.001

Weight Change Adjusted for 1 Year

P<0.001
# 1-Year Changes in Markers of Diabetes Control

<table>
<thead>
<tr>
<th>Markers of Diabetes Control</th>
<th>ILI</th>
<th>DSE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A1c (%), BL</td>
<td>7.25</td>
<td>7.29</td>
<td>0.26</td>
</tr>
<tr>
<td>Hemoglobin A1c (%), Y1</td>
<td>6.61</td>
<td>7.15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-0.64</td>
<td>-0.14</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fasting glucose (mg/dl), BL</td>
<td>151.9</td>
<td>153.6</td>
<td>0.21</td>
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<tr>
<td>Fasting glucose (mg/dl), Y1</td>
<td>130.4</td>
<td>146.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-21.5</td>
<td>-7.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes medications, BL</td>
<td>86.5%</td>
<td>86.5%</td>
<td>0.93</td>
</tr>
<tr>
<td>Diabetes medications, Y1</td>
<td>78.6%</td>
<td>88.7%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-7.8%</td>
<td>2.2%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## 1-Year Changes in Markers of Blood Pressure Control

<table>
<thead>
<tr>
<th>Markers of Blood Pressure Control</th>
<th>ILI</th>
<th>DSE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP (mmHg), BL</td>
<td>128.2</td>
<td>129.4</td>
<td>0.26</td>
</tr>
<tr>
<td>Systolic BP (mmHg), Y1</td>
<td>121.4</td>
<td>126.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-6.8</td>
<td>-2.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diastolic BP (mmHg), BL</td>
<td>69.9</td>
<td>70.4</td>
<td>0.11</td>
</tr>
<tr>
<td>Diastolic BP (mmHg), Y1</td>
<td>67.0</td>
<td>68.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-3.0</td>
<td>-1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Antihypertensive medications, BL</td>
<td>75.3%</td>
<td>73.7%</td>
<td>0.23</td>
</tr>
<tr>
<td>Antihypertensive medications, Y1</td>
<td>75.2%</td>
<td>75.9%</td>
<td>0.54</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-0.1%</td>
<td>2.2%</td>
<td>0.02</td>
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## 1-Year Changes in Markers of Lipid Control

<table>
<thead>
<tr>
<th>Markers of Lipid Control</th>
<th>ILI</th>
<th>DSE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-cholesterol (mg/dl), BL</td>
<td>112.2</td>
<td>112.4</td>
<td>0.78</td>
</tr>
<tr>
<td>LDL-cholesterol (mg/dl), Y1</td>
<td>107.0</td>
<td>106.7</td>
<td>0.74</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-5.2</td>
<td>-5.7</td>
<td>0.49</td>
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<tr>
<td>HDL-cholesterol (mg/dl), BL</td>
<td>43.5</td>
<td>43.6</td>
<td>0.80</td>
</tr>
<tr>
<td>HDL-cholesterol (mg/dl), Y1</td>
<td>46.9</td>
<td>44.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>3.4</td>
<td>1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Triglycerides (mg/dl), BL</td>
<td>182.8</td>
<td>180.0</td>
<td>0.38</td>
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<tr>
<td>Triglycerides (mg/dl), Y1</td>
<td>152.5</td>
<td>165.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>-30.3</td>
<td>-14.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lipid lowering medications, BL</td>
<td>49.4%</td>
<td>48.4%</td>
<td>0.52</td>
</tr>
<tr>
<td>Lipid lowering medications, Y1</td>
<td>53.0%</td>
<td>57.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>3.7%</td>
<td>9.4%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## 1-Year Changes in Percent of Participants Meeting ADA Goals

<table>
<thead>
<tr>
<th>ADA Goal</th>
<th>ILI</th>
<th>DSE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A1c &lt; 7%, BL</td>
<td>46.3%</td>
<td>45.4%</td>
<td>0.50</td>
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<tr>
<td>Hemoglobin A1c &lt; 7%, Y1</td>
<td>72.7%</td>
<td>50.8%</td>
<td>&lt;0.001</td>
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<tr>
<td>Y1 - Baseline</td>
<td>26.4%</td>
<td>5.4%</td>
<td>&lt;0.001</td>
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<tr>
<td>Blood pressure &lt; 130/80 mmHg, BL</td>
<td>53.5%</td>
<td>49.9%</td>
<td>0.01</td>
</tr>
<tr>
<td>Blood pressure &lt; 130/80 mmHg, Y1</td>
<td>68.6%</td>
<td>57.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>15.1%</td>
<td>7.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LDL-cholesterol &lt; 100 mg/dl, BL</td>
<td>37.1%</td>
<td>36.9%</td>
<td>0.87</td>
</tr>
<tr>
<td>LDL-cholesterol &lt; 100 mg/dl, Y1</td>
<td>43.8%</td>
<td>44.9%</td>
<td>0.45</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>6.7%</td>
<td>8.0%</td>
<td>0.34</td>
</tr>
<tr>
<td>All three goals, BL</td>
<td>10.8%</td>
<td>9.5%</td>
<td>0.13</td>
</tr>
<tr>
<td>All three goals, Y1</td>
<td>23.6%</td>
<td>16.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Y1 - Baseline</td>
<td>12.8%</td>
<td>6.5%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Conclusions

- At one year, the Look AHEAD intensive intervention resulted in clinically significant weight loss and improved fitness in individuals with type 2 diabetes.

- This was associated with improved diabetes control and cardiovascular risk factors and reduced medication use for ILI relative to DSE.

- Continued intervention and follow-up will determine whether these changes will be maintained and will reduce future cardiovascular disease events.
Translating Look AHEAD to Clinical Practice

- Is the medical establishment ready to embrace weight loss as a valid treatment?
- Is the nutrition establishment ready to embrace a toolbox approach to weight loss?
- Issues of reimbursement: are payors ready to reimburse for weight management? And can our weight management schemes be structured to “pay for performance”?
Non-Surgical Weight Loss for Extreme Obesity in Primary Care Settings:

Results of the Louisiana Obese Subjects Study

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Introduction

- Research is needed in
  - primary care management of obesity
  - approaches to management of class III obesity

- The LA Office of Group Benefits approached us to study these issues
  - Insures 240,000 people in Louisiana (100,000 governmental employees and their dependents)
  - Must offer services to all beneficiaries
LOSS - a pragmatic clinical trial

- Selects clinically relevant alternative interventions to compare
- Includes a diverse population
- Recruits participants from heterogeneous practice settings
- Collects data on a broad range of health outcomes
Primary Aim

To test whether weight loss at 2 years for an intensive medical treatment for Class III obesity produces greater weight loss than usual care

Secondary Aims

To assess group differences in
- Changes in BP and risk factors for cardiovascular diseases
- Safety and tolerability
- QOL and psychosocial measures
- Economic measures
Study Design employed 8 clinical sites, corresponding to population centers.

Physician PI, office manager and interventionist received 8 hours of instruction in obesity management and 4 hours in research procedures.
Screening, Randomization and Enrollment

- Letters from OGB inviting to open house at site
- Open house with slide set explaining study
- One screening visit, one randomization visit

Inclusion Criteria

- Participant in EPO or PPO programs of OGB
- BMI 40-60 kg/m²
- 20-60 years of age
- Diabetes permitted
- DASI (Duke Activity Status Index) score 25 or lower
- Few exclusions (weight loss medications, severe mental disorders, cancer, heart failure)
130,244 letters of invitation

959 attended intro sessions

597 were screened

465 were randomized

132 did not meet criteria

3 obesity surgery

New Orleans
45 screened & 23 randomized censored

Monroe
68 screened & 49 randomized censored

200 randomized to Intensive Medical Intervention

119 visits Year 1 (60%)

101 visits Year 2 (51%)

190 randomized to Usual Care

89 visits Year 1 (47%)

86 visits Year 2 (45%)
Intervention Components

- Intensive Intervention (3 phases)
  - Phase 1 (1-3 months)
    - Low Calorie Liquid Diet (Health One dispensed)
  - Phase 2 (4-8 months)
    - Group Behavioral therapy weekly
    - Structured Diet (meal replacements recommended)
    - Pharmacotherapy (sibutramine, also orlistat, diethylpropion)
  - Phase 3 (8-24+ months)
    - Group behavioral therapy, monthly contact + pharmacotherapy
    - Toolbox Approaches

- Usual Care
  - Access to Mayo Clinic Weight Management website
Additional aspects of LOSS

- All medical care delivered by the patient’s PCP; LOSS sites delivered weight loss only.
- LOSS PIs used medication management algorithm for diabetic participants.
- Weight loss medications dispensed by the LOSS sites.
- $100 gift card given to encourage attendance at 2 year visit
- All data capture by an electronic web-based data entry system
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intensive Medical Intervention</th>
<th>Usual care</th>
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</thead>
<tbody>
<tr>
<td>N</td>
<td>200</td>
<td>193</td>
</tr>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Male</td>
<td>33 (17%)</td>
<td>31 (16%)</td>
</tr>
<tr>
<td>White</td>
<td>29 (17%)</td>
<td>26 (14%)</td>
</tr>
<tr>
<td>Black</td>
<td>4 (5%)</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Female</td>
<td>167 (83%)</td>
<td>162 (84%)</td>
</tr>
<tr>
<td>White</td>
<td>120 (77%)</td>
<td>124 (65%)</td>
</tr>
<tr>
<td>Black</td>
<td>46 (23%)</td>
<td>38 (20%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

- Treatment arms balanced for ethnicity & gender
- Treatment arms balanced for age, BMI, and metabolic parameters (data not shown)
Weight Loss Among Participants in the LOSS Trial

Baseline (n=190/200)

Week 12 (n=152)

Week 26 (n=139)

Week 38 (n=117)

1 Year (n=95/119)

Week 78 (n=73)

Usual Care Condition

Low Calorie Liquid Diet

Intensive Medical Intervention

2 Years BOCAF (n=200)

2 Years LOCAF (n=200)

2 Years (n=86/101)
### Health Outcomes Comparisons
#### Completers analysis

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IMI (119/200)</td>
<td>UC (92/193)</td>
</tr>
<tr>
<td><strong>% observed</strong></td>
<td>60%</td>
<td>48%</td>
</tr>
<tr>
<td><strong>% wt loss</strong></td>
<td>-13.1%</td>
<td>-0.9%</td>
</tr>
<tr>
<td>_SD</td>
<td>±1.2</td>
<td>±0.6</td>
</tr>
<tr>
<td><strong>FPG mean Δ mg/DL</strong></td>
<td>-5.0</td>
<td>+4.6</td>
</tr>
<tr>
<td><strong>HDL % change</strong></td>
<td>+6.8%</td>
<td>-0.1%</td>
</tr>
<tr>
<td><strong>ALT % change</strong></td>
<td>-11.9%</td>
<td>+5.1%</td>
</tr>
</tbody>
</table>

No significant group differences in BP, HR at year 1 or 2. No significant group differences in LDL or TG at year 2.
Safety

- Data Safety Monitoring Board tracked Serious Adverse Events (SAEs)
  - 20 SAEs in IMI vs. 12 in UC groups
  - No SAEs judged related to study treatment.
  - Cardiovascular problems (stent placement, acute MI, cardiac workups), also orthopedic, gyn, gi and respiratory hospitalizations.
  - One death in IMI (48 YO male with history of hypertension, bipolar disorder and asthma; death due to myocardial infarction; death due to myocardial infarction; 22.9 Kg weight loss; not taking sibutramine;) judged unrelated to study procedures by DSMB.
  - 3 gastric bypass surgeries in the UC group.
Summary

- The study population broadly represents severely obese patients commonly encountered in US medical practice.
- After brief training, most primary care sites with no prior experience were able to safely and effectively deliver the intervention and collect research data.
- For those who attended the 2 year IMI visit, mean weight loss was 9.7% ± 13.5%, a clinically significant improvement over usual care.
- Odds of meaningful weight loss among participants at 2 years:
  - Of those who attended, 61% lost 5% or more and 41% lost 10% or more.
  - Of all randomized subjects, 31% lost 5% or more and 21% lost 10% or more.
Conclusions

- These results indicate that trained PCPs can be successful in helping a subset of patients with severe obesity achieve meaningful weight loss.
- Future studies should target retention and weight loss maintenance for improvement.
- The impact on health costs for the study population should be evaluated.
- More investigators should engage in research to define optimal approaches to primary care treatment for obesity, especially severe obesity.
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Thank you

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