"Eat Less and Exercise More!"
Follow up at Six Weeks versus Six Months.

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Disclosure

Robert Dubin, M.D.

I do not have any relationship(s) with commercial interests.

A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.
Current Events

- **July 28, 2011:** American Association of Clinical Endocrinologists (AACE) Declares Obesity a Disease State
  The Association believes that the declaration will help lead the way for more effective therapies and treatments to help the 34 percent of Americans currently suffering with obesity.

- **September 8, 2011:** US Senate Committee on Appropriations directed the FDA to support the development of new treatments for obesity.

- **November 29, 2011:** The Centers for Medicare & Medicaid Services (CMS) Medicare is adding coverage for preventive services to reduce obesity.
Comparative Effectiveness of Weight-Loss Interventions in Clinical Practice


A Two-Year Randomized Trial of Obesity Treatment in Primary Care Practice

Thomas A. Wadden, Ph.D., Sheri Volger, R.D., M.S., David B. Sarwer, Ph.D., Marion L. Vetter, M.D., R.D., Adam G. Tsai, M.D., Robert I. Berkowitz, M.D., Shiriki Kumanyika, Ph.D., M.P.H., Kathryn H. Schmitz, Ph.D., M.P.H., Lisa K. Diewald, R.D., M.S., Ronald Barg, M.D., Jesse Chittams, M.S., and René H. Moore, Ph.D.
Old Barriers

  – Less than 50% of PCPs provide weight-related advice
  – Less than 25% of PCPs refer patients for weight-related tx.

• How we feel? (Salinas GD, et al. Postgraduate Med. 2011;123:5)
  – Lack of confidence (training)
  – Lack of available resources (time/$)
  – Lack of patient motivation

  – The majority (88%) of obese patients want their doctor to help them with their weight
  – Eighty-four percent believe that physicians can help them
  – Most patients are comfortable discussing their weight and feel it is an important issue.
Spectrum of Intervention

- None
-Minimal
-Moderate
-Intensive

Physician advice: minimal intervention
- the “control group”

Physician advice; brief counseling, ect...
- “Eat less, exercise more” (ELEM)
Outcome of Interest

- Minimal intervention (ELEM): ineffective
- With modification: *follow-up frequency*
  - *Shorter follow-up frequency is beneficial?*
Optimal Follow-up Frequency

- **Depression**: After starting rx: follow up “weeks” (APA); “4 weeks” (FDA)  

- **SLE**: q 3 months better than 1 year for monitoring disease activity.  

- **Asthma**: q 6 months for moderate persistent disease.  

- **Chronic renal failure**: No differences in high (<1wk)-intermediate (<1mo)-low frequency (>1mo) follow-up except patient satisfaction.  

- **Diabetes**: PCP encounters q 2 weeks were associated with faster achievement of A1C, BP and LDL-C targets.  
Optimal Follow-up Frequency (Obesity)


• United States Preventative Services Task Force (2010): the USPSTF did not find any evidence to determine the optimal times for initiation, cessation or interval of obesity screening.

• American Heart Association, American Academy of Family Physicians, American College of Preventative Medicine: periodic measuring of height and weight with BMIs calculated at every healthcare visit.
Hypothesis/Aims

• A shorter follow-up interval is beneficial for following patients with obesity in a primary care clinic

• Using a minimal intervention (ELEM 6 weeks) would encourage patients to lose weight versus regularly scheduled follow-up
Methods

• **Inclusion:**
  – BMI $>25$ kg/m$^2$
  – Metabolic syndrome

• **Exclusion:**
  – Currently on a formal diet
  – Any acute, active or uncontrolled disease
    • CHF, hepatic/renal, infection, psychiatric
  – Pregnancy
## Patient Characteristics

<table>
<thead>
<tr>
<th>Variable (units)</th>
<th>6 months</th>
<th>6 weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>40</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>64.3 +/- 14.2</td>
<td>66 +/- 11.4</td>
<td>NS</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>34.7 +/- 4.5</td>
<td>34.6 +/- 5.8</td>
<td>NS</td>
</tr>
<tr>
<td>Male (%)</td>
<td>26/40 (66%)</td>
<td>22/40 (55%)</td>
<td>NS</td>
</tr>
<tr>
<td>Caucasian (%)</td>
<td>38/40 (95%)</td>
<td>38/40 (95%)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes Mellitus (%)</td>
<td>25/40 (62.5%)</td>
<td>25/40 (62.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>35/40 (87.5%)</td>
<td>34/40 (85%)</td>
<td>NS</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>37/40 (92.3%)</td>
<td>34/40 (85%)</td>
<td>NS</td>
</tr>
</tbody>
</table>
Methods

• Prospective analysis
  – All patients were told to ELEM by the provider
  – Brief (<2 minutes) counseling was provided if they did not voice understanding ELEM
  – Intervention follow-up: weight re-check with nurse at 6 weeks

• Control group: regularly scheduled follow-up with provider at 6 months with ELEM (chart review)
Results

Weight Status

- ELEM (6 weeks): N=33
  - Gain: 9
  - Loss: 12
  - No change: 78.7%
  - P-value: 0.0006

- ELEM (6 months): N=40
  - Gain: 25
  - Loss: 25
  - No change: 17.5%
  - P-value: <0.0005
### Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>ELEM (6 weeks)**</th>
<th>ELEM (6 months)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean weight change (kg)</td>
<td>-0.9 (+/- 1.8)</td>
<td>-0.4 (+/- 5.83)</td>
<td>0.6</td>
</tr>
<tr>
<td>Weight gain (kg)</td>
<td>1.7 (+/- 0.5)</td>
<td>2.0 (+/- 1.5)</td>
<td>0.2</td>
</tr>
<tr>
<td>Weight loss (kg)</td>
<td>2.4 (+/- 1.4)</td>
<td>2.7 (+/- 3.0)</td>
<td>0.5</td>
</tr>
<tr>
<td>No shows or cancelations</td>
<td>7/40 (17.5%)*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*Including no shows: 65% lost weight (p=0.001 vs. controls)

**ELEM (6 weeks) Seventy-three percent of patients who followed-up regardless of outcome, felt that the intervention provided a positive incentive to managing their weight.
Limitations

• Non-randomized
• Single-center
• Small sample size
• Small differences in mean weight changes
• Two different time points
• No long-term data

• Why?
• Pooled data (17 trials): brief advice vs. no advice
  – significant increase in the rate of quitting (relative risk (RR) 1.66, 95% confidence interval (CI) 1.42 to 1.94).
  – Follow-up support after offering the advice may increase the quit rates slightly.
  – Authority and accountability
Conclusions

• ELEM-6 week follow-up resulted in improved weight status versus regular follow-up at 6 months
• The majority of patients, regardless of outcome, felt that ELEM-6 weeks had a positive incentive on their ability to manage their weight
• Physicians may have an influence on patient behavior using a minimal intervention with shorter follow-up intervals
  – There may be a sense of accountability for patients
• Additional research: larger more diverse cohorts and longer follow-up time