Weight loss and lifestyle modification: predictors of success in the Look AHEAD and DASH intervention studies

Catherine M. Champagne
PhD, RDN, LDN
Professor & Chief
Dietary Assessment & Nutrition Counseling
Pennington Biomedical Research Center
Baton Rouge, Louisiana

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• Notice of Requirements For Successful Completion
  – Please refer to learning goals and objectives
  – Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
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  – Participants will be notified by speakers if any product used for a purpose other than for which it was approved by the Food and Drug Administration.

Presentation outline
• Discussion of the following trials, including background, methodology and other details:
  • Look AHEAD
  • DASH interventions (PREMIER & Weight Loss Maintenance)
• Discussion of dietary and behavioral variables within each trial
• Discussion of strategies for success in weight loss and weight maintenance

Learning objectives
• Describe the behavioral intervention approaches utilized in the Look AHEAD and DASH intervention trials sponsored by NIH
• Identify which dietary and behavioral variables contributed to the success of those individuals in Look AHEAD and DASH intervention trials – presented within the discussion of each
• Identify issues that need to be addressed in order to create appropriate approaches for success in achieving and maintaining a healthy weight

Rationale for the Trial
• Obesity and Type 2 Diabetes are common and associated with increased morbidity and mortality.
• There are limited data on long-term effects of intentional weight loss achieved through lifestyle changes.
Study Objective
To determine the long-term effects (up to 13.5 years) of an intensive lifestyle intervention program designed to produce weight loss and increase physical activity on cardiovascular morbidity and mortality in overweight or obese persons with type 2 diabetes.

Study Design
- Randomized Controlled Trial
- Single blind
- 1:1 to study groups
- Intensive lifestyle intervention (ILI)
- Diabetes support and education (DSE)

Primary Outcome
- Composite endpoint of CVD including:
  - Cardiovascular death
  - Fatal myocardial infarction and stroke
  - Non-fatal myocardial infarction
  - Non-fatal stroke
  - Hospitalization for angina
    - Over 13.5 yr. follow-up.

Other Outcomes
- Cardiovascular disease risk factors
- Diabetes complications
- General health
- Quality of life and psychological outcomes
- Hospitalizations
- Costs and cost effectiveness

Inclusion Criteria
- Type 2 diabetes
  - Any treatment
  - <30% on insulin
- Overweight
  - BMI ≥ 25 or 27 kg/m²
- Age 45-75 years
- Prior CVD history allowed if safe
  - ≥ 33% minorities
- HbA1c <11%
- BP <160/100 mmHg
- Triglycerides <600 mg/dl
- Source of medical care outside of Look AHEAD
- Pass a maximal exercise test
- Ability to adhere
### Participant Retention

- **ILI: Months 1 – 6**
  - Weekly contact
  - 3 group sessions/month
  - 1 individual session/month
  - Personal weight loss goal = 10%
  - Study weight loss goal > 7%

- **ILI: Months 7 - 12**
  - Reduced contact:
    - 2 group sessions/month
    - 1 individual session/month
    - 2 face to face contacts/month required
  - Individual weight loss goal:
    - Continue weight loss if < 10%
    - Weight maintenance if ≥ 10%

- **ILI Years 2+ (Weight Maintenance)**
  - Contact further reduced:
    - 1 on-site individual session/month
    - 1 phone call or e-mail/month
    - Periodic refresher courses or campaigns
    - 2 – 3 times per year
    - Each lasting 6 – 8 weeks

### Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>ILI Mean (N=2,570)</th>
<th>DSE Mean (N=2,575)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ILI: Months 1 – 6</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weekly contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 group sessions/month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 individual session/month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal weight loss goal = 10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study weight loss goal &gt; 7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Look AHEAD Research Group, Diabetes Care, 2007;30:1374-83.**
ILI Recommendations

- **Dietary Intake**
  - 1200-1500 kcal/day < 250 lb
  - 1500-1800 kcal/day ≥ 250 lb
  - ≤30% calories from fat (≤10% sat fat)
- Meal replacements provided
- Menu plans

- **Physical Activity**
  - 175 minutes/week (achieved gradually)
  - 10,000 steps/day

ILI Behavioral Strategies

- **Self-monitoring**
- **Stimulus control**
- **Problem solving**
- **Relapse prevention**
- **Goal setting**
- **Motivational interviewing**

Diabetes Support and Education (DSE)

- Years 1-4 (3-4 meetings / year)
- Years 4+ (1 meeting/year)
- Health education topics
  - Diet
  - Exercise
  - Social Support

Primary Outcome

First post-randomization occurrence of a composite CVD outcome (CVD deaths, non-fatal myocardial infarction, non-fatal stroke, or hospitalized angina) over a planned maximum follow-up of 13.5 years

Intervention stopped (9/2012)

- DSMB recommended stopping the intervention, NIDDK agreed
- Futility analysis showed that the probability of observing a significant positive result at end of trial was 1%.
- Maximum follow-up was 11 years
  - Median 9.6 years

Effect of Lifestyle on Body Weight at 4 Years in the Look AHEAD Trial
# Sessions Attended in Years 2-4 for Those Who Lost > 10% at Year 1

<table>
<thead>
<tr>
<th>Weight Change at Year 4</th>
<th>Treatment Sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥10%</td>
<td>23.6</td>
</tr>
<tr>
<td>5-9.9%</td>
<td>22.7</td>
</tr>
<tr>
<td>0-4.9%</td>
<td>18.5</td>
</tr>
<tr>
<td>Gained</td>
<td>16.8</td>
</tr>
</tbody>
</table>

\[ p < .0001 \]

Mean Annual Number of Meal Replacements Used in Years 2-4 for

<table>
<thead>
<tr>
<th>Weight Change - Year 4</th>
<th>Mean Annual Number of Meal Replacements</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥10%</td>
<td>125.7</td>
</tr>
<tr>
<td>5-9.9%</td>
<td>153.2</td>
</tr>
<tr>
<td>0-4.9%</td>
<td>80.9</td>
</tr>
<tr>
<td>Gained</td>
<td>84.2</td>
</tr>
</tbody>
</table>

\[ p < .02 \]
\[ p < .05 \]

Mean Weekly Kcal Expenditure at Year 4 (as Determined by Paffenbarger)

<table>
<thead>
<tr>
<th>Weight Change - Year 4</th>
<th>Kcal/wk of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥10%</td>
<td>1997.9</td>
</tr>
<tr>
<td>5-9.9%</td>
<td>1406.2</td>
</tr>
<tr>
<td>0-4.9%</td>
<td>1127.3</td>
</tr>
<tr>
<td>Gained</td>
<td>949.3</td>
</tr>
</tbody>
</table>

\[ p < 0.005 \] for all comparisons with ≥10% group

Main Outcome Paper from Look AHEAD

- It showed many positive benefits from weight loss in the Lifestyle and Diabetes Support and Education Groups,
- but did not reduce cardiovascular mortality!

ILI had significantly greater weight loss than DSE

ILI had significantly greater improvements in fitness than DSE
ILI had significantly greater improvements in A1c than DSE

- **Cumulative Hazard for Primary Outcome**
  - **Composite 1: MI, Stroke, CVD Death**
  - **Look-AHEAD: Intensive Lifestyle Intervention has broad benefits**
    - BMI, CVD risk factors and A1C, despite less medication
    - Increased rates of partial diabetes remission
    - Urinary incontinence in women
    - Sleep apnea
    - Depression symptoms
    - Quality of life
  - Physical function
  - Mobility
  - Reduced NAFLD
  - Biomarkers
  - Sexual dysfunction in women
  - NO BENEFIT ON CVD

**Bottom Line**
An intensive lifestyle intervention to reduce weight
- produced many short, mid- and long-term benefits,
- but did not reduce fatal and non-fatal heart attacks and strokes in a group of middle-aged and older obese individuals with type 2 diabetes.
Lifestyle Participants Have Lower Health Care Costs

- Look AHEAD produced a mean weight loss of 7.9% at 1 year and 2.5% at 10 years. It also produced substantial differences in physical fitness.
- There are 3 conclusions from the evaluation of costs for medication and hospital use:
  - The ILI appeared to result in a reduction in medical care use and costs across a spectrum of disease areas.
  - Cost savings appeared to accumulate gradually throughout 10 years and they persisted and expanded over time as participants aged.
  - Cost savings were reasonably similar across broad subgroups of participants.

Espeland MA et al. Diabetes Care 2014

Possible explanations considered for lack of significant differences in CVD event rates

- Study appeared to have sufficient power.
- Larger sustained weight losses may be needed.
- Education sessions and greater use of statins in DSE and more intensive medical management of CVD risk factors may have reduced differences between groups.
- All participants had diabetes. Earlier intervention may be needed.

Sponsors and Donors

- Federal Sponsors
  - NIDDK
  - NIH
  - CDC

- Major Donors
  - FedEx Corporation
  - Health Management Resources
  - LifeScan, Inc., a Johnson & Johnson Company
  - OPTIFAST ® of Nestle HealthCare Nutrition, Inc.
  - Hoffmann-La Roche, Inc.
  - Abbott Nutrition
  - Slim-Fast Brand of Unilever North America

Conclusions

Look AHEAD found that intensive lifestyle intervention did not reduce the risk of cardiovascular morbidity and mortality compared with a control program of diabetes education and support in overweight and obese participants with type 2 diabetes.

Dietary Approaches to Stop Hypertension

- Clinical Centers
  - Brigham & Women’s Hospital, Boston, MA, USA
  - Duke Medical Center, Durham, NC, USA
  - Johns Hopkins Medical Institutions, Baltimore, MD, USA
  - Pennington Biomedical Research Center, Baton Rouge, LA, USA
- Coordinating Center
  - Kaiser Permanente Center for Health Research, Portland, OR, USA
- Sponsor
  - NHLBI, Bethesda, MD, USA

Nutrient Targets

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Control</th>
<th>CV</th>
<th>Combination† or DASH Diet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat %</td>
<td>37</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td>Sat. Fat %</td>
<td>16</td>
<td>15</td>
<td>6</td>
</tr>
<tr>
<td>CHO %</td>
<td>48</td>
<td>48</td>
<td>55</td>
</tr>
<tr>
<td>Protein %</td>
<td>15</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Fiber, g/d</td>
<td>9</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>Potassium, mg/d</td>
<td>1700</td>
<td>4700</td>
<td>3 - 4.5</td>
</tr>
<tr>
<td>Magnesium, mg/d</td>
<td>165</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>Calcium, mg/d</td>
<td>450</td>
<td>450</td>
<td>1240</td>
</tr>
<tr>
<td>Sodium, g/d</td>
<td>3 – 3.5</td>
<td>3 – 3.5</td>
<td>3 – 3.5</td>
</tr>
</tbody>
</table>
Main DASH Effects:

The Combination Diet IS the DASH Diet

DASH-Sodium Trial

• Can we further reduce blood pressure with sodium reduction in both the usual US diet & DASH diet at 3 levels of sodium
  – 3400 mg, 2300 mg, and 1500 mg
• What is the effect on different sub-populations
  – Non-hypertensives, hypertensives, minority populations, men vs women, and age groups

Effects of Sodium on Blood Pressure in Hypertensives and by Race

Effects of Sodium on Blood Pressure by Gender and Age

DASH and DASH-Sodium Dietary Pattern

• Grains & grain products, 7-8 servings daily
• Vegetables, 4-5 servings daily
• Fruits, 4-5 servings daily
• Low fat or nonfat dairy foods, 2-3 servings daily
• Meats, poultry, and fish, 2 or less servings daily
• Nuts, seeds, and legumes, 4-5 servings per week

Plus: Control Sodium Intake

A Clinical Trial of Comprehensive Lifestyle Modification

• Clinical Centers
  – Kaiser Permanente Center for Health Research, Portland, OR, USA
  – Duke Medical Center, Durham, NC, USA
  – Johns Hopkins Medical Institutions, Baltimore, MD, USA
  – Pennington Biomedical Research Center, Baton Rouge, LA, USA
• Coordinating Center
  – Kaiser Permanente Center for Health Research, Portland, OR, USA
• Sponsor
  – NHLBI, Bethesda, MD, USA
Objectives

- To determine the longer-term effects, over 18 months, on BP and hypertensive status of two multicomponent behavioral interventions
  - ESTABLISHED (EST)
  - ESTABLISHED PLUS DASH (EST + DASH) compared to an ADVICE ONLY comparison group
- To determine the additional effects of the DASH diet beyond 'established' recommendations
- To determine adherence over 18-months to behavioral interventions

Design

Randomization

ADVICE ONLY
EST
EST + DASH

18-months
End of Intervention

6-months
Primary
Outcome

Behavioral Interventions

- Goals of both 'EST' and 'EST + DASH' groups
  - Weight loss, >15 lb (6.8 kg)
  - Increased physical activity, ≥ 180 min/wk
  - Reduced sodium intake, < 100 mmol/day
  - Reduce total fat ≤ 30%
- Additional goals for 'EST + DASH' group
  - Increased fruits/vegetables, 9-12 servings/d
  - Increased low-fat dairy products, 2-3 servings/d
  - Reduced saturated fat, < 7% kcal
  - Reduced total fat, < 25% kcal

Intervention Components

- 3 Phases
  - Intensive-weekly sessions – 3 months
  - Intermediate-biweekly sessions - 3 months
  - Maintenance-monthly sessions - 12 months
- Group support and problem solving
- Individual visits (motivational interviewing)
- Self-Monitoring of diet and activity

Baseline Characteristics

<table>
<thead>
<tr>
<th>Mean or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>African-American</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Blood Pressure</td>
</tr>
<tr>
<td>% with Hypertension</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>% Overweight (BMI&gt;25)</td>
</tr>
</tbody>
</table>
Limitations

• The Advice Only comparison group also made some lifestyle changes (e.g. reduced weight, sodium) and these changes increased through 18 months.

• Extensive BP measurement and follow-up may also have contributed to lifestyle changes and changes in BP for the Advice Only group.

Conclusion

• Individuals with above optimal BP including stage 1 hypertension can make multiple lifestyle changes.

• If many are sustained, these lifestyle changes lower BP which should reduce their CVD risk.

http://www.kpchr.org/public/premier/intervention/

WEIGHT LOSS MAINTENANCE TRIAL

The Weight Loss Maintenance Clinical Trial addresses the questions:
1. How long weight loss can be maintained?
2. What strategies are most effective for maintenance?

A multicenter, randomized clinical trial to determine the effectiveness of two innovative behavioral interventions, compared to an advice only control group in maintaining weight loss.

Purpose

• A major factor contributing to the rise in obesity is weight regain after initial weight loss

• There is extensive evidence suggesting that weight loss can be achieved over the short term, however weight regain is extremely common

• Need for research in the area of innovative approaches to sustaining weight loss

• Participating institutions and funding agency same as PREMIER.
Inclusion Criteria

- Age >25 years
- BMI 25-45 kg/m²
- Currently taking medication for hypertension and/or dyslipidemia
- If diabetic, not on diabetic medications
- Access to telephone and internet skills

Study Design

- 20 Weekly Group Sessions
  - Actively participate in group exercise
  - Taste healthier foods
  - Learn strategies to help change behavior
  - Share successes and challenges
  - Support others in their efforts to lose weight

20 Weekly Group Sessions

Phase I

- Weight Loss Program
- Weight Loss ≥ 4 kg

Phase II

- Randomization
  - Self-Directed (SD)
  - Personal Contact (PC)
  - Internet Technology (IT)

Yield from Phase I 63%

- N 1032
- Mean Age 56 years
- African American 38%
- Female 63%
- Mean Weight Loss in Phase I 8.4 kg
- Range of Weight Loss 4.0 - 30.3 kg

Phase II: Study Population

- Randomly assigned to one of three groups:
  - Personal Contact (PC) - monthly follow-up with interventionist either by phone or in-person
  - Self-directed (SD) - yearly visit
  - Internet Technology Group (IT) - regular follow-up using the internet, including various website links and email

- Random assignment given at screening visit after completion of Phase I
- No choice of group assignment

Phase II Groups
Phase II: Intervention Goals
- Maintain **225 minutes** per week of moderate intensity physical activity
- Reduce calories to maintain prior weight loss
- Follow the DASH dietary pattern

Phase II Intervention Contacts

<table>
<thead>
<tr>
<th></th>
<th>PC</th>
<th>IT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of Contacts</td>
<td>Monthly</td>
<td>Weekly or More</td>
</tr>
<tr>
<td>Types of Contacts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Email</td>
<td>0</td>
<td>Weekly self-monitoring modules</td>
</tr>
<tr>
<td>- IVR phone calls</td>
<td>0</td>
<td>As needed</td>
</tr>
<tr>
<td>- Personal phone calls</td>
<td>9yr (15 min)</td>
<td>0</td>
</tr>
<tr>
<td>- In-person visits</td>
<td>3yr (45 min)</td>
<td>1 orientation</td>
</tr>
<tr>
<td>Contact Flexibility</td>
<td>Scheduled personal</td>
<td>Unlimited electronic</td>
</tr>
</tbody>
</table>

Phase II PC: Intervention Contacts

Percent with weight at or below entry weight

Percent who maintained at least 4 kg weight loss

Summary
- There is extensive evidence suggesting that weight loss can be achieved over the short term, however weight regain is extremely common
- Phase I was associated with ≥4 kg weight loss in 63% in WLM participants
- Phase II was associated with high levels of completed contacts at end of year 1 (>90% in PC; >80% in IT)
- Lower level of completed logins among AA females (IT)
Behavioral Strategies for Success in Weight Management

• Provide accountability and motivation
• Promote problem solving skills
  – Orderly method for coping with barriers or problems
• Encourage self-monitoring
  – Weekly weighing
  – Food and activity monitoring

Behavioral Strategies for Success in Weight Management

• Encourage reduced calorie and fat diet
  – Structured meal plans and portion controlled diets early on (key success in Look AHEAD)
• Promote increased physical activity
  – Home-based or supervised exercise
• If possible, provide extended treatment
  – Continue contact (telephone, mail, email, internet)

What do we need going forward?

• Continued training in motivational interviewing, relapse prevention, management of time and stress levels – we already know nutrition, so we need regular emphasis on improving our behavioral skills!
• Look for way more accepting for our participants in self-monitoring: smartphone apps, new technologies to keep them engaged in the lifestyle change process!

References

• Look AHEAD Citations:


References


