Comparative Effectiveness of Diabetes Prevention Programs

Nancy M. Bennett, MD, MS
Professor of Medicine and Public Health Sciences
Director, Center for Community Health

Jennifer Carroll, MD
Associate Professor of Family Medicine
Diabetes and Pre-Diabetes

• 20.8M people have diabetes in US; 95% Type 2
• Estimated 54M people have pre-diabetes
• 61% of Monroe County adults are overweight or obese
• Estimated 20% of MC adults are pre-diabetic
• Rate of diabetes in MC doubled from 2001-2006
• 20% of African Americans in Rochester have DM compared to 10% of MC population overall, and 39% (vs. 24%) are obese
Costs of Diabetes

- $58B in reduced national productivity
- $116B in excess medical expenditures
- An average expenditure of $6,649 more/year than non-diabetics (230% more)
What We Know: What Does NOT Work

• Brief interventions
  Goldstein, Whitlock, & DePue (2004)

• Web-based interventions
  Verheijden et al. (2004)

• Interventions in primary care
  Yarnell, Pollak, Ostbye, Krause, & Michener (2003)
What DOES Work?

• Evidence based programs developed and studied in research settings

• Require translation to clinical and community settings

• Diabetes Prevention Program
Comparative effectiveness of practice-based diabetes prevention programs
The Diabetes Prevention Program

**Program**
For first 6 months:
- 3 Group mtgs./month
- 1 individual mtg./month
- Providers: Nutritionist, physical activity counselor, PA
For following 6 months:
- 2 Group mtgs./month

**Effectiveness**
- Delayed diabetes onset by average of 11 years
- Required 5-10% weight loss and increased PA to 150 mins/wk
- Reduced relative incidence of diabetes by 58%
- Cost effective in a research setting
Healthy Living Program

**Program**
- Groups held in community sites
- 1.5 hours 2 X /week
- Physical activity – 45 minutes
- Comprehensive health promotion curriculum
- Not focused on weight loss in original program

**Effectiveness**
- Average wt loss = 3 lbs.
- Small % achieved 5-7% loss
- Average waist and hip significantly decreased
- Significant increase in PA
- Significant increase in vegetables consumed
- Significant decrease in fats and salt
Comparative Effectiveness of Diabetes Prevention Programs: CTSI Pilot

• Trial of two interventions to increase physical activity and decrease weight among pre-diabetics, to prevent diabetes among patients served by community health centers

• Translation of research program (DPP) to clinical setting, and comparison to another program (HLP) specifically developed for African American and Latino populations
Specific Aims

• To test the feasibility of recruitment and randomization of low income pre-diabetics in primary care offices.
• To test the feasibility of collecting measures of weight, physical activity, behavior, and motivation.
• To collect robust preliminary data to determine effect direction and size for an R21 or R01.
Design

- Pre-diabetic patients in four community health centers
- Randomized trial – DPP vs HLP
- Recruitment goal – 50 per site recruited with 25 randomized to each arm in each site
- Expected 40% attrition rate
Inclusion Criteria

• Adults (18 years or older) who are overweight or obese (BMI ≥ 25 kg/m²)
• Pre-diabetes (tested within the previous 12 months), as defined by the ADA:
  – Hemoglobin A1C 5.7 – 6.4%
  – Fasting plasma glucose 100-125 mg/dl
  – Oral glucose tolerance test 140-199 mg/dl
• Able to participate – Physical Activity Readiness Questionnaire (PAR-Q)
Exclusion Criteria

- Diabetes at baseline or previous use of anti-diabetic medication, other than during pregnancy
- Medical conditions likely to limit life span and/or increase risk of intervention
- Conditions or behaviors likely to affect conduct of the trial
- Medications and medical conditions likely to confound the assessment for diabetes
Interventions: HLP vs DPP

<table>
<thead>
<tr>
<th>Characteristics of programs</th>
<th>HLP</th>
<th>DPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>Sessions per week</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total sessions</td>
<td>24</td>
<td>22</td>
</tr>
<tr>
<td>Hours per week</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Total hours</td>
<td>36</td>
<td>19</td>
</tr>
<tr>
<td>Total hours of counseling</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Total hours of physical activity</td>
<td>18</td>
<td>0</td>
</tr>
</tbody>
</table>
Outcomes

- Primary outcomes:
  - percent weight loss relative to baseline
  - self-reported minutes/wk of physical activity

- Secondary outcomes:
  - BMI change
  - self-reported nutrition and physical activity
  - measures of motivation
## Measurements

<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline</th>
<th>Q 4 wks</th>
<th>22 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biometrics: ht, wt, waist, hip, BP, HR</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cardio-resp endurance, strength, flexibility</td>
<td>X</td>
<td>w12 only</td>
<td>X</td>
</tr>
<tr>
<td>Physical Activity (Self report) mins/wk</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Nutrition (self report)</td>
<td>X</td>
<td>w12 only</td>
<td>X</td>
</tr>
<tr>
<td>Motivation</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Analysis

• Univariate and bivariate descriptive analyses
• Primary analysis will compare weight loss and minutes of physical activity per week - 3 way ANOVA including program, time, and clinic
• Regression as needed to model temporal change in weight loss.
• Construction of model of changes in motivation leading to behavior change – identification of factors.
Results
Assessed for eligibility (n+1215)

No inclusion criteria (n = 458)
Exclusion (n = 160)
Refused (n = 130)
Other reasons (n = 382):
Total = 1130

Randomized (n=85)

Allocated to HLP (n = 42)
Allocated to DPP (n = 43)

Analyzed (n = 13)
Analyzed (n = 18)
## Participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HLP n (%)</th>
<th>DPP n (%)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>33 (78.57)</td>
<td>43 (86.00)</td>
<td>76 (82.61)</td>
</tr>
<tr>
<td>Male</td>
<td>9 (21.43)</td>
<td>7 (14.00)</td>
<td>16 (17.39)</td>
</tr>
<tr>
<td><strong>Race/ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>5 (11.90)</td>
<td>6 (12.00)</td>
<td>11 (12.00)</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>9 (21.43)</td>
<td>9 (18.00)</td>
<td>18 (19.57)</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>26 (61.90)</td>
<td>30 (60.00)</td>
<td>56 (60.87)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (4.76)</td>
<td>5 (10.00)</td>
<td>7 (7.61)</td>
</tr>
<tr>
<td><strong>Do you have insurance? (% yes)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 (88.10)</td>
<td>45 (90.00)</td>
<td>82 (89.13)</td>
<td></td>
</tr>
<tr>
<td><strong>Insurance Type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public (Medicaid/Medicare)</td>
<td>25 (59.53)</td>
<td>32 (64.00)</td>
<td>57 (61.96)</td>
</tr>
<tr>
<td>Private</td>
<td>12 (28.57)</td>
<td>13 (26.00)</td>
<td>25 (27.17)</td>
</tr>
<tr>
<td>None</td>
<td>5 (11.90)</td>
<td>5 (10.00)</td>
<td>10 (10.87)</td>
</tr>
</tbody>
</table>
# Age and BMI

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HLP</th>
<th>DPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [mean (std)]</td>
<td>44.0 (13.99)</td>
<td>42.4 (14.42)</td>
</tr>
<tr>
<td>Baseline BMI [mean (std)]</td>
<td>34.0 (4.8)</td>
<td>36.9 (7.7)</td>
</tr>
<tr>
<td>Weight loss</td>
<td>1.2%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Increased minutes PA per week</td>
<td>227</td>
<td>145</td>
</tr>
<tr>
<td>Dietary measure</td>
<td>HLP (n=13)</td>
<td>DPP (n=18)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td></td>
<td>Baseline</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Fruit, servings/day</td>
<td>1.4</td>
<td>2.6</td>
</tr>
<tr>
<td>Vegetables, servings/day</td>
<td>1.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Sugar sweetened beverages, servings/day</td>
<td>1.8</td>
<td>1.0</td>
</tr>
<tr>
<td>% use of “good” fats most often</td>
<td>42</td>
<td>73</td>
</tr>
<tr>
<td>% use of “bad” fats most often</td>
<td>58</td>
<td>27</td>
</tr>
</tbody>
</table>
Preliminary Findings

- Modest weight loss but significant increase in physical activity and improvements in nutrition in both groups.
- Effect sizes considerably smaller than in more controlled research
- Satisfaction great in both groups
- Small differences between groups make larger trial challenging
Preliminary Findings

• Recruitment hampered by difficulty identifying pre-diabetics and by exclusion criteria
• Randomization and collection of data feasible in this population
• Enrollment low and drop off between enrollment and first session
• Retention and data collection hampered by life circumstances of participants
Challenges

• Implementation challenges:
  – Logistics: job insecurity, childcare, transportation
  – Language and fluency
  – Specificity of target group

• Trial challenges:
  – Identification of pre-diabetics
  – Exclusion criteria
  – Recruitment and retention
Future Directions

• Broaden inclusion criteria for program participation to include metabolic syndrome indicators
• Consider efforts to increase PC identification of pre-diabetics
• Implementation of the DPP in 6 clinical settings – Greater Rochester Health Foundation
• Develop separate trial for HLP / PCORI
• Continue measurement of motivation
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Thank you

Questions?