

Behavioral Intervention Implementation Table: Exemplar Interventions*

INTERVENTION	Healthy diet and physical activity counseling (FDPS)1,2	Reduction in the Incidence of Type 2 Diabetes with Lifestyle Interventions or Metformin (DPP)3,4	Effects of comprehensive lifestyle modification on blood pressure control (PREMIER)5,6
Primary Population	<p>Participants were recruited through the screening of high-risk groups, such as first-degree family members of patients with diabetes</p> <p>Participant characteristics included being ages 40-60 years old, overweight (BMI>25) with an impaired fasting glucose</p>	<p>Participants recruited through 27 medical centers (Primarily University based) and participants were deemed to be high risk for diabetes</p> <p>Participant characteristics included being 25 yrs or older, BMI of 24 or more (22 or higher in Asians) and fasting plasma glucose of 95-125 or glucose of 140-199, 2 hrs after 75g glucose challenge</p> <p>Recruitment was designed to enroll half of persons from racial/ethnic minority groups (AA, Hispanic, Asian, Pacific Islander, AI)</p>	<p>Participants were recruited through 4 medical centers through mass mailings, community-based screening, and mass-media announcements</p> <p>Participant characteristics included being 25 yrs and older, BMI18.5-45, having a SBP 120-159 and DBP 80-95 and not taking antihypertensives.</p> <p>Participants were considered “generally healthy” and individuals with DM and other CV health conditions were excluded</p>
Primary Outcomes Measured	Onset of diabetes in overweight persons with an impaired fasting glucose	Onset of diabetes in overweight persons with an impaired fasting glucose	Change in SBP from baseline to 6 months

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Study Findings	58% reduction in risk of diabetes (11% vs 23% incidence after 4 years in intervention vs controls)	Incidence of diabetes was 4.8 vs 7.8 vs 11.0 cases per 100 per-years in lifestyle intervention vs metformin vs placebo group. Lifestyle intervention reduced the incidence of diabetes by 58% vs placebo; metformin reduced incidence of diabetes by 31% vs placebo.	4.3mmHg decrease in SBP at 6 months in those who received established recommendations + DASH (“minus” advice only).
Behavioral Intervention	<p>Individual nutrition counseling aimed to reduce weight, total intake of fat and intake of saturated fat and increase intake of fiber</p> <p>Subjects were given detailed individual advice on how to achieve goals of; weight reduction $\geq 5\%$; fat intake $< 30\%$ of energy; saturated fat intake $< 10\%$ of energy (mono or polyunsaturated fats, 20% of energy, or $\leq 25\%$ if surplus from monounsaturated fat); cholesterol < 300 mg/day; 1.0 g protein per kg ideal body weight per day; carbohydrate intake $> 50\%$ of energy; increase fiber to ≥ 15 g/1,000 kcal; and moderate exercise for ≥ 30 minutes/day.</p> <p>Individual guidance on increase of endurance physical activity (including walking, jogging and swimming)</p> <p>Optional supervised individually tailored circuit-type resistance-training sessions up to twice per week</p>	<p>Healthy diet and physical activity counseling with participants taught to record diet and exercise</p> <p>Goals were to achieve and maintain weight reduction $\geq 7\%$ of initial body weight through a healthy low-calorie, low-fat diet and engage in moderate-intensity physical activity, such as brisk walking for ≥ 150 minutes/week.</p> <p>Intervention described as flexible, culturally sensitive, and acceptable in specific communities where they are implemented</p> <p>Offered supervised exercise sessions twice per week for duration of intervention (not mandatory).</p>	<p>Group and individual lifestyle counseling sessions</p> <p>Participant goals were 1) weight loss ≥ 15 lb at 6 months for those with BMI ≥ 25 kg/m²; 2) ≥ 180 minutes/week of moderate-intensity physical activity; 3) daily intake ≤ 100 mEq of dietary sodium; and 4) daily intake ≤ 1 oz alcohol (2 drinks) for men and $\frac{1}{2}$ oz of alcohol (1 drink) for women.</p> <p>Dietary counseling based on DASH diet. Specific goals for the DASH diet; increased consumption of fruits and vegetables (9-12 servings/d) and low-fat dairy products (2-3 servings/d), and reduced intake of saturated fat ($\leq 7\%$ of energy) and total fat ($\leq 25\%$ of energy)</p>

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Comparison Group	Controls received general oral and written information about diet and exercise at base line and at subsequent annual visits, but no specific individualized programs were offered	Intervention 2: standard lifestyle recommendations + metformin 850 mg PO BID Control: standard lifestyle recommendations + placebo pill	Intervention 2: established recommendations only Control: advice only
Training Required	Primary care provider for recruitment only Nutritionist for dietary counseling (training not defined) Circuit trainer-background not described	Primary care provider for recruitment only Case manager (training not defined) for counseling Supervised exercise leader not defined	Interventionist (typically a registered dietician) Telephone interviewers Staff conducted individual and group sessions and physical measurements Dietary Assessment Center (Used Nutrition Data System Version NDS-R 1998) assessed data

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Mode of Delivery	Face to face visits	Face to face visits	Face to face visits
Intensity of Intervention (when and how much)	<p>A nutritionist performed 7 sessions in the first year and one session every three months thereafter for up to 84 months (mean follow-up was 38.4 months)</p> <p>Optional circuit training occurred up to twice per week</p> <p>Annual oral glucose tolerance test</p> <p>Weight, waist circumference, BP, cholesterol measurements at initial screening and annually</p>	<p>A case manager taught one-on-one sessions over 24 weeks using a 16 core lesson curriculum which followed the Food Guide Pyramid 14</p> <p>Subsequent sessions led by the case manager were monthly and either individual or group focused on behavior reinforcement</p> <p>6 months core curriculum 1.8-4.6 years maintenance (mean 2.8 years)</p> <p>Optional supervised exercise sessions up to twice per week throughout intervention</p> <p>Semiannual FBG and annual 2 hr oral glucose tolerance test</p>	<p>18 visits with staff during 6 months (14 group meetings and 4 individual counseling sessions)</p> <p>Interventionist (registered dietician) conducted one 30 minute advice session at 0m and 6m</p> <p>Two telephone interviews on 24 hr. dietary recall at 0m and 6m</p> <p>Two laboratory visits for blood and urine studies at 0m and 6m</p>

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Materials Provided for Practice (Web site)	<p>Written material on nutrition</p> <p>Food records/journals</p> <p>Access to circuit training equipment (optional)</p> <p>Circuit trainer (optional)</p> <p>Lab for glucose, insulin, cholesterol tests</p> <p>Calibrated scale</p> <p>Tape measure</p> <p>Blood pressure cuff</p>	<p>Written material: Lifestyle manuals of operation (www.bsc.gwu.edu/dpp)</p> <p>Modified Block food-frequency questionnaire</p> <p>Modified Activity Questionnaire</p> <p>Lab for FBG and two hour oral glucose tolerance test</p>	<p>Written material on HTN</p> <p>Food diaries</p> <p>Written record of physical activity</p> <p>Calibrated scale and wall mounted stadiometer</p> <p>Blood pressure cuff</p> <p>Rose Angina questionnaire (Chest pain and claudication)</p> <p>Questionnaire on medications, symptom, adverse events and alcohol consumption</p> <p>Lab for FBG, 24 hr urine (electrolytes and BUN)</p> <p>Treadmill (submaximal tests)</p> <p>Tape measure (waist circumference)</p> <p>Dietary Assessment center for analysis of dietary recalls</p> <p>Submaximal treadmill protocol</p>
To Whom is Intervention Targeted?	Dietary advice was tailored to each subject on the basis of 3-day food records completed 4 times/year	Lifestyle advice was tailored to the individual with emphasis on self-esteem, empowerment, and social support.	

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Settings of Studies	<p>Finland</p> <p>Participants with a first degree relative who had diabetes were recruited through primary care clinics</p> <p>Individual nutrition counseling not specified</p> <p>Circuit training location not specified</p>	<p>U.S.</p> <p>27 medical centers</p> <p>Case manager session locations not defined</p> <p>Location of supervised exercise sessions not defined</p>	<p>U.S.</p> <p>Recruited from 4 medical centers</p> <p>Individual and group meeting location not specified</p> <p>Print materials were reviewed at home</p>
Reported Adherence to Intervention	<p>Self-reported; 87% of the intervention group decreased consumption of fat (70% control), 72% increased consumption of vegetables (62% control) and 36% of intervention group increased exercise (16% control); The rate of participation in optional supervised exercise sessions was 50-85% during the first year at different medical centers.</p>	<p>Self-reported through the modified Block food-frequency questionnaire and the Modifiable Activity Questionnaire annually; 50% of the intervention group achieved weight loss goal by 24 weeks, 74% met exercise goal by 24 weeks</p>	<p>Adherence to dietary recommendations was self-reported through two 24hr telephone dietary recalls; Biomarkers of dietary intake were 24-hour urinary excretion of sodium, potassium (reflecting fruit and vegetable intake), phosphorus (reflecting dairy intake), and urea nitrogen (reflecting protein intake); Physical activity self-reported by patient and assessed through submaximal treadmill protocol; 70% of participants in the DASH intervention group attended at least 15/18 counseling sessions; Change in mean paired weight of the DASH intervention group after 6 months was -5.8kg vs -1.1kg in the advice only group; Change in mean paired HR on treadmill testing after 6 months was -9 beats/min in the DASH intervention vs -5.3 beats/min in the advice only group</p>

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Reference	Tuomilehto J, Lindström J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. <i>New Engl J Med.</i> 2001;344:1343-50. PMID: 11333990	Knowler WC, Barrett CE, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. <i>New Engl J Med.</i> 2002;346:393-403. PMID: 11832527.	Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. <i>JAMA.</i> 2003;289:2083-93. PMID: 12709466.

*This table is based on a modified version of the TIDieR Checklist (Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ.* 2014;348:g1687).