## CLINICAL REVIEW

## Preventing Diabetes in the Clinical Setting

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**OBJECTIVE:** Translating lessons from clinical trials on the prevention or delay of type 2 diabetes to populations in nonstudy settings remains a challenge. The purpose of this paper is to review, from the perspective of practicing clinicians, available evidence on lifestyle interventions or medication to prevent or delay the onset of type 2 diabetes.

**DESIGN:** A MEDLINE search identified 4 major diabetes prevention trials using lifestyle changes and 3 using prophylactic medications. We reviewed the study design, key components, and outcomes for each study, focusing on aspects of the interventions potentially adaptable to clinical settings.

**RESULTS:** The lifestyle intervention studies set modest goals for weight loss and physical activity. Individualized counseling helped participants work toward their own goals; behavioral contracting and self-monitoring were key features, and family and social context were emphasized. Study staff made vigorous follow-up efforts for subjects having less success. Actual weight loss by participants was modest; yet, the reduction in diabetes incidence was quite significant. Prophylactic medication also reduced diabetes risk; however, lifestyle changes were more effective and are recommended as first-line strategy. Cost-effectiveness analyses have shown both lifestyle and medication interventions to be beneficial, especially as they might be implemented in practice.

**CONCLUSION:** Strong evidence exists for the prevention or delay of type 2 diabetes through lifestyle changes. Components of these programs may be adaptable for use in clinical settings. This evidence supports broader implementation and increased reimbursement for provider services related to nutrition and physical activity to forestall morbidity from type 2 diabetes.

 $K\!EY$  WORDS: type 2 diabetes; prevention; lifestyle; nutrition; physical activity.

DOI: 10.1111/j.1525-1497.2005.00277.x J GEN INTERN MED 2006; 21:84–93.

Type 2 diabetes affects approximately 8% of U.S. adults.<sup>1</sup> The prevalence is rising among adults and youth,<sup>2,3</sup> paralleling the dramatic increase in obesity.<sup>4</sup> Increased incidence of diabetes, especially among youth, portends a serious increase in early morbidity, health care costs, and lost productivity. Diabetes prevention has become a key target for clinicians, patients, and policymakers, as substantial evidence has accumulated that diabetes can be prevented or delayed in

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those at high risk. Presenting the results of the Diabetes Prevention Program (DPP) trial, Secretary of Health and Human Services Tommy Thompson declared, "In view of the rapidly rising rates of obesity and diabetes in America, this good news couldn't come at a better time .... By promoting healthy lifestyles, we can improve the quality of life for all Americans, and reduce health care costs dramatically."<sup>5</sup> A working group from the American Diabetes Association and the National Institute of Diabetes and Digestive and Kidney Diseases published a cogent position statement regarding the scientific findings and health policy implications from diabetes prevention trials.<sup>6</sup> The current article provides practicing clinicians with a more detailed review of evidence regarding prevention of type 2 diabetes, insights into the components of successful interventions, and consideration as to which aspects of interventions are most adaptable for use in clinical practice.

#### **METHODS**

A MEDLINE literature search from 1980 to 2004 was performed to identify articles about prevention or delay of type 2 diabetes in adults. Key phrases included diabetes prevention, type 2 diabetes, lifestyle intervention, pharmacologic prevention, nutrition and exercise, and combinations thereof. References of relevant articles were searched as well. The inclusion criteria were clinical trials including an active intervention with longitudinal follow-up to decrease the onset of type 2 diabetes. Six reviewers agreed upon inclusion of the studies identified. Three prevention studies utilizing prophylactic medication and 4 utilizing lifestyle changes to prevent diabetes were identified. As lifestyle interventions proved more efficacious and have been recommended for first line use,<sup>7</sup> the main focus of this review is the 4 major studies that describe successful lifestyle interventions to prevent or delay the onset of diabetes.

## Study Interventions and Outcomes

The design and outcomes of the 4 major lifestyle intervention studies are summarized in Table 1. Studies ranged in size from 415 subjects (Malmö, Sweden, 1980s)<sup>8</sup> to 3,234 (DPP, U.S., 1996 to 2001)<sup>9</sup>; the length of follow-up ranged from approximately 3 to 6 years. All the studies included a lifestyle intervention encouraging participants to improve nutrition, lose weight (for overweight subjects), and increase physical activity. Actual weight lost in these studies was modest, with

Manuscript received April 6, 2005 Initial editorial decision June 22, 2005 Final acceptance August 30, 2005

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	Diabetes Prevention Program (DPP) <sup>8,29</sup>	Diabetes Prevention Study (DPS) <sup>10,30</sup>	Da-Qing IGT and Diabetes Study <sup>32</sup>	Malmö Feasibility Study <sup>31</sup>
Population				
Country	USA	Finland	China	Sweden
Years	1996 to 2001	1993 to 2000	1986 to 1992	1974 to 1985
Ν	3234	522	577	415
Inclusion criteria	IGT and $\uparrow$ FPG	IGT	IGT	Mild DM (no symptoms), IGT normal controls
Age (y, mean $\pm$ SD)		$55\pm7$	$45.0\pm9.1$	Range $=$ 47 to 49
BMI, (kg/m <sup>2</sup>	$34.0\pm6.7$	$31.3 \pm 4.6$ (intervention	$25.8\pm3.8$	$27.7 \pm 3.7$ (group 1; DM,
mean $\pm$ SD)		group)		lifestyle)
		$31.0 \pm 4.5$ (control		$26.6 \pm 3.1$ (group 2; IGT,
		group)		lifestyle)
				$26.7 \pm 4.0$ (group 3; IGT
				controls) 24.3 ± 2.8 (group 4; normal
				$24.3 \pm 2.8$ (group 4, normal controls)
Follow-up (mean y)	2.8	3.2	6	5
Race	55% Caucasian	100% Caucasian	100% Asian	100% Caucasian
Mate	20% African American	100% Caucasian	10070763611	100% Caucasian
	16% Hispanic			
	5% American Indian			
	4% Asian American			
tudy design				
Туре	RCT; individuals	RCT; individuals	RCT; clinics randomized	Nonrandomized feasibility
	randomized	randomized		study Baseline differences in
				groups
Number of sites	27	5	33	1
Arms	4 arms:	2 arms:	4 arms:	Lifestyle intervention
	Lifestyle intervention,	Lifestyle intervention,	Diet alone, $n=130$	Group 1 (DM), $n=41$
	n=1079	n=265	Exercise alone, $n=141$	Group 2 (IGT), $n=181$
	Metformin, $n=1073$ Troglitazone	Control group, $n=257$	Diet $\pm$ exercise, $n=126$ Control, $n=133$	No intervention Group 3 (IGT), n=79
	(discontinued 1998)		control, n=135	Group 4 (normals), $n=114$
	Control. $n=1082$			$(1000) \neq (1000000); n = 114$
Goals	001101, 11-1002			
Weight loss	7% weight loss	$\geq$ 5% weight loss	For BMI $<25$ : none	Not mentioned
0	0	- 0	For BMI $\geq$ 25: 0.5 to 1.0 kg loss/mo	
			until BMI=23	
Diet	${<}25\%$ kcal from fat	< 30% kcal from fat	BMI<25:	$\downarrow$ Simple carbohydrates
		< 10% saturated fat	25 to 30 kcal/kg intake	$\uparrow$ Complex carbohydrates
		$\geq$ 15 g fiber/1000 kcal	55% to 65% carbohydrates	$\downarrow$ Saturated fats
			10% to 15% protein	Substitute polyunsaturated
			25% to 30% fat BMI < 25:	fats
			$\beta MI < 25$ : $\downarrow$ kcal intake	↓ Kilocalories for obese subjects
Physical activity	150 min physical activity	30 min moderate	$\uparrow$ Leisure physical activity by 1 to	Not mentioned
Filysical activity	per week	intensity physical	2 study-specific units per day*	Not mendoned
	per week	activity per day	2 study specific units per day	
ntermediate outcome	5	uctivity per duy		
Weight change				
kg (mean)	Lifestyle $\downarrow 5.6$	Lifestyle $\downarrow 4.2$ at 1 y	Did not develop DM Did develop	Lifestyle (groups 1 and 2)
Ū.	Metformin $\downarrow 2.1$	↓ 3.5 at 2 y	Control: $\uparrow 0.27 \downarrow 1.55$	↓6at1y
	Placebo 1 0.1	Control $\downarrow 0.8 \text{ at } 1 \text{ y}$	DM diet: $\uparrow 0.93 \downarrow 2.43$	$\downarrow$ 2.0 to 3.3 at 5 y
		$\downarrow 0.8$ at 2 y		
			Exercise: $\uparrow 0.71 \downarrow 1.93$	Control (groups 3 and 4)
0/	F00/	D	Diet+exercise: $\downarrow 1.77 \qquad \downarrow 3.33$	$\downarrow$ 0.2 to 2.0 at 5 y
% subjects	50% in lifestyle arm	By year 1: 43% lifestyle		
meeting weight		group		
loss goal % subjects	38% in lifestyle arm	13% control group		82% group 1 & 71% group 2
	56% in mestyle ann			maintained overall weight
maintaining weight loss goal				reduction over 5 y
Physical activity				reduction over 5 y
% subjects	74% in lifestyle arm	By year 1: 86% lifestyle		
meeting activity	, 170 m mestyre arm	group		
meeting activity		71% control group		
goal				
goal % subjects	58% in lifestyle arm	71% control group		
goal % subjects maintaining	58% in lifestyle arm	71% control group		

	Diabetes Pre Program (E			Prevention OPS) <sup>10,30</sup>		g IGT and es Study <sup>32</sup>	Malmö Feasibi Study <sup>31</sup>	lity
Diabetes outcomes								
Incidence	Cumulative 3	y DM	Cumulative	2 y DM	Cumulative 6 y l	OM incidence:	Cumulative 6 y DM in	cidence:
	incidence:		incidence:		Control 67	7.7%	Lifestyle (group 2)	10.6%
	Control	28.9%	Control	14%	Diet 43	8.8%	Control (group 3)	28.6%
	Lifestyle	14.4%	Lifestyle	6%	Exercise 4	1.1%	Control (group 4)	0%
	Metformin	21.7%	Cumulative incidence: Control Lifestyle	4 y DM 23% 11%	Diet $\pm$ exercise	e 46.0%		
Risk reduction in	DM risk reduc	tion	DM risk red		DM risk reduction	on over 6 v:	DM risk reduction ove	er 6 v:
intervention vs	over 3 v:		over 6 v:		Diet	31%	Lifestyle 63%	5
control group	Lifestyle Metformin	58% 31%	Lifestyle	58%	Exercise Diet $\pm$ exercise	46% e 42%	(group 2 vs group 3	)

#### Table 1 (continued)

\*One study-specific physical activity unit =30 minutes of mild intensity (e.g., slow walking), or 20 minutes of moderate intensity (e.g., brisk walking), or 10 minutes of strenuous intensity (e.g., slow running), or 5 minutes of very strenuous intensity (e.g., jumping rope) exercise.

IGT, impaired glucose tolerance; FPG, fasting plasma glucose; DM, type 2 diabetes mellitus; BMI, body mass index [weight in kilograms/(height in meters)<sup>2</sup>]; RCT, randomized-controlled trial; kcal, indicates kilocalories.

about half the weight on average regained over the course of the studies. Nonetheless, significant decreases in diabetes incidence were demonstrated in the lifestyle intervention groups. The Finnish Diabetes Prevention Study<sup>10–12</sup> and the U.S. DPP<sup>9</sup> each demonstrated a relative risk reduction of 58% through lifestyle change compared with placebo.

Table 2 describes the design and outcomes of diabetes prevention trials using medication. The DPP<sup>8</sup> demonstrated a 31% reduction in diabetes risk in subjects receiving metformin, compared with placebo. The Study to Prevent NIDDM (STOP-NIDDM)<sup>13,14</sup> was an international study of 1,429 overweight adults with impaired glucose tolerance (IGT), who were followed for an average of 3.3 years. Subjects were randomized to receive acarbose or placebo. Compared with placebo, subjects receiving acarbose were 25% less likely to develop diabetes. The Troglitazone in Prevention of Diabetes Study,15 randomized 266 Hispanics with gestational diabetes to 400 mg of troglitazone daily or placebo. After a median follow-up of 30 months, the annual diabetes incidence was 12.1% with placebo and 5.4% in the drug arm, a risk reduction of over 50%. The DPP troglitazone study arm was terminated when a patient on troglitazone died from liver failure. In the DPP, the relative advantage of lifestyle intervention over metformin was greater in older subjects, those with lower baseline body mass index, and those with lower baseline fasting glucose.<sup>9</sup> Prophylactic medication clearly reduces diabetes risk; however, lifestyle changes are more effective overall and are recommended as first-line strategy.<sup>7</sup>

#### **CLINICAL ISSUES**

## Who Was Targeted in the Diabetes Prevention Trials?

Lifestyle interventions are most effective in patients at high risk for disease.<sup>16</sup> Accordingly, all 4 diabetes prevention lifestyle studies enrolled subjects with IGT as evidenced by oral glucose tolerance testing (OGTT). Impaired glucose tolerance is defined as a 2-hour postprandial glucose level between 140 and 199 mg/dL on standard OGTT. Persons with IGT are known to be at high risk for progression to diabetes.<sup>17</sup>

#### How Should We Identify Patients in Clinical Practice?

Patients at risk for diabetes are asymptomatic; reliable methods are needed to identify those at high risk. Hemoglobin A<sub>1C</sub> is not recommended for screening or diagnosis<sup>18</sup> because of nonstandardized methods of testing. Impaired glucose regulation can be identified by documenting impaired fasting glucose (IFG) or IGT, although some patients exhibit 1 abnormality without the other. By definition, IGT requires glucose tolerance testing for identification. Impaired glucose tolerance is more strongly associated with cardiovascular risk than IFG<sup>19,20</sup>; however, both are markers for microvascular risk.<sup>21</sup> Although controversial, glucose tolerance testing is not generally recommended for screening in clinical practice<sup>22,23</sup> as it is costly. inconvenient, and less reproducible than fasting plasma glucose (FPG). The American Diabetes Association (ADA) Expert Committee<sup>18</sup> recommended decreasing the lower limit for IFG from 110 to 100 mg/dL to optimize sensitivity for predicting future diabetes. This change also increases the proportion of persons with IGT who can be identified by the fasting blood test, making this a rational screening strategy.

Clinical characteristics also predict risk of diabetes.<sup>24</sup> The clinical characteristics associated with type 2 diabetes risk include obesity and overweight, age (risk rises steadily from puberty into geriatric years), a history of gestational diabetes, polycystic ovary syndrome, a family history of type 2 diabetes, and membership in certain high-risk minority groups: African American, Hispanic, Native American, and Asian-Pacific Islanders.<sup>25-27</sup> The U.S. Preventive Services Task Force (US-PFTF) finds "insufficient evidence" to recommend screening all asymptomatic adults for diabetes because "It has not been demonstrated that . . . screening provides an incremental benefit compared with initiating treatment after clinical diagnosis." They do, however, recommend screening persons at high risk, including those with hypertension or hyperlipidemia ("B" recommendation: good evidence).28 The ADA recommends screening youth and adults with multiple risk factors for type 2 diabetes; FPG is the preferred first-line test.<sup>3,29</sup> Emerging evidence suggests that youth-onset type 2 diabetes is an aggressive disease associated with increased risk of morbidity.<sup>30</sup> In sum, patients with multiple risk factors are logical targets

	Diabetes Prevention Program (DPP) <sup>8</sup>	Study to Prevent Noninsulin-Dependent Diabetes Mellitus (STOP-NIDDM) <sup>12,13</sup>	Troglitazone in Prevention of Diabetes (TRIPOD) <sup>14</sup>
Population			
Country	USA	Canada, Germany, Austria, Norway, Denmark, Sweden, Finland, Israel, Spain	USA (Los Angeles county)
Years	1996 to 2001	1995 to 2001	1995 to 2000
Ν	3234	1429	266
Inclusion criteria	IGT and $\uparrow$ FPG	IGT and ↑ FPG	Hispanic women with history of gestational DM
Age (y, mean $\pm$ SD)	$50.6\pm10.7$	$54.3 \pm 7.9$ (intervention) $54.6 \pm 7.9$ (control)	High risk by 5 h OGTT 34.9 $\pm$ 6.6 (intervention) 34.3 $\pm$ 6.5 (placebo)
BMI (kg/m <sup>2</sup> ,	$34.0\pm6.7$	$31.0 \pm 4.3$ (intervention)	$34.5 \pm 6.5$ (placebo) $30.6 \pm 6.1$ (intervention)
mean $\pm$ SD)	$34.0 \pm 0.7$	$30.9 \pm 4.2$ (control)	$30.3 \pm 5.3$ (control)
Follow-up (mean y)	2.8	3.3	3.5
Drug	Biguanide antihyperglycemic (metformin) Thiazolidinedione (troglitazone—stopped early secondary to liver failure)	$\alpha$ -glucosidase inhibitor (acarbose)	Thiazolidinedione (troglitazone). Study terminated early secondary to liver failure
Study design	,		
Туре	RCT; individuals randomized	International, multicenter double-blind RCT	Double-blind RCT
Number of sites	27	9 countries	1
Arms	4 arms:	2 arms:	2 arms:
	Lifestyle intervention, $n=1079$ Metformin (850 mg twice daily), $n=1073$ Troglitazone (400 mg/d, discontinued 998)	$\alpha$ -glucosidase inhibitor titrated to 100 mg 3 times daily or maximum tolerated dose. $n=714$	Thiazolidinedione $400 \text{ mg/d}$ , $n=133$
	Placebo, $n=1082$	Placebo, $n=715$	Placebo, $n=133$
Diet	Standard lifestyle recommendations for med arms; written information on diet.	Instruction in weight-reducing diet	Dietary advice at annual visits
Decension	Annual counseling on healthy lifestyle.	Yearly visits with dietitian	Advised to smalle 20 mins 2 d (mls
Exercise	Encouraged to ↑ physical activity. 77% in placebo	Encouraged to exercise regularly 30% of treatment group discontinued	Advised to walk 30 min, 3 d/wk 11% (30 women) lost to follow-up
Adherence to medication	17% III placebo	early, most because of GI side effects	(11 placebo, 19 drug)
medication	72% in metformin	early, most because of GI side effects	(11 placebo, 19 dlug)
Diabetes outcomes			
Incidence	Cumulative incidence DM over 3 y:	Cumulative incidence DM at 3.3 y:	Average annual DM incidence:
mendence	Placebo 28.9%	Acarbose 32.4%	Placebo 12.1%
	Metformin 21.7%	Placebo 41.5%	Troglitazone 5.4%
	Lifestyle 14.4%	110/0	Annual incidence rates posttrial: Placebo 21.2%
			Troglitazone 3.1%
Risk reduction in	DM risk reduction over 3.3 y:	DM risk reduction over 3 y:	
intervention vs control group	Lifestyle 58% Metformin 31%	Acarbose 25%	Hazard ratio=.45

#### Table 2. Drug Trials to Prevent or Delay Diabetes

IGT, impaired glucose tolerance; FPG, fasting plasma glucose; DM, type 2 diabetes mellitus; OGTT, indicates oral glucose tolerance test; BMI, body mass index [weight in kilograms/(height in meters)<sup>2</sup>]; RCT, randomized-controlled trial.

for diabetes prevention efforts, especially if risk is confirmed through finding of IFG.

## What Preventive Strategies Should We Use to Decrease Diabetes Risk?

In the DPP, lifestyle changes were more effective than medication, and lifestyle changes do not involve exposure to medications and risk of side effects. This approach is embodied at the level of the general population in the Surgeon General's Call to Action<sup>31</sup> and the 2005 USDA Dietary Guidelines for Americans.<sup>32</sup> The studies reviewed here support directing intensive lifestyle intervention efforts toward those at highest risk based on clinical characteristics, IFG, and/or IGT.

## What are the Components of Successful Diabetes Prevention Strategies?

These studies set goals for modest weight loss for overweight participants, and for increased physical activity of moderate intensity. The recommended dietary content was similar throughout these studies, comprising less than 25% to 30% of caloric intake from fat. The DPS additionally encouraged high fiber intake; the Da Qing study specified 55% to 60% of caloric intake from carbohydrates and 10% to 15% from protein.

The DPP and DPS set weight loss goals of 7% and 5% of body weight, respectively.<sup>33,34</sup> The Malmö<sup>35</sup> and Da Qing<sup>36</sup> studies called for decreased caloric intake with a gradual weight loss in overweight subjects. The DPP and DPS set physical activity goals of 150 minutes/week, or 30 minutes/day, 5 days/week, of moderate intensity physical activity (DPP recommended brisk walking). These recommendations are consistent with the 2005 USDA Dietary Guidelines for Americans,<sup>32</sup> which promote "at least 30 minutes of moderate-intensity physical activity ... most days of the week." Da Qing recommended increased leisure physical activity defined in study-specific units, and Malmö provided 2-hour-long sessions per week of various physical activities.

Evidence from relevant epidemiologic studies provides an additional insight into dietary factors likely to lower diabetes risk. Several cohort studies showed that diabetes risk was highest for sedentary individuals who ate a "western diet" (red meat, processed meats, French fries, high fat dairy products, refined grains, sweets, and desserts).<sup>37,38</sup> Conversely, a "prudent diet" emphasizing fruits, vegetables, legumes, fish, and whole grains was associated with a lower risk. A number of prospective studies found diets high in whole grains or cereal fiber to be associated with a reduced risk for type 2 diabetes.<sup>39–42</sup>

While the "glycemic index (GI)" has gained popular attention recently, consistent evidence to support its use is lacking. The GI and its derivative, the glycemic load (GL), have been proposed as physiologic ways to categorize carbohydrates; foods are classified by how rapidly they are digested and absorbed compared with a standard food (commonly, glucose or white bread). A high GI characterizes readily digestible starch, refined grain products, and potatoes, while foods with a low/moderate GI include legumes, unprocessed grains, and nonstarchy fruits and vegetables. A few studies have shown increased diabetes risk in patients ingesting high GL; however, this finding has not been universal, and the clinical utility of the GI in diabetes prevention remains unproven.<sup>43–46</sup>

All 4 studies featured intensive interaction with staff and individualized counseling, with group sessions on a voluntary basis. Table 3 lists the key components of the lifestyle interventions, including staff qualifications and training. Each DPP participant in the lifestyle arm was assigned a master's level case manager who provided individual counseling sessions based on behavior change theory. Malmö participants could choose individual or group sessions; most opted for individual counseling.

The Finnish DPS drew upon Prochaska's Trans-theoretical (Stages of Change) Model.<sup>47–49</sup> The DPP invoked similar principles, and also sought to address the cultural background of the participants. Staff used 5 different ethnic versions of the DPP curriculum and helped participants individualize goals within their particular cultural context. Table 4 lists the topics covered in the DPP's 16 individual sessions. Complete curricular contents are available at http:// www.bsc.gwu.edu/dpp/index.htmlvdoc. Voluntary group sessions augmented individual counseling in the DPP and DPS, including lectures, cooking lessons, supermarket visits, and exercise sessions.

Each of these studies emphasized behavioral contracting around self-derived goals. While investigators set diet and weight goals for the studies overall, participants used individualized counseling sessions to set their own goals. Cognizant of various stages of change, study staff helped individual participants tailor and modify goals progressively to achieve success. Participants documented their goals in concrete terms reinforced by behavioral contracting.

Patient empowerment and self-efficacy were further enhanced through promotion of self-monitoring through use of scales and measuring cups; subjects recorded their own diet and physical activity levels and maintained charts documenting their progress.

	Diabetes Prevention Program (DPP) <sup>29</sup>	Diabetes Prevention Study (DPS) <sup>30</sup>	Da-Qing IGT and Diabetes Study <sup>32</sup>	Malmö Feasibility Study <sup>31</sup>
Staff training Staff	MDs, nurses, technicians	Not mentioned	MDs, nurses, technicians	Staff included dietitian, nurse, physiotherapist, and MD
Training	Behavior change training	Not mentioned	Behavior change training	Not mentioned
Counseling	2 d/y		2 d/y	
Format	16 core curriculum sessions on nutrition, physical activity, and behavioral self-management	Food records used as basis for tailored dietary advice 4 times/y in individualized sessions	Individual counseling on diet and exercise by physicians at 3-mo intervals	Subjects in the interventior group could choose small group or individual counseling
	Individual and group elements	7 visits with nutritionist in year 1	Small group counseling sessions weekly for 1 mo, monthly for 3 mo	Subjects received dietary information at monthly group meetings for 6 mo
	Individualized plans	Individual guidance on ↑ physical activity to improve cardiovascular fitness		60-min activity sessions 2 times/wk (e.g., calisthenics, walking- jogging, soccer, badminton) under the guidance of a physiotherapist
	Optional physical activity sessions led 2 times/wk by DPP staff Brisk walking recommended	Voluntary group walking, biking, and supervised resistance training		Smokers were advised to stop or reduce smoking
Follow-up	Follow-up sessions every 2 mo with phone calls between visits	1 session every 3 mo	1 group session every 3 mo for remainder of study	
		If weight goal not achieved in 6 to 12 mo, a very low calorie diet (VLCD) was considered		
Social support	Spouses invited to join sessions	Spouses invited to join sessions, especially if responsible for shopping/cooking		Spouses invited to monthly group meetings

#### Table 3. Key Components of Lifestyle Interventions

Session	Title	Content	Rationale
Session 1A	Welcome to the Lifestyle Balance Program	Reasons for joining DPP, benefits, goals	Build commitment, heighten awareness of risk, and increase awareness of benefits. Begin to set personal goals
Session 1B	Getting Started Being Active	Participants choose intervention goal to begin with: increasing physical activity or losing weight	Increase commitment and ownership by encouraging patient to choose own goals
Session 1B	Getting Started Losing Weight		
Session 2	Move Those Muscles	Personal experience, preferences, self-monitoring	Build awareness of habits and preferences by self-monitoring of activity. Increase self-efficacy by reviewing past successes
Session 3	Being Active: A Way of Life	Finding time for physical activity; safety	Begin to schedule physical activity to fit it into patient's lifestyle
Session 4	Be a Fat Detective	Sources of fat, self-monitoring, goal setting	Learn to identify fat sources. Begin to set personal fat goals
Session 5	Three Ways to Eat Less Fat	Measuring portions	Learn to weigh and measure foods and estimate appropriate portion size
Session 6	Healthy Eating	Meal planning	Learn the importance of planning for timing and content of meals and helpful eating behaviors (e.g., eating slowly)
Session 7	Take Charge of What's Around You	Cues at home; stimulus control; choices	Learn cues in environment that prompt unhealthy food and activity choices; learn to alter cues
Session 8	Tip the Calorie Balance	What it takes to lose 1 to 2 pounds/wk	Learn energy balance and what it takes to lose 1 to 2 pounds a week
Session 9	Problem Solving	Identify problems, brainstorm solutions, plan steps, evaluate outcomes	Learn 5-step problem-solving approach: describe problem, brainstorm solutions, pick solution, create action plan, and evaluate success
Session 10	Four Keys to Healthy Eating Out	Planning, assertion, stimulus control, choices	Develop healthy dining out approach: anticipate and plan, assertion, stimulus control, and healthy food choice
Session 11	Talk Back to Negative Thoughts	Substituting positive thoughts	Identify common pattern of negative thoughts and practice countering them with positive statements
Session 12	The Slippery Slope of Lifestyle Change	Triggers for slip-ups; strategies for recovery	Recognize that slips are normal; identify personal triggers for slips, reactions, and strategies for recovery
Session 13	Jump Start Your Activity Plan	Heart rate, fitness, variety of physical activity	Introduce aerobic fitness: measure heart rate and perceived exertion, add variety to fitness plan
Session 14	Make Social Cues Work for You	Dealing with social pressure	Managing problematic social cues; increasing helpful social cues
Session 15	You Can Manage Stress	Assertion, social supports, problem solving	Acquire stress management techniques: assertion, social support, problem solving, planning, countering negative thoughts
Session 16	Ways to Stay Motivated	Ongoing goals and support strategies	Acquire relapse prevention skills/maintain motivation: review personal reasons for joining, personal successes, setting new goals, seeking social supports

These studies acknowledged the importance of family and social context in targeting diabetes prevention efforts. Spouses of study subjects were encouraged to participate in the individualized counseling sessions in the DPP, DPS, and Malmö studies. Fisher et al.<sup>50</sup> identified the family as the primary social context for the recognition, understanding, and management of diabetes and other chronic health conditions. Family is a key source of social supports and stresses, and interventions that target 1 member necessarily affect others. Therefore, these studies sought to engage family members whenever possible to optimize outcomes.

These studies incorporated vigorous follow-up efforts, especially for subjects having less success. Subjects failing to meet initial goals were actively encouraged by staff. The DPP used computer monitoring to track program adherence and trigger actions for "recovery" of participants failing to reach goals. DPP staff used a stepped strategy to optimize outcomes, with a "toolbox" of problem-solving strategies valued at \$100 annually per participant, including exercise tapes and classes, personal trainers, cookbooks, and other resources.

Provider profiling was utilized as a means for quality assurance at the systemic level. Each of the 27 DPP sites received monthly feedback on their performance in attaining weight and activity goals relative to other sites.

### How Can a Busy Clinician Incorporate Practical Strategies to Promote Lifestyle Change into an Office Visit?

These trials utilized behavior change strategies in the context of ongoing relationships with trial staff. Similarly, brief behavior-change counseling strategies can be effectively incorporated into patient encounters in the office setting.<sup>51,52</sup> Research on lifestyle change has shown that individuals progress through 5 sequential stages in making changes, and that different strategies are useful at various stages.<sup>47–49,53–55</sup> Counseling messages individualized to the patient's readiness to change are more successful, while mismatched messages often lead to patient and clinician frustration. By recognizing that many patients are in the early stages of change, clinicians can modify their expectations and redefine success as helping patients move along the continuum of change rather than as reaching a desired final outcome.

Behavioral counseling to decrease diabetes risk can be guided by the Five A's model, which was adapted by the US-PFTF<sup>56</sup> from the National Cancer Institute's model for physician counseling of smokers,<sup>57</sup> and has been studied in a variety of brief primary care interventions.<sup>58–60</sup> The Five A's involve *assessing* the patient's lifestyle risk factors and readiness to change, *advising* specific behavioral change, *agreeing* on behavior change goals, *assisting* the patient in acquiring information, skills, and confidence required to progress toward goals, and *arranging* follow-up. Asking patients nonjudg-mentally about current diet and exercise behaviors, the physician can readily assess current practices, knowledge of risks, and readiness to change. Subsequent behavior change *advice* should be clear, strong, and personalized: "As your doctor, I think it's important for you to change your diet and increase your physical activity so you can reduce your risk for developing diabetes in the next few years."

Within the Five A's model, brief counseling approaches can be guided by the principles of motivational interviewing,<sup>61</sup> a patient-centered approach that elicits behavior change by helping patients address their ambivalence regarding recommended change. Brief versions of motivational interviewing developed for primary care settings emphasize building rapport, assessing patients' beliefs about the importance of behavior change, and their self-efficacy for change.<sup>62</sup> Counseling strategies for patients who do not believe that health behavior change is important include providing information, giving feedback, and exploring the patient's ambivalence. Counseling strategies for patients with low self-efficacy include reviewing prior successful change attempts, focusing on manageable steps, and enhancing problem-solving skills.

The importance of *arranging* follow-up underscores the ongoing nature of behavior change and the role of the clinicianpatient relationship in supporting changes. Follow-up on progress within regularly scheduled clinic appointments is essential, but may not be sufficient. Additional follow-up with a dietitian, nurse, or behavioral expert may help some patients make and sustain meaningful health behavior changes. Examples of brief counseling interventions matched to stages of change are given in Table 5.

### What Specific Recommendations Should Practitioners Make Regarding Physical Activity?

To decrease the risk of developing diabetes, patients should engage in moderate-intensity physical activity most days of the week. The type of exercise must be tailored to the patient's ability and preferences. To increase sustainability, the patient should enjoy the activity and be willing to make it a priority. For most patients, brisk walking is an appropriate start; those with arthritis may prefer water-based exercise or nonweightbearing activities like bicycling. In addition, patients should be counseled to increase physical activity in daily routines, such as taking the stairs or parking farther away from buildings. Patients should accumulate at least 150 minutes/week of physical activity. Exercise should be of moderate intensity; patients may feel slightly out of breath and feel their heart beating more quickly, but they should not feel exhausted or unable to sustain the activity. Further counseling suggestions are given in Table 6.

### Should Persons with IFG Who Plan to Begin Exercising Undergo Exercise Stress Testing?

The American College of Cardiology/American Heart Association recommend testing asymptomatic individuals with multiple cardiac risk factors, or men over age 45 and women over age

	Precontemplation (No Intention of Making Change)	Contemplation (Considering Making Change, But Ambivalent)	Preparation (Intends to Take Action Within Next Month)	Action (Has Changed Behavior Less Than 6 mo)	Maintenance (Has Changed Behavior More Than 6 mo)
	Patient-Centered Goals	Evaluate Pros and Cons of Behavior Change	Personal Commitment	Stimulus Control	Reinforce Self-Efficacy
Agree	"Would you be willing to think about the benefits of weight loss and exercise, and we can talk more the next time you're in?"	"While you see some obstacles to exercise and weight loss, you also see some benefits. What are some of those benefits for you?"	"Have you thought about setting a date to start changing your diet and exercise?"	"Do you think it would help if you replaced some of the cookies and ice cream in your house with healthier snacks?"	"It sounds like you got a little off track over the holidays. How confident are you that you can get your exercise and diet back on track?"
Assist	Encourage Increased Awareness "Would you be interested in learning more about some of the personal health benefits of just modest exercise and weight loss?"	Self-Reevaluation "Can you picture yourself as a more active, healthier person? What would that be like for you?"	Self-Monitoring "It might be helpful to keep track of what you're eating now, so when you start to change your diet, you'll know what to change."	Feedback, Self-Reward "Do you think a pedometer might give you some helpful feedback on how far you're walking each day?"	Plan for Relapse "Can you anticipate any obstacles or situations that would keep you from exercising and eating the way you have been?"
Arrange	Validate Lack of Readiness "At your next appointment, after you've given it some thought, we can talk more about whether you think exercise and weight loss are the right thing for you now."	Brainstorm Obstacles and Solutions "At your next appointment, let's talk more about some of those barriers to your exercise and weight loss."	Establish Social Resources "If you'd like, I could refer you to our dietitian. You could meet with her regularly to get a better understanding of your diet, what you might change, and what you don't need to change."	Bolster Self-Efficacy "At your next appointment, bring in your food records so we can see how much you've reduced your calorie intake."	Plan for Follow-up Social Support "At your next appointment, could you bring in your wife? I'd like to share with her all the progress you've been making in reducing your diabetes risk."

#### Table 5. Brief Counseling Messages Tailored to Stages of Change

#### Table 6. Counseling on Physical Activity and Nutrition

Goal of 150 min of moderate-intensity exercise weekly         Tailor physical activity to individual's ability and interest         Walking for most; bicycling or water-based for those with arthritis         Encourage increased activity in daily routines         Take the stairs; park farther away; get off bus 1 stop early         Previously inactive individuals should begin with short amounts of moderate-intensity exercise (for example, 10 min) and gradually increase the duration and/or intensity         Goal-set with individuals on preferred way to accrue 150 min weekly         For example, 30 min of walking 5 d weekly or 50 min of walking 3 d weekly         Make goals specific in time, amount, and activity         Encourage self-monitoring of activity by keeping written records, using a pedometer, or using a heart rate monitor         Nutrition         Standard at room temperature)         Encourage portion size awareness and reading food labels         Increase dietary fiber to 20 to 30 g/d         Diet should be high in whole grains, fruits and vegetables, beans, and nuts         Goal-set with individual on preferred initial changes to diet         For example, piece of fruit at lunch each day, or red meat no more than once a week         Make goals specific in time, amount, and type         Encourage self-monitoring by keeping food logs         Both         Encourage self-monitoring by keeping food logs         Both	hysical activity
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	Arrange close follow-up

55 who plan to begin a vigorous exercise program. However, this recommendation is rated level IIB (conflicting evidence).  $^{63}$ 

### What Specific Recommendations can Practitioners Make Regarding Dietary Change and Composition?

The overall goal for diabetes prevention is to reach and maintain an active, healthy weight with a tendency toward a hypocaloric diet. As summarized in Table 6, evidence supports limiting total calories and fat (<25% of caloric intake) and increasing dietary fiber (20 to 30 g/day). Essential skills include understanding portion sizes and reading food labels. Involvement of a dietitian is optimal to assess dietary history, navigate challenges inherent in change, and prevent relapse.

#### Are Diabetes Prevention Efforts Cost-Effective?

The DPP Research Group conducted detailed cost-effective analyses from both the health system and societal perspectives.<sup>64,65</sup> From a societal perspective, lifestyle and drug interventions cost \$24,400 and \$34,500, respectively, for each case of diabetes prevented or delayed within the 3-year time horizon of the study. These costs are well within the generally accepted range for preventive strategies, and would be relatively lower if benefits were to persist beyond the study period. Sensitivity analysis estimating societal costs for lifestyle and drug interventions as they might be implemented in clinical practice projected \$13,200 and \$14,300, respectively, per case prevented. Lifetime cost-utility analysis<sup>65</sup> projected costs per quality-adjusted life year of \$1,100 and \$8,800 for the lifestyle intervention from the health care and societal perspectives, respectively. Cost-effectiveness simulations for diabetes prevention are limited in that they are based on experience with research subjects, which may not generalize to the broader population, and such models are based on assumptions regarding long-term health outcomes. We do not yet have direct evidence from studies with long-term follow-up as to whether diabetes prevention efforts represent a cost-effective way to prevent or delay the clinically important complications of diabetes.<sup>6</sup>

# How Can Health Care Systems Help Prevent Diabetes?

Although we have focused on practitioners, health systems may have an important role in diabetes prevention. We lack data on system-based approaches to diabetes prevention, but a variety of such techniques improve outcomes for patients already diagnosed with diabetes. Examples include computerized reminders and provider feedback,66 multidisciplinary teams providing patient education and follow-up,66 self-management education in community settings,<sup>67</sup> disease management (organized, multicomponent approach to diabetes care), and case managers coordinating care.<sup>67</sup> Some of these approaches may be adaptable for diabetes prevention. Multidisciplinary care teams consisting of nurses, dietitians, and health educators may provide more intensive counseling and increase the contact that a patient has with the health care system. Printed materials or interactive computer programs in offices can reinforce counseling efforts. Telephone support can be brief and effective. Group classes may help selected patients. Public health interventions are also needed to create safe environments for exercise and promote healthy lifestyles in schools and workplaces. Future studies judging the effec-

#### CONCLUSIONS

Clinical trials have shown conclusively that diabetes can be prevented by lifestyle modification, at costs generally considered acceptable to society. Evidence from these trials suggests that clinicians should recommend behavior changes for asymptomatic patients at high risk for diabetes. High-risk patients can be identified through clinical characteristics augmented with judicious screening by fasting glucose. Although the diabetes prevention trials used intensive strategies for effecting lifestyle change, clinicians can translate key elements from those strategies into brief, office-based counseling on physical activity and dietary change.

Implementing diabetes prevention will require significant paradigm shifts for both patients and clinicians. Modest goals for weight loss and physical activity are appropriate; behavioral contracting and self-monitoring may enhance self-efficacy and outcomes for patients. We must educate clinicians in training and in practice about the potential benefits of diabetes prevention and strengthen training for behavioral change within medical education.

Diabetes prevention efforts need to be tailored for particular participants and settings. Despite implementation across very different cultures, however, these lifestyle prevention studies demonstrated remarkably consistent outcomes. Cultural adaptations for office-based counseling may be challenging in diverse communities; enlisting community resources may enhance these efforts.

Relationships and social context are key factors for diabetes prevention. In these trials, close coaching relationships with study staff facilitated lifestyle change by participants. Successful diabetes prevention efforts will likely require enlisting important family members, enhancing clinician-patient relationships, practice innovations facilitating feedback to clinicians and patient follow-up, and broader societal changes supporting healthy lifestyles in the context of schools, communities, and workplaces.

The rigorous cost-effectiveness analyses of the DPP provide a compelling case for increased insurance coverage of nutrition and physical activity interventions in persons at high risk for diabetes. Even in an era when patients switch insurance carriers every few years, savings may accrue rapidly through prevention or delay of diabetes. Less costly group intervention in clinical settings bears further investigation, and studies of the effects on complication rates are needed.

These diabetes prevention trials have shown dramatically how diabetes can be prevented or delayed through lifestyle changes. Many aspects of these prevention programs appear adaptable for use in clinical settings at present. Successfully implementing diabetes prevention on a large scale will require improved clinician-patient communications as well as innovative systems of care, making further translational research a priority.

This work was supported by the National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Research and Training Center (P60 DK20595). Dr. Burnet is supported by a Mentored, Patient Oriented, Career Development Award (K23 DK064073-01), and Dr. Chin was a Robert Wood Johnson Foundation Generalist Physician Faculty Scholar.

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