Medical Management of Prediabetes

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From clinical trial evidence which of the following types of diabetes can be prevented?

- a. Type 1 diabetes
- b. Type 2 diabetes
- c. Gestational diabetes
- d. Steroid induced diabetes

Clinical trials of diabetes prevention have been conducted in all of the following populations EXCEPT?

- a. Chinese men and women
- b. Elderly Americans
- c. Women with gestational diabetes
- d. Obese children
- e. Persons at risk of type 1 diabetes

Which of the following are **proven** risk factors for type 2 diabetes?

- a. Obesity
- b. Sugar sweetened beverage consumption
- c. Having a first degree relative with diabetes
- d. Gestational diabetes
- e. Being sedentary

Prediabetes refers to which of the following results?

- a. Fasting plasma glucose 5.6-6.9mmol/L
- b. 2 hour glucose after 75g OGTT of 7.9-11.0mmol/L
- c. An HbA1c of 5.7-6.9% on a NSGP standardized assay
- d. All of the above

Most diabetes prevention studies have been conducted populations that meet which of the following criteria for pre-diabetes?

- a. Fasting plasma glucose 5.6-6.9mmol/L
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Which of the following medications have been demonstrated to reduce the risk of diabetes in patients with prediabetes?

- a. Metformin
- b. Pioglitazole
- c. Acarbose
- d. Liraglutide
- e. Orlistat
- f. None of the above

Which of the following medications have been approved by the US Food and Drug Administration for diabetes prevention?

- a. Metformin
- b. Pioglitazole
- c. Acarbose
- d. GLP-1 receptor agonists
- e. Orlistat
- f. None of the above

The Diabetes Prevention Programme found that lifestyle change was most effective in preventing diabetes among which of the following groups of persons?

- a. Men
- b. Those with elevated fasting glucose
- c. Participants over 60 years old
- d. Participants under 45 years old

Which of the following medications have been demonstrated to reduce the risk of both cardiovascular events and diabetes?

- a. Metformin
- b. Pioglitazole
- c. Acarbose
- d. Atorvastatin

Which of the following have the potential to "reverse" diabetes

- a. Bariatric surgery
- b. Metformin
- c. Very Low Calorie Diets
- d. Sitagliptin

Objectives

At the end of this presentation and with the use of supplemental reading the participant should be able to:

- a.Describe the natural history of type 2 diabetes
- b. Identify modifiable and non-modifiable risk factors for type 2 diabetes
- c.Define pre-diabetes
- d.Explain the clinical importance of pre-diabetes why it can be a critical point for intervention
- e.Discuss the findings from major clinical trails that have attempted to reduce the risk of type 2 diabetes in vulnerable populations through pharmacological and non-pharmacological methods.
- f.Discuss the role of newer pharmacological agents on type 2 diabetes risk and prevention

What is Diabetes?

- Definition A syndrome of inappropriate metabolism of carbohydrate protein and fat related to insufficient production of insulin, inappropriate usage of insulin or both
- This dysmetabolism is the cause of the many complications of the disease, resulting in a huge cost to the healthcare system

Why is Diabetes Important?

- Associated with acute and chronic complications
- Acute
 - diabetic ketoacidosis, hyperglycemic hyperosmolar states, hypoglycemic states
- Chronic
 - Microvascular Complications eye, kidney, nerve damage
 - Macrovascular heart, peripheral vascular disease, stroke and amputations

Symptoms of Diabetes

- Can be asymptomatic type 1 diabetes tends to be acute in onset so this period is short but for type 2 diabetes symptoms may only occur 3-5 years after the onset of the disease !!
- Increased thirst (polydypsia)
- Increased urination (polyuria)
- Weight loss
- Blurred vision
- Coma ketoacidosis or hyperglycemic hyperosmolar coma (HHS)
- Death

Diagnosing Diabetes The 1997 ADA criteria

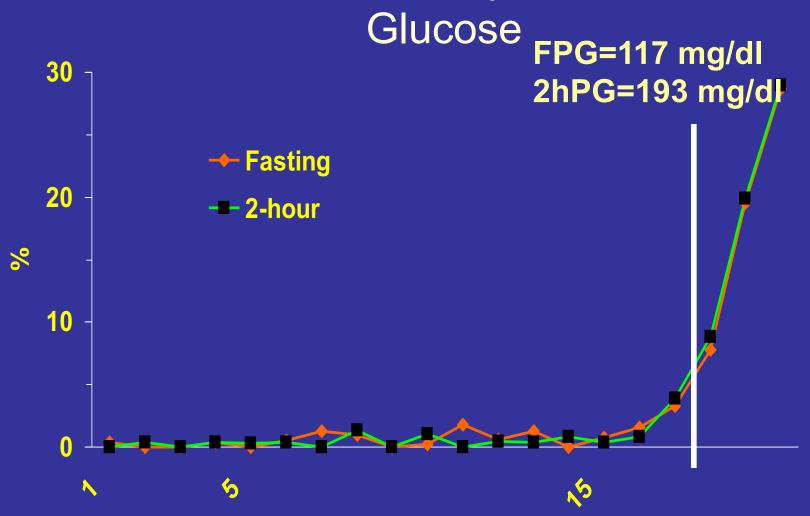
 Symptoms of diabetes with a random plasma glucose of ≥ 11.1 mmol/l

Fasting (no caloric intake for at least 8 hours)
 plasma glucose ≥ 7.0 mmol/l*

 2 hour plasma glucose during an Oral Glucose Tolerance Test using 75g of anhydrous glucose dissolved in water of ≥ 11.1 mmol/l*

*Confirm by repeat testing on another day

Retinopathy in 5,023 Pima Indians by 5-Percentile Groups of Plasma



Groups by Glucose

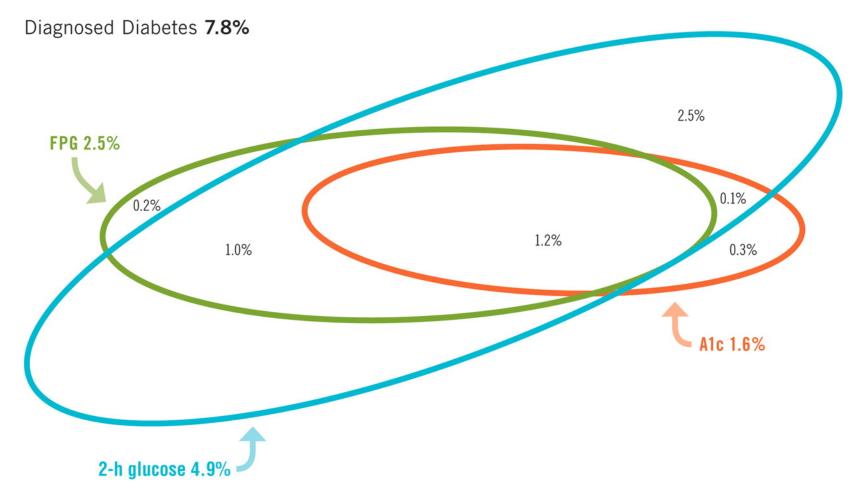
Gabir, Diabetes Care, 2000

Diabetes Diagnosis - Expert Committee

- Glucose measurements are not as standardized.
- Glucose is not stable at room temperature even in a Fluoridated Tube.
- The HbA1c requires no preparation, is more stable at room temperature, less day to day variability, more work internationally has been done to standardize the assay.
- Recommended a HbA1c value > 6.5% be used to diagnose diabetes

Undiagnosed diabetes in the U.S. population aged ≥20 years by three diagnostic criteria—NHANES 2005–2006.

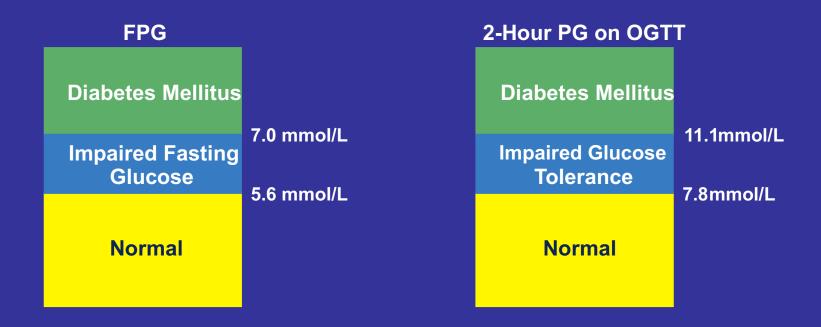
No Diabetes 86.9%



Catherine C. Cowie et al. Dia Care 2010;33:562-568



Glucose Tolerance Categories



Adapted from The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care*. 1997;20:1183-1197 Report of a WHO Consultation. Definition, diagnosis and classification of diabetes mellitus and its complications: part 1. Geneva: WHO/NCD/NCS 1999, p1-66

Prediabetes

- Abnormal fasting plasma glucose (Impaired Fasting Glucose /IFG)
 - 5.6 6.9mmol/L (ADA definition)
- Abnormal 2 hour plasma glucose after 75g OGTT (Impaired Glucose Tolerance /IGT)
 - 7.8-11.0mmol/L
- Abnormal HbA1c 5.6-6.4%

Prediabetes

 Not a clinical entity in itself but identifies persons who are at increased risk of type 2 diabetes

 Associated with obesity, dyslipidemia (high triglycerides or low HDL-cholesterol) and hypertension

Barbados Heath of the Nation Study Undiagnosed Diabetes and Pre-Diabetes Prevalence (95% Confidence Interval)

	Fasting Plasma Glucose	HbA1c
Undiagnosed Diabetes	3.5 (2.4-5.1)%	5.5 (4.1-7.3)%
Pre-diabetes	15.0 (12.8-17.5)%	34.1 (30.6-37.7)%

Excluding 16% of the sample with established diabetes

Type 1 diabetes

Aeitology is unclear

- Autoimmunity and Genetic factors may increase predisposition to an environmental trigger
- No clear risk factors have been identified

 Antibodies may predict risk but routine screening not recommended as diagnostic methods not standardized, no interventions helpful

Type 2 Diabetes

Aetiology is unclear but risk factors consistently identified include

Non Modifiable

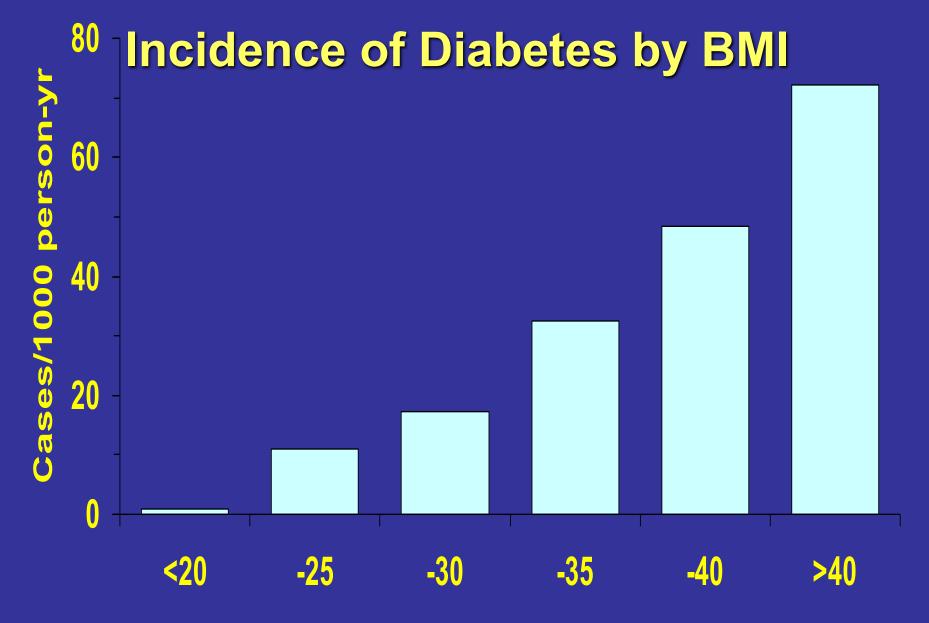
- Age
- Genetic Factors Family history of diabetes / Ethnicity
- Macrosomia mother at increased risk?
- History of gestational diabetes

Type 2 Diabetes

Aetiology is unclear but risk factors consistently identified include

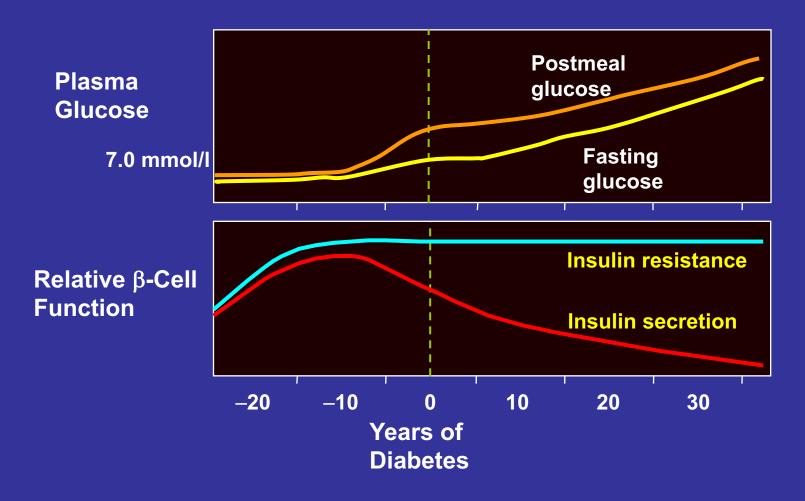
Modifiable Risk Factors

- Obesity
- Sedentary lifestyle
- Dyslipidaemia
- Hypertension
- Smoking
- Diet



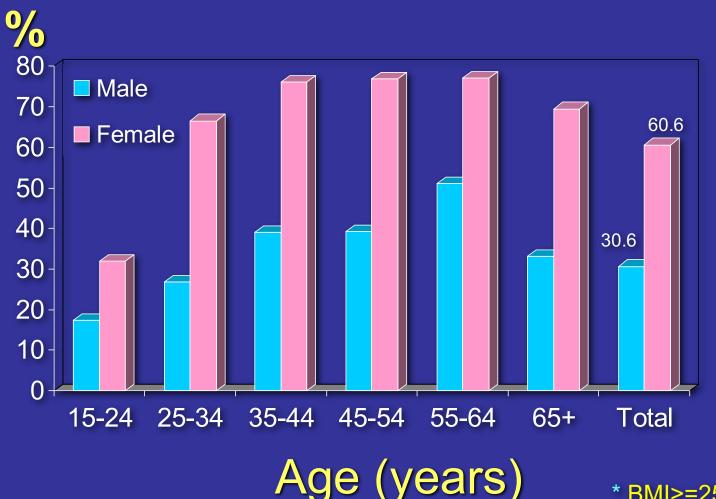
Knowler: Am J Epidem, 1981 Body Mass Index (kg/m2)

Natural History of Type 2 Diabetes

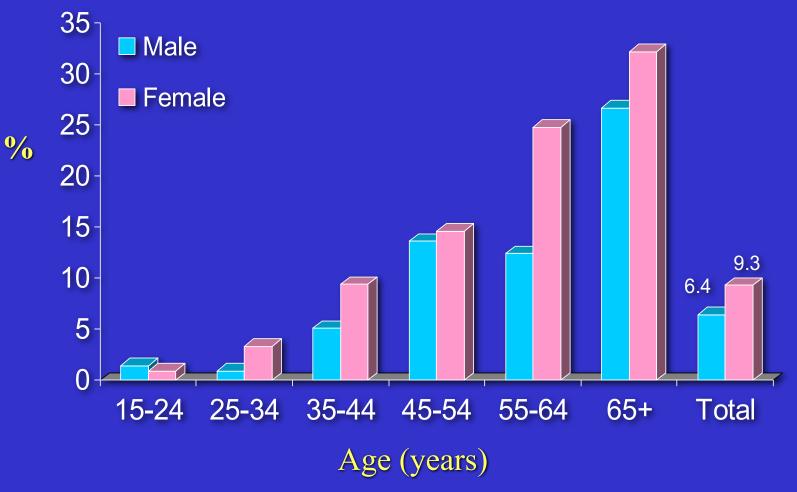


Adapted from International Diabetes Center (IDC). Minneapolis, Minnesota.

Prevalence of Overweight & Obesity* by Age Group & Gender



Prevalence of Diabetes in Jamaica by Age Group & Gender



2007/08 Jamaica Health and Lifestyle Survey

Jamaica Health and Lifestyle Survey I and II Comparison

Disease Condition	JHLS-2000	JHLSII-2008
Diabetes Mellitus	7.2(6.0-8.3)	7.9(6.7-9.0)
Hypertension*	20.9(18.4-23.2)	25.2(23.3-27.2)
Overweight (25-29.99 kg/m²)	26.1(23.5-28.7)	26.4 (24.5- 28.6)
Obese (≥30 kg/m²)*	19.7(17.4-22.0)	25.3 (22.8- 27.4)

^{*} Statistically significant

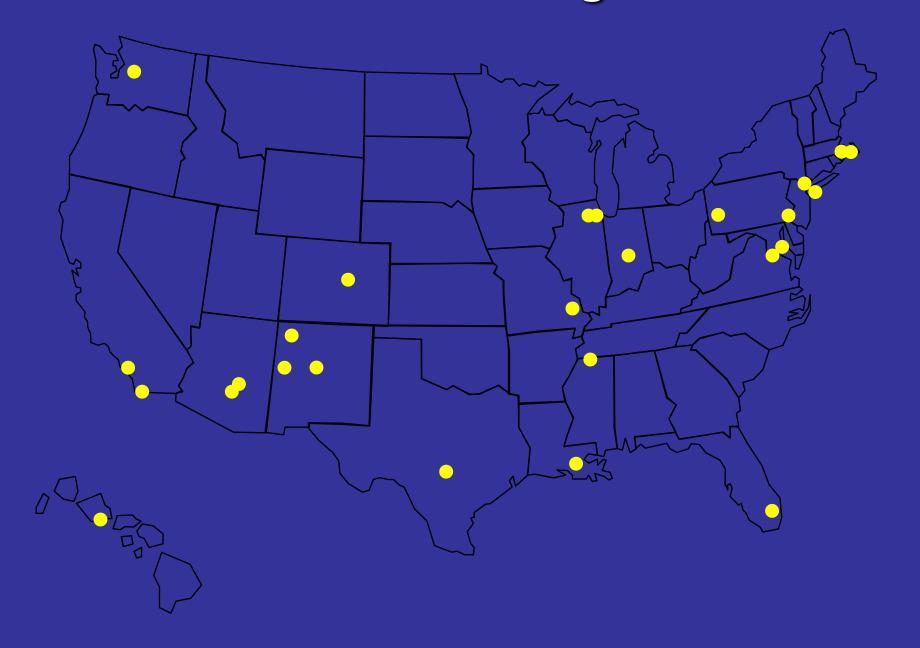
UDOP 2009 31

Preventing Type 2 Diabetes

Evidence from several clinical trials that lifestyle changes can prevent type 2 diabetes in persons with impaired glucose tolerance

- Da Qing Study
- Finnish Diabetes Prevention Study
- Diabetes Prevention Program

Diabetes Prevention Program Clinics



Eligibility Criteria

- Age ≥ 25 years
- Plasma glucose
 - 2 hour glucose 140-199 mg/dl (7.8- < 11.1 mmol/L) and
 - Fasting glucose 95-125 mg/dl (5.3- <7.0 mmol/L)</p>
- Body mass index ≥ 24 kg/m²
- All ethnic groups
 goal of up to 50% from high risk populations

DPP Treatments

- Lifestyle Goals
 - 7% weight loss
 - 150 minutes activity each week
- Metformin Goals
 - -850 mg twice daily





Study Interventions

Eligible participants



Randomized



Standard lifestyle recommendations



Intensive Lifestyle (n = 1079)



$$(n = 1073)$$

$$(n = 1082)$$

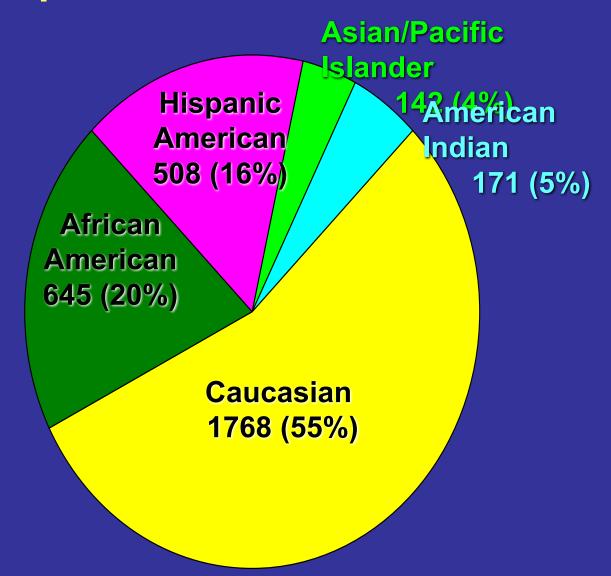
Primary Outcome: Diabetes

- Annual fasting plasma glucose (FPG) and 75 gm Oral Glucose Tolerance Test
 - FPG \geq 126 mg/dL (7.0 mmol/L) or
 - $-2-hr \ge 200 \text{ mg/dL } (11.0 \text{ mmol/L}),$
 - Either confirmed with repeat test
- Semi-annual FPG
 - ≥ 126 mg/dL, confirmed

Lifestyle Intervention Structure

- 16 session core curriculum (over 24 weeks)
- Long-term maintenance program
- Supervised by a case manager
- Access to lifestyle support staff
 - Dietitian
 - Behavior counselor
 - -Exercise specialist

DPP Population



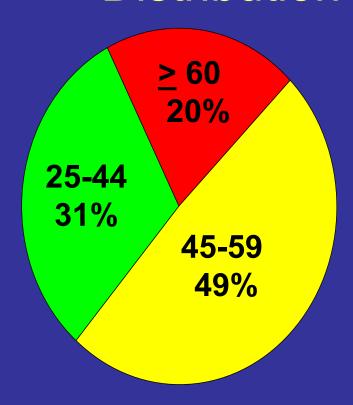
The DPP Research Group, Diabetes Care 23:1619-29, 2000

DPP Population

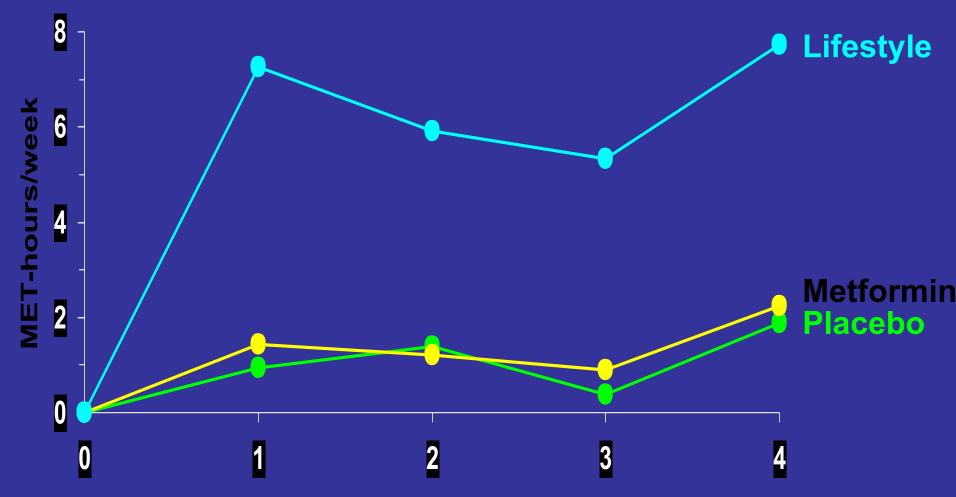


Men 32% Women 68%

Age Distribution

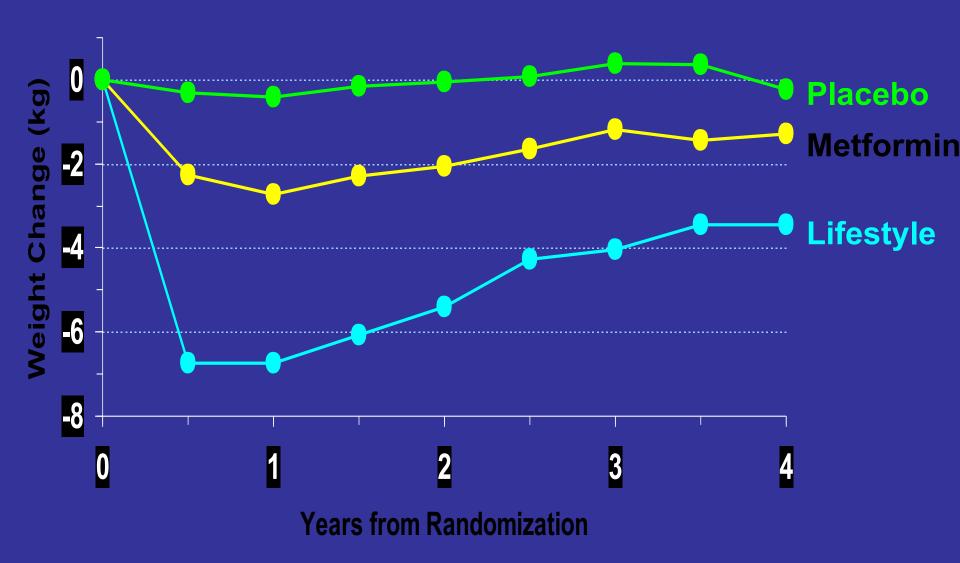


Mean Change in Leisure Physical Activity

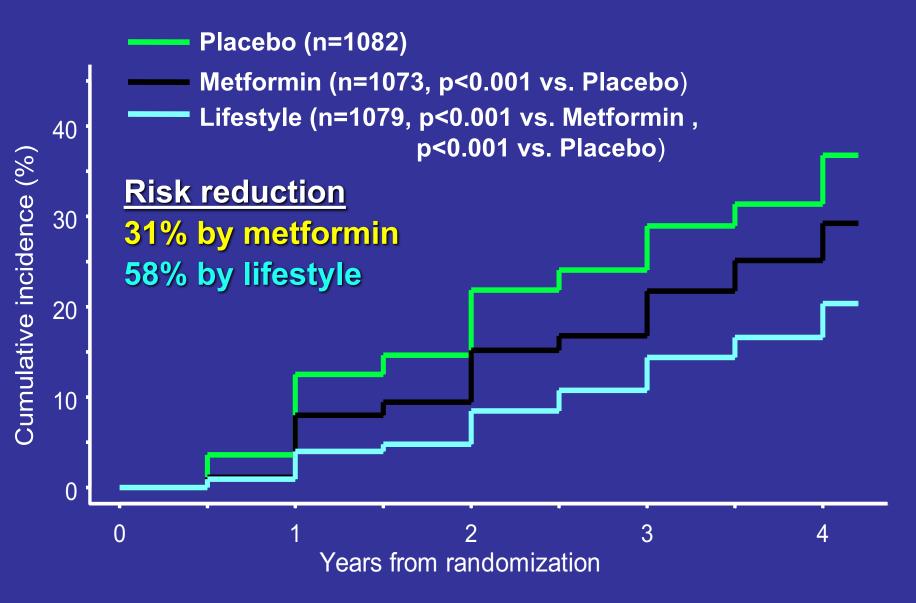


Years from Randomization

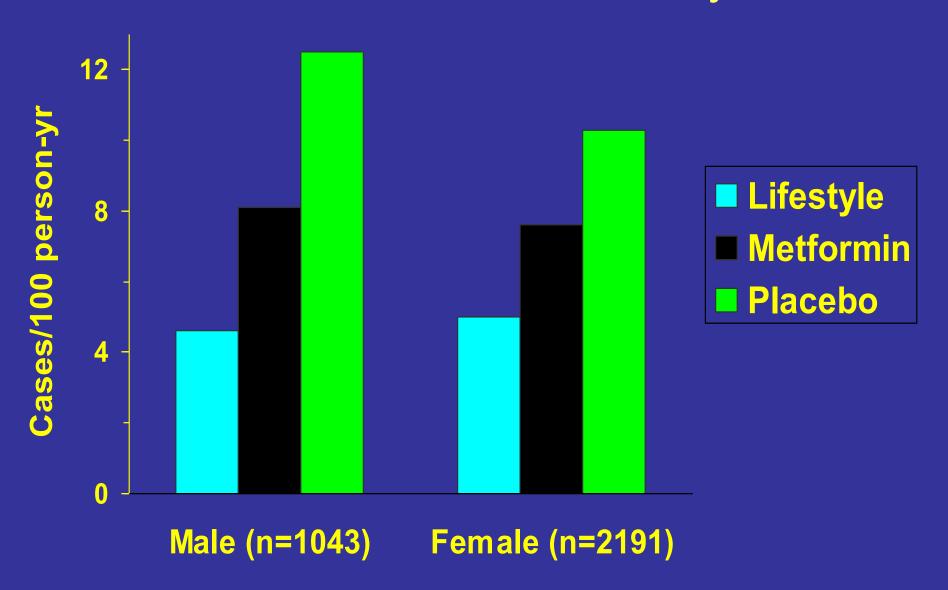
Mean Weight Change



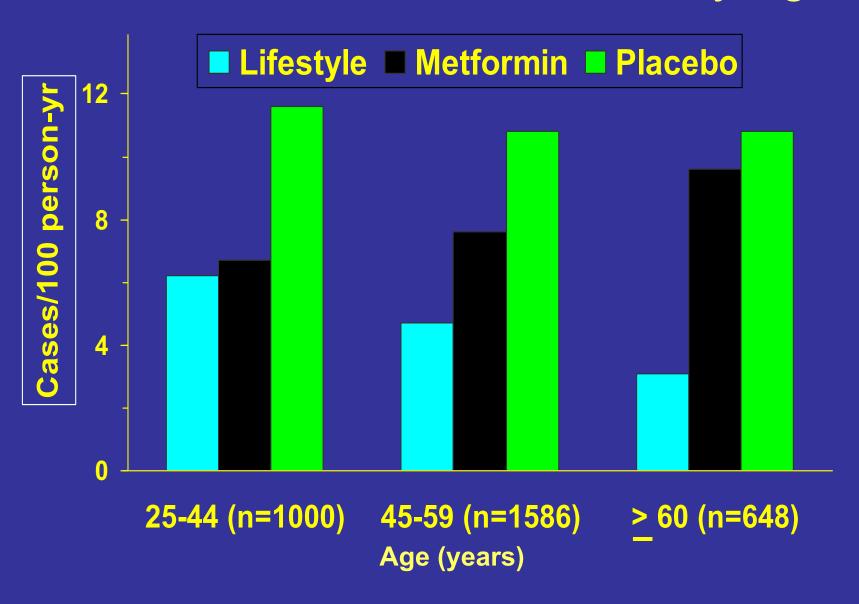
Incidence of Diabetes



Diabetes Incidence Rates by Sex



Diabetes Incidence Rates by Age



Metformin in DPP

- Most effective in DPP participants:
 - -BMI > 35
 - **Age 25-44 years**
- Little risk reduction in DPP participants :
 - -BMI 24-30
 - –Age ≥60 years





DPPOS Diabetes Risk Reduction

- Delay in diabetes onset after 10 years follow-up:
 - –4 years for Lifestyle
 - -2 years for Metformin
- The lower rate of diabetes development for lifestyle and metformin during DPP means:
 - Original Lifestyle participants have a 34% lower risk of diabetes compared to Placebo
 - Original Metformin participants have a 18% lower risk of diabetes compared to Placebo





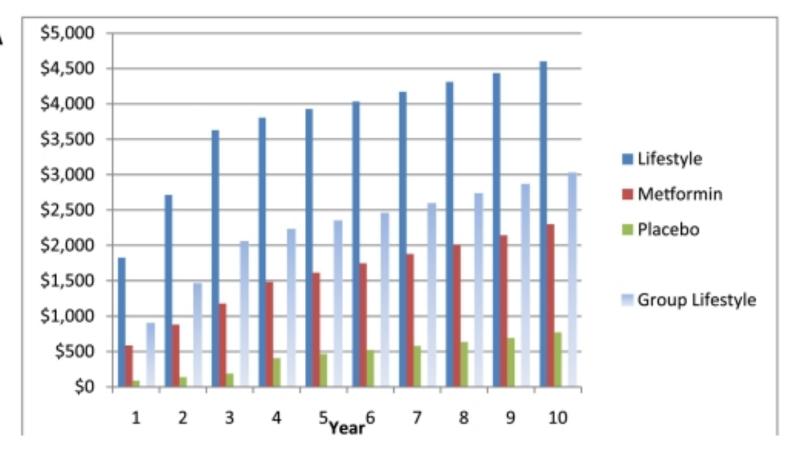
DPPOS 15 year Follow Up

 Diabetes incidence 27% in the lifestyle intervention group and 18% in the metformin group

 No differences in combined microvascular complications: placebo 12·4%, metformin 13·0%, lifestyle 11·3% but incidence lower in those who did not develop diabetes, regardless of group

Cost Effectiveness



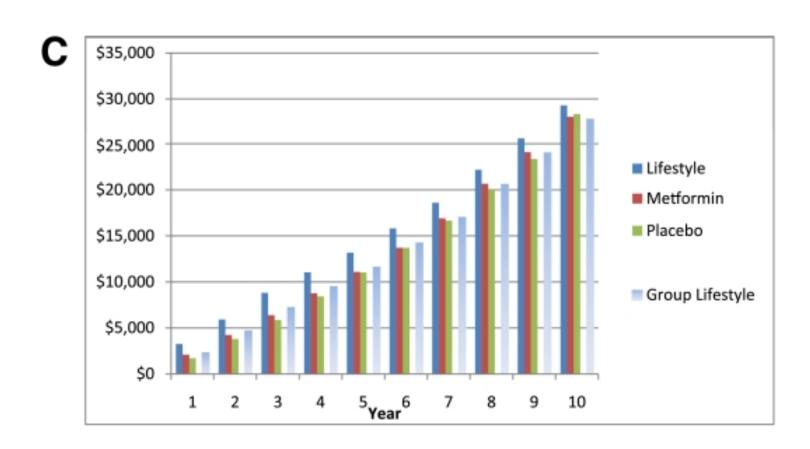




Cumulative, undiscounted, per participant, direct medical costs of the DPP/DPPOS interventions by intervention group and study year.



Cost Effectiveness





Cumulative, undiscounted, per participant, total direct medical costs of the DPP/DPPOS interventions and medical care received outside the DPP/DPPOS by intervention group and study year



Making Lifestyle more Cost Effective

Group vs. individual sessions for lifestyle

 New approaches to delivery –virtual small groups, Internet-driven social networks

Use of technology – Mobile apps

Diabetes Educators of the Caribbean Diabetes Prevention Workshop



The *DREAM* Trial

Aims: Does ramipril 15 mg/d prevent diabetes?

Does rosiglitazone 8 mg/d prevent diabetes?

Design: 2 X 2 factorial, double-blind RCT

Sample: Age 30+; IGT (FPG <7 & 2 hr 7.8-11) &/or IFG (FPG 6.1-6.9)

Pts: 5269 in 191 sites, 21 countries, & F/U 3 yrs

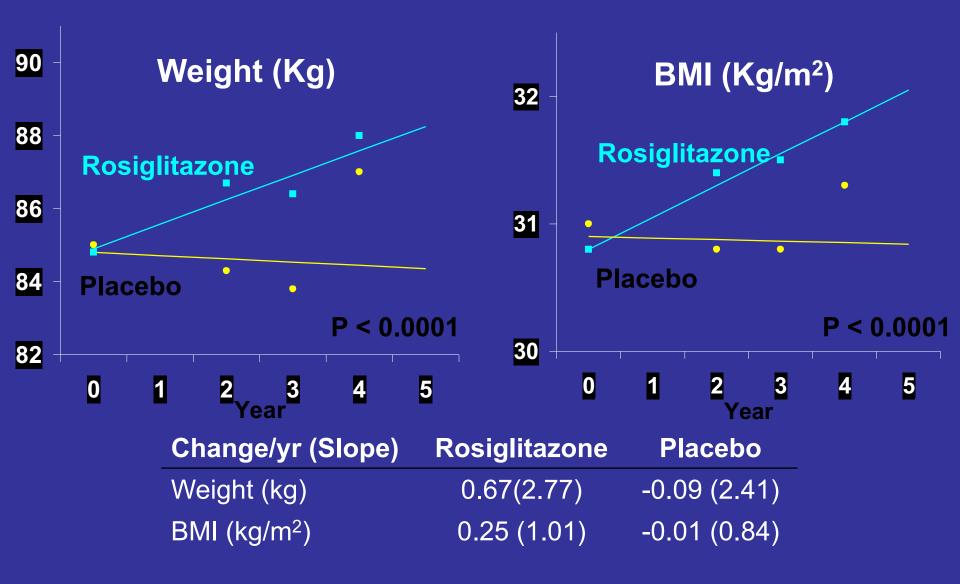
Outcome: Incident DM (confirmed FPG \geq 7 or 2 hr \geq 11.1; or MD diagnosis) or death*

^{*}because undiagnosed diabetes may be more frequent in those who die than in those who do not

Adherence/Adverse Effects

		Rosiglitazone	Placebo		
On Study Drug	at 1 year	88.4%	91.3%		
	at 2 years	83.7%	87.7%		
	at 3 years	79.5%	84.0%		
Reasons for Stopping Study Drug					
Participant Refusal		19.1%	16.7%		
Edema		4.8%	1.6%		
MD advice		1.9%	1.5%		
Weight Gain		1.9%	0.6%		

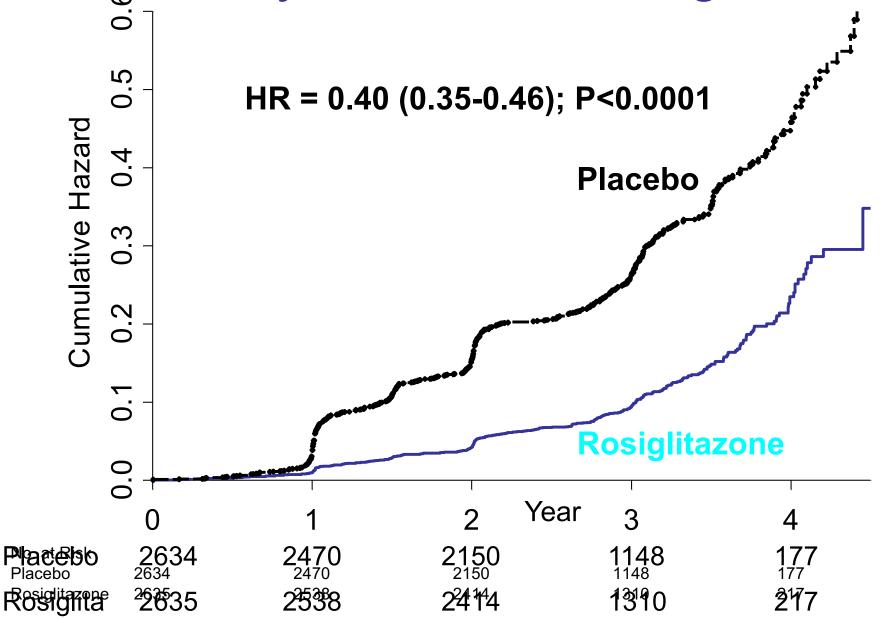
Rosiglitazone & Weight, BMI



Rosiglitazone & Primary Outcome

	Rosi N=2635	Placebo N=2634	HR (95% CI)	Р
Primary Composite	306 (11.6)	686 (26.0)	0.40 (0.35-0.46)	<0.0001
Diabetes	280 (10.6)	658 (25.0)	0.38 (0.33-0.44)	<0.0001
Dx by FPG/OGTT	231 (8.8)	555 (21.1)	0.38 (0.33-0.44)	<0.0001
MD Diagnosed	49 (1.9)	103 (3.9)	0.47 (0.33-0.66)	<0.0001
Death	30 (1.1)	33 (1.3)	0.91 (0.55-1.49)	0.70

Primary Outcome: Rosiglitazone



Summary & Conclusions: Rosiglitazone

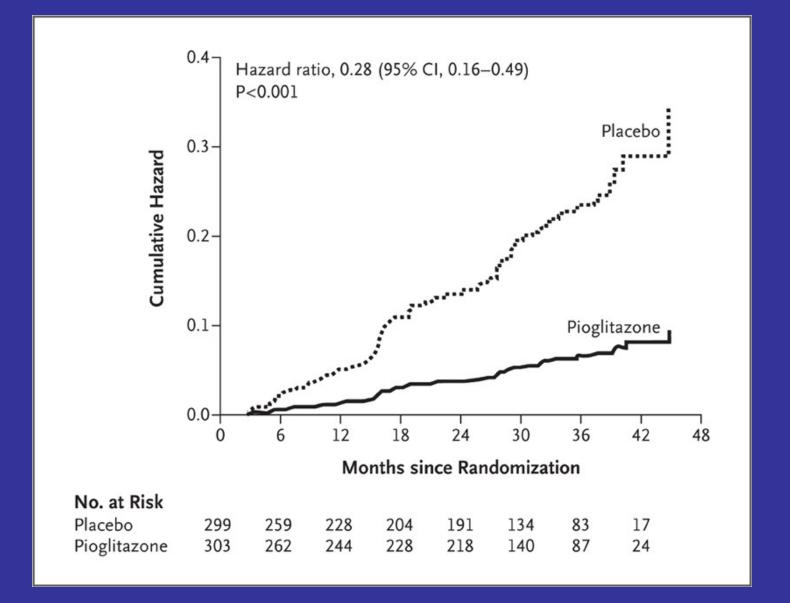
- A dose of 8 mg/day reduces new DM by > 60% in people with IGT or IFG
- Promotes regression to normal FPG & 2 hr PG by >70%
- Effective in all regions of the world
- Eliminates the gradient of DM risk with increasing weight
- ~ 3% increase in body weight, but a favourable effect on waist/hip ratio
- Reduces ALT

ACT Now Study

 A total of 602 patients were randomly assigned to receive pioglitazone or placebo.

 Intervention - 30 mg of pioglitazone per day or placebo. One month after randomization, the dose of pioglitazone was increased to 45 mg per day.

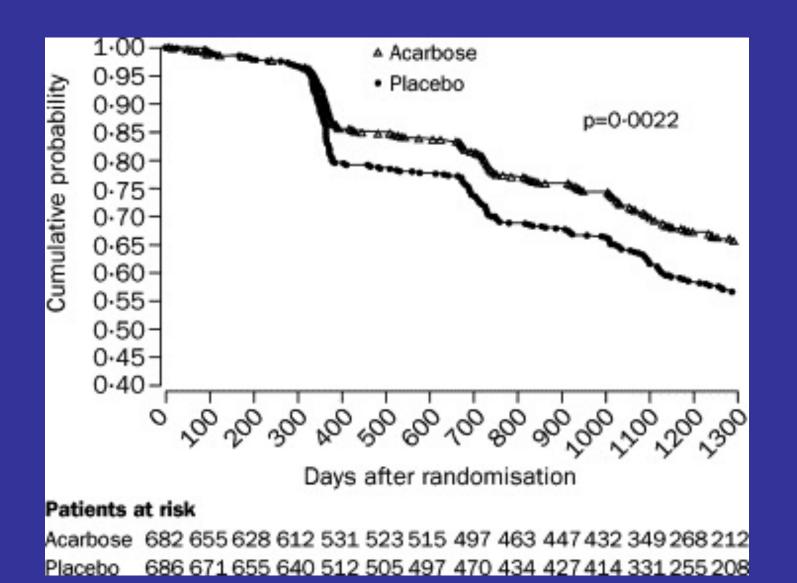
ACT Now



STOP NIDDM Trial

- Population multi-centre study conducted in patients with IGT from Canada, Germany, Austria, Norway, Denmark, Sweden, Finland, Israel, and Spain - 714 patients to acarbose and 715 to placebo.
- Intervention- placebo or 100 mg of acarbose 3 times a day, taken with the first bite of each meal
- Drop out 211 (31%) of 682 patients in the acarbose group and 130 (19%) of 686 on placebo.

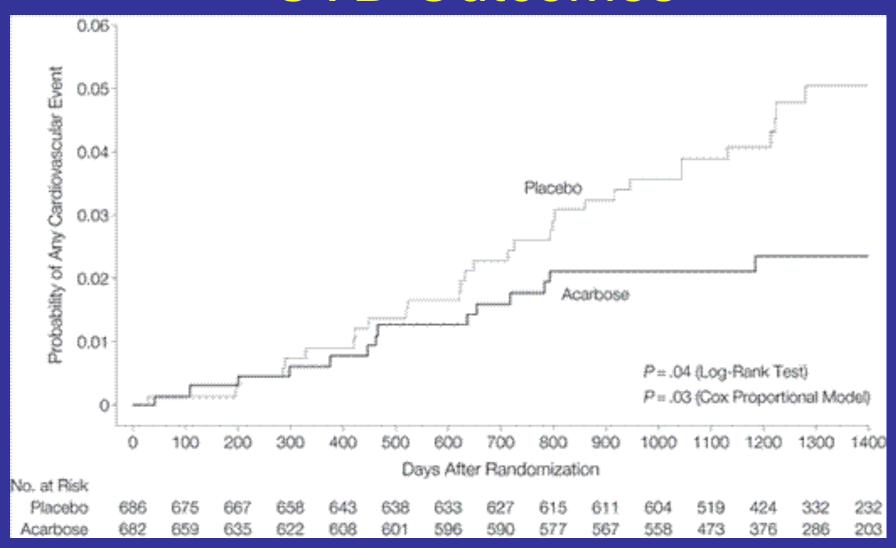
STOP NIDDM Trial - Diabetes



STOP NIDDM Trial - Diabetes

• 221 (32%) patients randomised to acarbose and 285 (42%) randomised to placebo developed diabetes (relative hazard 0.75 [95% CI 0.63-0.90]; p=0.0015).

STOP NIDDM Trial - CVD Outcomes



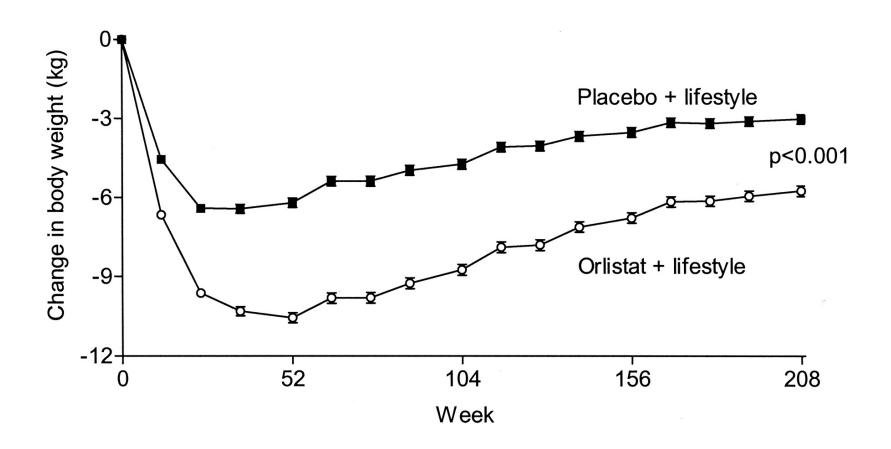
STOP NIDDM Trial - CVD

- 49% relative risk reduction in the development of cardiovascular events (hazard ratio [HR], 0.51; 95% confidence interval [CI]; 0.28-0.95; P =.03) adjusted HR(0.47; 95% CI, 0.24-0.90; P =.02) mainly from reduction in the risk of myocardial infarction (HR, 0.09; 95% CI, 0.01-0.72; P =.02).
- 34% relative risk reduction in the incidence of new cases of hypertension (HR, 0.66; 95% CI, 0.49-0.89; P = .006) – adjusted HR (0.62; 95% CI, 0.45-0.86; P = .004)

XENical in the Prevention of Diabetes in Obese Subjects (XENDOS) Study

• 3,305 patients with a BMI ≥30 kg/m² (21% with impaired glucose tolerance)

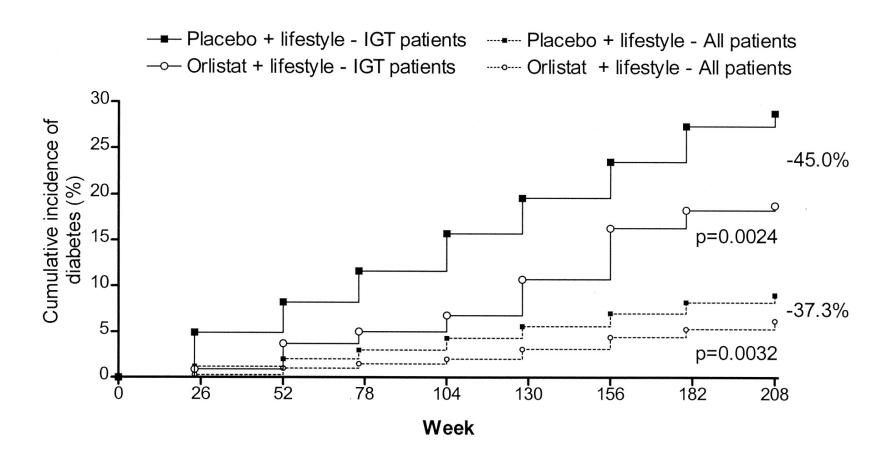
 Intervention – Orlistat 120 mg or placebo, three times daily. Weight loss (means ± SEM) during 4 years of treatment with orlistat plus lifestyle changes or placebo plus lifestyle changes in obese patients (LOCF data).



Jarl S. Torgerson et al. Dia Care 2004;27:155-161



Cumulative incidence of diabetes by study group in all obese patients (IGT or NGT at baseline) and only in obese patients with IGT at baseline.



Jarl S. Torgerson et al. Dia Care 2004;27:155-161



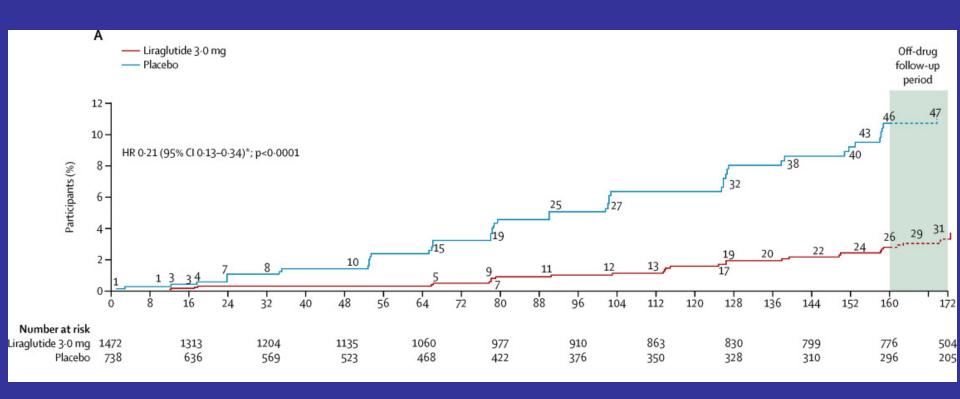
Liraglutide

 2254 adults with prediabetes and a body-mass index of at least 30 kg/m², or at least 27 kg/m² with comorbidities recruited in 2:1 ratio

 Intervention - once-daily subcutaneous liraglutide 3·0 mg or matched placebo

 By week 160, 26 (2%) of 1472 individuals in the liraglutide group versus 46 (6%) of 738 in the placebo group

Liraglutide and Type 2 diabetes incidence



Medications for Diabetes Prevention

None recommended by FDA

 ADA - balance the risk/benefit of each medication - cost, side effects, and durable efficacy require consideration.

 Metformin has the strongest evidence base and demonstrated long-term safety as pharmacologic therapy for diabetes prevention

Medications for Diabetes Prevention

- Metformin less effective than lifestyle modification in the DPP/ DPPOS, though group differences declined over time
- Metformin may be cost-saving over a 10year period
- For women with history of GDM, metformin and intensive lifestyle modification led to an equivalent 50% reduction in diabetes risk

Medications for Diabetes Prevention

Metformin should be recommended as an option for high-risk individuals (e.g., those with a history of GDM or those with BMI ≥35).

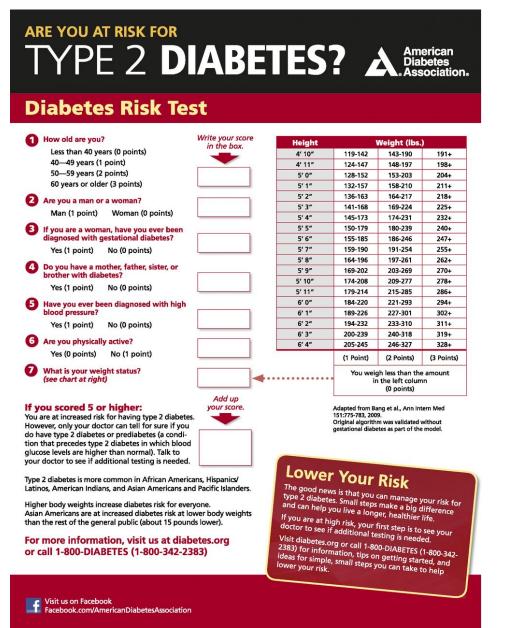
Check Vitamin B12 levels with use

ADA Screening for Pre-Diabetes

Overweight persons (BMI > 25 or 23 kg/m²) with

- First-degree relative with diabetes
- High-risk race/ethnicity
- History of CVD
- Hypertension (≥140/90 mmHg or on therapy for hypertension)
- HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a triglyceride level >250 mg/dL (2.82 mmol/L)
- Women with polycystic ovary syndrome
- Physical inactivity
- Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)

ADA risk test (diabetes.org/socrisktest).





Diabetes Reversal

If diabetes does occur can it be reversed?

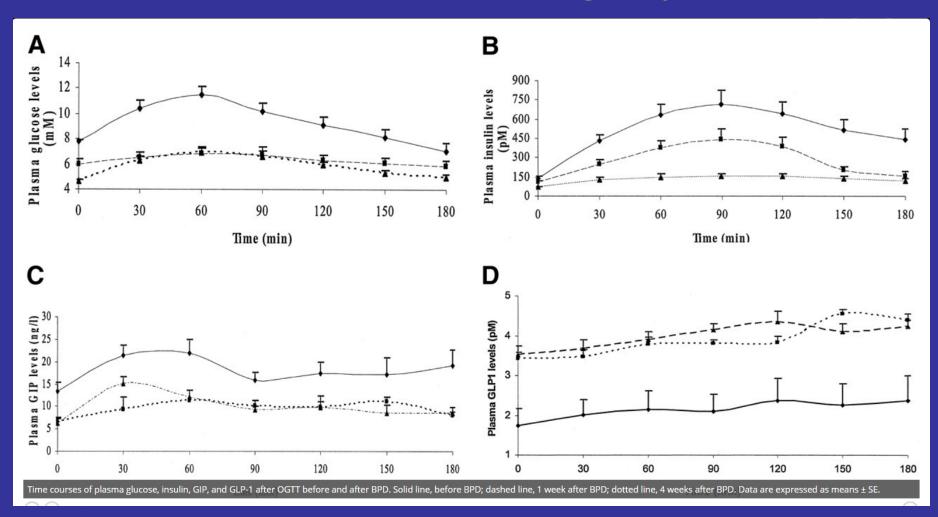
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If diabetes does occur can it be reversed?

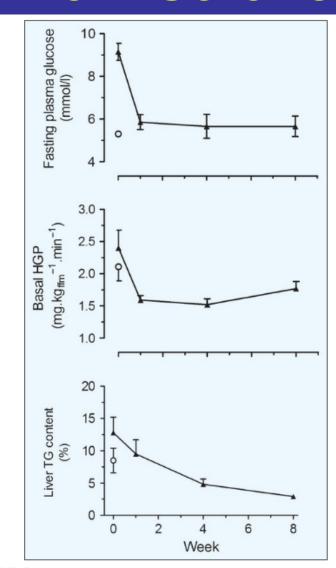
Potentially - needs to be done early.

 Reversal related to duration of diabetes and also degree of weight loss

Diabetes Reversal – Bariatric Surgery



Reversing Diabetes Very Low Calorie Diet



DIRECT Study

- Population: 20-65 years who had been diagnosed with type 2 diabetes within the past 6 years, BMI of 27-45 kg/m², and were not receiving insulin
- Intervention: withdrawal of antidiabetic and antihypertensive drugs, total diet replacement (825-853 kcal/day formula diet for 3-5 months), stepped food reintroduction (2-8 weeks), and structured support for long-term weight loss (15kg) maintenance

Results

• Of 305 participants remission of diabetes took place in 68 (46%) participants in the intervention group and 6 (4%) participants in the control group (odds ratio 19·7, 95% CI 7·8-49·8; p<0·0001).

Remission related to weight loss

Summary

- Intensive lifestyle interventions can prevent or delay progression to type 2 diabetes in persons with pre-diabetes
- Several medications have been shown to reduce disease progression and may have other health benefits.
- New approaches can also help reverse type 2 diabetes in those who fail prevention efforts

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- c. Participants over 60 years old
- d. Participants under 45 years old

The Diabetes Prevention Programme found that lifestyle change was most effective in preventing diabetes among which of the following groups of persons?

- a. Men
- b. Those with elevated fasting glucose
- c. Participants over 60 years old
- d. Participants under 45 years old

Which of the following medications have been demonstrated to reduce the risk of both cardiovascular events and diabetes?

- a. Metformin
- b. Pioglitazole
- c. Acarbose
- d. Atorvastatin

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- b. Metformin
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MARK YOUR CALENDER! DIABETES CLINICAL UPDATE 2018

THE CCDE ADVISORY BOARD

INVITES YOU TO JOIN US

FOR A ONE DAY DIABETES WORKSHOP & SYMPOSIUM

- THE 2018 AMERICIAN DIABETES ASSOCIATION (ADA) GUIDELINES
- CARDIOVASCULAR OUTCOMES AND THE NEW ORAL AGENTS USED TO MANAGE T2DM
- PATIENT/ PROVIDER PERSPECTIVES IN DIABETES MANAGEMENT IN JAMAICA TODAY –
 SUCCESSES/ BARRIERS TO CARE
- TARGETED THERAPY FOR PREVENTING AND SLOWING RENAL DISEASE IN DIABETES
- NEW INSULINS AND INJECTABLE AGENTS FOR THE MANAGEMENT OF DIABETES
- THE WAY FORWARD FOR DIABETES CARE IN JAMAICA DEVELOPING A STRATEGY

