

Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among People at Increased Risk

Study Characteristics

Randomized Controlled Trials (Adults)

Author, Year, PMID*	Country Setting Multicenter	Recruitment setting Intervention setting	Funding	Eligibility criteria: Definition of "at risk for DM"	Eligibility criteria: Age, y Adiposity	Other eligibility criteria	Exclusion criteria
Ackermann 2008 18779029	US Urban Multicenter	Community Community	NIDDK and the Indiana University School of Medicine	"At risk for DM" (ADA risk score and capillary blood glucose 110-199 mg/dL)	None BMI ≥ 24 kg/m ²		Diagnosis of DM, CV event, severe COPD, advanced arthritis, poorly controlled HTN
Ackermann 2014 24740868	US Regional Recruited in two test markets, but each person watch TV in their home	Community Television	UnitedHealth; Comcast	Prediabetes diagnosis from healthcare provider or one or more of the following risk factors: (a) high blood pressure; (b) abnormal blood cholesterol; (c) a parent or sibling who has/had type 2 DM; or (d) a personal history of gestational DM	≥ 18 overweight or obese; ≤ 140 kg		Planning bariatric surgery within 6 months; physician-diagnosed DM; poorly controlled high blood pressure ($>180/105$ mmHg); being pregnant or actively planning pregnancy; symptoms of chest pain, dizziness, or severe shortness of breath with exertion; advice from a healthcare provider not to increase physical activity or attempt weight loss; another condition that significantly limits physical activities (e.g., advanced heart or lung disease, anemia, severe arthritis)
Admiraal 2013 23894322	Netherlands Urban	Primary care clinic	The Netherlands Organization	PreDM, IGT, or IFG (by various	18-60 NR	FPG 5.7–6.9 mmol/L, 2h OTT 7.8–10.9	Newly diagnosed type 2 DM (i.e. a fasting glucose ≥ 7.0 mmol/l, a 2-h post-load glucose ≥ 11.0 mmol/l, or

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	Multicenter	Primary care clinic	for Health Research and Development (ZonMw)	glycemic criteria)		mmol/L, HbA1c 42–46 mmol/mol, and/or a value of 2.39 or more for the homeostasis model assessment of estimated insulin resistance (HOMA-IR)	a hemoglobin (Hb)-A1c level ≥ 48 mmol/mol), those already in a lifestyle program, those pregnant, know chronic disease or using drugs that interfere with plasma glucose levels
Bhopal 2014 24622752	UK Regional Unclear	Direct referrals, Primary care clinic, Community Unclear	National Prevention Research Initiative	PreDM or IGT (by glycemic criteria) (WHO criteria)	≥ 35 NR	Indian or Pakistani origin; waist measurements ≥ 90 in men and ≥ 80 in women	Long-term oral corticosteroids, or weight loss medication, or with health disorders making adherence contraindicated or improbable, or pregnant, or who were unlikely to remain in the UK for 3 years
Cezaretto 2012 21538199	Brazil Urban Unclear	Primary care clinic Primary care clinic	NR	PreDM, IGT, or metabolic syndrome (by glycemic criteria) (ADA and IDF criteria)	18-79 None	None	Living out of Sao Paulo metropolitan area; pregnant women; neurological or unstable psychiatric problems; antidiabetic agents or medications for weight control; and neoplasias, chronic communicable diseases, hepatic or renal failure, and untreated thyroid dysfunctions
Cole 2013 23589326	US Urban	Department of Defense beneficiaries	Brooke Army Medical Center Department of Pathology	PreDM, IGT, or IFG (by glycemic	≥ 18 NR	Fluent in English	Diagnosis of DM or not having attended the initial prediabetes education class

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	Single center	Unclear		criteria) (ADA criteria)			
De la Rosa 2008 No PMID	US Urban Single center	Primary care clinic Primary care clinic	NR	Metabolic syndrome (IDF criteria) or other at risk for DM & CVD	NR NR	NR	NR
Dunbar 2010 No PMID	Australia Regional Multicenter	Primary care clinic Primary care clinic	Ray and Joy Uebergang Foundation, Warrnambool, Australia	DM risk score (FINDRISC ≥ 12)	40-75 None	Individuals in GGT DPP who completed the program, did not develop DM and were willing to participate in the follow-up	Outside 40-75 years age limit; developed DM
Gagnon 2011 21489843	Canada Urban Single center	Primary care clinic, Specialty clinic, or Community Specialty care clinic	Novo Nordisk Endocrine Resident Research Award; Ministry of Health of Québec; Funding Agency for Human Health Research of Quebec	IGT or IFG (by glycemic criteria) (WHO criteria)	>18 BMI ≥ 27 kg/m ²	None	Unable to comply with the proposed intervention, had taken pharmacological treatment for obesity or any medications known to alter glucose tolerance
Gillison 2015 25592314	UK Regional	Primary care clinic	NIHR	IGT or IFG (by glycemic criteria) (WHO criteria) or at	40-74 28 Kg/m ² - 45 Kg/m ²	None	Existing heart disease or type 2 DM, or currently using weight loss drugs, not fluent in English, terminal illness and anyone who, in

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	Multicenter	Primary care clinic		high cardiovascular risk hypertension, hypercholesterolemia, family history of DM or heart disease, history of gestational DM, or polycystic ovary syndrome			their General Practitioner's opinion, had other co-morbidities which would prevent engagement with the intervention.
Iqbal Hydrie 2012 22888411	Pakistan Urban Multicenter	Primary care clinic Unclear	NR	IGT (undefined)	>30 NR	NR	NR
Janus 2012 22929458	Australia Regional Multicenter	Primary care clinic Primary care clinic	National Health and Medical Research Council	DM risk score (AUSDRISK score ≥ 15)	50-75 NR	NR	Diagnosed DM, cancer, severe mental illness, substance abuse, recent MI, pregnancy, difficulty with spoken and written English, belonging to a cultural group for whom the AUSDRISK test is not calibrated and other household members involved in study
Kanaya 2012 22698027	US Urban Multicenter	Community Community	NIDDK and NIA	DM risk score (ad hoc) and glycemic criteria (ad hoc: capillary blood glucose 106-160 mg/dL)	None None	None	DM; MI in past 6 mo; CHF, or stroke; heart procedure or heart surgery in past 6 mo; implanted defibrillator; hip or knee replacement in past 3 mo; insufficient cognitive functioning; pregnancy; and individuals not conversant in English or Spanish, or with plans to move out of the area

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							within 1 year, and whose spouse or partner had already enrolled
Katula 2011 23498294	US Suburban Single center	Community Community	NIDDK	PreDM (by glycemic criteria) (ADA)	None BMI 25–40 kg/m ²	None	Recent history of an acute CVD event, clinical history of type 2 DM, uncontrolled HTN, cancer or other conditions limiting life expectancy, chronic use of medicines known to influence glucose metabolism, and major psychiatric or cognitive problems
Knowler 2002 11832527	US Regional Multicenter	Primary care clinic Unclear	NIH, CDC, Indian Health Service, General Clinical Research Center Program, National Center for Research Resources; the American Diabetes Association; Bristol-Myers Squibb; and Parke- Davis	PreDM or IGT (by glycemic criteria) (ADA)	≥25 BMI ≥24 kg/m ² (≥22 kg/m ² in Asians)	None	Individuals taking medicines known to alter glucose tolerance or if they had illnesses that could seriously reduce their life expectancy or their ability to participate in the trial.
Kosaka 2005 15649575	Japan Urban Single center	Primary care clinic Primary care clinic	NR	IGT or IFG (by glycemic criteria) (WHO)	NR NR	NR	Previous history of DM; diagnosed or suspected malignant neoplasm; diagnosed or suspected disease of the liver, pancreas, endocrine organs, or kidney; ischemic heart

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							disease or cerebrovascular disease or a history of such disease
Kulzer 2009 19509014	Germany Regional Single center	Unclear Unclear	Roche Diagnostics, Germany	PreDM (by glycemic criteria) (undefined)	20-70 BMI \geq 26 kg/m ²	Ability to read and understand German	Manifest DM or diagnosis of a serious illness. All patients gave informed consent.
Liao 2002 12196418	US Urban Single center	Primary care clinic Primary care clinic	National Institutes of Health Grants, the Medical Research Service of the Department of Veterans Affairs	PreDM (by glycemic criteria) (undefined)	NR NR	Japanese-American	History or evidence of significant CAD, valvular heart disease; HTN; arthritis; pulmonary, neurologic, or psychiatric disease or dementia that hindered their ability to participate; unusual dietary restrictions; current use of lipid-lowering drugs; or tobacco use. Participants were also excluded if laboratory tests showed evidence for liver or kidney disease or anemia or if triglyceride levels were $>$ 300 mg/dL.
Ma 2013 23229846	US Urban Single center	Primary care clinic Primary care clinic	NIDDK, AHA, Palo Alto Medical Foundation Research Institute	Prediabetes or metabolic syndrome (by glycemic criteria) (ADA)	\geq 18 BMI \geq 25 kg/m ²	None	Serious medical or psychiatric conditions (eg, stroke, psychotic disorder) or special life circumstances (eg, pregnancy, planned move)
Moore 2011 20945253	Australia Urban, rural Multicenter	Primary care clinic, Community Unclear	Victorian Government (Australia)	PreDM, IGT, or IFG (by glycemic criteria) (WHO)	NR NR	NR	DM

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Nilsen 2011 22117618	Norway Regional Multicenter	Primary care clinic Primary care clinic	NR	DM risk score (FINDRISC Score ≥9)	18-64 None	None	Diagnosis of DM, the presence of serious heart, lung, kidney or liver failure, serious psychiatric illness, substance abuse and not mastering the Norwegian language
Ockene 2012 22390448	US Urban Single center	Community Community	NIDDK, NHLBI	DM risk score (San Antonio Diabetes Risk Score)	≥25 BMI >24 kg/m ²	Self-reported Latino/Hispanic; >30% likelihood of being diagnosed with DM in next 7.5y	FPG ≥126 mg/dL, inability or unwillingness to give informed consent, clinically diagnosed DM, a plan to move out of the area within the study period, presence of a psychiatric illness which limits ability to participate, no telephone, inability to walk unaided or walk five city blocks (1/4 mile) without stopping, having a medical condition likely to limit lifespan, taking a medication or having a medical condition that interfered with the assessment for DM, or having an endocrine disorder that alters blood sugar
Oldroyd 2006 16297488	UK Urban Single center	Primary care clinic Primary care clinic	Grants from the British Heart Foundation, Northern & Yorkshire NHS Research and Development and the Royal College of General Practitioners	IGT (by glycemic criteria) (WHO)	24-75 None	European origin	Individuals who were pregnant, on therapeutic diets or unable to undertake moderate physical activity

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Pan 1997 9096977	China Urban Multicenter	Primary care clinic Primary care clinic	World Bank; Ministry of Public Health PRC; CDC; China-Japan Friendship Hospital; Da Qing First Hospital	IGT (by glycemic criteria) (WHO)	>25 NR	NR	NR
Penn 2009 19758428	UK Urban Single center	Primary care clinic Unclear	Wellcome Trust	PreDM, IGT, or IFG (by glycemic criteria) (WHO)	>40 BMI >25 kg/m ²	None	A diabetic value in a second OGTT, previous DM, or with chronic illness that would make participation in moderate physical activity impossible, or on a special diet for medical reasons
Ramachandran 2006 16391903	India Urban NR	Community Unclear	M/S US Vitamins	IGT (by glycemic criteria) (WHO)	35-55 NR	NR	NR
Ramachandran 2013 24622367	India Regional Multicenter	Work sites Unclear	UK-India Education and Research Initiative (UKIERI) and World Diabetes Foundation	PreDM or IGT (by glycemic criteria) (unclear criteria)	35-55 BMI 23 kg/m ²	Positive family history of type 2 DM	Major illness such as cancer, chronic liver or kidney disease; no disorders with cognitive impairment, severe depression or mental imbalance; physical disability that would prevent regular physical activity; recruitment in another trial
Roumen 2008 18445174	Netherlands Urban Multicenter	Specialty care clinic Specialty care clinic	Dutch Diabetes Research Foundation; the	PreDM or IGT (by glycemic criteria) (ad hoc: 2 hour	40-70 None	Caucasian	Known DM, chronic illness, medication known to interfere with glucose tolerance, participation in vigorous exercise and/or diet program

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			Netherlands Organization for Health Research and Development; Netherlands Organization for Scientific Research	glucose 7.8-12.5 mmol/L)			
Saito 2011 21824948	Japan Regional Multicenter	Primary care clinic Primary care clinic	All Japan Federation of Social Insurance Associations (the Zensharen)	PreDM, IGT, or IFG (by glycemic criteria) (WHO)	30-60 BMI ≥25 kg/m ²	None	DM or receiving treatment for DM; having a history of ischemic heart disease, stroke, chronic hepatitis, liver cirrhosis, chronic
Sakane 2011 21235825	Japan Regional Multicenter	Primary care clinic Primary care clinic	Ministry of Health, Welfare, and Labour of Japan	IGT (by glycemic criteria) (WHO)	30-60 None	None	1DM, 2) a history of gastrectomy, 3) physical conditions such as ischemic heart disease, heart failure, exercise induced asthma, and orthopedic problems where exercise was not allowed by a doctor, 4) definitive liver and kidney diseases, 5) autoimmune diseases, and 6) a habit of drinking heavily, already begun lifestyle modifications
Tate 2003 12684363	US Urban Single center	Unclear Email	ADA	"At risk for DM" (undefined)	None BMI 27-40 kg/m ²	None	Major health or psychiatric diseases, pregnancy, or recent weight loss of ≥4.5kg

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Tuomilehto 2001 11333990	Finland Regional Multicenter	Primary care clinic Multiple sites (implied)	Finnish Academy, the Ministry of Education, the Novo Nordisk Foundation, the Yrjo Jahansson Foundation, and the Finnish Diabetes Research Foundation	IGT (by glycemic criteria) (WHO)	40-65 BMI \geq 25 kg/m ²	None	Diagnosis of DM, the presence of chronic disease rendering survival for 6 years unlikely, and other characteristics (psychological or physical disabilities) deemed likely to interfere with participation in the study
Vermunt 2011 21775759	Netherlands Regional Multicenter	Primary care clinic Primary care clinic	NR	DM risk score (FINDRISC \geq 13)	40-70 NR	NR	NR
Weinstock 2013 23843020	US Regional Multicenter	Urban, community, and rural health centers Urban, community, and rural health centers	NIH - NIDDK	Metabolic syndrome (IDF criteria)	>18 years old BMI \geq 30 kg/m ²	NR	DM and presence of severe medical problems that could interfere with participation (e.g., severe current psychiatric illness)

* Of primary study.

Randomized Controlled Trials (Pediatric)

Author, Year, PMID*	Country Setting Multicenter	Recruitment setting Intervention setting	Funding	Eligibility criteria: Definition of "at risk for DM"	Eligibility criteria: Age, y Adiposity	Other eligibility criteria	Exclusion criteria
Patrick 2013 23759410	US Urban Multicenter	Primary care clinic website, counseling calls, group sessions, text messages, and printed materials	National Institute of Diabetes and Digestive and Kidney Diseases	DM risk score (ADA risk score)	12- 16 years old BMI>85th percentile for age and sex, or weight >120% of ideal for height	Any two of the following risk factors: family history of T2DM in a first- or second-degree relative, race/ethnicity (American Indian, African-American, Hispanic, Asian/Pacific Islander), or signs of insulin resistance; access to the internet	DM diagnosis, pregnant, not planning to be in the San Diego area over the entire study period, or any medical condition that would prevent them from participating in the intervention
Savoie 2014 24062325	US Urban Single center	Specialty care clinic Community	Government	PreDM or IGT (by glycemic criteria) (ad hoc: 2 hour glucose 130-199 mg/dL)	10-16 BMI >95 th percentile	Tanner stage ≥2	DM or other serious medical condition that would preclude participation in the program. Individuals taking medications that affect weight, insulin sensitivity, or glucose metabolism

* Of primary study.

Non-Randomized Comparative Studies

Author, Year, PMID*	Country Setting Multicenter	Recruitment setting Intervention setting	Funding	Eligibility criteria: Definition of "at risk for DM"	Eligibility criteria: Age, y Adiposity	Other eligibility criteria	Exclusion criteria
Costa 2012 22322921	Spain Urban, rural Multicenter	Primary care clinic Primary care clinic	Commission of the European Communities, Directorate C - Public Health	DM risk score PreDM (by glycemic criteria) (FINDRISC >12 or WHO criteria)	45-75 None		Severe psychiatric disease, chronic liver and kidney disease, blood disorders
Eriksson 1991 1778354	Sweden Urban Unclear	Primary care clinic Primary care clinic	NR	IGT (by glycemic criteria) (WHO criteria)	47-49 NR	NR	NR
Islam 2014 24852392	US Urban Multicenter	Community Community	CDC, NIH, National Center for Advancing Translational Sciences	DM risk score (ADA risk score)	18-85 NR	Self-identification as Sikh Asian Indian	NR
Knowler 2009 19878986	US Regional Multicenter	Primary care clinic NR	NIH, CDC, Indian Health Service, General Clinical Research Center Program, National Center for Research Resources; the American Diabetes	PreDM or IGT (by glycemic criteria) (ADA/WHO)	≥35 BMI ≥24 kg/m ²	None	Individuals taking medicines known to alter glucose tolerance or if they had illnesses that could seriously reduce their life expectancy or their ability to participate in the trial.

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			Association; Bristol-Myers Squibb; and Parke- Davis				

* Of primary study.

Before-After Studies

Author, Year, PMID*	Country Setting Multicenter	Recruitment setting Intervention setting	Funding	Eligibility criteria: Definition of "at risk for DM"	Eligibility criteria: Age, y Adiposity	Other eligibility criteria	Exclusion criteria
Absetz 2007 17586741	Finland Regional Multicenter	Primary care clinic Primary care clinic	Academy of Finland and the Finnish Ministry of Health	DM risk score (FINDRISC ≥12)	50-65 None	None	Mental health problem or substance abuse, acute cancer, T2DM, MI in past 6 mo
Gilis-Januszewska 2011 No PMID	Poland Urban Multicenter	Primary care clinic Primary care clinic	NR	DM risk score (FINDRISC >14)	NR NR	NR	Known OGTT DM
Jiang 2013 23275375	US Regional Multicenter	Community Community	US Congress	IGT or IFG (by glycemic criteria) (ADA)	≥18 NR	American Indian/Alaska Native	A previous DM diagnosis, pregnancy, dialysis, and any condition that would affect successful participation based on provider judgment

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Kyrios 2009 19351299	Australia Urban, rural Multicenter	Primary care clinic Unclear	Victorian Department of Human Services	PreDM (by glycemic criteria) (WHO)	≥34 NR	NR	NR
Laatikainen 2007 17877832	Australia Regional Multicenter	Primary care clinic Multiple sites (implied)	Australian Government Department of Health and Ageing, Canberra, Australia	DM risk score (FINDRISC ≥12)	NR NR	NR	Cancer, recent MI or stroke, cognitive impairment, substance abuse, pregnancy or previous type 2 DM.
Makrilakis 2010 20536519	Greece Urban Multicenter	Primary care clinic Primary care clinic	Commission of the European Communities	DM risk score (FINDRISC ≥15)	40-64 BMI >25 kg/m ²	No unknown DM on two 75-g oral glucose tolerance tests OGTT	Previously diagnosed or unknown DM
Penn 2013 24227871	UK Rural Unclear	Primary care clinic, community Primary care clinic, community	Middlesbrough Council, Middlesbrough Primary Care Trust, Public Health North East, Sport England	PreDM, IGT, or IFG (by glycemic criteria) (WHO)	45-65 BMI ≥25 kg/m ² or family history of DM	NR	Previous diagnoses of type 2 DM or inability to participant in moderate physical activity
Ramachandran 2009 19277602	India Urban Unclear	Community Unclear	India Diabetes Research Foundation	IGT (by glycemic criteria) (WHO)	35-55 NR	NR	NR

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Saaristo 2010 20664020	Finland Regional Multicenter	Primary care clinic Primary care clinic	Hospital districts of Pirkanmaa, Southern Ostrobothnia, Northern Ostrobothnia, Central Finland, and Northern Savo, the Finnish National Public Health Institute, the Finnish Diabetes Association, the Ministry of Social Affairs and Health, Slottery Machine Association, the Academy of Finland, and the Commission of the European Communities, Directorate C-Public Health	DM risk score (FINDRISC ≥ 15) or diagnosis of IFG or IGT (undefined) or ischemic CVD, gestational DM	None None	None	Individuals who had previously diagnosed or screening detected DM at baseline or did not have OGTT
Sepah 2014 24723130	US Regional Online	Community Online	Omada Health	PreDM (self-reported)	≥ 18 BMI ≥ 24 kg/m ² (≥ 22)	Able to engage in light physical activity	NR

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					kg/m ² if Asian)		
Swanson 2012 22068253	US Suburban Single center	Primary care clinic Primary care clinic	NR	PreDM, IGT, or IFG (by glycemic criteria) (ADA)	NR NR	None	NR
Vanderwood 2010 20805260	US Urban, rural Multicenter	Primary care clinic, Specialty care clinic, Community, Work sites Primary care clinic, Specialty care clinic, Community	Diabetes Control Program, part of the Montana Department of Public Health and Human Services	PreDM, IGT, or IFG (prior diagnosis) or CVD or DM risk factors (see other eligibility criteria)	≥18 BMI ≥25 kg/m ²	Hypertension, dyslipidemia, history of gestational DM, or gave birth to a baby ≥9 pounds	DM, unstable cardiac disease, cancer and currently undergoing treatment, ESRD or currently on dialysis, unable to participate in regular moderate physical activity, or were pregnant or planning to become pregnant in the next 6 mo
Vojta 2013 23498291	US Regional Multicenter	Community Community	CDC	PreDM (undefined)	≥18 NR	NR	NR

* Of primary study.

Abbreviations

ADA, American Diabetes Association
 AUSDRISK, Australian Diabetes Risk Score
 BMI, body mass index
 CAD, coronary heart disease

CDC, Centers for Disease Control and Prevention
 CHF, congestive heart failure
 COPD, chronic obstructive pulmonary disease
 CVD, cardiovascular disease

DM, diabetes mellitus
 ESRD, end stage renal disease
 FINDRISC, Finnish Diabetes Risk Score
 FPG, fasting plasma glucose
 g, gram

GGT DPP, Greater Green Triangle diabetes prevention program
HTN, hypertension
IDF, International Diabetes Federation
IFG, impaired fasting glucose
IGT, impaired glucose tolerance
kg, kilogram
m, meter
MI, myocardial infarction
mo, month
NHLBI, National Heart, Lung, and Blood Institute
NIA, National Institute on Aging
NIDDK, National Institute of Diabetes and Digestive and Kidney Disease
NIH, National Institute of Health
NR, not reported
NRCS, nonrandomized comparative studies
OGTT, oral glucose tolerance test
RCT, randomized controlled trial
UK, United Kingdom
US, United States
WHO, World Health Organization
y, year