Diabetes Prevention in the Real World: Effectiveness of Pragmatic Lifestyle Interventions for the Prevention of Type 2 Diabetes and of the Impact of Adherence to Guideline Recommendations

A Systematic Review and Meta-analysis

Alison J. Dunkley,[1] Danielle H. Bodicoat,[1] Colin J. Greaves,[2] Claire Russell,[1] Thomas Yates,[1] Melanie J. Davies,[1] and Kamlesh Khunti[1]

Diabetes Care 2014;37:922–933 | DOI: 10.2337/dc13-2195

OBJECTIVE

To summarize the evidence on effectiveness of translational diabetes prevention programs, based on promoting lifestyle change to prevent type 2 diabetes in real-world settings and to examine whether adherence to international guideline recommendations is associated with effectiveness.

RESEARCH DESIGN AND METHODS

Bibliographic databases were searched up to July 2012. Included studies had a follow-up of ≥12 months and outcomes comparing change in body composition, glycemic control, or progression to diabetes. Lifestyle interventions aimed to translate evidence from previous efficacy trials of diabetes prevention into real-world intervention programs. Data were combined using random-effects meta-analysis and meta-regression considering the relationship between intervention effectiveness and adherence to guidelines.

RESULTS

Twenty-five studies met the inclusion criteria. The primary meta-analysis included 22 studies (24 study groups) with outcome data for weight loss at 12 months. The pooled result of the direct pairwise meta-analysis shows that lifestyle interventions resulted in a mean weight loss of 2.32 kg (95% −2.92 to −1.72; I^2 = 93.3%). Adherence to guidelines was significantly associated with a greater weight loss (an increase of 0.4 kg per point increase on a 12-point guideline-adherence scale).

CONCLUSIONS

Evidence suggests that pragmatic diabetes prevention programs are effective. Effectiveness varies substantially between programs but can be improved by maximizing guideline adherence. However, more research is needed to establish optimal strategies for maximizing both cost-effectiveness and longer-term maintenance of weight loss and diabetes prevention effects.

[1]*Diabetes Research Centre, University of Leicester, Leicester, U.K.*
[2]*Primary Care, University of Exeter Medical School, Exeter, U.K.*

Corresponding author: Alison J. Dunkley, ajd38@le.ac.uk.

Received 17 September 2013 and accepted 14 January 2014.

This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc13-2195/-/DC1.

See accompanying articles, pp. 906, 909, 912, 934, 943, 950, and 957.

A major opportunity exists to drastically reduce the incidence of type 2 diabetes, a disease that has a huge impact on patients and health care systems worldwide. Large, high-quality clinical trials (1–3) show that relatively modest changes in diet and physical activity reduce the incidence of type 2 diabetes by >50% for people with impaired glucose regulation. Impaired glucose regulation is an intermediate condition between normal glucose regulation and type 2 diabetes, which confers an increased risk of progression to type 2 diabetes (4). Indeed, within-trial data show that the rate of progression to type 2 diabetes at 7 years of follow-up was reduced to almost zero for people who had succeeded in making five modest lifestyle changes (2). The main drivers of diabetes prevention appear to be weight loss and physical activity (5,6). However, a substantial challenge remains in translating these findings into routine clinical practice. The intensive and prohibitively expensive interventions used in clinical trials, to ensure lifestyle change, need to be translated into practical affordable interventions that are deliverable in real-world health care systems and which, nevertheless, retain a reasonable degree of effectiveness (7).

Since the publication of the original diabetes prevention clinical trials between 1996 and 2001, a number of translational or "real-world" diabetes prevention programs (8,9) have aimed to translate the evidence (1,10–12). A meta-analysis of the evidence on translational interventions was published in 2010 (9), although this review excluded 15 studies that were conducted in non–health care settings. A more recent meta-analysis was published in 2012 (13). However, the authors only focused on translation of evidence from the U.S. Diabetes Prevention Program and also included studies where up to half of the population already had diabetes. Other systematic reviews of diabetes prevention interventions have either not included a meta-analysis (6,8,14–17) or have not focused on translational studies (3,6,15,16,18–22). Overall, the systematic reviews conducted to date indicate that real-world diabetes prevention programs vary widely in their effectiveness, although most produce lower levels of weight loss than the more intensive interventions used in the clinical efficacy trials (9). Explaining this variation is important. If we can identify the components of lifestyle interventions that are reliably associated with increased effectiveness, this will inform the design of more efficient (cost-effective) diabetes prevention programs.

Recently published evidence-based guidelines (23,24) make distinct recommendations about which intervention components should be included to maximize the effectiveness of lifestyle interventions for diabetes prevention. Such recommendations include the use of group-based interventions to minimize cost and the use of specific behavior-change strategies that are associated with increased effectiveness. These recommendations come from systematic reviews of the wider literature on supporting changes in diet and physical activity in a range of populations (25,26). Lifestyle interventions for diabetes prevention vary in their content; however, whether closer adherence to the guideline recommendations might improve the performance of real-world diabetes prevention interventions remains unclear. To consolidate the evidence, we undertook a systematic review of studies considering the effectiveness of translational interventions for prevention of type 2 diabetes in high-risk populations. The primary aim was to conduct a meta-analysis of the effectiveness of pragmatic interventions on weight loss and conduct a meta-regression to examine whether closer adherence to guideline recommendations for diabetes prevention improves the effectiveness of real-world interventions. If sufficient data were available, a secondary aim was to consider other diabetes risk factors using similar methods.

RESEARCH DESIGN AND METHODS

Search Strategy and Study Selection

We included experimental and observational studies that considered the effectiveness of a lifestyle intervention (diet or exercise) alone or compared with control, where the stated aim of the intervention was diabetes risk reduction or prevention of type 2 diabetes, and where the focus of the study was to translate evidence from previous diabetes efficacy trials into routine health care or a community setting. For studies to be eligible for inclusion, we required them to include adults (≥18 years old) identified as being at high risk of developing type 2 diabetes (for example, obese, sedentary lifestyle, family history of diabetes, older age, metabolic syndrome, impaired glucose regulation, prediabetes, or elevated diabetes risk score) (24), have a minimum follow-up of 52 weeks, and have an outcome relating to diabetes risk, as measured by a change in body composition or a change in glycemic control or report progression to diabetes (incidence or prevalence). The focus of the review was primary prevention; therefore, we excluded trials where >10% of the population had established diabetes. We included only studies published in the English language and as full-length articles.

We searched Embase, MEDLINE, and the Cochrane Library (Issue 7, 2012), using a combination of MeSH terms and keywords that were tailored to individual bibliographic databases. We restricted searches to articles published after January 1998; the starting point of 1998 was chosen to facilitate the identification of studies that were informed by or translating evidence from previous diabetes prevention efficacy trials (1,10–12). In order to avoid missing papers, the final search strategy included only terms related to the intervention and the study design. An example search strategy (MEDLINE) is outlined in Supplementary Table 1. We combined the results of an initial search and an updated supplementary search, which together identified papers up to the end of July 2012.

Two reviewers independently assessed abstracts and titles for eligibility and retrieved potentially relevant articles, with differences resolved by a third reviewer where necessary. Where studies appeared to meet all the inclusion criteria but data were incomplete, we contacted authors for additional data or clarification. In an attempt to identify further papers not identified through electronic searching, we examined the reference lists of included papers and relevant reviews.

Data Extraction and Quality Assessment

Data were extracted by one reviewer, and a second reviewer subsequently

checked for consistency. We extracted data on sample size, population demographics, intervention details, and length of follow-up. Where available, we recorded outcome data for the mean change from baseline to 12 months' follow-up for the following outcomes: weight, BMI, waist circumference, fasting glucose, 2-h glucose, glycated hemoglobin (HbA_{1c}), total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, systolic blood pressure (BP), and diastolic BP. Incidence of type 2 diabetes was also recorded. We retrieved all papers relating to a particular study, including those on design and methodology (if reported separately), and any Supplementary Data.

We assessed the quality of selected studies according to the U.K.'s National Institute for Health and Clinical Excellence (NICE) quality appraisal checklist for quantitative intervention studies (27). The checklist includes criteria for assessing the internal and external validity of experimental and observational quantitative studies (randomized controlled trials [RCTs], nonrandomized controlled trials, and before and after studies) and allows assignment of an overall quality grade (categories ++, +, or −).

Coding of Intervention Content

We coded intervention content (Supplementary Tables 1 and 3) in relation to the recommendations for lifestyle interventions for the prevention of diabetes provided by both the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes prevention) (23) and NICE (24). Where a study intervention was inadequately described, we requested further details from the authors. If available information was insufficient to allow coding, we coded data as missing; where an intervention appeared to be well described but a particular component (e.g., engaging social support) was not mentioned or could not be implied from other text, we assumed that the component was not used. In the analysis, we assumed that missing values indicated that the guideline criterion was not met.

Data Synthesis and Analysis

We converted all values reported in imperial units into metric units. Capillary blood glucose values were converted to plasma equivalent values (28). If studies did not directly report the mean SD, for change from baseline to 12 months for the outcomes of interest, they were calculated. We calculated the mean change by subtracting the baseline mean value from the mean at 12 months. We calculated the SD from reported *P* values or CI, as recommended by the Cochrane Collaboration (29). Where data were insufficient, to allow calculation of the SD, we imputed values for each outcome based on the correlation estimates from those studies that reported; for weight, the correlation used in these imputations was 0.95 (30–34).

For the primary outcome of interest (weight), we conducted direct pairwise comparison meta-analyses to examine the effect size (change from baseline to 12 months) where data were available. Only intervention arms were included in the meta-analysis. This was because we were interested in whether adherence to guidelines improved weight loss; therefore, only arms in which people received an intervention were applicable. Meta-regression was used to assess the relationship between weight change at 12 months and the total IMAGE guidance score and the total NICE guidance score, as explanatory variables, in separate univariate analyses. We performed further metaregression with the individual guideline components as the explanatory variables where at least three studies fell into each category. We conducted similar analyses for the secondary outcomes of interest; however, as these outcomes were reported in fewer studies and to avoid multiple testing, metaregression of individual guideline components against secondary outcomes was not performed. We performed sensitivity analyses for the primary outcome, weight, where missing guideline data were treated as unknown and a total guidance score was not given for those studies and where we restricted the analysis to RCTs only.

We assessed publication bias using the Egger test and heterogeneity using the I^2 statistic. Due to high levels of heterogeneity, we used random-effects models throughout to calculate effect sizes. We performed all analyses in Stata version 12.1 (StataCorp, College Station, TX).

RESULTS

Identification of Studies

Results relating to identification and selection of eligible trials are summarized in Fig. 1. Searches yielded 6,326 citations, and 3,872 unique titles or abstracts were screened for eligibility. After full text retrieval of 114 potentially relevant papers, 20 additional papers were identified from reference lists, making a total of 134. Authors for 13 studies were then contacted in order to clarify eligibility criteria or for additional outcome data. Replies were received for 12 studies, 10 of which were subsequently included in the 25 studies (30–54) (35 articles [30–64]) that met the review criteria.

Summary of Included Studies

The 25 studies (30–54) included in the systematic review are summarized in Table 1. Study interventions included either dietary intervention or physical activity intervention or both. Standard/brief advice on diet and/or exercise was considered to be comparable with usual care and not judged to be an active intervention. One study focused solely on the effectiveness of physical activity intervention (54), 1 combined dietary intervention and a supervised exercise program (44), and 23 considered the effectiveness of combined dietary and physical activity intervention. Eleven of the studies were RCTs, 11 were before and after studies, and the remaining studies included a matched cohort, a prospective cohort, and a nonrandomized controlled trial. All papers were published within the last 10 years.

Studies were conducted in the U.S. (*n* = 11), Australia (*n* = 2), Europe (*n* = 11), and Japan (*n* = 1); however, ethnicity was poorly reported. The number of people who were enrolled into the intervention arm in individual studies ranged from 8 to >2,700, with 22 studies including at least 50 participants. The criteria used, alone or in combination, to identify high risk included elevated BMI; elevated diabetes risk score (Finnish Diabetes Risk Score [FINDRISC] [65], American Diabetes Association [ADA] [66]); raised random, fasting, or 2-h glucose (finger prick or venous sample); older age; ethnicity; family history of diabetes; and previous medical history of cardiovascular disease, polycystic ovary syndrome, gestational diabetes

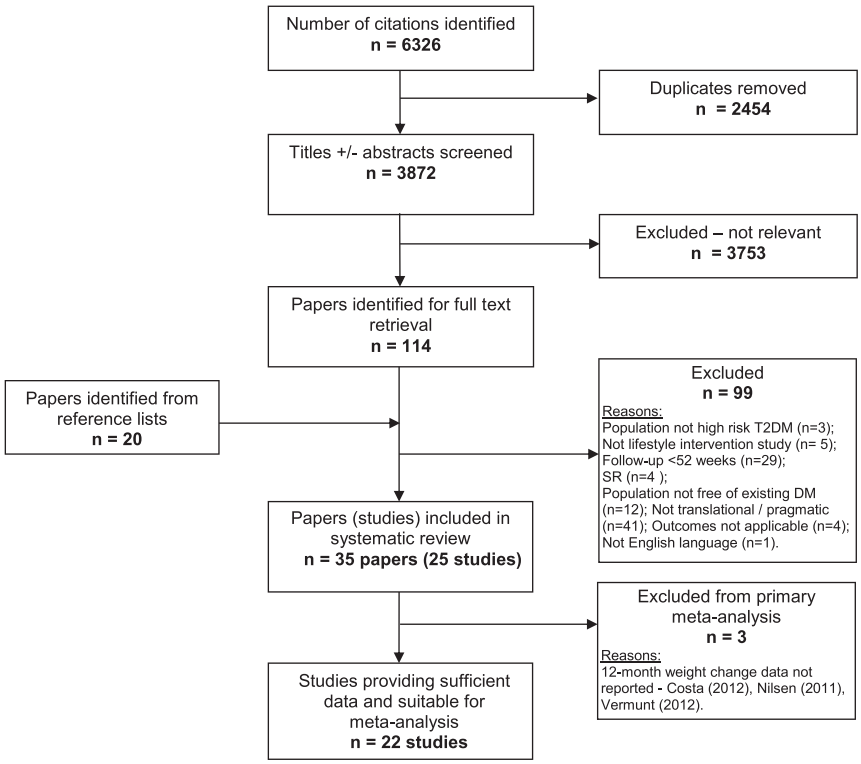

Figure 1—Flowchart of selection of studies from search to final inclusion. DM, diabetes mellitus; T2DM, type 2 diabetes mellitus.

mellitus, metabolic syndrome, or elevated BP or lipids. Length of follow-up ranged from 12 months to ~4 years. The mean age and BMI of participants ranged from 38 to 65 years and 25 to 37 kg/m^2, respectively, and the proportion of males ranged from 7 to 66%.

Outcome data for change in weight were available for 24 of 25 studies (not Costa [39]); 22 of 25 studies reported weight at 12 months (Supplementary Table 4). Additional 12-month data reported for 23 studies (Supplementary Tables 1 and 5) included change in BMI (18 studies), waist size (16), fasting glucose (15), 2-h glucose (10) HbA_{1c} (7), total cholesterol (13), LDL (7), HDL (12), triglycerides (10), systolic BP (13), diastolic BP (11), and the incidence of diabetes after 12 months (8). Outcome data for change in physical activity and diet were poorly reported. Overall, considerable heterogeneity was evident between studies in relation to several key characteristics including the setting, population, criteria used to identify diabetes risk, interventions, and follow-up.

Study Quality

A breakdown of study quality is presented in Supplementary Table 6. Most studies achieved a high-quality grading for internal validity (19 of 25). However, details relating to the source/eligible population and area and the selected participants were less well reported; only 11 studies achieved a high-quality score for external validity.

Scoring of Intervention Content

Details of coding scores for study interventions are presented in Supplementary Table 3. Fourteen of the 25 intervention groups included in the main meta-analysis attained an overall score of ≥9 out of a possible 12 in relation to meeting NICE guideline recommendations; 19 scored ≥7. For IMAGE guideline recommendations, an overall score of ≥5 out of a possible 6 was achieved by 12 study groups.

Meta-analysis

Twenty-two studies involving 5,500 participants (estimated 43% male) were included in the meta-analysis for mean weight change at 12 months. One study was excluded from the primary meta-analysis, as weight change was not recorded as a study outcome (39), and two studies were excluded from all analyses, as they only reported 18-month data (45,53). Two studies included in the meta-analysis had two intervention arms (43,54), meaning that 24 study groups were analyzed.

The pooled result of the direct pairwise meta-analysis (Fig. 2) shows that lifestyle interventions resulted in a mean weight loss of 2.32 kg (95% CI −2.92 to −1.72; I^2 = 93.3%). Supplementary Figs. 1 and 2 show the metaregression results for the NICE and IMAGE guidelines for weight, respectively. Greater adherence to guideline recommendations was significantly associated with greater weight loss for both sets of guidelines (Table 2). Adherence to individual guideline elements also tended to result in greater weight loss, some of which were statistically significant (Table 2). Sensitivity analyses without imputed data are also shown in Table 2. This showed that, where data were complete, the effect sizes were generally larger for both NICE and IMAGE guidance: −0.52 kg per point increase on the 12-point adherence scale (95% CI −0.95 to −0.10) and −0.77 kg per point increase on the 6-point adherence scale (95% CI −1.28 to −0.26), respectively.

None of the study level covariates (proportion of males, mean age, proportion of white European ethnicity) were significantly associated with the mean

Table 1—Characteristics of studies included in the systematic review

First author and year	Study design	Study name	Definition of high risk of T2D	Focus of interventions	No. recruited overall (and by group)	No. of study groups	Follow-up (months)	Setting	Country	Ethnicity (%)	Age, mean	M (%)	BMI (kg/m^2), mean
Absetz 2007 (and 2009)	Before and after	GOAL	Aged 50–65 years; any risk factor from obesity, ↑BP, ↑PG, ↑lipids; FINDRISC score ≥12	Lifestyle (diet and exercise)	352	1	12 and 36	Primary care	Finland	N/R	58 (F); 59 (M)	25	33 (F); 32 (M)
Ackermann 2008 (and 2011)	RCT	DEPLOY	BMI ≥24 kg/m^2 and ADA diabetes risk score ≥10, CBG random (110–199 mg/dL) or fasting (100–199 mg/dL)	Lifestyle (diet and exercise)	92	2	12	Community (YMCA)	U.S.	82% white, 3% Hispanic, 12% Af-Am, 5% other	58	45	31
Almeida 2010	Matched cohort	KPCO	Existing IFG (110–125 mg/dL) identified from medical records	Lifestyle (diet and exercise)	1,640 (1,520 data available)	2	12	Integrated health care organization	U.S.	N/R	55	47	30
Boltri 2008	Before and after	DPP in faith-based community	ADA diabetes risk score ≥10, CBG fasting (100–125 mg/dL)	Lifestyle (diet and supervised exercise)	8	1	12	Community (church)	U.S.	Af-Am community	52*	42*	32
Costa 2012	Prospective cohort	DE-PLAN Spain	FINDRISC score ≥14 or 2-h OGTT (≥7.8 and <11.1 mmol/L)	Lifestyle (diet and exercise)	552 (219 + 333)	2	Median 4.2 years	Primary care	Spain	White European	62	32	31
Davis-Smith 2007	Before and after	N/R	ADA diabetes risk score ≥10, CBG fasting (100–125 mg/dL)	Lifestyle (diet and exercise)	11	1	12	Community (church)	U.S.	Af-Am community	N/R	27	36†
Faridi 2010	Nonrandomized controlled trial	PREDICT	≥1 risk factor from BMI ≥25 kg/m^2, FH diabetes, gestational diabetes mellitus	Lifestyle (diet and exercise)	146	2	12	Community (church)	U.S.	100% Af-Am	N/R	32	33
Gilis-Januszewska 2011	Before and after	DE-PLAN Poland	FINDRISC score ≥14	Lifestyle (diet and exercise, optional supervised sessions)	175	1	12	Primary care	Poland	NR	NR	22	32
Katula 2011	RCT	HELP PD	BMI ≥ 25 < 40 kg/m^2 and CBG random, FPG (95–125 mg/dL)	Lifestyle (diet and exercise)	301 (151 + 150)	2	12	Community various venues	U.S.	74% white, 25% Af-Am, 1% other	58	43	33

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Table 1—Continued

First author and year	Study design	Study name	Definition of high risk of T2D	Focus of interventions	No. recruited overall (and by group)	No. of study groups	Follow-up (months)	Setting	Country	Ethnicity (%)	Age, mean	M (%)	BMI (kg/m^2), mean
Kramer 2009	Before and after	GLB 2005–2008	BMI ≥25 kg/m^2 and metabolic syndrome or CBG fasting (100–125 mg/dL)	Lifestyle (diet and exercise)	42	1	12	Primary care and university-based support center	U.S.	100% white	57	21	35
Kramer 2012	Before and after	GLB 2009	Fasting glucose 100–125 mg/dl	Lifestyle (diet and exercise)	60 (31 + 29)	2	12	Community (YMCA) and university	U.S.	90% Caucasian	55	35	~36
Kulzer 2009	RCT	PREDIAS	FINDRISC score ≥10 or assessed as ↑risk diabetes by primary care physician	Lifestyle (diet and exercise)	182 (91 + 91)	2	12	Outpatient setting	Germany	N/R	56	57	32
Laatikainen 2007 (and 2012)	Before and after	GGT study	FINDRISC score ≥12	Lifestyle (diet and exercise)	311	1	12	Primary care	Australia	N/R	57	28	34
Makrilakis 2010	Before and after	DE-PLAN Greece	FINDRISC score ≥15	Lifestyle (diet and exercise)	191	1	12	Primary care, workplace	Greece	NR	56	40	32
Mensink 2003 (and 2003); (Roumen 2008 and 2011)	RCT	SLIM study	Aged >40 years and FH diabetes or BMI ≥25 kg/m^2, IGT (OGTT 2-h G ≥7.8 and <12.5) and FPG <7.8 mmol/L	Lifestyle (diet and supervised exercise)	114 (55 + 59)	2	12, 24, 36, 48 (Roumen)	Unclear	Netherlands	White Caucasian	57	56	30
Nilsen 2011	RCT	N/R	FINDRISC score ≥9	Lifestyle (diet and exercise)	213 (104 + 109)	2	18	Primary care	Norway	NR	47	50	37
Ockene 2012	RCT	Lawrence Latino DPP	BMI ≥24 kg/m^2, >30% increased likelihood of diabetes over next 7.5 years from validated risk algorithm	Lifestyle (diet and exercise)	312 (150 + 162)	2	12	Community, family health center	U.S.	60% Dominican, 40% Puerto Rican	52	26	34
Parikh 2010	RCT	Project HEED	BMI ≥25 kg/m^2 and prediabetes (CBG fasting <126 mg/dL, and IGT on 2-h CBG following 75-g glucose)	Lifestyle (diet and exercise)	99 (50 + 49)	2	12	Various community venues	U.S.	89% Hispanic, 9% Af-Am	48	15	32

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Table 1—Continued

First author and year	Study design	Study name	Definition of high risk of T2D	Focus of interventions	No. recruited overall (and by group)	No. of study groups	Follow-up (months)	Setting	Country	Ethnicity (%)	Age, mean	M (%)	BMI (kg/m^2), mean
Payne 2008	Before and after	N/R	Aged ≥45 or aged ≥35 years; Aboriginal, Torres Strait Islanders, Pacific Islanders, Indian, Chinese; and BMI ≥30 kg/m^2 and/or ↑BP; existing CVD, PCOS, gestational diabetes mellitus; 1st-degree FH diabetes; IGT or IFG	Lifestyle (diet and exercise program)	122 (62 + 60)	2	12	Outpatient facility	Australia	N/R	53	22	35
Penn 2009	RCT	N/R	BMI >25 kg/m^2 and aged >40 years, IGT (OGTT 2-h G ≥7.8 and <11.1 mmol/L)	Lifestyle (diet and exercise)	102 (51 + 51)	2	12 and 3.1 years mean	Outpatient setting	U.K.	N/R	57	40	34
Ruggiero 2011	Before and after	N/R	BMI ≥24.9 kg/m^2	Lifestyle (diet & exercise)	69	1	12	Various community venues	U.S.	Hispanic	38	7	31
Saaristo 2010 (Rautio 2011 and 2012)	Before and after	FIN-D2D	FINDRISC score ≥15, IFG, IGT, CVD event, or gestational diabetes mellitus	Lifestyle (diet and exercise)	2,798	1	12	Primary care	Finland	NR	54	49	~31
Sakane 2011	RCT	N/R	IGT identified as follows: IFG ≥5.6 and <7.0 mmol/L, random PG (≥ 7.8 < 11.1 mmol/L within 2 h of meal) or (≥6.1 and <7.8 at ≥2 h after meal)	Lifestyle (diet and exercise)	296 (146 + 150)	2	12 and 36	Various: primary care, workplace, collaborative center	Japan	N/R	51	51	25
Vermunt 2012 (and 2011)	RCT	N/R	FINDRISC score ≥13	Lifestyle (diet and exercise)	925 (479 + 446)	2	18, 30	Primary care	Netherlands	NR	NR	NR	~29
Yates 2009 (and 2011)	RCT	PREPARE	BMI ≥25 kg/m^2 (23 for SAs), screened detected IGT	Lifestyle (exercise)	98 (33 + 31 + 34)	3	12, 24	Outpatient setting	U.K.	75% white,†24% SA, 1% black	65†	66†	29.2†

Payne 2008 randomly allocated to two exercise groups, but most results are presented overall. 2-h G, 2-h glucose; Af-Am, African American; CBG, capillary blood glucose; CVD, cardiovascular disease; DE-PLAN, Diabetes in Europe Prevention Using Lifestyle, Physical Activity and Nutritional Intervention; DEPLOY, Diabetes Education and Prevention with a Lifestyle Intervention Offered at the YMCA; F, female; FH, family history; FIN-D2D, Finnish National Diabetes Prevention Program; FPG, fasting plasma glucose; GGT, Greater Green Triangle; GLB, Group Lifestyle Balance; GOAL, Good Ageing in Lahti Region; HEED, Help Educate to Eliminate Diabetes; HELP PD, Healthy Living Partnerships to Prevent Diabetes; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; KPCO, Kaiser Permanente Colorado; M, male; N/R, not reported; OGTT, oral glucose tolerance test; PCOS, polycystic ovary syndrome; PG, plasma glucose; PREDIAS, Prevention of Diabetes Self-Management Program; PREDICT, Partners Reducing Effects of Diabetes; PREPARE, Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement; SA, South Asian; T2D, type 2 diabetes; SLIM, Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht; YMCA, Young Men's Christian Association. *Boltri 2008 estimated from larger cohort (n = 26) who were screened with CBG; †given for completers.

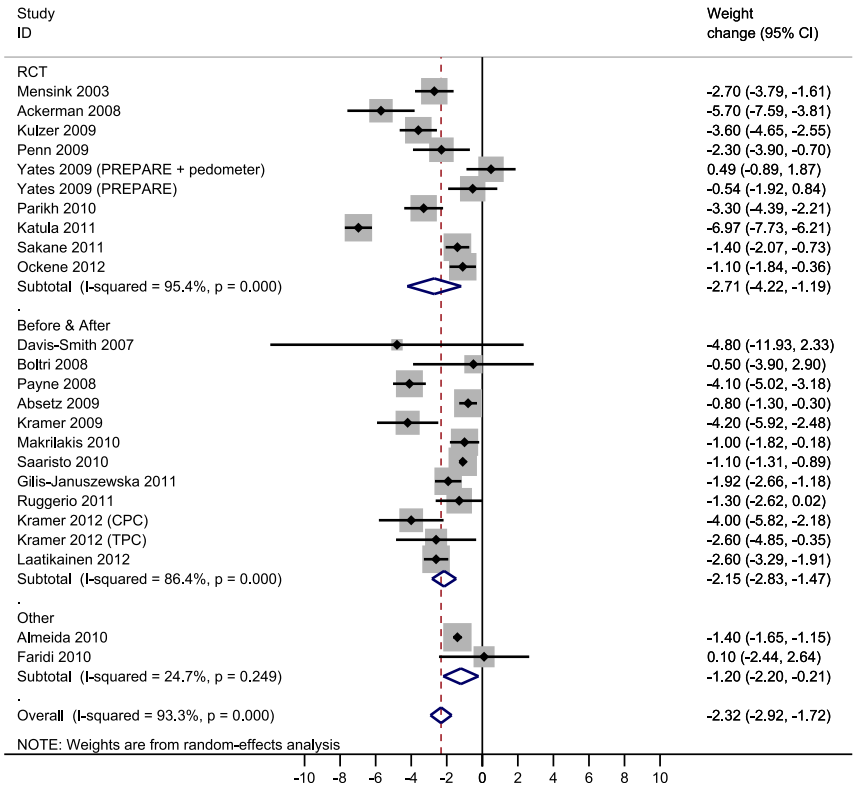

Figure 2—Forest plot showing mean weight change in each study and the overall pooled estimate. Boxes and horizontal lines represent mean weight change and 95% CI for each study. Size of box is proportional to weight of that study result. Diamonds represent the 95% CI for pooled estimates of effect and are centered on pooled mean weight change. PREPARE, Pre-diabetes Risk Education and Physical Activity Recommendation and Encouragement.

difference in weight change. Sensitivity analysis, restricted to RCTs only, indicated a mean weight change (−2.7 kg [95% CI −4.2 to −1.2]) that is similar to the overall result. Additional analysis comparing the difference in weight lost between the treatment and control arms, for RCTs only, suggests that on average the intervention arm lost an extra −1.93 kg (95% CI −3.10 to −0.76; $P = 0.001$). Furthermore, sensitivity analyses that included studies scoring ++ for external validity demonstrated a slightly greater weight loss in higher-quality studies (−3.1 kg [95% CI −4.6 to

Table 2—Meta-regression results for weight change from baseline to 12 months

Explanatory variable	No. of studies	No. of participants	Effect (95% CI), kg	*P*
NICE (continuous)	24	5,500	−0.37 (−0.64 to −0.11)	0.008
NICE without imputation (continuous)	17	4,885	−0.52 (−0.95 to −0.10)	0.020
IMAGE (continuous)	24	5,500	−0.56 (−0.96 to −0.17)	0.008
IMAGE without imputation (continuous)	18	4,942	−0.77 (−1.28 to −0.26)	0.006
IMAGE B (continuous)	24	5,500	−0.61 (−0.99 to −0.22)	0.004
IMAGE B without imputation (continuous)	18	4,942	−0.78 (−1.26 to −0.29)	0.004
Engage social support (yes vs. no)	24	5,500	−1.58 (−3.06 to 0.10)	0.037
No. of contacts (frequency)	23	5,417	−0.09 (−0.13 to −0.05)	<0.001
Contact time (h)	23	5,147	−0.15 (−0.21 to −0.08)	<0.001
≥16 h of contact time (yes vs. no)	23	5,147	−2.20 (−3.61 to −0.79)	0.004
Self-regulatory techniques (yes vs. no)	24	5,500	−1.17 (−3.00 to 0.66)	0.200
Empathy-building approach (yes vs. no)	24	5,500	0.86 (−0.71 to 2.43)	0.269
Spread sessions over 9–18 months (yes vs. no)	24	5,500	−1.62 (−3.07 to −0.18)	0.029
Motivation (yes vs. no)	24	5,500	−1.49 (−3.05 to 0.07)	0.060
Gradual building of confidence (yes vs. no)	24	5,500	−0.58 (−2.24 to 1.08)	0.477
Fidelity (yes vs. no)	24	5,500	−0.79 (−2.59 to 1.02)	0.377
Additional physical activity sessions (yes vs. no)	24	5,500	−0.53 (−2.62 to 1.56)	0.604

−1.6]). Additionally, there was very limited evidence of publication bias (P = 0.05, Egger test).

All other outcomes showed an improvement at 12 months (Supplementary Table 7), but not all of these reached statistical significance. Supplementary Table 8 shows the effect of adherence to NICE and IMAGE guidelines on the other outcomes. For both NICE and IMAGE guidelines, respectively, greater adherence resulted in better outcomes for waist circumference (−0.52 cm, P = 0.007; −0.80 cm, P = 0.001) and triglycerides (−0.03 mmol/L, P = 0.016; −0.04 mmol/L, 0.023). For BMI, the improvements were only significant for adherence to NICE guidelines (−0.12 kg/m^2, P = 0.028). There was no effect on any of the other outcomes. Across the eight studies that reported incident diabetes, the pooled incidence rate was 34 cases per 1,000 person-years (95% CI 22–56), which gives the number needed to treat as 29.

CONCLUSIONS

The 22 translational diabetes prevention programs included in our meta-analysis significantly reduced weight in their intervention arms by a mean 2.3 kg at 12 months of follow-up. Where data were available, we found significant reductions in other diabetes and cardiovascular risk factors, including blood glucose, BP, and some cholesterol measures. Adherence to guideline recommendations on intervention content and delivery was significantly associated with a greater weight loss such that, for each 1-point increase on the 12-point scale for adherence to NICE recommendations an additional 0.4 kg (P = 0.008) of weight loss was achieved; furthermore, for waist size a significant reduction of 0.5 cm was achieved for each point increase. The pooled diabetes incidence rate was 34/1,000 person-years (number needed to treat: 29). Outcome data on changes in the key lifestyle behavior targets (physical activity and diet) were poorly reported.

Relationship With Other Literature

The mean level of weight loss achieved was approximately one-half to one-third of the levels reported at the same time point within the intervention arms of clinical efficacy trials such as the U.S. Diabetes Prevention Program [DPP] (~6.7 kg) and the Finnish Diabetes Prevention Study [DPS] (~4.2 kg) (1,10). This is consistent with the findings of a meta-analytic systematic review published in 2010 by Cardona-Morrell et al. (9), which identified a mean net weight loss after 12 months of 1.82 kg (95% CI −2.7 to −0.99). Cardona-Morrell et al. interpreted the lower level of weight loss and a lack of significant differences in fasting plasma glucose and 2-h glucose as meaning that the interventions "appear to be of limited clinical benefit." Our view is that, despite the drop-off in intervention effectiveness in translational studies, the level of weight loss found in our analysis is still likely to have a clinically meaningful effect on diabetes incidence. This is based on data from the U.S. DPP study, which show that each kilogram of mean weight loss is associated with a reduction of ~16% in future diabetes incidence (5). Furthermore, a recent meta-analysis, which included studies without an intervention in order to look at natural diabetes progression rates in high-risk individuals, found progression rates to diabetes from impaired fasting glucose, impaired glucose tolerance, and both were 47, 56, and 76 per 1,000 person-years, respectively (67). The rate of 34 per 1,000 person-years that we found suggests that the real-world lifestyle interventions studied here did lower diabetes progression rates.

For our review, the mean proportion of weight lost at 12 months' follow-up was −2.6%. This amount was slightly lower than was demonstrated by a recent meta-analysis conducted by Ali et al. (13), which considered translational studies aimed at populations with existing diabetes (≤50%) or at high future risk. They found a mean weight loss of −4.1% (95% CI −5.9 to −2.4) after at least 9 months of follow-up (13). This difference may in part be due to a lower mean BMI at baseline for studies included in our review, compared with the Ali et al. review (range 25–36 kg/m^2 and 31–40 kg/m^2, respectively) and a slightly longer follow-up period (12 months vs. ≥9). Additionally, their review focused on interventions based only on the U.S. DPP, where we considered a broader set of interventions.

Changes in the four key dietary and physical activity targets (≤30% energy from fat, ≤10% energy from saturated fat, fiber ≥15 g/1,000 kcal, ≥30 min moderate physical activity daily) have also been shown to have independent effects on diabetes risk reduction, irrespective of weight loss (5). However, few of the studies that we examined provided data on dietary intake or physical activity, so we cannot be sure whether diabetes prevention in these studies is driven by increased physical activity, dietary change, or both.

The strong association between increased weight loss and increased adherence to guideline recommendations is of particular interest. Where complete data were available, the coefficients were larger: −0.52 kg per point increase (95% CI −0.95 to −0.10) for adherence to NICE guidance on a 12-point scale and −0.77 kg per point increase (95% CI −1.28 to −0.26) for adherence to IMAGE guidance on a 6-point scale. This may reflect a reduction in the statistical noise caused by missing data, or it may reflect the fact that studies that had a stronger behavioral science input were more likely to report the intervention content in detail (and were also more likely to be effective). Overall, these data suggest that a high proportion of the variation in weight loss could be explained by variations in intervention design. The implication is that a design based on guideline recommendations should lead to performance at the higher end of the range (≥4 kg).

Strengths and Limitations

This study is novel in that it provides an updated meta-analysis of a global set of lifestyle interventions for diabetes prevention. Our study used comprehensive search criteria and focused on establishing the utility of pragmatic attempts to achieve diabetes prevention in real-world service delivery settings. It also provides novel data that appear to validate the usefulness of recent guideline-based recommendations on the content of lifestyle interventions for diabetes prevention.

The study is limited in that there were insufficient data to analyze outcomes beyond 12 months; our findings may not translate into long-term therapeutic value due to uncertainty around sustaining outcomes, such as weight loss, in the longer term (68). Furthermore, results in individual studies were not always

reported on an intention-to-treat basis, leading to a likely overestimation of effect sizes. Assuming no change in weight for those with missing data, sensitivity analyses that we conducted suggest that weight loss could be up to 0.5 kg less in practice than the figures reported in the studies.

Due to the nature of pragmatic implementation studies, which include a number of uncontrolled studies, our analysis was restricted to intervention arms only; however, sensitivity analysis, restricted to RCTs only, indicated a mean weight change (−2.7 kg [95% CI −4.2 to −1.2]) that is similar to the overall result. These findings suggest that the estimate based on intervention arms only is likely to be robust.

Implications for Practice

Our review suggests that pragmatic lifestyle interventions are effective at promoting weight loss and could potentially lead to a reduced risk of developing diabetes and cardiovascular disease in the future. However, the difficulties in translating this evidence into practice and in delivering guideline-based interventions need to be overcome. The ability to implement these findings in practice may be further hampered by a lack of resource for service provision, the design of efficient risk identification systems, and engagement of politicians and health care organizations in funding national diabetes prevention programs; diabetes prevention strategies require substantial up-front investment to accrue longer-term benefits (7).

Future Directions

More research is needed to examine the longer-term effectiveness and cost-effectiveness of pragmatic lifestyle interventions for diabetes prevention, including diabetes incidence as well as weight loss outcomes. The practical value of diabetes prevention interventions would be much clearer if we had data on longer-term outcomes. Research is also needed to identify the role of different types of physical activity and dietary changes (6,69) and on ways to increase effectiveness without increasing cost. Possible approaches might include the use of larger group sizes and substitution or supplementation of intervention techniques using self-delivered formats (e.g., Internet, smart phone, or workbook) (70).

Summary

Overall, the interventions were effective, but there was wide variation in effectiveness. Adherence to international guidelines on intervention content and delivery explained much of the variance in effectiveness, implying that effectiveness could be improved by maximizing guideline adherence. However, more research is needed to establish optimal strategies for maximizing both cost-effectiveness and longer-term maintenance of the lifestyle changes that these programs can achieve.

Acknowledgments. The authors specifically thank the following people who contributed to the conduct of the study: Lauren Cooper, Janette Camosso-Stefinovic, Navneet Aujla, and Laura Gray (all from the University of Leicester). The authors thank the following people for responding to requests for additional information or data from the studies they were involved in: Ellen Blaak (Mensink et al.), John Boltri, Bernardo Costa, Aleksandra Gilis-Januszewska, David L. Katz (Faridi et al.), Marie-France Langlois (Bouchard/Gagnon et al.), Euny C. Lee (Parikh), Kathleen McTigue, Vegard Nilsen, Linda Penn, David Simmons, and Paulien Vermunt.

Funding. This project was supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care–Leicestershire, Northamptonshire and Rutland, the University of Leicester Clinical Trials Unit, and the NIHR Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit. C.J.G.'s time was partly supported by the NIHR (Career Development Fellowship CDF-2012-05-259).

This report is independent research, and the views expressed in this publication are those of the author(s) and not necessarily those of the National Health Service, the NIHR, or the Department of Health. No funding bodies had any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Duality of Interest. C.J.G., T.Y., M.J.D., and K.K. were involved in the development of the NICE guidelines on diabetes prevention, and C.J.G. was involved with development of the IMAGE guidelines. C.J.G. in the last 3 years has received payment from *1*) Weight Watchers to make a presentation to some of their U.K. staff, summarizing evidence on weight-loss interventions, the health/economic consequences of weight loss, and the content of current NICE guidance; *2*) Stanford Burgess Health for consultancy on the development of a Web site to support diabetes prevention; and *3*) Novartis Pharma Service, Inc., for delivery of a workshop on supporting behavior change at the Middle East Summit on Cardiovascular Management in October 2011. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. A.J.D. conceived the idea for the review, developed the search strategy, selected and retrieved relevant papers, made the final decisions regarding inclusion/exclusion of all papers, designed the data extraction tool, carried out extraction/checking of data and quality assessments, and wrote the manuscript. D.H.B. conducted the meta-analyses and meta-regression and wrote the manuscript. C.J.G. conceived the idea for the review, coded interventions for adherence to guidelines, and wrote the manuscript. C.R. selected and retrieved relevant papers, carried out extraction/checking of data and quality assessments, and reviewed and edited the manuscript. T.Y. and M.J.D. reviewed and edited the manuscript. K.K. conceived the idea for the review, made the final decisions regarding inclusion/exclusion of all papers, and reviewed and edited the manuscript.

Prior Presentation. Parts of this study were presented in abstract form at the U.K. Society for Behavioural Medicine Annual Scientific Meeting, Oxford, U.K., 9–10 December 2013.

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