RESEARCH
Review

Lifestyle Weight-Loss Intervention Outcomes in Overweight and Obese Adults with Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Clinical Trials

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ABSTRACT

The majority of people with type 2 diabetes are overweight or obese, and weight loss is a recommended treatment strategy. A systematic review and meta-analysis was undertaken to answer the following primary question: In overweight or obese adults with type 2 diabetes, what are the outcomes on hemoglobin A1c (HbA1c) from lifestyle weight-loss interventions resulting in weight losses greater than or less than 5% at 12 months? Secondary questions are: What are the lipid (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides) and blood pressure (systolic and diastolic) outcomes from lifestyle weight-loss interventions resulting in weight losses greater than or less than 5% at 12 months? And, what are the weight and metabolic outcomes from differing amounts of macronutrients in weight-loss interventions? Inclusion criteria included randomized clinical trial implementing weight-loss interventions in overweight or obese adults with type 2 diabetes, minimum 12-month study duration, a 70% completion rate, and an HbA1c value reported at 12 months. Eleven trials (eight compared two weight-loss interventions and three compared a weight-loss intervention group with a usual care/control group) with 6,754 participants met study criteria. At 12 months, 17 study groups (8 categories of weight-loss intervention) reported weight loss <5% of initial weight (−3.2 kg [95% CI: −5.9, −0.6]). A meta-analysis of the weight-loss interventions reported nonsignificant beneficial effects on HbA1c, lipids, or blood pressure. Two study groups reported a weight loss of ≥5%: a Mediterranean-style diet implemented in newly diagnosed adults with type 2 diabetes and an intensive lifestyle intervention implemented in the Look AHEAD (Action for Health in Diabetes) trial. Both included regular physical activity and frequent contact with health professionals and reported significant beneficial effects on HbA1c, lipids, and blood pressure. Five trials (10 study groups) compared weight-loss interventions of differing amounts of macronutrients and reported nonsignificant differences in weight loss, HbA1c, lipids, and blood pressure. The majority of lifestyle weight-loss interventions in overweight or obese adults with type 2 diabetes resulted in weight loss <5% and did not result in beneficial metabolic outcomes. A weight loss of >5% appears necessary for beneficial effects on HbA1c, lipids, and blood pressure. Achieving this level of weight loss requires intense interventions, including energy restriction, regular physical activity, and frequent contact with health professionals. Weight loss for many overweight or obese individuals with type 2 diabetes might not be a realistic primary treatment strategy for improved glycemic control. Nutrition therapy for individuals with type 2 diabetes should encourage a healthful eating pattern, a reduced energy intake, regular physical activity, education, and support as primary treatment strategies.
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TYPE 2 DIABETES AFFECTS APPROXIMATELY 11% OF US adults and 8% of adults worldwide[1,2]; an additional 37% of US adults have prediabetes (51% of those aged 65 years or older).[1] For both conditions, overweight and obesity are major risk factors.[3] Professional organizations and medical care providers recommend weight loss as a primary strategy for glycemic control. For example, the

American Diabetes Association recommends weight loss for all overweight or obese individuals who have or are at risk for diabetes.[3] Weight-loss therapies include lifestyle interventions (eg, nutrition therapy, increased physical activity, education, and support), weight-loss medications, and bariatric surgery. For individuals with prediabetes, strong evidence exists for the benefits of modest weight loss, regular physical activity, and continued education and support for the prevention or delay of type 2 diabetes.[4] In those with newly diagnosed type 2 diabetes, a large retrospective cohort study also found that individuals who lost approximately 10% of their body weight after diabetes diagnosis were more likely to achieve glycemic control and blood pressure targets, despite weight regain, 4 years later compared with individuals with stable or weight gain trajectories.[5] However, the feasibility and health benefits of weight loss greater than or less than 5% in overweight or obese individuals with type 2 diabetes are unclear. Unanswered are questions about the amount of weight loss needed to achieve beneficial outcomes, achievability of needed weight loss, and types of weight-loss interventions that result in beneficial outcomes on hemoglobin A1c (HbA1c), lipids, and blood pressure. The ideal macronutrient composition of weight-loss interventions is also controversial.

The 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity reported that in overweight and obese adults with type 2 diabetes, a 2% to 5% weight loss from lifestyle interventions results in lowering of HbA1c by 0.2% to 0.3% and that weight loss of 5% to 10% is associated with HbA1c reductions of 0.6% to 1.0%.[6] This summary of weight-loss benefits in individuals with type 2 diabetes was based on a 2004 systematic review[7] and a Norris and colleagues 2005 Cochrane Review and meta-analysis[8,9] of weight-loss intervention studies in adults with type 2 diabetes with a follow-up of 1 to 5 years, as well as 1- and 4-year results of the Look AHEAD (Action for Health in Diabetes) trial.[10,11] All but two of the weight-loss studies in the reviews and meta-analysis were published before 2000; therefore, an update on this data is important, which is undertaken in this review and meta-analysis.

Randomized clinical trials and observational studies have shown that medical nutrition therapy for type 2 diabetes effectively improves glycemic control as well as other metabolic outcomes.[12] However, weight loss is not the primary goal of the nutrition therapy interventions in these studies, although it is sometimes reported. In individuals with type 2 diabetes, a variety of nutrition therapy interventions resulted in positive metabolic outcomes, with a common focus of the interventions being a reduced energy intake.[12] However, as the disease progresses and insulin deficiency becomes more prominent, glucose-lowering medications, including insulin, generally need to be added to nutrition therapy to achieve desired glycemic control. At this point, prevention of weight gain, rather than weight loss, often becomes a goal of nutrition therapy.

Registered dietitian nutritionists and medical care professionals routinely provide weight-loss advice to overweight and obese adults with diabetes. There remain uncertainties, however, regarding benefits from various lifestyle weight-loss intervention on improving glycemic control and other metabolic outcomes. Therefore, a systematic review and meta-analysis was undertaken to determine the role of lifestyle weight-loss intervention in nutrition therapy for type 2 diabetes. The primary question was: In overweight or obese adults with type 2 diabetes, what are the outcomes on HbA1c from lifestyle weight-loss intervention resulting in weight losses greater than or less than 5% at 12 months? Secondary questions are: What are the lipid (total cholesterol, LDL-cholesterol [LDL-C], HDL-cholesterol [HDL-C], and triglycerides [TG]) and blood pressure (systolic [SBP] and diastolic [DBP]) outcomes from weight-loss intervention resulting in weight losses greater than or less than 5% at 12 months? And, what are the weight and metabolic outcomes from differing amounts of macronutrients in lifestyle weight-loss intervention in individuals with type 2 diabetes?

RESEARCH DESIGN AND METHODS

Literature Search and Inclusion Criteria

The PubMed online database and Cochrane Library, along with the references of selected articles, were searched to retrieve related abstracts. Medical subject headings used in the online search included "Diabetes Mellitus, Type 2" and "Weight Loss" and "Randomized Clinical Trial" (publication type) and ("2000/01/01" [publication date]: "2014/03/01" [publication date]) and English [language]. As noted, articles were reviewed from January 1, 2000 to March 1, 2014. The year 2000 was selected to begin the search as studies published before that date are included in the 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity in Adults.[6] Study inclusion criteria were the following: a randomized clinical trial $\geq$1 year in duration; lifestyle weight-loss intervention implemented in overweight or obese adults with type 2 diabetes; program completion rate of $\geq$70%; and a 1-year HbA1c value reported. Only studies using lifestyle interventions (ie, diet and/or physical activity) were included, as they are the primary therapies recommended for weight loss in individuals with diabetes. Trials using weight-loss medications or bariatric surgery were not included. The review protocol was not registered. All studies initially identified from the database search were screened by reviewing the abstract. Studies that did not meet all eligibility criteria after review of the abstract or full-text were excluded from additional consideration in this review. From title and abstract analysis, 51 articles were selected for detailed review. After the analysis of the articles, 40 were excluded because they did not meet all of the study criteria (Figure 1).

Data Extraction

Two reviewers independently abstracted relevant data from the full-text articles of studies meeting all study criteria. The original study authors were contacted for additional information where needed in two studies. Changes from participants' mean baseline data to 12 months from weight-loss intervention study groups on study outcomes were assessed. The primary end points were the weighted mean differences in weight loss, both actual (kilograms) and percentage of weight loss, from the weight-loss interventions and resulting effect on HbA1c. Secondary end points were the weighted mean differences on blood lipid

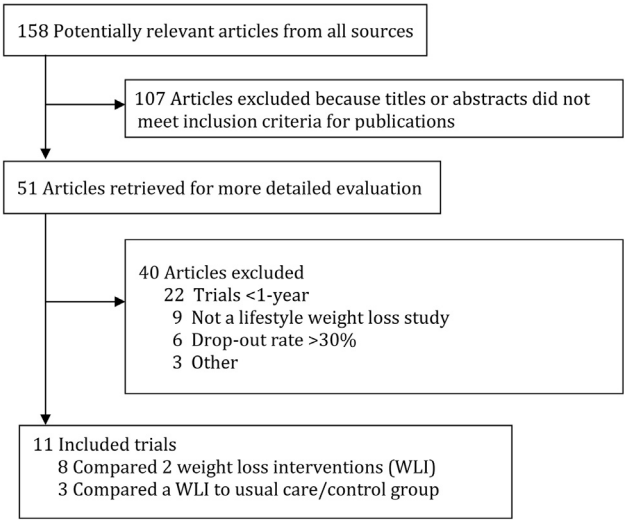

Figure 1. Flow diagram of study selection for weight-loss intervention clinical trials in overweight/obese adults with type 2 diabetes.

levels (total cholesterol [TC], LDL-C, HDL-C, and TG) and blood pressure (SPB and DBP) also from baseline to 12 months from lifestyle weight-loss intervention study groups. Weight-loss interventions implementing differing macronutrient compositions and their weighted mean differences in weight loss and HbA1c outcomes were also secondary end points. Study-specific macronutrients were described qualitatively.

Studies were broken down by weight-loss intervention and resulting mean weight loss in kilograms and percentages and mean change in HbA1c. Weight-loss trials were divided into studies with <5% mean weight loss at 12 months, studies with ≥5% weight loss at 12 months, and usual care/control studies. Data were pooled from study groups in similar categories of weight-loss intervention. For weight-loss intervention studies comparing differing macronutrient compositions data were extracted on reported mean percentages of macronutrient intake, reported mean daily calorie intake and mean daily calorie deficit, mean weight loss (kilograms and percentages), and mean changes in HbA1c, lipids, and blood pressure at 12 months. Given that all studies in this review were randomized controlled trials with similar populations and of similar duration, a formal assessment of bias using an evidence grading system was not used. Study quality is discussed in general terms in the Discussion section.

Statistical Analysis

Meta-analyses were performed using PROC MIXED in SAS 9.3 (SAS Institute, Inc). Each study group of a given trial was treated as a random effect to account for heterogeneity of study populations. Study variances were supplied under the PARMS statement. Forest plots were developed in Microsoft Excel.[13] Effect sizes were estimated for 12-month changes in weight, HbA1c, TC, LDL-C, HDL-C, TG, SBP, and DBP by weight loss category. Similarly, effect sizes were estimated by macronutrient composition for changes in weight and HbA1c.

RESULTS

Literature Search and Study Characteristics

The literature review identified 158 citations for screening. Of these, 51 articles were reviewed with 40 excluded because they did not meet study eligibility criteria. Thirty-one did not meet the criteria for study length, completion rate, study design, or 12-month laboratory data being reported; 6 involved weight-loss drug therapy and 3 bariatric surgery. Eleven randomized clinical trials with a completion rate of ≥70% and 12-month HbA1c outcomes data (Figure 1) fulfilled all eligibility criteria.[10,14-23]

Mean baseline data for study participants, weight-loss intervention interventions, mean weight loss (kilograms and percentages), baseline and mean HbA1c outcomes, and group (<5% or ≥5% weight loss at 12 months or control/usual care) are summarized in Table 1. Across the 11 weight-loss intervention studies (22 study groups), there were 6,754 participants. Nine studies (17 study groups) with 1,365 participants reported weight loss <5% of baseline weight[14-23]; two trials (two study groups) with 2,678 participants reported weight loss ≥5% of baseline weight[10,20]; and 2,711 participants were in the usual care/control study groups (three trials, three study groups).[10,14,15] The mean baseline weight of participants with weight losses <5% was 98.4 kg (range=85.7 to 107.1 kg), for participants with weight losses ≥5% 99.9 kg (range=86 to 100.5 kg), and for participants in the usual care/control study groups 100.6 kg (range=96 to 106.7 kg).

Three of the 11 studies compared a weight-loss intervention with a usual care/control group[10,14,15] and eight of the studies compared two different weight-loss interventions,[16-23] resulting in a total of 19 weight-loss intervention study groups (Table 1). The authors identified 10 categories of weight-loss intervention that were implemented in the 19 weight-loss intervention study groups: meal replacements used for two or more meals per day and as an adjunct to a reduced-energy diet[14,16]; reduced energy intake to achieve a 5% weight loss or a recommended daily caloric deficit of 500 kcal below estimated caloric needs[15,16]; group behavioral weight-management focusing on changes in lifestyle with a strong emphasis on goal setting and problem solving[17]; high-carbohydrate diets with >55% of recommended energy intake from carbohydrate[18,21,22]; low-carbohydrate diets with ≤25% of recommended energy intake from carbohydrate[19,23]; low-fat diets with <30% of recommended energy intake from fat[19,20,23]; high-monounsaturated fat diet with 20% of recommended energy intake from monounsaturated fat[18]; high-protein diets with 30% of recommended energy intake from protein[21,22]; Mediterranean-style diet rich in vegetables, whole grains, olive oil, and energy intake restricted to 1,500 kcal/day for women and 1,800 kcal/day for men, and 150 minutes of weekly physical activity[20]; and intensive lifestyle intervention in which meal replacements or structured food plan and 175 minutes of weekly physical activity were prescribed and participants received frequent follow-up and support using a variety of contact methods.[10,11]

Participants in 7 of the 11 trials reported actual food intake through the use of food records, primarily 3-day food diaries.[14,18-23] Actual food intakes were not reported in three studies.[15-17] Participants in the Look AHEAD trial completed a questionnaire at years 1 and 4 that included

Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a]

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
Meal replacements											
Metz and colleagues, 2000[14]	56 (41 [80])	96	54.6±9.0[b]	45	Meal replacements (prepared meal plan)	5.5±6.4[b] (5.7)	3.0±5.4[b] (3.1)		8.8±1.4[b]	−0.2±1.5[b]	
Li and colleagues, 2005[16]	52 (46 [88])	93	54.4±9.3[b]	59	Soy-based meal replacement	5.3±0.6[c] (5.6)	4.4±0.8[c] (4.7)		7.6±1.4[c]	−0.3	
Pooled data	108 (87 [81])					5.4 (5.7)	3.7 (3.9)				
Reduced energy intake											
Wolf and colleagues, 2004[15]	73 (54 [74])	107.1±25.5[b]	53.3±8.6[b]	38	Individualized meal plan; weight loss goal 5% of initial weight	4.0 (5.6 to 2.5)[d] (3.7)	2.4 (4.1 to 0.6)[d] (2.2)		7.9±1.6[c]	−0.2±1.4[c]	
Li and colleagues, 2005[16]	52 (36 [70])	93	56.6±10.4[b]	67	Daily caloric deficit of 500 kcal/day of estimated calorie needs	2.9±0.7[c] (3.1)	2.4±0.8[c] (2.5)		7.5±1.7[c]	−0.2	
Pooled data	125 (90 [72])					3.6 (3.4)	2.4 (2.3)				
Group behavioral weight management											
West and colleagues, 2007[17]	109 (103 [94])	97±17[b]	54±10[b]	0	Group behavioral weight management	4.7±0.5[c] (4.8)	4.8±0.6[c] (4.9)	18 mo 3.5±0.6[c] (3.6)	7.5±1.4[c]	−0.6±0.1[c]	18 mo −0.1±0.1[c]
West and colleagues, 2007[17]	108 (99 [92])	97±16[b]	52±10[b]	0	Group behavioral weight management plus motivational interviewing	3.1±0.5[c] (3.1)	2.7±0.6[c] (2.7)	18 mo 1.7±0.6[c] (1.7)	7.6±1.4[c]	−0.4±0.0[c]	18 mo −0.2±0.1[c]
Pooled data	217 (202 [93])					3.7 (4.0)	3.8 (3.9)				
High CHO,[e] ≥55% of kcal from CHO											
Brehm and colleagues, 2009[18]	62 (52 [85])	102.1±2.0[c]	56.5±0.8[c]	37	60% CHO, 15% protein, 25% fat; 200 to 300 kcal/day less than daily kcal requirements	3.8±2.0[c] (3.7)	3.8±0.6[c] (3.7)		7.2±0.1[c]	−0	18 mo (−0)
Larsen and colleagues, 2011[21]	46 (44 [96])	95.5 (91.5-99.6)[d]	56.8 (55.8-61.7)[d]	39	55% CHO, 15% protein, 30% fat; 30% energy restriction for 3 mo followed by 9 mo energy balance	3.1 (3.2)	2.2±4.3[b] (2.3)		7.8±0.6[b]	−0.3±1.0[b]	

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
Krebs and colleagues, 2012[22]	212 (150 [71])	101.9±20.1[b]	58.0±9.2[b]	34	55% CHO, 15% protein, 30% fat; energy intake reduced by 500 kcal/day	3.2 (3.1)	2.4±6.6[b] (2.3)	2 y 2.9 (2.8)	8.0±1.2[b]	−0.2	2 y ↑0.1
Pooled data	320 (246 [77])					3.3 (3.2)	2.6 (2.6)				
Low-CHO, ≤25% of kcal from CHO											
Davis and colleagues, 2009[19]	55 (45 [82])	93.6±18[b]	54±6[b]	18	20 to 25 g daily CHO for 2 weeks; Atkins diet thereafter	4.8±3.5[b] (5.1)	3.1±4.8[b] (3.3)		7.5±1.5[b]	−0.0±0.9[b]	
Guldbrand and colleagues, 2012[23]	30 (26 [87])	91.4±19[b]	61.2±9.5[b]	47	20% CHO, 30% protein, 50% fat; 1,600 kcal/day for women, 1,800 kcal/day for men	3.9 (4.3)	1.9±2.0[b]	2 y 2.0 (2.2)	7.5±3.1[b]	−0.2	2 y −0
Pooled data	85 (71 [84])					4.4 (4.7)	2.6 (2.8)				
Low-fat, <30% kcal from fat											
Davis and colleagues, 2009[19]	50 (40 [80])	101±19[b]	53±7[b]	26	25% fat; modeled after the Diabetes Prevention Program	4.4±5.3[b] (4.4)	3.1±5.8[b] (3.0)		7.4±1.4[b]	↑0.2±1.4[b]	
Esposito and colleagues, 2009[20]	107 (97 [91])	85.7±9.9[b]	51.9±10.7[b]	49	<30% fat; based on American Heart Association guidelines; 1,500 kcal/day for women and 1,800 kcal/day for men; physical activity goal of 175 min/wk	Not reported	4.2±3.5[b] (4.9)	4 y 3.2±1.9[b] (3.7)	7.8±0.0[b]	−0.6±0.6[b]	4 y −0.5±0.4[g]
Guldbrand and colleagues, 2012[23]	31 (28 [90])	98.8±2.1[b]	62.7±11[b]	42	30% fat, 50% CHO, 20% protein; 1,600 kcal/day for women and 1,800 kcal/day for men	4.6 (4.7)	3.9±5.9[b] (4.3)	2 y 2.9 (2.9)	7.2±2.9[b]	↑0.1	2 y ↑0.2
Pooled data	188 (165 [88])					4.5 (4.5)	3.9 (4.3)				

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
High MUFA,[f] 20% of kcal from MUFA											
Brehm and colleagues, 2009[18]	62 (43 [69])	103.7±2.8[c]	56.5±0.8[c]	37	20% MUFA (40% fat), 45% CHO, 15% protein 200 to 300 kcal/day less than daily kcal requirements	4.5 (4.3)	4.0±0.8[c]		7.4±0.1[c]	↑0.1	18 mo ↑0.1
High-Protein, >30% of kcal from protein											
Larsen and colleagues, 2011[21]	53 (48 [90])	94.6 (90.5-98.8)[d]	59.6 (57.5-61.8)[d]	57	30% protein, 40% CHO, 30% fat; 30% energy restriction for 3 mo followed by 9 mo of energy balance	2.8 (3)	2.2±3.8[b] (2.3)		7.9±0.5[b]	−0.3±1.0[b]	
Krebs and colleagues, 2012[22]	207 (144 [70])	103.4±19[b]	57.7±9.9[b]	46	30% protein, 40% CHO, 30% fat; total energy intake reduced by ∼500 kcal/day of energy requirements	3.2 (3.1)	3.2±6.6[b] (3.0)	2 y 4.0 (3.9)	8.1±1.2[b]	−0.1	2 y ↑0.1
Pooled data	260 (192 [74])					3.1 (3.1)	2.9 (2.8)				
Pooled data <5% weight loss	n=1,365	98.4					3.2 kg (3.2%)		7.6	−0.2	
Study groups with ≥5% weight loss at 12 mo											
Mediterranean-style Diet											
Esposito and colleagues, 2009[20]	108 (98 [91])	86.0±10.4[b]	52.4±11.2[b]	50	1,500 kcal/day for women and 1,800 kcal/day for men; diet rich in vegetables, whole grains, 30 to 50 g of added olive oil (∼50% CHO, >30% fat); PA goal of 175 min/wk	Not reported	6.2±3.2[b] (7.2)	4-y: 3.8±2.0[b] (4.4)	7.7±0.9[b]	−1.2±1.0[b]	4 y −0.9±0.6[b]

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with ≥5% weight loss at 12 mo											
ILI[g]											
Look AHEAD Trial, 2007; 2010[10,11]	2,570 (2,419 [94])	100.5±19.6[b]	58.6±6.8[b]	41	Portion-controlled diets that included liquid meal replacements and frozen food entrées or structured food plans; goal a minimum weight loss of 7% of initial body weight during 1st year; physical activity goal of 175 min/wk	Not reported	8.6±6.9[b] (8.6)	4-y:4.7 (4.4 to 5.0)[d] (4.7)	7.3±0[c]	−0.6±1.0[c]	4 y −0.2 (0.2 to 0.1)[d]
Pooled data weight loss >5%	n=2,678	99.9					8.5 kg (8.5%)		7.3%	−0.6%	
Usual care/control study groups											
Metz and colleagues, 2000[14]	63 (51 [81])	96	54.0±9.9[b]	40	Macronutrient equivalent diet based on exchange lists	1.5±3.2[b] (1.0)	1.0±3.8[b] (1.0)		8.8±1.2[b]	−0.2±1.3[b]	
Wolf and colleagues, 2004[15]	73 (63 [87])	106.7±24.3[b]	53.4±8.0[b]	42	Received educational materials	1.0 (1.0)	↑0.6 (↑1.0 to ↑2.2)[d] (↑0.5)		7.5±1.5[c]	−0.0±3.0[c]	
Look AHEAD Trial, 2007; 2010[10,11]	2,575 (2,396 [93])	100.8±18.8[b]	58.9±6.9[b]	41	Diabetes support and education; 3 group sessions during 1st year but were not weighed and received no counseling in behavioral strategies	Not reported	0.7±4.8[c] (0.6)	4-y: 1.1 (0.8 to 1.4)[d] (1.1)	7.3±0[c]	−0.1	4 y −0.0 (0.13 to 0.06)[d]
Pooled data	2,711 (2,510 [92])	100.6					0.6 (0.6)		7.4%	−0.1%	

[a]Baseline data were subjects enrolled, weight, age, sex, weight-loss interventions; mean kilogram weight loss (% of weight loss) from baseline; mean hemoglobin A1c (%) at baseline and changes. Weight-loss studies are divided into studies with <5% weight loss at 12 months, studies with ≥5% weight loss at 12 months, and usual care/control studies. Data are pooled from study groups in similar categories of weight-loss interventions.
[b]Values are mean±standard deviation.
[c]Values are mean±standard error of mean.
[d]Values are means or between-group difference (95% CI).
[e]CHO=carbohydrate.
[f]MUFA=monounsaturated fatty acids.
[g]ILI=intensive lifestyle intervention.

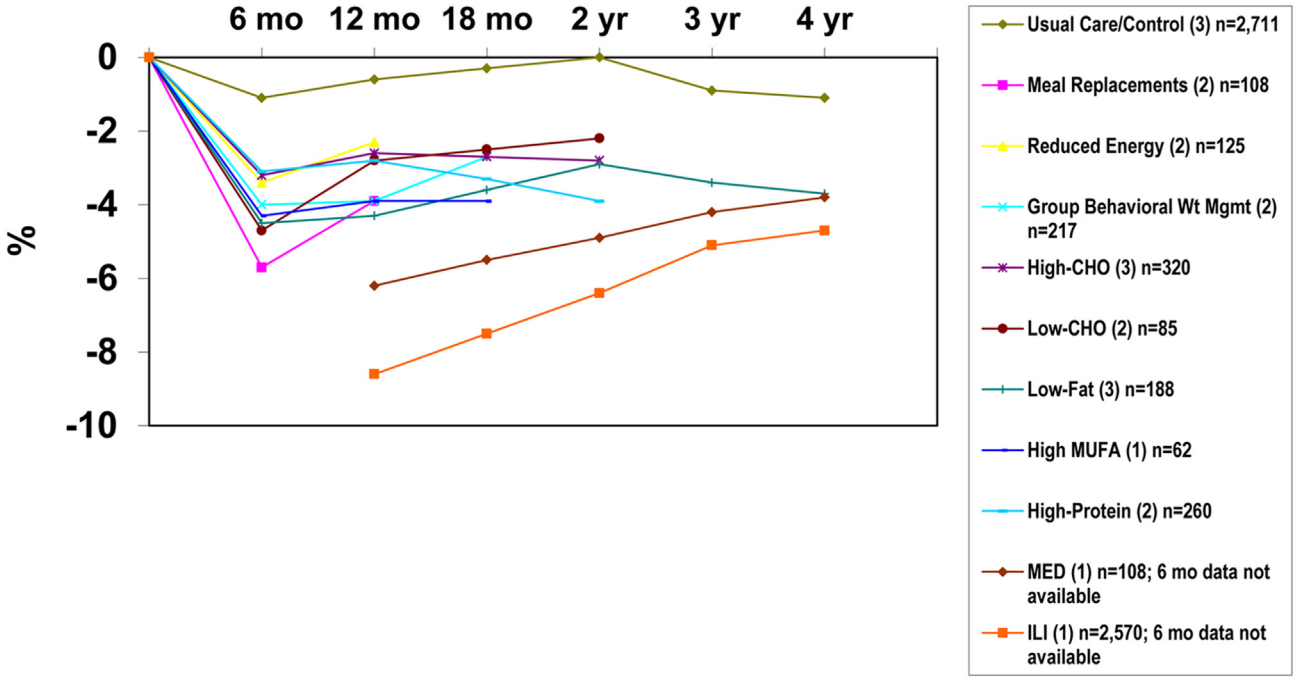

Figure 2. Mean percentage of weight loss/maintenance in individuals with type 2 diabetes from 11 studies of weight-loss interventions (19 weight-loss intervention study groups with 10 categories of weight-loss intervention; n=6,754).

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	0.1	0.10	9.4%	0.1 (-0.09, 0.29)
Brehm[18] High CHO[c]	0	0.11	6.7%	0 (-0.21, 0.21)
Davis[19] Low CHO	-0.02	0.13	5.1%	-0.02 (-0.28, 0.24)
Davis[19] Low Fat	0.24	0.22	2.1%	0.24 (-0.19, 0.67)
Esposito[20] Low-fat	-0.6	0.06	11.2%	-0.6 (-0.71, -0.48)
Gulbrand[23] Low Fat	0.1	0.52	0.5%	0.1 (-0.92, 1.12)
Gulbrand[23] Low CHO	-0.2	0.57	0.4%	-0.2 (-1.3, 0.9)
Krebs[22] High Protein	-0.1	0.10	2.5%	-0.1 (-0.3, 0.1)
Krebs[22] High CHO	-0.2	0.10	2.5%	-0.2 (-0.39, 0)
Larsen[21] High CHO	-0.28	0.15	4.0%	-0.28 (-0.56, 0)
Larsen[21] High Protein	-0.23	0.15	3.3%	-0.23 (-0.52, 0.06)
Li[16] Meal Replacements	-0.3	0.07	19.5%	-0.3 (-0.43, -0.16)
Li[16] Reduced Energy Intake	-0.15	0.08	19.5%	-0.15 (-0.29, 0)
Metz[14] Meal Replacements	-0.24	0.24	1.8%	-0.24 (-0.7, 0.22)
West[17] Group + Motivational Interviewing	-0.44	0.08	5.9%	-0.44 (-0.6, -0.27)
West[17] Group Behavioral	-0.62	0.11	3.4%	-0.62 (-0.84, -0.39)
Wolf[15] Reduced Energy Intake	-0.2	0.19	2.1%	-0.2 (-0.57, 0.17)
12-month Wt loss <5%	**-0.224**			**-0.224 (-0.64, 0.19)**
Esposito[20] Med-Style	-1.25	0.09	44.3%	-1.25 (-1.42, -1.07)
Look AHEAD[10] Intensive Lifestyle	-0.64	0.02	55.7%	-0.64 (-0.67, -0.6)
12-month Wt loss ≥5%	**-0.91**			**-0.91 (-2.3, 0.48)**
Look AHEAD [10] Diabetes Education	-0.12	0.02	60.2%	-0.12 (-0.15, -0.08)
Metz[14] Usual Care	-0.2	0.18	28.0%	-0.2 (-0.55, 0.15)
Wolf[15] Usual Care	0	0.25	11.8%	0 (-0.49, 0.49)
Usual Care/Control	**-0.128**			**-0.128 (-1.56, 1.31)**
Test for heterogeneity: Q=2.39, df=21, I^2=777%				

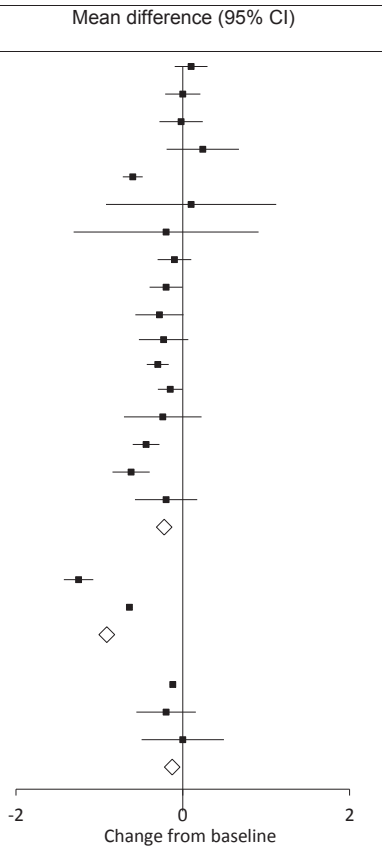

Figure 3. Forest plot for hemoglobin A1c (HbA1c) (%) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	3	7.17	1.2%	3 (-11.04, 17.04)
Brehm[18] High CHO[c]	2	4.90	2.2%	2 (-7.59, 11.59)
Davis[19] Low CHO	3.9	4.38	3.1%	3.9 (-4.69, 12.49)
Davis[19] Low Fat	-5.9	4.28	3.7%	-5.9 (-14.29, 2.49)
Esposito[20] Low-fat	-5.8	0.67	62.1%	-5.8 (-7.11, -4.48)
Gulbrand[23] Low Fat	0	6.95	1.8%	0 (-13.62, 13.62)
Gulbrand[23] Low CHO	-7.8	7.07	1.8%	-7.8 (-21.64, 6.04)
Krebs[22] High Protein	-3.9	2.32	3.3%	-3.9 (-8.44, 0.64)
Krebs[22] High CHO	-1.5	2.28	3.3%	-1.5 (-5.95, 2.95)
Larsen[21] High CHO	0.4	5.75	1.8%	0.4 (-10.87, 11.67)
Larsen[21] High Protein	-5.9	3.76	3.6%	-5.9 (-13.27, 1.47)
Li[16] Meal Replacements	-10.76	6.80	1.3%	-10.76 (-24.08, 2.56)
Li[16] Reduced Energy Intake	-5.3	3.80	5.2%	-5.3 (-12.74, 2.14)
Metz[14] Meal Replacements	6.2	4.09	3.2%	6.2 (-1.81, 14.21)
Wolf[15]Reduced Energy Intake	-1.8	3.90	2.4%	-1.8 (-9.43, 5.83)
12-month Wt loss <5%				**-4.39 (-15.47, 6.69)**
Esposito[20] Med-Style	-15.1	1.48	100.0%	-15.1 (-18.01, -12.18)
12-month Wt loss ≥5%				**-15.1 (-46.43, 16.23)**
Metz[14] Usual Care	1	6.51	59.6%	1 (-11.76, 13.76)
Wolf[15] Usual Care	9	6.01	40.4%	9 (-2.77, 20.77)
Usual Care/Control				**4.24 (-64.36, 72.83)**

Test for heterogeneity: Q=0.970, df=17, I^2=1652%

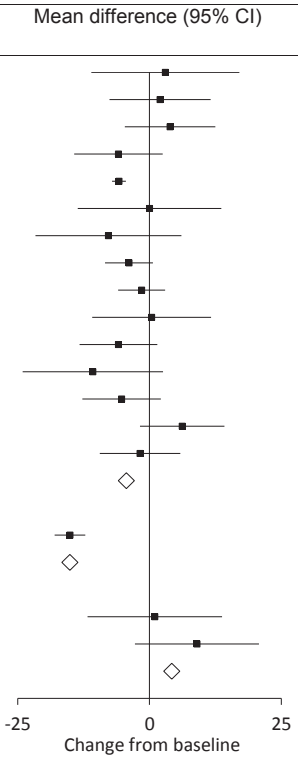

Figure 4. Forest plot for total cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

questions on reducing calorie and fat intake and use of meal replacements; no data from food records were reported.[24]

Although physical activity was suggested or encouraged in several studies,[15,17,18,19,21] only three weight-loss intervention (Mediterranean-style, intensive lifestyle intervention, and one low-fat diet)[10,20] study groups recommended, measured, and reported adherence to physical activity. Four trials did not mention physical activity.[14,16,22,23] Changes in glucose-lowering, lipid, or BP medications can also have an effect on weight-loss intervention outcomes. General decreases in medications at 12 months were reported in seven studies.[10,15,16,19-21,23] Only one study reported an increase in medications at 12 months; the Look AHEAD control study group reported an increase in lipid medications.[25] Four trials did not report on medication changes.[14,17,18,22]

Duration of diabetes can also impact weight-loss intervention outcomes. Participants in the Mediterranean-style diet group were newly diagnosed with type 2 diabetes[20] and participants in the Look AHEAD trial had a mean (±standard deviation) duration of diabetes of 6.8±6.5 years.[26] Only two other trials, all with weight losses <5%, reported on duration of diabetes (range=8.6 to 9.8 years).[21,23]

Data Analysis

Weight Changes. Data from 17 study groups with weight losses <5% at 12 months were pooled into eight categories of weight-loss intervention; the reported average weight losses ranged from 1.9 to 4.8 kg (2.0% to 4.9%).[14-23] Two study groups, the Mediterranean-style diet and intensive lifestyle intervention (Look AHEAD trial), reported weight losses ≥5% at 12 months; weight loss of 6.2±3.2 kg and 8.6±6.9 kg (7.2% and 8.6%), respectively.[10,20] Figure 2 illustrates the mean percentages of weight loss/maintenance from the 10 weight-loss intervention categories and the usual care/control group. Six-month weight changes from baseline in the Mediterranean-style and intensive lifestyle intervention groups were not available. Pooled weight loss from weight-loss intervention groups indicated some maintenance of weight loss, even over several years of follow-up.

Hemoglobin A1c. The overall estimated change in HbA1c at 12 months for the eight categories of weight-loss intervention with weight loss <5% was a decrease of 0.2% (95% CI: −0.6, 0.2), which was not significant compared with baseline (P=0.2787) (Figure 3).[14-23] Two weight-loss intervention study groups reporting ≥5% weight loss at 12 months had significant improvements in HbA1c. The Mediterranean-style diet study group in newly diagnosed patients reported a decrease in HbA1c of 1.2% (95% CI: −1.4, −1.1) at 12 months from a baseline of 7.8% (P<0.0001).[20] The intensive lifestyle intervention in the Look AHEAD trial reported a decrease of 0.6% (95% CI: −0.7, −0.6) at 12 months from a baseline of 7.3% (P<0.0001).[10,26]

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	0	7.00	2.7%	0 (-13.71, 13.71)
Brehm[18] High CHO[c]	-3	4.60	5.2%	-3 (-12.02, 6.02)
Davis[19] Low CHO	-1.5	3.64	9.7%	-1.5 (-8.62, 5.62)
Davis[19] Low Fat	-7	4.03	8.9%	-7 (-14.9, 0.9)
Gulbrand[23] Low Fat	-3.9	4.87	7.9%	-3.9 (-13.43, 5.63)
Gulbrand[23] Low CHO	-7.7	6.35	4.8%	-7.7 (-20.15, 4.75)
Krebs[22] High Protein	-0.3	2.26	7.4%	-0.3 (-4.73, 4.13)
Krebs[22] High CHO	-3	2.22	7.4%	-3 (-7.35, 1.35)
Larsen[21] High CHO	1.7	4.40	6.6%	1.7 (-6.91, 10.31)
Larsen[21] High Protein	-2	3.13	11.1%	-2 (-8.13, 4.13)
Li[16] Meal Replacements	-6.1	6.21	3.3%	-6.1 (-18.27, 6.07)
Li[16] Reduced Energy Intake	8.76	4.22	9.0%	8.76 (0.48, 17.03)
Metz[14] Meal Replacements	7	3.74	8.1%	7 (-0.32, 14.32)
Wolf[15] Reduced Energy Intake	1.6	3.81	7.8%	1.6 (-5.86, 9.06)
12-month Wt loss <5%				**-0.67 (-16.87, 15.53)**
Look AHEAD[10] Intensive Lifestyle	-4.44	0.54	100.0%	-4.44 (-5.49, -3.38)
12-month Wt loss ≥5%				**-4.44 (-61.49, 52.61)**
Look AHEAD[10] Diabetes Education	-3.7	0.54	35.5%	-3.7 (-4.76, -2.63)
Metz[14] Usual Care	-0.3	3.84	42.3%	-0.3 (-7.83, 7.23)
Wolf[15] Usual Care	3.7	4.41	22.3%	3.7 (-4.95, 12.35)
Usual Care/Control				**-0.62 (-34.7, 33.47)**

Test for heterogeneity: Q=0.43, df=17, I^2=3826%

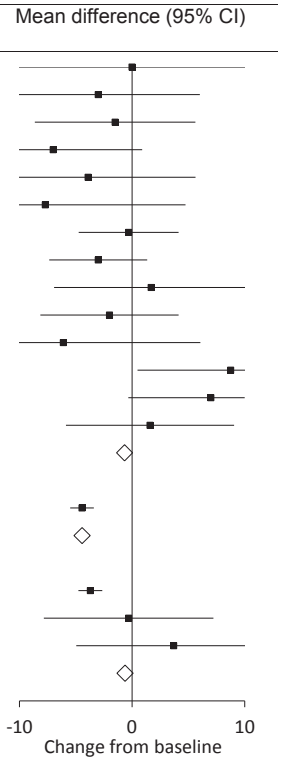

Figure 5. Forest plot for low-density lipoprotein cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Lipids. Ten of the studies measured baseline and 12-month lipid levels.[10,14-16,18-23] Changes in TC were estimated from 16 study groups with reported TC and variance (measures at baseline were used if not reported at 12 months) (Figure 4). For weight loss <5%, the meta-analysis reported a decrease of 4.4 mg/dL (95% CI: −15.5, 6.7) (0.11 mmol/L [95% CI: −0.40, 0.17]), which was not significant from baseline (P=0.4117).[14-16,18-23] The Mediterranean-style diet study group (weight loss ≥5%) reported a significant decrease in TC at 12 months (15.1 mg/dL [95% CI: −18.0, −12.2; P<0.01]) (0.39 mmol/L [95% CI: −0.47, −0.32]).[20]

Changes in LDL-C were estimated from 15 study groups with reported LDL-C and variance (Figure 5). For study groups with a weight loss <5%, the meta-analysis reported a decrease of 0.7 mg/dL (95% CI: −16.9, 15.5) (0.02 mmol/L [95% CI: −0.44, 0.40]), which was not significant from baseline (P=0.9309).[14,15,18-23] The intensive lifestyle intervention study group (weight loss ≥5%) reported a significant decrease in LDL-C at 12 months of −4.4 mg/dL (95% CI: −5.5, −3.4; P<0.001) (0.11 mmol/L [95% CI: −0.14, −0.09]).[10,26]

Changes in HDL-C were estimated from 17 study groups with reported HDL-C and variance (Figure 6). For weight loss <5%, estimated change from 15 study groups reported an increase of 1.2 mg/dL (95% CI: −0.4, 2.8) (0.03 mmol/L [95% CI: −0.01, 0.07]), which was not significant from baseline (P=0.1245).[14-16,18-23] Both the Mediterranean-style diet and intensive lifestyle intervention reported significant increases in HDL-C of 3.9 mg/dL (95% CI: 1.2, 6.6; P<0.01) (0.10 mmol/L [95% CI: 0.03, 0.17]) and 3.4 mg/dL (95% CI: 2.8, 3.9; P<0.0001) (0.09 mmol/L [95% CI: 0.07, 0.10]), respectively.[10,20,26]

Changes in TG were estimated from 17 study groups with reported TG and variance (Figure 7). Estimated change for weight loss <5% from 15 study groups was a decrease of 16.9 mg/dL (95% CI: −89.0, 55.1) (0.19 mmol/L [95% CI: −1.01, 0.62]), which was not significant from baseline (P=0.6232).[14-16,18-23] Both the Mediterranean-style and intensive lifestyle intervention study groups reported significant decreases in TG, 39.0 mg/dL (95% CI: −56.4, −21.6; P<0.001) (0.44 mmol/L [95% CI: −0.64, −0.24]) and 29.3 mg/dL (95% CI: −32.8, −25.8; P<0.0001) (0.33 mmol/L [95% CI: −0.37, −0.29]), respectively.[10,20,26]

Blood Pressure. Eight of the trials (14 weight-loss intervention study groups) reported the effect of weight loss on blood pressure (Figures 8 and 9).[10,14,18-23] For weight loss <5% a nonsignificant decrease from baseline to 12 months in SBP of 2.2 mm Hg (95% CI: −5.8, 1.3)[14,18-23] and a nonsignificant decrease in DBP of 3.5 mm Hg (95% CI: −9.8, 2.7)[14,18-23] were reported. The Mediterranean-style diet and intensive lifestyle intervention study groups reported favorable decreases in SBP at 12 months, 2.3 mm Hg (95% CI: −2.9, −1.7; P<0.01) and 9.9 mm Hg (95% CI: −13.9, −5.9; P<0.0001), respectively, as well as for DBP, 4.0 mm Hg (95% CI: −9.9, 1.9;

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	5	1.20	0.9%	5 (2.64, 7.35)
Brehm[18] High CHO[c]	5	0.71	2.2%	5 (3.6, 6.39)
Davis[19] Low CHO	6.2	1.55	0.5%	6.2 (3.16, 9.23)
Davis[19] Low Fat	2.3	1.28	0.9%	2.3 (-0.21, 4.81)
Esposito[20] Low-fat	1	0.08	89.4%	1 (0.84, 1.15)
Gulbrand[23] Low Fat	3.1	2.01	0.5%	3.1 (-0.84, 7.04)
Gulbrand[23] Low CHO	4.3	2.34	0.3%	4.3 (-0.28, 8.88)
Krebs[22] High Protein	1.1	0.69	0.8%	1.1 (-0.25, 2.45)
Krebs[22] High CHO	0.7	0.68	0.8%	0.7 (-0.62, 2.02)
Larsen[21] High CHO	2.9	1.31	0.7%	2.9 (0.32, 5.47)
Larsen[21] High Protein	3.1	1.55	0.4%	3.1 (0.05, 6.14)
Li[16] Meal Replacements	-0.97	10.00	0.0%	-0.97 (-20.56, 18.62)
Li[16] Reduced Energy Intake	2.26	5.10	0.1%	2.26 (-7.74, 12.26)
Metz[14] Meal Replacements	1.9	0.73	2.1%	1.9 (0.47, 3.32)
Wolf[15] Reduced Energy Intake	0.5	1.74	0.4%	0.5 (-2.91, 3.91)
12-month Wt loss <5%				**1.22 (-0.37, 2.82)**
Esposito[20] Med-Style	3.9	1.36	74.5%	3.9 (1.22, 6.57)
Look AHEAD[10] Intensive Lifestyle	3.37	0.27	25.5%	3.37 (2.84, 3.89)
12-month Wt loss ≥5%				**3.76 (-10.62, 18.15)**
Look AHEAD[10] Diabetes Education	1.35	0.14	36.0%	1.35 (1.07, 1.62)
Metz[14] Usual Care	0.3	0.89	53.7%	0.3 (-1.44, 2.04)
Wolf[15] Usual Care	-0.9	1.64	10.3%	-0.9 (-4.11, 2.31)
Usual Care/Control				**0.55 (-8.26, 9.37)**
Test for heterogeneity: Q=1.46, df=19, I^2=1200%				

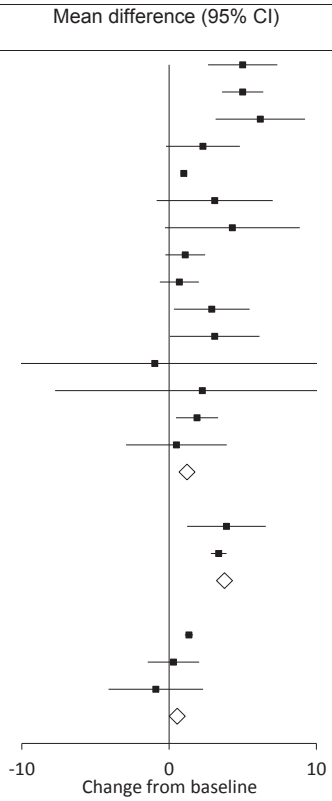

Figure 6. Forest plot for high-density lipoprotein cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

$P<0.001$) and 3.1 mm Hg (95% CI: −3.4, −2.8; $P<0.0001$), respectively.[10,11,20,26]

Macronutrient Composition and Outcomes

Five trials compared lifestyle weight-loss intervention with differing macronutrient compositions (high-monounsaturated fat vs high-carbohydrate,[18] low-carbohydrate vs low-fat,[19,23] and high-protein vs high-carbohydrate[21,22]; Table 2). All five trials reported that 12-month weight changes did not differ statistically between study groups and decreases ranged from 2.5 to 4.0 kg. Meta-analysis of high-carbohydrate, low-carbohydrate, low-fat, or high-protein diets and their effects on changes in HbA1c, lipids, and BP from baseline to 12 months were all nonsignificant (data not shown). Food records were completed by participants in all five trials and were used to measure adherence to diet recommendations. Although the reported macronutrient composition shifted from baseline toward the recommended carbohydrate, protein, or fat percentages at 12 months, the total daily caloric intake was relatively similar (range=1,440 to 1,810 kcal) across the various macronutrient weight-loss intervention groups.

DISCUSSION

Of the 19 lifestyle weight-loss intervention study groups included in this review, 17 (8 weight-loss intervention categories) reported a weight loss at 12 months of <5% of initial weight. A meta-analysis of the weight-loss intervention reported nonsignificant beneficial effects on HbA1c, lipids, and BP. Only two study groups with 12-month weight losses of ≥5% (the Mediterranean-style diet in the Esposito trial[20] and the intensive lifestyle intervention in the Look AHEAD trial[10]) had significant decreases in HbA1c, as well as significant improvements in lipids and BP. Both study groups recommended and measured physical activity and participants had frequent contact with health professionals (registered dietitian nutritionists were the primary counselors in these trials).

In the meta-analysis, the 17 lifestyle weight-loss intervention study groups with <5% weight loss had nonsignificant HbA1c changes at 12 months; however, individually, 6 did report significant improvements in HbA1c: 1 meal replacement,[14] 1 high-carbohydrate,[21] 1 low-fat,[20] 1 high-protein,[21] and 2 study groups of the Group Behavioral Weight Management trial in which the HbA1c improvements at 12 months were not maintained to 18 months.[17] Nonsignificant changes in HbA1c were reported from 11 weight-loss intervention groups: meal replacements,[16] reduced energy intake,[15,16] high carbohydrate,[18,22] low carbohydrate,[19,23] low-fat,[19,23] high monounsaturated fat,[18] and high protein.[22]

Previous evidence documenting the effectiveness of weight loss in individuals with type 2 diabetes and improved glycemic control has been mixed. A review of long-term (1 year or longer in duration) weight-loss trials used to develop

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	-1.0	17.3	3.6%	-1 (-34.9, 32.9)
Brehm[18] High CHO[c]	-5.0	17.0	3.1%	-5 (-38.32, 28.32)
Davis[19] Low CHO	-13.3	11.6	7.6%	-13.3 (-36.09, 9.49)
Davis[19] Low Fat	-0.9	9.4	13.1%	-0.9 (-19.3, 17.5)
Esposito[20] Low-fat	-19.5	4.1	29.1%	-19.5 (-27.44, -11.55)
Gulbrand[23] Low Fat	-8.9	12.7	9.2%	-8.9 (-33.85, 16.05)
Gulbrand[23] Low CHO	0.0	8.1	9.2%	-25.6 (-50.97, -0.22)
Larsen[21] High CHO	-27.0	17.7	3.2%	-27 (-61.67, 7.67)
Larsen[21] High Protein	-41.6	13.1	5.1%	-41.6 (-67.23, -15.96)
Li[16] Meal Replacements	-28.0	16.5	3.7%	-28 (-60.25, 4.25)
Li[16] Reduced Energy Intake	-28.9	23.7	2.3%	-28.89 (-75.37, 17.59)
Metz[14] Meal Replacements	14.2	1.8	2.9%	14.2 (-20.38, 48.78)
Wolf[15] Reduced Energy Intake	-28.4	10.5	7.9%	-28.4 (-49.04, -7.75)
12-month Wt loss <5%				**-16.9 (-88.97, 55.07)**
Esposito[20] Med-Style	-39.0	8.9	75.2%	-39 (-56.41, -21.58)
Look AHEAD[10] Intensive Lifestyle	-29.3	1.8	24.8%	-29.29 (-32.73, -25.84)
12-month Wt loss >5%				**-35.11 (-189.15, 118.91)**
Look AHEAD[10] Diabetes Education	-15.2	1.8	7.8%	-15.18 (-18.68, -11.67)
Metz[14] Usual Care	5.1	4.3	81.9%	5.1 (-3.28, 13.48)
Wolf[15] Usual Care	56.7	9.7	10.3%	56.7 (37.63, 75.76)
Usual Care/Control				**9.07 (-117.39, 135.54)**
Test for heterogeneity: Q=19.76, df=19, I^2=3.8%				

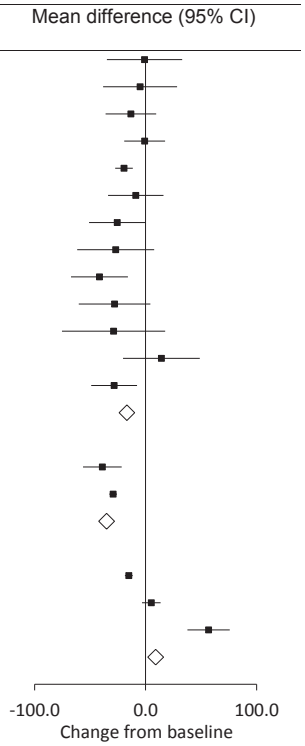

Figure 7. Forest plot for triglycerides (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL triglyceride to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglyceride to mg/dL, multiply mmol/L by 88.6. Triglyceride of 159 mg/dL=1.80 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

practice guidelines for diabetes reported inconsistent improvements in HbA1c for individuals who achieved modest weight loss.[27] A meta-analysis and Cochrane review of weight-loss intervention in participants with type 2 diabetes with long-term follow-up reported a 12-month weight loss of approximately 3.1% (range=−4.5 to −1.7) and decreases in HbA1c of approximately 0.3% (range=−0.8 to 0.2) from weight-loss intervention; the weight loss was significant at $P<0.05$, but the effect on HbA1c was not significant.[8,9] The 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline also reported that weight losses <5% lowered HbA1c by 0.2% to 0.3% and weight losses ≥5% lowered HbA1c by 0.6% to 1.0%, but did not report the statistical significance of these data.

Compared with individuals without diabetes, it is generally more difficult for individuals with diabetes to lose and/or maintain weight loss.[8,28,29] Seventeen of the 19 study groups reported weight losses <5% (1.9 to 4.8 kg; mean of 3.2%) at 12 months; and in a systematic review of weight-loss intervention (diet alone, diet and exercise, and meal replacements) in individuals primarily without diabetes, the mean weight loss at 12 months was 4.5 to 7.5 kg (5% to 8%).[30]

Several factors may contribute to the quality of the studies and inconsistent outcomes across weight-loss studies in individuals with diabetes. First, the lifestyle weight-loss intervention may have been implemented too late in the disease process. The progressive nature of type 2 diabetes has been well documented[31]; therefore, a weight-loss intervention implemented earlier in the disease process as was done in the Mediterranean-style study group may be more effective, especially if implemented before some diabetes medications (eg, insulin secretagogues) are needed that have weight-gain side effects.[32] Secondly, the majority of lifestyle weight-loss intervention may not have been intense enough to produce the weight loss necessary to improve metabolic outcomes. Individuals in the intensive lifestyle intervention study group were seen weekly for the first 6 months and three times per month for the next 6 months; during years 2 through 4, participants were seen individually at least once a month, contacted another time each month by telephone or e-mail, and offered a variety of ancillary group classes. And thirdly, energy restriction is reported to be at least as important, if not more important, than weight loss for improving glycemic control. In general, glucose levels improve rapidly when energy intake is reduced, even before much weight is lost.[5] In addition, weight loss plateaus because of compensatory physiological mechanisms, despite continued maintenance of reduced energy intake.[29,33-35] A reduced energy intake may maintain improved outcomes but does not continue to produce weight loss.[36] A variety of nutrition therapy interventions focusing on reduced energy intake have been shown to improve HbA1c levels and other outcomes. These include reduced energy/fat intake, portion control and healthy food choices, carbohydrate counting, simplified meal plans,[12] as well as a variety of eating patterns.[37]

The ideal macronutrient percentages for weight loss have been an area of controversy. Low-carbohydrate and/or high-protein diets have been recommended for better

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	-2.0	2.3	1.3%	-2 (-6.5, 2.5)
Brehm[18] High CHO[c]	-1.0	1.0	5.4%	-1 (-2.99, 0.99)
Davis[19] Low CHO	2.0	2.1	1.2%	2 (-2.12, 6.12)
Davis[19] Low Fat	-1.8	3.2	0.6%	-1.8 (-8.06, 4.46)
Esposito[20] Low-fat	-2.0	0.2	80.3%	-2 (-2.36, -1.63)
Gulbrand[23] Low Fat	-10.0	2.3	1.7%	-10 (-14.57, -5.42)
Gulbrand[23] Low CHO	-8.0	2.7	1.3%	-8 (-13.36, -2.63)
Krebs[22] High Protein	-0.2	1.1	1.1%	-0.2 (-2.44, 2.04)
Krebs[22] High CHO	-1.3	1.1	1.1%	-1.3 (-3.52, 0.92)
Larsen[21] High CHO	-0.8	1.7	2.3%	-0.8 (-4.03, 2.43)
Larsen[21] High Protein	-5.0	1.6	2.2%	-5 (-8.09, -1.9)
Metz[14] Meal Replacements	-8.8	1.7	1.7%	-8.8 (-12.05, -5.54)
12-month Wt loss <5%				**-2.24 (-5.83, 1.34)**
Esposito[20] Med-Style	-2.3	0.3	43.4%	-2.32 (-2.9, -1.73)
Look AHEAD[10] Intensive Lifestyle	-9.9	2.1	56.6%	-9.9 (-13.94, -5.85)
12-month Wt loss >5%				**-5.24 (-13.77, 3.3)**
Look AHEAD[10] Diabetes Education	-7.0	0.3	92.8%	-7.03 (-7.61, -6.44)
Metz[14] Usual Care	-5.1	0.4	7.2%	-5.1 (-5.89, -4.3)
Usual Care/Control				**-6.61 (-27.56, 14.34)**
Test for heterogeneity: Q=1.74, df=15, I^2=762%				

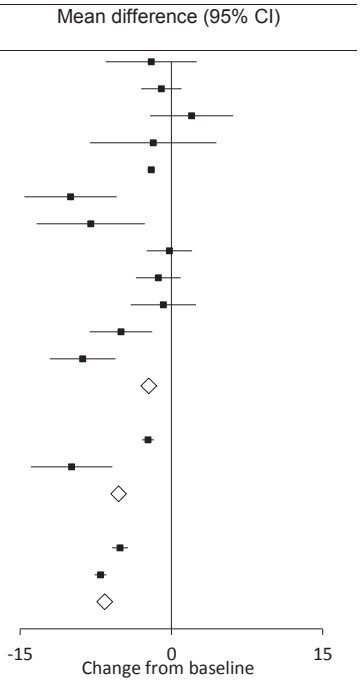

Figure 8. Forest plot for systolic blood pressure (mm Hg) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

weight-loss outcomes in individuals with diabetes.[38,39] To better determine macronutrient composition of weight-loss intervention, a secondary question reviewed five trials comparing different macronutrient percentages and their outcomes. As noted, all study groups reported a similar decrease in caloric intake of approximately 300 kcal, a caloric

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	-5.0	1.4	10.0%	-5 (-7.74, -2.25)
Brehm[18] High CHO[c]	-4.0	1.6	6.3%	-4 (-7.13, -0.86)
Davis[19] Low CHO	-2.9	1.4	9.5%	-2.9 (-5.64, -0.15)
Davis[19] Low Fat	-2.2	1.8	6.2%	-2.2 (-5.79, 1.39)
Esposito[20] Low-fat	-3.0	4.0	0.5%	-3 (-10.84, 4.84)
Gulbrand[23] Low Fat	-8.0	1.6	10.4%	-8 (-11.16, -4.83)
Gulbrand[23] Low CHO	-6.0	2.0	6.9%	-6 (-9.93, -2.06)
Krebs[22] High Protein	-0.1	0.9	7.5%	-0.1 (-1.78, 1.58)
Krebs[22] High CHO	-0.5	0.8	7.5%	-0.5 (-2.15, 1.15)
Larsen[21] High CHO	0.6	1.7	6.6%	0.6 (-2.66, 3.86)
Larsen[21] High Protein	0.2	1.5	6.7%	0.2 (-2.81, 3.21)
Metz[14] Meal Replacements	-5.1	0.9	21.9%	-5.1 (-6.8, -3.39)
12-month Wt loss <5%				**-3.53 (-9.80, 2.73)**
Esposito[20] Med-Style	-4.0	3.0	6.2%	-4 (-9.88, 1.88)
Look AHEAD[10] Intensive Lifestyle	-3.1	0.2	93.8%	-3.07 (-3.37, -2.76)
12-month Wt loss >5%				**-3.13 (-19.13, 12.87)**
Look AHEAD[10] Diabetes Education	-1.6	0.2	40.0%	-1.64 (-1.94, -1.33)
Metz[14] Usual Care	-3.8	1.0	60.0%	-3.8 (-5.69, -1.9)
Usual Care/Control				**-2.94 (-13.31, 7.44)**
Test for heterogeneity: Q=0.90, df=15, I^2=1568%				

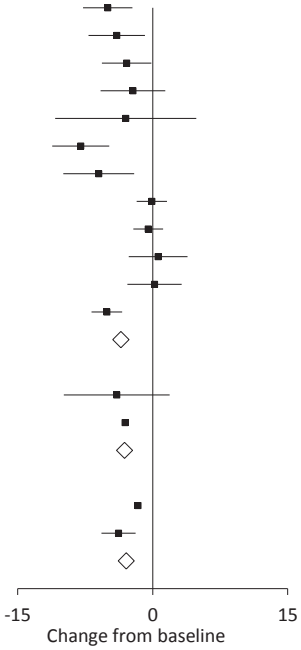

Figure 9. Forest plot for diastolic blood pressure (mm Hg) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Table 2. Lifestyle weight-loss intervention trials in overweight and obese adults with type 2 diabetes comparing differing macronutrient compositions: Recommended and reported macronutrient percentages and daily calorie intake, mean weight loss, and mean change in hemoglobin A1c levels at 12 months

Weight-loss intervention	Author(s), no. of subjects	Recommended macronutrient (carbohydrate, protein, fat), % and daily calorie deficit	Reported macronutrient intake at 12 mo (carbohydrate, protein, fat), %	Reported kcal/day intake at 12 mo (calorie deficit)	Weight loss, kg, mean±SD[a] at 12 mo (%)	Change in hemoglobin A1c, % mean±SD at 12 mo
High CHO[b]	Brehm and colleagues,[18] n=62	60, 15, 25; −200 to 300 kcal/day	54, 18, 28	1,550 (−330)	−3.8±4.3 (3.7)	0±0.8
	Larsen and colleagues,[21] n=46	55, 15, 30; 3-mo −30% kcal (∼1,500 kcal/day), 9-mo energy balance	49, 19, 32	1,580 (−610)	−2.2±4.3 (2.3)	−0.3±1.0
	Krebs and colleagues,[22] n=212	55, 15, 30; −500 kcal/day	48, 21, 31	1,620 (−255)	−2.4 ± 6.6 (2.3)	−0.2±1.1
Low CHO	Davis and colleagues,[19] n=50	20 to 25 g/day CHO for 2 wk; Atkins diet thereafter	33, 23, 44	1,640±600 (−340)	−3.1±4.8 (3.3)	0±0.9
	Gulbrand and colleagues,[23] n=30	20, 30, 50; 1,600 kcal/day for women, 1,800 kcal/day for men	28, 24, 48	1,440 (−250)	−1.9±12.0 (2.0)	−0.2±1.4
Low fat	Davis and colleagues,[19] n=50	25 fat; modeled after the Diabetes Prevention Program	50, 19, 31	1,810±590 (−50)	−3.1±5.8 (3.0)	+0.2±1.5
	Gulbrand and colleagues,[23] n=31	50, 20, 30; 1,600 kcal for women, 1,800 kcal for men	48, 20, 32	1,580 (−225)	−3.9±5.9 (4.3)	+0.1±0.9
High protein	Larsen and colleagues,[21] n=53	40, 30, 30; 3-mo −30% kcal (∼1,500 kcal/day), 9-mo energy balance	42, 27, 31	1,590 (−530)	−2.2±3.8 (2.3)	−0.2±1.1
	Krebs and colleagues,[22] n=207	40, 30, 30; −500 kcal/day	45, 22, 33	1,730 (−150)	−3.2±6.6 (3.0)	−0.1±1.0
High MUFA[c]	Brehm and colleagues,[18] n=62	45, 15, 40 (20 MUFA); 200 to 300 kcal/day	46, 16, 38 (14 MUFA)	1,550 (−350)	−4.0±5.2 (3.9)	+0.1±0.8

[a]SD=standard deviation.
[b]CHO=cholesterol.
[c]MUFA=monounsaturated fatty acids.

intake of approximately 1,600 kcal, and a weight loss of approximately 3 kg. Of concern are the low-carbohydrate diets that report 46% of caloric intake from fat,[19,23] with one trial reporting 20% of total caloric intake from saturated fats.[19] In studies conducted in individuals without diabetes, high-fat diets, especially diets high in saturated fat, consumed long term are reported to contribute to insulin resistance.[40-42] The effect on insulin sensitivity of high-fat and high-saturated fat intakes, especially in reduced-energy diets in individuals with diabetes, is an area of research that requires additional studies.

Of interest, are two studies that did not meet study criteria because of high drop-out rates. Iqbal and colleagues[43] compared the effects of a low-carbohydrate (30 g/day) vs a low-fat diet (≤30% calories from fat and 500 kcal/day deficit) for 24 months in obese individuals with diabetes. No clinically significant changes in weight, HbA1c, or lipids were reported at any of the time points. Caloric intake and macronutrient intake also did not differ significantly between groups at any point, suggesting that low-carbohydrate diets may be difficult to sustain. Similarly, Brinkworth and colleagues[44] did not find significant differences between groups of obese individuals with type 2 diabetes in weight, glycemic control, or lipids in a 64-week randomized controlled trial that compared energy-restricted high-protein to high-carbohydrate diets. Therefore, it can be concluded that a reduced total energy intake is more readily achieved and important than changes in macronutrient distributions and should be prioritized in lifestyle weight-loss intervention.

As with all systematic reviews and meta-analyses, we are limited to abstracting the data reported in the primary studies. It is difficult to account for the potential bias of published studies that favor successful interventions and for enrolling participants most likely to be successful. Community or clinical weight-management programs are likely to experience a higher drop-out rate and with fewer subjects achieving weight and metabolic goals. However, if one assumes that the tendency to enroll subjects likely to be successful is evenly distributed across all intervention types, then the intervention comparison analyses would be appropriate. Furthermore, there are, of course, individual variations in response to lifestyle weight-loss intervention and the conclusions from this analysis only reflect mean responses in the study groups.

Although 7 of the 11 trials did report study participants' food/nutrient intake, 4 did not. Self-reported food intake has well-recognized limitations as under-reporting of energy intake often is common.[45] Periodic recording of food intake also may not accurately reflect the intake over the duration of the study. Of concern is that food/nutrient intake was not reported in the largest of the weight-loss trials, the Look AHEAD Study.

Other limitations of the study data are that not all studies reported participants' duration of diabetes and medication changes. Future weight-loss studies in individuals with type 2 diabetes should focus on methods to more accurately measure adherence to nutrition therapy recommendations, the role of weight loss across the continuum of diabetes, and the interactions of lifestyle changes and medications.

The strength of this study is the inclusion of studies of ≥12 months of follow-up and required completion rate. Weight-loss intervention studies of shorter-term interventions (≤6 months) often report beneficial outcomes that are not maintained long term. Because diabetes is a chronic and progressive disease, nutrition therapy recommendations, including those for weight loss, just as for medications, must change as the disease changes. Weight loss is an important strategy for the prevention or delay of type 2 diabetes and can also be beneficial in individuals with newly diagnosed diabetes, but as insulin deficiency becomes more prominent, the amount of weight that is typically lost in weight-loss programs might not improve metabolic outcomes.

CONCLUSIONS

For overweight or obese individuals with type 2 diabetes, a weight loss of at least 5% improved glucose, lipids, and blood pressure control over 12 months. This amount of weight loss was atypical in the majority of the lifestyle weight-loss interventions reported, shown primarily in the intense, comprehensive, and sustained patient-contact protocol, such as those in the Look AHEAD trial. Such interventions may be impractical in most health care settings today and more translation research is needed to optimize weight-loss intervention for individuals with diabetes. Until more evidence emerges, nutrition therapy for overweight and obese individuals with type 2 diabetes should continue to focus primarily on encouraging a healthful eating pattern with careful attention to reduced portion sizes, energy intake, and participation in regular physical activity to improve metabolic outcomes.[12,27,36] To the extent that weight loss is included as part of the nutrition therapy intervention, a balanced emphasis should be given to realistic goals and expectations in relation to weight-loss and metabolic outcomes.

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STATEMENT OF POTENTIAL CONFLICT OF INTEREST

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