



## **Bilaga 4 Tabell över inkluderade studier**

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Included RCT of diabetes type 2

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Andrews et al 2011 [1] England	RCT, multicentre, parallel-group. Assigned in a 2:5:5 ratio (usual care: intensive diet: intensive diet intervention plus activity).  Newly diagnosed type 2 diabetes, diagnosed 5–8 months previously, 30-80 years  Five secondary care National Health Service trusts  6 and 12 months	<b>Intervention 1 (I)</b> n=248, 36% women  Intensive diet to lose 5–10% initial bodyweight and to maintain this loss. Based on Diabetes UK dietary guidelines and the Balance of Good Health leaflet from the UK Food Standards Agency. Goal-oriented Motivational Interviews. Individual visits: dietitian and study nurses.  <b>Age</b> , mean (SD) 60.1 (10.2) years  <b>Bodyweight</b> , mean (SD) 90.2 (16.7) kg  <b>BMI</b> , mean (SD): 31.5 (5.7) kg/m <sup>2</sup>	n=99, 37% women  Usual care, standard dietary and exercise advice  <b>Age</b> , mean (SD) 59.5 (11.1) years  <b>Bodyweight</b> , mean (SD): 93.9 (19.0) kg  <b>BMI</b> , mean (SD): 32.3 (5.9) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD): 49.9 (11) mmol/mol  <b>Drop out</b> , 2.0% drop-out at 6 months 6.1% at 12 months	Primary  <b>HbA1c</b> IFCC mean (SD)  C: 6 months: 51.48 (11.14) mmol/mol, 12 months: 50,93 (9,95) mmol/mol  I: 6 months: 48,31 (11,59) mmol/mol, 12 months 48,09 (10,38) mmol/mol  I2: 6 months: 48,64 (10.93) mmol/mol, 12 months: 49,18 (10,16) mmol/mol  I vs I2 not significant 6 and 12 months  I vs C: I significantly lower at 6 and 12 months  I2 vs C: I2 significantly lower at 6 and 12 months  <b>Systolic blood pressure</b> mean (SD)  C: 6 months: 134 (13) mmHg, 12 months: 133 (12) mmHg	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, mean (SD): 49.1 (10.2) mmol/mol</p> <p><b>Drop out</b>, 0.4% at 6 months, 0.8% at 12 months</p> <p>-----</p> <p><b>Intervention 2 (I2)</b></p> <p>n=246, 34% women</p> <p>Intensive diet and activity: brisk walking 30 min 5 days per week</p> <p><b>Age</b>, mean (SD): 60.0 (9.7) years</p> <p><b>Bodyweight</b>, mean (SD): 91.1 (16.9) kg</p> <p><b>BMI</b>, mean (SD): 31.6 (5.6) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, 49.6 (10.8) mmol/mol</p> <p><b>Drop out</b>, 1.2% at 6 months, 2.4% at 12 months</p>		<p>I: 6 months: 133 (15) mmHg, 12 months 132 (14) mmHg</p> <p>I2: 6 months: 133 (15) mmHg, 12 months: 133 (15) mmHg</p> <p>No significant differences between groups</p> <p><b>Diastolic blood pressure</b> mean (SD)</p> <p>C: 6 months: 79 (8) mmHg, 12 months: 79 (10) mmHg</p> <p>I: 6 months: 79 (9) mmHg, 12 months 79 (8) mmHg</p> <p>I2: 6 months: 79 (8) mmHg, 12 months: 79 (9) mmHg</p> <p>No significant differences between groups</p> <p>Secondary</p> <p><b>Total Cholesterol</b> mean (SD)</p> <p>C: 6 months: 4.51 (0.88) mmol/L, 12 months: 4.36 (0.94) mmol/L</p> <p>I: 6 months: 4.33 (0.89) mmol/L, 12 months 4.22 (0.87) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I2: 6 months: 4.36 (0.96) mmol/L, 12 months: 4.28 (0.95) mmol/L</p> <p>No significant differences between groups.</p> <p><b>HDL Cholesterol</b> mean (SD)</p> <p>C: 6 months: 1.28 (0.32) mmol/L, 12 months: 1.34 (0.40) mmol/L</p> <p>I: 6 months: 1.28 (0.32) mmol/L, 12 months 1.28 (0.32) mmol/L</p> <p>I2: 6 months: 1.33 (0.38) mmol/L, 12 months: 1.31 (0.35) mmol/L</p> <p>Significant differences at 6 months for I vs I2 and (I lower) I2 vs C (C lower). At 12 month no significant differences.</p> <p><b>LDL Cholesterol</b> mean (SD)</p> <p>C: 6 months: 2.41 (0.76) mmol/L, 12 months: 2.24 (0.81) mmol/L</p> <p>I: 6 months: 2.29 (0.78) mmol/L, 12 months 2.17 (0.71) mmol/L</p> <p>I2: 6 months: 2.33 (0.81) mmol/L, 12 months: 2.22 (0.76) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No significant differences between groups</p> <p><b>Triglycerides</b> mean (SD)</p> <p>C: 6 months: 1.81 (1.13) mmol/L, 12 months: 1.71 (0.97) mmol/L</p> <p>I: 6 months: 1.67 (0.94) mmol/L, 12 months 1.74 (1.35) mmol/L</p> <p>I2: 6 months: 1.50 (0.76) mmol/L, 12 months: 1.63 (1.26) mmol/L</p> <p>Significant differences at 6 months for I vs I2 (I2 lower), I vs C (I lower), I2 vs C (I2 lower). At 12 months not significant.</p> <p><b>Weight</b> mean (SD)</p> <p>C: 6 months: 94.2 (20.0) kg, 12 months: 93.5 (18.1) kg</p> <p>I: 6 months: 88.5 (16.9) kg, 12 months 88.7 (17.3) kg</p> <p>I2 mean (SD): 6 months: 88.4 (16.0) kg, 12 months: 88.7 (16.0) kg</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Significant differences at 6 and 12months for I and I2 vs C (I and I2 lower). Not significant for I vs I2.</p> <p><b>Waist Circumference</b> mean (SD)</p> <p>C: 6 months: 108 (13) cm, 12 months: 108 (12) cm</p> <p>I: 6 months: 104 (12) cm, 12 months 104 (13) cm</p> <p>I2: 6 months: 104 (13) cm, 12 months: 104 (12) cm</p> <p>Significant differences at 6 and 12months for I and I2 vs C (I and I2 lower). Not significant for I vs I2.</p> <p><b>BMI</b> mean (SD)</p> <p>C: 6 months: 32.4 (6.1) kg/m<sup>2</sup>, 12 months: 32.2 (5.6) kg/m<sup>2</sup></p> <p>I: 6 months: 30.9 (5.8) kg/m<sup>2</sup>, 12 months 30.9 (5.9) kg/m<sup>2</sup></p> <p>I2: 6 months: 30.7 (5.3) kg/m<sup>2</sup>, 12 months: 30.7 (5.3) kg/m<sup>2</sup></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Significant differences at 6 and 12 months for I and I2 vs C (I and I2 lower). Not significant for I vs I2</p> <p><b>Medications (% of patients taking medications)</b></p> <p><b><i>Diabetes medication</i></b></p> <p>C: 6 months: 34.3%, 12 months: 44.4% (44/99)</p> <p>I: 6 months: 39.9%, 12 months: 42.7%</p> <p>I2: 6 months: 39.4%, 12 months: 42.3% (104/246)</p> <p>Significant differences at 12 months for I vs C (I lower). Not significant for other time points and comparisons.</p> <p><b><i>Blood pressure medication</i></b></p> <p>C: 6 months: 62.6%, 12 months: 65.7%</p> <p>I: 6 months: 67.7%, 12 months: 70.2%</p> <p>I2: 6 months: 59.4%, 12 months: 63.8%</p> <p>No significant differences between groups.</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Lipid drug</b></p> <p>C: 6 months: 64.5%, 12 months: 66.7%</p> <p>I: 6 months: 66.5%, 12 months: 67.7%</p> <p>I2: 6 months: 62.6%, 12 months: 66.3%</p> <p>No significant differences between groups.</p> <p>Adverse events not reported</p>	
Barnard et al 2009 [2] USA	<p>RCT using a randomisation list</p> <p>Individuals with type 2 diabetes recruited through newspaper advertisements.</p> <p>Of 1,049 subjects screened by telephone, 99 met participation criteria. Mean duration diabetes 8 years. For all, 1 hour to establish a diet plan. Thereafter weekly 1-hour sessions for 22 weeks, followed</p>	<p>n=49, 55% women</p> <p>Low-fat vegan diet (about 10 E% fat, 15 E% protein, and 75 E% CHO). Unrestricted energy intake.</p> <p><b>Bodyweight</b>, mean (SE): 97 (3.3) kg</p> <p><b>Age</b>, mean (SD) 56.7 (9.8) years</p> <p><b>BMI</b>, mean (SD) 33.9 (7.8) kg/m<sup>2</sup></p> <p><b>HbA1c mean (SE)</b>, 8.05 (0.16)%</p>	<p>n=50, 66% women</p> <p>Conventional diet (15–20 E% protein, less than 7 E% saturated fat and 60–70 E% CHO and MUFA). Prescribed energy intake deficit of 500–1 000 kcal.</p> <p><b>Bodyweight</b>, mean (SE): 99.3 (3.0) kg</p> <p><b>Age</b>, mean (SD): 54.6 (10.2) years</p> <p><b>BMI</b>, mean (SD) 35.9 (7.0) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SE): 7.93 (0.14)%</p>	<p>Primary</p> <p><b>Weight</b></p> <p>I: mean (SE): 92.6 (3.5) kg</p> <p>C: mean (SE): 96.3 (3.2) kg</p> <p>No significant differences</p> <p><b>Total Cholesterol</b></p> <p>I: mean (SE): 4.28 (0.12) mmol/L</p> <p>C: mean (SE): 4.76 (0.14) mmol/L</p> <p>No significant differences</p> <p><b>LDL Cholesterol</b></p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	<p>by optional biweekly sessions for 52 weeks</p> <p>Area of Washington DC, USA</p> <p>Follow-up after 74 weeks</p>	<p><b>Drop out</b>, rate at 74 weeks 14% (n=7) for laboratory assessments and 18% (n=9) for dietary records. No reason given.</p>	<p><b>Drop out</b>, rate at 74 weeks 10% (n=5) for laboratory assessments and 14% (n=7) for dietary records. No reason given.</p>	<p>I: mean (SE): 2.35 (0.11) mmol/L</p> <p>C: mean (SE): 2.80 (0.14) mmol/L</p> <p>No significant differences</p> <p><b>HDL Cholesterol</b></p> <p>I: mean (SE): 1.33 (0.07) mmol/L</p> <p>C: mean (SE): 1.21 (0.05) mmol/L</p> <p>No significant differences</p> <p><b>Triglycerides</b></p> <p>I: mean (SE): 1.29 (0.11) mmol/L</p> <p>C: mean (SE): 1.70 (0.33) mmol/L</p> <p>No significant differences</p> <p>Secondary</p> <p><b>HbA1c</b></p> <p>I: mean (SE): 60.77 (2.08) mmol/mol</p> <p>C: mean (SE): 61.64 (1.97) mmol/mol</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No significant differences. If controlling for medication significantly greater reduction in the vegan group (-0.40 vs 0.01; p=0.03)</p> <p><b>Waist Circumference</b></p> <p>I: mean (SE): 106.6 (2.8) cm</p> <p>C: mean (SE): 110.5 (2.1) cm</p> <p>No significant differences.</p> <p><b>BMI</b></p> <p>I: mean (SE): 32.3 (1.2) kg/m<sup>2</sup></p> <p>C: mean (SE): 34.8 (1.1) kg/m<sup>2</sup></p> <p>No significant differences.</p> <p><b>Systolic blood pressure</b></p> <p>I: mean (SE): 123.8 (2.4) mmHg</p> <p>C: mean (SE): 126.6 (2.4) mmHg</p> <p>No significant differences.</p> <p><b>Diastolic blood pressure</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				I: mean (SE): 74.0 (1.4) mmHg C: mean (SE): 77.3 (1.5) mmHg No significant differences No serious adverse events reported	
Bowen et al 2016 [3] USA	RCT with three arms (one arm not relevant here)  Uncontrolled type 2 diabetes ( $\geq 53$ mmol/mol) and no formal diabetes or nutrition education in the past year  Outpatients, received usual diabetes care from their primary care provider throughout the study  Follow up at 6 months	n=50 (44 analysed) 62% women  Nutrition education with certified diabetes educator with carbohydrate counting (negotiated individualized carbohydrate gram goals) during 3 months  <b>Age</b> , median (IQR) 54 (47 to 68) years  <b>Bodyweight</b> , median (IQR) 98.9 (86.2 to 114.3) kg  <b>BMI</b> , median (IQR) 34 (30, 37) kg/m <sup>2</sup>  <b>HbA1c</b> , median (IQR) 68.3 (59.6, 82.5) mmol/mol  <b>Drop out</b> , 12%	n=50 (46 analysed) 46% women  Nutrition education with certified diabetes educator with modified plate model (plate size restrictions without counting) during 3 months  <b>Age</b> , median (IQR) 55 (45 to 60) years  <b>Bodyweight</b> , median (IQR) 101.6 (85.7 to 117.5) kg  <b>BMI</b> , median (IQR) 34 (30, 39) kg/m <sup>2</sup>  <b>HbA1c</b> , median (IQR): 67.2 (58.5, 90.2) mmol/mol  <b>Drop out</b> , 8%	Unadjusted completers analysis of mean within-group changes (95% CI) at 6 months  <b>HbA1c (mmol/mol)</b> I: -4.9 (-9.6 to -0.1), p=0.04 C: -12.4 (-18 to -6.6), p<0.001  <b>Weight (kg)</b> I: -0.94 (-4.24 to 2.36), NS C: -3.63 (-6.31 to -0.95), p=0.008  No adverse events reported	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Brehm  2009 [4] USA	RCT  Type 2 diabetes patients with overweight/obesity  Outpatients in research centre, not on insulin, lipid lowering drugs (other than statins), corticosteroids or weight loss drugs  Follow up at 8 months and 1 year	n=43, 60% women  Two parallel groups with individual meal plans based on 200–300 kcal/day less than calculated daily caloric requirement  Individual or group meetings with dietitian weekly months 1 and 2, biweekly months 3 and 4, and monthly months 5 to 12  High-MUFA group  Less starchy food, fruit and meat/meat substitutes, more fat (canola, olive, avocado), more beans, legumes, and nuts. More oil, nuts, seeds, and olives  45 E% CHO, 15 E% protein, 40 E% fat (with 20 E% MUFA)	n=52, 67% women  High-CHO group  More starchy food, fruit and meat/meat substitutes, less fat, no beans or legumes or nuts 60 E% CHO, 15 E% protein, 25 E% fat  <b>Age</b> , mean $\pm$ SEM Not given/arm 56.5 $\pm$ 0.8 years for all participants  <b>Bodyweight</b> , mean $\pm$ SEM 102.1 $\pm$ 2.0kg  <b>BMI</b> , mean $\pm$ SEM Not given/arm 35.9 $\pm$ 0.3 kg/m <sup>2</sup> for all participants  <b>HbA1c</b> , mean $\pm$ SEM: 55.2 $\pm$ 1.1 mmol/mol  <b>Drop out</b> , 31%	<b>Body weight</b>  I: mean $\pm$ SEM: 8 months 99.3 $\pm$ 2.9kg, 12 months 99.7 $\pm$ 3.0kg  C: mean $\pm$ SEM: 8 months 98.3 $\pm$ 2.1kg, 12 months 98.3 $\pm$ 2.0kg  No significant difference between groups, p=0.867  <b>HbA1c</b>  I: mean $\pm$ SEM: 8 months 53 $\pm$ 2.2%, 12 months 58.5 $\pm$ 3.3 mmol/mol  C: mean $\pm$ SEM: 8 months 54.1 $\pm$ 2.2%, 12 months 55.2 $\pm$ 2.2 mmol/mol  No significant difference between groups  <b>Total Cholesterol</b>  I: mean $\pm$ SEM: 8 months 4.71 $\pm$ 0.17 mmol/L, 12 months 4.76 $\pm$ 0.17 mmol/L  C: mean $\pm$ SEM: 8 months 4.86 $\pm$ 0.14 mmol/L, 12 months 4.66 $\pm$ 0.13 mmol/L  No significant difference between groups	Moderate risk for bias  Randomisation technique and change in medications not described  Larger drop-out rate in high-MUFA group

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>Age</b>, mean <math>\pm</math>SEM Not given/arm 56.5 <math>\pm</math>0.8 years for all participants</p> <p><b>Bodyweight</b>, mean <math>\pm</math>SEM 103.7 <math>\pm</math>2.8 kg</p> <p><b>BMI</b>, mean <math>\pm</math>SEM Not given/arm 35.9 <math>\pm</math>0.3 kg/m<sup>2</sup> for all participants</p> <p><b>HbA1c</b>, mean <math>\pm</math>SEM 57.4<math>\pm</math>1.1 mmol/mol</p> <p><b>Drop out</b>, 16%</p>		<p><b>Triglycerides</b></p> <p>I: mean<math>\pm</math>SEM: 8 months 2.22 <math>\pm</math> 0.31 mmol/L, 12 months 2.27 <math>\pm</math> 0.23 mmol/L</p> <p>C: mean<math>\pm</math>SEM: 8 months 1.96 <math>\pm</math> 0.14 mmol/L, 12 months 2.0 <math>\pm</math> 0.20 mmol/L</p> <p>No significant difference between groups</p> <p><b>LDL Cholesterol</b></p> <p>I: mean<math>\pm</math>SEM: 8 months 2.69 <math>\pm</math> 0.15 mmol/L, 12 months 2.61 <math>\pm</math> 0.16 mmol/L</p> <p>C: mean<math>\pm</math>SEM: 8 months 2.77 <math>\pm</math> 0.13 mmol/L, 12 months 2.51 <math>\pm</math> 0.13 mmol/L</p> <p>No significant difference between groups</p> <p><b>HDL Cholesterol</b></p> <p>I: mean<math>\pm</math>SEM: 8 months 1.19 <math>\pm</math> 0.03 mmol/L, 12 months 1.22 <math>\pm</math> 0.03 mmol/L</p> <p>C: mean<math>\pm</math>SEM: 8 months 1.19 <math>\pm</math> 0.04 mmol/L, 12 months 1.24 <math>\pm</math> 0.04 mmol/L</p> <p>No significant difference between groups</p> <p><b>Systolic blood pressure</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: mean <math>\pm</math> SEM: 8 months <math>127 \pm 2.4</math> mmHg, 12 months <math>130.0 \pm 2.4</math> mmHg</p> <p>C: mean <math>\pm</math> SEM: 8 months <math>130 \pm 2.3</math> mmHg, 12 months <math>129 \pm 2.3</math> mmHg</p> <p>No significant differences.</p> <p><b>Diastolic blood pressure</b></p> <p>I: mean <math>\pm</math> SEM: 8 months <math>75 \pm 1.3</math> mmHg, 12 months <math>73 \pm 1.5</math> mmHg</p> <p>C: mean <math>\pm</math> SEM: 8 months <math>74 (1.1)</math> mmHg, 12 months <math>73 (1.4)</math> mmHg</p> <p>No significant differences between groups</p> <p>No reported side-effects</p>	
Brinkworth et al 2016 [5] Australia	RCT  Overweight and obese adults with type 2 diabetes, aged 35 to 68 years with HbA1c $\geq$ 7.0% and/or using diabetes medication including insulin), ITT	n=58, 36% women  Very-low-carbohydrate, low-saturated fat diet, hypocaloric (LC): 14E% CHO, 28E% protein, 58E% fat (<10% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) for 2 years.	n=57, 49% women  Low-fat, high-carbohydrate, low-glycaemic index diet, hypocaloric (HC): 53E% CHO, 17E% protein, 30E% fat (<10% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) for 2 years.	<b>Body weight (mean (SD))</b>  I: baseline 101.8 (2.0) kg, 12 months 92.6 (2.0) kg,  C: baseline 101.1 (2.0) kg, 12 months 91.0 (2.0) kg;  p=0.83 time x diet interaction.	

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Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Outpatient research clinic 1 year follow-up	Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly. <b>Age</b> , (mean, SD) 58±7 years <b>Bodyweight</b> , (mean, SD) 101.7±14.4 kg <b>BMI</b> , (mean, SD) 34.2±4.5 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 56.3±12 mmol/mol <b>Drop out</b> , 29%	Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly. <b>Age</b> , (mean, SD) 58±7 years <b>Bodyweight</b> , (mean, SD) 101.6±15.8 kg <b>BMI</b> , (mean, SD) 35.1±4.1 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 57.4±12 mmol/mol <b>Drop out</b> , 35%	The overall mean weight loss percentage at 12 months was 9%.  <b>Quality of life (QoL Diabetes-39)</b> (self-administered) Diabetes control I: baseline 19.3 (2.2), 6 months 17.1 (2.3) 12 months 18.5 (2.8) C: baseline 20.3 (2.2) 6 months 14.1 (2.3) 12 months 15.8 (2.8)  Anxiety and Worry I: baseline 31.8 (2.9) 6 months 25.9 (3.0) 12 months 31.5 (3.8) C: baseline 25.9 (2.9) 6 months 17.3 (3.0) 12 months 22.1 (3.9)  Social Burden I: baseline 9.3 (1.7) 6 months 9.4 (2.2) 12 months 10.8 (2.3)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: baseline 7.7 (1.7) 6 months 8.0 (2.1) 12 months 8.1 (2.3)</p> <p>Sexual Functioning</p> <p>I: baseline 24.3 (4.0) 6 months 18.0 (3.6) 12 months 19.6 (3.5)</p> <p>C: baseline 22.8 (4.1) 6 months 12.7 (3.7) 12 months 11.9 (3.5)</p> <p>Energy and Mobility</p> <p>I: baseline 18.1 (2.1) 6 months 14.2 (2.1) 12 months 19.3 (2.3)</p> <p>C: baseline 17.5 (2.1) 6 months 11.7 (2.1) 12 months 12.5 (2.3)</p> <p>Problem Areas in Diabetes</p> <p>I: baseline 22.7 (2.0) 6 months 12.1 (1.5) 12 months 15.4 (1.8)</p> <p>C: baseline 22.3 (2.1) 6 months 11.9 (1.4) 12 months 12.3 (1.9)</p> <p>Significant improvements in all scores except for social burden, with no significant differences between groups.</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Brown et al 2020 [6] United Kingdom	RCT, prospective, parallel-group, non-blinded.  Conducted in London, UK  (Imperial College Healthcare National Health Service (NHS) Trust and in Guy's and St Thomas' NHS FoundationTrust).  Type 2 diabetes, obesity and treated with insulin  Recruited from primary and secondary care  Follow-up 12 months	n=45, 55.6% women  Low-energy total diet replacement (Cambridge Weight Plan, Northants UK) for 12 weeks (800–820 kcal/day, 57% carbohydrate, 14% fat, 26% protein and 3% fibre) in addition to at least 2.25 litres of energy-free beverages. A fibre supplement was recommended, if required, to avoid constipation. Followed by 12 weeks structured food reintroduction. Then energy deficit diet follow-up at 3-month intervals until 12 months.  <b>Age</b> , Median (IQR) 58.5 (50.1 to 64.2) years  <b>Bodyweight</b> , mean (SD) 104.0 (20.2) kg	n=45, 57.8%women  Standardized dietetic care.  Standardized weight management program using a 600-kcal deficit diet for 12 months, aiming for weight loss of 0.5–1.0 kg/week, based on current national guidelines.  <b>Age</b> , Median (IQR) 56.1 (51.0 to 64.5) years  <b>Bodyweight</b> , mean (SD) 103.1 (18.9) kg  <b>BMI</b> , mean (SD) 36.8 (5.3) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD): 9.3 (1.7)%  <b>HbA1c</b> , mean (SD): 78.8 (18.7) mmol/mol  <b>Drop out</b> , 20.0%	Primary  <b>Weight</b> I vs C: mean change (95% CI): –4.3 (–6.3 to –2.3) kg  Significant effect favoring I  At 12 months, weight loss of ≥5% occurred in 79% of participants in the I-group, and 47% of participants in the C-group. Weight loss of ≥10% occurred in 48% of participants in the I-group, and 19% in the C-group.  Secondary  <b>HbA1c (mmol/mol)</b> I vs C: mean change (95% CI): –6.1 (–12.8 to 0.5) mmol/mol  No significant differences between groups  <b>Insulin dose</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>BMI:</b> mean (SD) 36.6 (5.1) kg/m<sup>2</sup></p> <p><b>HbA1c:</b> mean (SD) 8.7 (1.7)%</p> <p><b>HbA1c,</b> mean (SD) 72.2 (19.0) mmol/mol</p> <p><b>Drop out,</b> 26.7%</p>		<p>I vs C: mean change (95% CI): -0.16 (-0.26 to -0.06) U/kg, -18.6 (-29.2 to -7.9) U</p> <p>Significant effect favoring I</p> <p><b>Stopping insulin</b></p> <p>I: n (%): 13 (29)</p> <p>C: n (%): 3 (7)</p> <p>Significant effect favoring I</p> <p><b>Metformin</b></p> <p>I: n (%): 26 (78.8)</p> <p>C: n (%): 34 (94.4)</p> <p>Not significantly different</p> <p><b>Sulfonylureas</b></p> <p>I: n (%): 4 (12.1)</p> <p>C: n (%): 12 (33.3)</p> <p>Significantly different (P=0.037 table S2)</p> <p><b>Gliptins</b></p> <p>I: n (%): 3 (9.1)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: n (%): 7 (19.4)</p> <p>Not significantly different</p> <p><b>Waist circumference</b></p> <p>I vs C: mean change (95% CI): -4.8 (-7.4 to -2.2) cm</p> <p>Significant effect favoring I</p> <p><b>QoL (EuroQol-5)</b></p> <p>I vs C: mean (95% CI): 8.6 points (2.0 to 15.2) Significant effect favoring I</p> <p><b>Triglycerides</b></p> <p>I vs C: mean change (95% CI) -0.36 (-0.83 to 0.11) mmol/L</p> <p>No significant difference between groups</p> <p><b>LDL Cholesterol</b></p> <p>I vs C: mean change (95% CI) 0.20 (-0.08 to 0.47) mmol/L</p> <p>No significant difference between groups</p> <p><b>HDL Cholesterol</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I vs C: mean change (95% CI) 0.05 (-0.03 to 0.13) mmol/L</p> <p>No significant difference between groups</p> <p><b>Systolic blood pressure</b></p> <p>I vs C: mean change (95% CI) 0.8 (-4.6 to 6.3) mmHg</p> <p>No significant difference between groups</p> <p><b>Diastolic blood pressure</b></p> <p>I vs C: mean change (95% CI) -0.62 (-4.5 to 3.3) mmHg</p> <p>No significant difference between groups</p> <p><b>Hypoglycemia</b></p> <p>between groups adjusted incidence rate ratio (95% CI) 0.55, (0.25 to 1.25)</p> <p>No significant differences between groups</p> <p><b>Serious adverse events</b></p> <p>I: number (%): 5 (11)</p> <p>C: number (%): 9 (20).</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				One SAE related to intervention	
Carter, Clifton and Keogh 2019 [7] Australia	RCT, stratified by sex and body mass index (as obese or non-obese)  Type 2 diabetes, over 18 years, any duration managed with diet, oral hypoglycaemic, agents (OHA) and/or insulin and who were overweight or obese.  Follow up at 24 months	n=70, 56% women  Intermittent energy restriction for 2 non-consecutive days/week, 2100 to 2500 kJ/day (500–600 kcal/day), and usual diet for 5 days/week. Given for 12 months  <b>Age</b> , (mean, SD) 61 (9.0) years <b>Bodyweight</b> , (mean, SD) 100 (19) kg <b>BMI</b> , (mean, SD) 35 (5.8) kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 55 (13.1) mmol/mol  <b>Drop out</b> , 37%	n=67, 57% women  Continuous energy restriction, 5000 to 6300 kJ/day (1200–1500 kcal/day) (45% carbohydrate, 30% protein and 25% fat) Given for 12 months  <b>Age</b> , (mean, SD) 61 (9.2) years <b>Bodyweight</b> , (mean, SD) 102 (17) kg <b>BMI</b> , (mean, SD) 37 (5.7) kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 58 (15.3) mmol/mol  <b>Drop out</b> , 40%	ITT-analysis of mean change (SEM) (95% CI) from baseline to 24-months for intermittent vs continuous groups  <b>HbA1c, mmol/mol</b> I: 1.1 (2.2) (-3.3 to 5.5) C: 4.4 ( ) (-2.2 to 9.8) P=0.32 for diet by time  <b>Body weight, kg</b> I: -3.9 (1.1) (-6.1 to -1.7) C: -3.9 (1.1) (-6.0 to -1.7) P=0.19 for diet by time  <b>BMI, kg/m2</b> I: -1.3 (0.4) (-2.1 to -0.6) C: -1.4 (0.4) (-2.2 to -0.7) P=0.26 for diet by time	Moderate risk of bias  Same study as the article below

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Blood lipids, mmol/L</b></p> <p><i>Total cholesterol</i></p> <p>I: 0.03 (0.2) (-0.3 to 0.4)</p> <p>C: -0.3 (0.2) (-0.9 to 0.2)</p> <p>P=0.12 for diet by time</p> <p><i>LDL-C</i></p> <p>I: 0.2 (0.2) (-0.2 to 0.5)</p> <p>C: -0.2 (0.2) (-0.6 to 0.3)</p> <p>P=0.13 for diet by time</p> <p><i>HDL-C</i></p> <p>I: -0.1 (0.06) (-0.2 to 0.02)</p> <p>C: -0.08 (0.06) (-0.2 to 0.04)</p> <p>P=0.15 for diet by time</p> <p><i>Triglycerides</i></p> <p>I: -0.02 (0.2) (-0.3 to 0.3)</p> <p>C: -0.2 (0.3) (-0.7 to 0.3)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>P=0.49 for diet by time</p> <p><b>Medication effect score</b></p> <p><i>Oral hypoglycemic agents</i></p> <p>I: -0.2 (0.1) (-0.5 to -0.01)</p> <p>C: -0.2 (0.1) (-0.4 to 0.03)</p> <p>P= 0.49</p> <p><i>Insulin</i></p> <p>I: -0.6 (0.2) (-1.2 to -0.1)</p> <p>C: -0.2 (0.1) (-0.5 to 0.02)</p> <p>P=0.002</p> <p><i>Total</i></p> <p>I: -0.4 (0.2) (-0.7 to -0.1)</p> <p>C: -0.2 (0.1) (-0.5 to 0.1)</p> <p>P=0.15</p> <p>None of the participants were following the diets at 24 months, but most reported following parts of the principles</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Carter, Clifton and Keogh 2018 [8] Australia	RCT, stratified by sex and body mass index (as obese or non-obese)  Type 2 diabetes, over 18 years, any duration managed with diet, oral hypoglycaemic, agents (OHA) and/or insulin and who were overweight or obese.  Follow up at 12 months	n=70, 56% women  Intermittent energy restriction for 2 days/week, 2100 to 2500 kJ/day (500–600 kcal/day), followed their usual diet for the other 5 days. Given for 12 months  <b>Age</b> , (mean, SD) 61 (9.0) years  <b>Bodyweight</b> , (mean, SD) 100 (19) kg  <b>BMI</b> , (mean, SD) 35 (5.8) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 55.2 (13.1) mmol/mol  <b>Drop out</b> , 27%	n=67, 57% women  Continuous energy restriction, 5000 to 6300 kJ/day (1200–1500 kcal/day) (45% carbohydrate, 30% protein and 25% fat) Given for 12 months  <b>Age</b> , (mean, SD) 61 (9.2) years  <b>Bodyweight</b> , (mean, SD) 102 (17) kg  <b>BMI</b> , (mean, SD) 37 (5.7) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 58.5 (15.3) mmol/mol  <b>Drop out</b> , 31%	ITT-analysis of mean change (SEM) (95% CI) from baseline to 12-months for intermittent vs continuous groups  <b>HbA1c, mmol/mol</b> I: -3.3 (1.1) (-6.6 to -0.9) C: -5.5 (2.2) (-8.7 to -2.2) P=0.65 for diet by time  <b>Body weight, kg</b> I: -6.8 (0.8) (-8.5 to -5.1) C: -5.0 (0.8) (-6.6 to -3.5) P=0.25 for diet by time  <b>BMI, kg/m2</b> I: -2.3 (0.3) (-2.9 to -1.7) C: -1.9 (0.3) (-2.4 to -1.3) P=0.43 for diet by time  <b>Blood lipids, mmol/L</b>	Moderate risk of bias  Same study as the article above

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Total cholesterol, LDL-C, HDL-C and triglycerides stated not to differ between groups, but were not reported per arm</p> <p><b>Medication effect score</b></p> <p><i>Oral hypoglycemic agents</i></p> <p>I: -0.3 (0.1)</p> <p>C: -0.2 (0.1)</p> <p>P= 0.45</p> <p><i>Insulin</i></p> <p>I: -1.2 (0.2)</p> <p>C: -0.3 (0.1)</p> <p>P=0.006</p> <p><i>Total</i></p> <p>I: -0.6 (0.1)</p> <p>C: -0.3 (0.1)</p> <p>P=0.11</p> <p><b>Hypoglycemia, mean number of events</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				I: 2.5 (SEM 0.8) C: 2.0 (SEM 1.0) P=0.74	
Davis et al 2012 [9] USA	RCT  Type 2 diabetes for at least 6 months, BMI $\geq 25$ kg/m <sup>2</sup> , and HbA1c between 6 and 11%.  Primary care, private practice, and hospital-based clinics  Follow-up at 6 and 12 months	n=55, 82% women  Low carb, diet modified after Atkins' model. Two-week phase of carbohydrate restriction of 20–25 g daily depending on baseline weight. Ability for 5g increments each week after weight loss. The energy intake (% of total energy) for carbohydrate/fat/protein was 33.4/43.9/22.7%  General (I and C) recommendations to achieve 150 min and physical activity per week  <b>Age:</b> mean (SD)54 (6) years <b>Weight:</b> mean (SD)93.6 (18) kg <b>BMI:</b> mean (SD)35.6 (6) kg/m <sup>2</sup>	n=50, 74% women  low fat, diet according to Diabetes Prevention Programme (DPP). Fat gram goal, 25% of energy needs, based on baseline weight  The energy intake (% of total energy) for carbohydrate/fat/protein was 50.1/30.8/18.9%  <b>Age,</b> mean (SD) 53 (7) years <b>Weight,</b> mean (SD) 101.1 (19) kg <b>BMI,</b> mean (SD) 37 (6) kg/m <sup>2</sup> <b>HbA1c,</b> mean (SD) 57.4 (15) mmol/mol <b>Drop out:</b> not given	<b>Quality of life</b>  Diabetes-39 questionnaire at 6 months and at 12 months.  Note that Questionnaires were excluded from the analysis if more than 4 items were missing (excluding values from Sexual Functioning Scale). The mean scores for each scale were imputed for missing values on questionnaires missing 4 or less items.  Data only in figure.  Significant improvements in scores for sexual function and energy and mobility, but not different between groups.  Anxiety and worry, diabetes control, social burden, and the summary questions in which participants rated overall quality of	Moderate risk of bias  Same study as ref [10]

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c:</b> mean (SD) 58.5 (16) mmol/mol</p> <p><b>Drop out:</b> not given</p>		<p>life or severity of diabetes were unchanged.</p> <p><u>Data extraction from figure mean (SD):</u></p> <p>Diabetes control baseline 35.8 (20.5)</p> <p>Diabetes control 6 month 34.0 (22.3)</p> <p>Diabetes control 12 month 32.1 (20.3)</p> <p>Anxiety and worry baseline 33.1 (19.2)</p> <p>Anxiety and worry baseline 6 month 27.5 (20.7)</p> <p>Anxiety and worry baseline 12 month 27.7 (23.1)</p> <p>Social burden baseline 19.4 (17.5)</p> <p>Social burden baseline 6 month 21.1 (19.2)</p> <p>Social burden baseline 12 month 19.8 (16.6)</p> <p>Sexual function baseline 32.1 (28.8)</p> <p>Sexual function 6 month 23.3 (26.0)</p> <p>Sexual function 12 month 26.2 (25.3)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				Energy and mobility baseline 33.1 (18.1) Energy and mobility 6 month 27.9 (17.7) Energy and mobility 12 month 27.9 (16.2)	
Davis et al 2009 [10] USA	RCT  Type 2 diabetes for at least 6 months, overweight, and HbA1c between 6 and 11%.  Primary care, private practice and hospital based clinics  Follow-up at 6 and 12 months	n=55, 82% women  Low carb, diet modified after Atkins' model. Two-week phase of carbohydrate restriction of 20–25 g daily depending on baseline weight. Ability for 5g increments each week after wight loss.  General (I and C) recommendations to achieve 150 min and physical activity per week  <b>Age:</b> mean (SD) 54 (6) years  <b>Bodyweight,</b> mean (SD) 93.6 (18) kg  <b>BMI:</b> mean (SD) 35.6 (6) kg/m <sup>2</sup>	n=50, 74% women  Low fat diet according to Diabetes Prevention Programme (DPP).  Fat gram goal, 25% of energy needs, based on baseline weight  <b>Age:</b> mean (SD) 53 (7) years  <b>Bodyweight,</b> mean (SD) 101.1 (19) kg  <b>BMI,</b> mean (SD) 37 (6) kg/m <sup>2</sup>  <b>HbA1c,</b> mean (SD) 57.38 (15.30) mmol/mol  <b>Drop out,</b> 12%	Primary  <b>Weight</b>  I: change (SD): 6 months -4.8 (3.5) kg, 12 months -3.1 (4.8) kg  C: change (SD): 6 months -4.4 (5.3) kg, 12 months -3.1 (5.8) kg  P difference all time points 0.005  <b>HbA1c, mmol/mol</b>  I: change (SD): 6 months -3.1 (10.06), 12 months -0.21 (9.73)  C: change (SD): 6 months -1.64 (12.02)%, 12 months 2.62 (15,30)  p difference all time points 0.71  Secondary	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c:</b> mean (SD) 58.48 (16.40) mmol/mol</p> <p><b>Drop out, 14%</b></p>		<p><b>Systolic blood pressure</b></p> <p>I: change (SD): 6 months -0.78 (17.7) mmHg, 12 months -2.0 (15.6) mmHg</p> <p>C: change (SD): 6 months -37 (19.8) mmHg, 12 months -1.8 (22.6) mmHg</p> <p>Difference 6 month 36.22,</p> <p>Difference 12 month -0.2</p> <p>p difference all time points 0.15</p> <p><b>Diastolic blood pressure</b></p> <p>I: change (SD): 6 months -0.93 (12.4) mmHg, 12 months -2.9 (9.4) mmHg</p> <p>C: change (SD): 6 months 0.95 (9.8) mmHg, 12 months -2.2 (11.6) mmHg</p> <p>Difference 6 month -1.88</p> <p>Difference 12 month -0.7</p> <p>p difference all time points 0.62</p> <p><b>Total cholesterol</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: change (SD): 6 months 0.05 (0.79) mmol/l, 12 months 0.10 (0.76) mmol/l</p> <p>C: change (SD): 6 months -0.27 (0.74) mmol/l, 12 months -0.13 (0.70) mmol/l</p> <p>p difference all time points 0.37</p> <p><b>LDL Cholesterol</b></p> <p>I: change (SD): 6 months -0.10 (0.52) mmol/l, 12 months -0.04 (0.63) mmol/l</p> <p>C: change (SD): 6 months -0.25 (0.56) mmol/l, 12 months -0.18 (0.66) mmol/l</p> <p>p difference all time points 0.23</p> <p><b>HDL Cholesterol</b></p> <p>I: change (SD): 6 months 0.16 (0.28) mmol/l, 12 months 0.16 (0.27) mmol/l</p> <p>C: change (SD): 6 months -0.01 (0.22) mmol/l, 12 months 0.06 (0.21) mmol/l</p> <p>p difference all time points 0.002</p> <p><b>Triglycerides</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: change (SD): 6 months -0.02 (0.85) mmol/l, 12 months -0.15 (0.88) mmol/l</p> <p>C: change (SD): 6 months 0.04 (0.56) mmol/l, 12 months -0.01 (0.89) mmol/l</p> <p>p difference all time points 0.53</p> <p>No reports on adverse events</p>	
Esposito et al 2009 [11] Italy	<p>RCT, parallel, single centre, teaching hospital</p> <p>Newly diagnosed type 2 diabetes</p> <p>Outpatients</p> <p>Duration, design: 4 years</p>	<p>n=108, 50% women</p> <p>Mediterranean-style diet</p> <p>Rich in vegetables, whole grain, poultry, fish, low in red meat</p> <p>CHO: ≤50 E% Fat: ≥30 E%, 30–50 g olive oil</p> <p>Energy intake: ≤1 800 kcal for men, ≤1 500 kcal for women</p> <p>For both diets, nutritionist/dietician gave dietary advice monthly (first year) or bimonthly</p> <p><b>Age</b>, mean (SD) 52. 4 (11.2) years</p>	<p>n=107, 51% women</p> <p>Low-fat diet, based on American Heart Association guidelines</p> <p>Rich in whole grain, restricted in additional fat, sweets, high-fat snacks</p> <p>Fat: ≤30 E%, SF ≤10 E% Energy intake: ≤1 800 kcal for men, ≤1 500 kcal for women</p> <p><b>Age</b>, mean (SD) 51.9 (10.7) years</p> <p><b>Weight</b> mean (SD) 85. 7 (9.9) kg</p> <p><b>BMI</b>, mean (SD) 29.5 (3.6) kg/m<sup>2</sup></p>	<p>Primary</p> <p><b>Need of anti-hyperglycemic medication</b></p> <p>(covers about 97% of patients with HbA1c &gt;7%)</p> <p>I proportion (95% CI) after 18 months: 12 (8 to 16)%, 4 years: 44 (34 to 53)%</p> <p>C proportion (95% CI) after 18 months: 24 (18 to 31), 4 years: 70% (62 to 79)</p> <p>Significant different for both time points favouring I. Hazard ratio (95%CI): 0.63 (0.51 to 0.86)</p> <p>Secondary</p> <p><b>Weight</b></p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>Weight</b>, mean (SD) 86.0 (10.4) kg</p> <p><b>BMI</b>, mean (SD) 29.7 (3.4) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 61.2 (9,8) mmol/mol</p> <p><b>Drop out</b>, 9% in 4 years</p>	<p><b>HbA1c</b>, mean (SD) 60.8 (9.8) mmol/mol</p> <p><b>Drop out</b>, 9% in 4 years</p>	<p>I vs C difference (95% CI): 1 year -2.0 (-3.0 to -0.9) kg, 4 years -0.6 (-1.6 to 1.2) kg</p> <p><b>BMI</b></p> <p>I vs C difference (95% CI): 1 year -1.0 (-2.2 to -0.3) kg/m<sup>2</sup>, 4 years -0.3 (-0.9 to 0.4) kg/m<sup>2</sup></p> <p><b>Waist circumference</b></p> <p>I vs C difference (95% CI): 1 year -1.3 (-1.7 to -0.5) cm, 4 years -0.4 (-0.9 to 0.5) cm</p> <p><b>HbA1c</b></p> <p>I vs C difference (95% CI): 1 year -6.6 (-9.8 to -3.3) mmol/mol, 4 years -4.4 (-9.8 to -1.1) mmol/mol</p> <p><b>Total Cholesterol</b></p> <p>I vs C difference (95% CI): 1 year -0.24 (-0.36 to -0.12) mmol/L, 4 years -0.15 (-0.39 to 0.05) mmol/L</p> <p><b>HDL Cholesterol</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I vs C difference (95% CI): 1 year 0.08 (0.04 to 0.12) mmol/L, 4 years 0.07 (0.02 to 0.14) mmol/L</p> <p><b>Triglycerides</b></p> <p>I vs C difference (95% CI): 1 year -0.22 (-0.32 to -0.10) mmol/L, 4 years -0.21 (-0.36 to -0.02) mmol/L</p> <p><b>Systolic blood pressure</b></p> <p>I vs C difference (95% CI): 1 year -3.1 (-4.9 to -1.2) mmHg, 4 years -1.5 (-4.5 to 1.2) mmHg</p> <p><b>Diastolic blood pressure</b></p> <p>I vs C difference (95% CI): 1 year -1.0 (-4.0 to -1.0) mmHg, 4 years -1.4 (-4.0 to 1.8) mmHg</p> <p><b>Adverse events</b></p> <p>I: 21%</p> <p>C: 23%</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				One patient in each group had a serious adverse event, not related to the study medications	
Esposito 2014 [12] Italy	RCT, parallel, single centre, teaching hospital  Newly diagnosed type 2 diabetes  Outpatients  Extended study after 4 years. Not planned for in the original study. Duration 8.1 years, when last patient reached primary endpoint.  See Esposito 2009 [11].	n=108, 50% women  Mediterranean-style diet. Vegetables, whole grain, poultry, fish. Low in red meat. CHO: ≤50 E% Fat: ≥30 E%, 30–50 g olive oil. Energy intake: 1 800 kcal for men, 1 500 kcal for women.  Diet diaries after instruction (both groups), reviewed by nutritionist/ dietician monthly (first year) or bimonthly.  <b>Age</b> , mean (SD) 52. 4 (11.2) years  <b>Bodyweight</b> : mean (SD) 86.0 (10.4) kg  <b>BMI</b> : mean (SD) 29.7 (3.4) kg/m <sup>2</sup>	n=107, 51% women  Low-fat diet, based on American Heart Association guidelines Whole grain. Restricted additional fat, sweets, high-fat snacks. Fat: ≤30 E%, SF ≤10 E%, Energy intake: 1 800 kcal for men, 1 500 kcal for women.  <b>Age</b> , mean (SD) 51.9 (10.7) years  <b>Bodyweight</b> , mean (SD) 85.7 (9.9) kg  <b>BMI</b> : mean (SD) 29.5 (3.6) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 60.8 (9.8) mmol/mol  <b>Drop out</b> , 10% in 8 years	Primary  <b>Patients requiring pharmacological treatment for hyperglycaemia</b>  I: median survival time (95% CI) 2.8 years (2.4 to 3.2)  C: median survival time (95% CI) 4.8 years (4.3 to 5.2), Unadjusted hazard ratio for the overall follow-up was 0.68 (0.50 to 0.89)  <b>Remission (fasting plasma glucose level &lt;100 mg/dL and HbA1c&lt;5.7% (39 mmol/mol)</b>  I vs C prevalence ratio: 5.2 (95% CI 2.5–8.9); P<0.001) across all years  Secondary  <b>Weight</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, mean (SD) 61.2 (9.8) mmol/mol</p> <p><b>Drop out</b>, 9% in 8 years.</p>		<p>I vs C cumulative differences (95% CI) -0.98 kg (CI -1.5 to -0.4)</p> <p><b>HbA1c</b></p> <p>I vs C cumulative differences (95% CI) -5.5 (-6.6 to -4.4) mmol/mol</p> <p><b>Waist circumference</b></p> <p>I vs C difference (95% CI): 3 years -0.6 (-1.3 to 0.1) cm, 6 years -0.7 (-1.7 to 0.3) cm</p> <p><b>Total cholesterol</b></p> <p>I vs C difference (95% CI): 3 years -0.08 (-0.18 to 0.08) mmol/L, 6 years -0.10 (-0.26 to 0.05) mmol/L</p> <p><b>HDL-Cholesterol</b></p> <p>I vs C difference (95% CI): 3 years 0.10 (0.01 to 0.20) mmol/L, 6 years 0.12 (0.01 to 0.24) mmol/L</p> <p><b>Triglycerides</b></p> <p>I vs C difference (95% CI): 3 years -0.17 (-0.36 to 0) mmol/L, 6 years -0.14 (-0.34 to 0.07) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Systolic Blood pressure, mmHg</b></p> <p>I vs C difference (95% CI): 3 years -2.8 (-4.9 to -0.3) mmHg, 6 years -1.8 (-4.5 to 1.0) mmHg</p> <p><b>Diastolic blood pressure</b></p> <p>I vs C difference (95% CI): 3 years -0.9 (-3.1 to 1.5) mmHg, 6 years -1.5 (-4.0 to 1.9) mmHg</p> <p><b>Antihypertensive medication at 4 years</b></p> <p>I: 23%</p> <p>C: 22.5%</p> <p><b>Lipid-lowering agents at 4 years</b></p> <p>I: 13%</p> <p>C: 16.5%</p> <p>Adverse events not reported</p>	
Goldstein et al 2011	RCT Type 2 diabetes, aged 35 to 75 years, BMI 30 to 39.9 kg/m <sup>2</sup> , HbA1C	n=26, 50% women Modified Atkins diet, very low carbohydrate diet containing	n=26, 46% women ADA diet (2001). Calorie-restricted 10% to 20% of the daily energy intake from protein and the other	Primary Unadjusted data from baseline. <b>Weight</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[13] Israel	<p>over 7%, not receiving insulin, and microalbumin excretion &lt; 60 mg/day.</p> <p>Before randomisation a 4-week personalized diet based on DASH.</p> <p>Advised to physical activities 3 times a week 30 min.</p> <p>University hospital clinic</p> <p>Follow up 6 and 12 months</p>	<p>25 g of carbohydrates daily for the first 6 weeks thereafter increasing 40 g daily. No restrictions</p> <p>were placed on intake of energy. Fat intake was encouraged,</p> <p>monounsaturated fatty acid (MUFA) and protein from poultry and fish.</p> <p>Weekly counselling for 12 weeks than monthly.</p> <p><b>Age</b>, mean (SD): 57 (9) years</p> <p><b>Bodyweight</b>, mean (SD) 91.7 (10.2) kg</p> <p><b>BMI</b>, mean (SD) 33.1 (3.6) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 74.87 (18.58) mmol/mol</p> <p><b>Drop out</b>: 6 months 23%, 12 months 46%</p>	<p>80% divided between fats (18 to 20% of calories as MUFA, 8 to 10% as polyunsaturated fatty acids (PUFA) and 9 to 10% as saturated fats), carbohydrates and 35 g of fibres. Men were allowed up to</p> <p>1500 kcal/day and women, 1200 kcal/day.</p> <p><b>Age</b>, mean (SD)</p> <p>55 (8) years</p> <p><b>Bodyweight</b>, mean (SD)</p> <p>92.2 (13.7) kg</p> <p><b>BMI</b>, mean (SD) 33.3 (3.0) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 72.68 (13.11) mmol/mol</p> <p><b>Drop out</b>: 6 months 23%, 12 months 38%</p>	<p>I: mean difference (SD): 6 months -5.9 (4.9) kg</p> <p>C: mean difference (SD): 6 months -4.7 (4.7) kg</p> <p>No significant difference between groups (P= 0.58)</p> <p><b>HbA1c</b></p> <p>I: mean difference (SD): 6 months -17.5 (19.7) mmol/mol: Calculated to final of 57.4 mmol/mol</p> <p>C: mean difference (SD): 6 months -10.93 (13.12) mmol/mol: Calculated to final of 61.8 mmol/mol</p> <p>No significant difference between groups. (P=0.31)</p> <p>Secondary</p> <p><b>Total cholesterol</b></p> <p>I: mean difference (SD): baseline 5.02 (0.65) mmol/L, 6 months -0.41 (0.55) mmol/L</p>	High risk of bias for outcomes at 12 months

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: mean difference (SD): baseline 5.17 (0.96) mmol/L, 6 months -0.39 (0.78) mmol/L</p> <p>No significant difference between groups. (P=0.60)</p> <p><b>Triglycerides</b></p> <p>I: mean difference (SD): baseline 2.31 (1.12) mmol/L, 6 months -0.71 (1.04) mmol/L</p> <p>C: mean difference (SD): baseline 2.21 (0.97) mmol/L, 6 months -0.34 (0.64) mmol/L</p> <p>No significant difference between groups. (P=0.15)</p> <p><b>HDL Cholesterol</b></p> <p>I: mean difference (SD): baseline 1.14 (0.33) mmol/L, 6 months 0.05 (0.21) mmol/L</p> <p>C: mean difference (SD): baseline 1.14 (0.26) mmol/L, 6 months 0.09 (0.23) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No significant difference between groups. (P=0.71)</p> <p><b>Systolic blood pressure</b></p> <p>I: mean difference (SD): baseline 141 (17) mmHg, 6 months -12 (22) mmHg</p> <p>C: mean difference (SD): baseline 136 (14) mmHg, 6 months -6 (13) mmHg</p> <p>No significant difference between groups. (P=0.32)</p> <p><b>Diastolic blood pressure</b></p> <p>I: mean difference (SD): baseline 79 (10) mmHg, 6 months -4.6 (13) mmHg</p> <p>C: mean difference (SD): baseline 80 (9) mmHg, 6 months -5.3 (8) mmHg</p> <p>No significant difference between groups. (P=0.76)</p> <p>No identified incidents of hypoglycaemia</p>	
Guldbrand et al	RCT, non-stratified, drawing blinded ballots	n=30, 53% women Low-carbohydrate diet. Energy content: 50E%fat, 20 E%	n=31, 58% women Traditional low-fat diet, caloric content of 1600 kcal for women or	<b>Weight</b> mean (SD)	Moderate risk of bias for outcomes

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
2012 [14] Sweden	Type 2 diabetes with or without oral anti-diabetic medication, incretin-based therapy, or insulin  Two primary health care centres in Sweden  Follow up points: 6, 12, 24 months	carbohydrates and 30 E% protein  Group information used to inform about which food items to choose from, and this was given at baseline, at 2, 6 and 12 months by two different Physicians  <b>Age</b> , mean (SD) 61.2 (9.5) years  <b>Bodyweight</b> , mean (SD) 91.4 (19) kg  <b>BMI</b> : mean (SD) 31.6 (5.0) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 58.48 (33.90) mmol/mol  <b>Drop out</b> , 13% (Discontinued intervention)	1800 kcal for men. Energy content: 30 E% fat (less than 10 E% from saturated fat), 55 to 60 E% carbohydrates and 10 to 15 E% protein.  <b>Age</b> , mean (SD) 62.7 (11) years  <b>Bodyweight</b> , mean (SD) 98.8 (21) kg  <b>BMI</b> , mean (SD) 33.8 (5.7) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 55.20 (31.70) mmol/mol  <b>Drop out</b> , 10%  (Discontinued intervention)	I: 6 months, 87.5 (19) kg, 12 months 89.5 (19) kg, 24 months 89.4 (22) kg  C: 6 months, 94.2 (21) kg, 12 months 94.9 (21) kg, 24 months 95.9 (21) kg  No significant differences between I vs C  <b>BMI</b> mean (SD) I: 6 months, 30.1 (5.1) kg/m <sup>2</sup> , 12 months 30.7 (5.3) kg/m <sup>2</sup> , 24 months 30.8 (5.8) kg/m <sup>2</sup> C: 6 months, 32.3 (5.5) kg/m <sup>2</sup> , 12 months 32.6 (5.3) kg/m <sup>2</sup> , 24 months 32.8 (5.5) kg/m <sup>2</sup>  No significant differences between I vs C  <b>Waist circumference</b> mean (SD) I: 6 months, 102 (14) cm, 12 months 104 (15) cm, 24 months 104 (16) cm C: 6 months, 106 (15) cm, 12 months 106 (14) cm, 24 months 108 (16) cm  No significant differences between I vs C	HbA1c, weight, BMI, waist circumference, blood pressure, TC, LDL, HDL and TG  High risk of bias for changes in insulin use

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>HbA1c mean (SD)</b></p> <p>I: 6 months, 54.10 (33.90) mmol/mol, 12 months 56.29 (36.10) mmol/mol, 24 months 58.48 (33.90) mmol/mol</p> <p>C: 6 months, 55.20 (32.79) mmol/mol, 12 months 56.29 (34.98) mmol/mol, 24 months 57.38 (33.90) mmol/mol</p> <p>No significant differences between I vs C</p> <p><b>Systolic blood pressure mean (SD)</b></p> <p>I: 6 months, 126 (17) mmHg, 12 months 127 (13) mmHg, 24 months 126 (14) mmHg</p> <p>C: 6 months, 128 (12) mmHg, 12 months 126 (12) mmHg, 24 months 125 (13) mmHg</p> <p>No significant differences between I vs C</p> <p><b>Diastolic blood pressure mean (SD)</b></p> <p>I: 6 months, 72 (8) mmHg, 12 months 70 (10) mmHg, 24 months 71 (8) mmHg</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: 6 months, 74 (8) mmHg, 12 months 69 (9) mmHg, 24 months 71 (11) mmHg</p> <p>No significant differences between I vs C</p> <p><b>Total cholesterol</b> mean (SD)</p> <p>I: 6 months, 4.4 (1.1) mmol/L, 12 months 4.3 (0.9) mmol/L, 24 months 4.4 (0.9) mmol/L</p> <p>C: 6 months, 4.2 (1.1) mmol/L, 12 months 4.3 (1.1) mmol/L, 24 months 4.0 (0.9) mmol/L</p> <p>No significant differences between I vs C</p> <p><b>LDL cholesterol</b> mean (SD)</p> <p>I: 6 months, 2.5 (0.7) mmol/L, 12 months 2.5 (0.8) mmol/L, 24 months 2.4 (0.7) mmol/L</p> <p>C: 6 months, 2.3 (0.8) mmol/L, 12 months 2.3 (0.8) mmol/L, 24 months 2.1 (0.7) mmol/L</p> <p>No significant differences between I vs C</p> <p><b>HDL-cholesterol</b> mean (SD)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 6 months, 1.25 (0.47) mmol/L, 12 months 1.24 (0.38) mmol/L, 24 months 1.36 (0.44) mmol/L</p> <p>C: 6 months, 1.10 (0.30) mmol/L, 12 months 1.17 (0.24) mmol/L, 24 months 1.20 (0.32) mmol/L</p> <p>No significant differences between I vs C</p> <p><b>Triglycerides</b> mean (SD)</p> <p>I: 6 months, 1.5 (1.2) mmol/L, 12 months 1.4 (0.8) mmol/L, 24 months 1.5 (0.8) mmol/L</p> <p>C: 6 months, 1.8 (1.3) mmol/L, 12 months 1.7 (0.9) mmol/L, 24 months 1.7 (0.9) mmol/L</p> <p>No significant differences between I vs C</p> <p>No cardiovascular disease or other serious adverse events during the study.</p>	
Guldbrand 2012	RCT, non-stratified, drawing blinded ballots  Type 2 diabetes with or without oral anti-	n=30, 53% women  Low-carbohydrate diet. Energy content: 50E%fat, 20 E%	n=31, 58% women  Traditional low-fat diet, caloric content of 1600 kcal for women or	<b>Quality of life</b>  SF-36  <i>Physical function</i>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[15] Sweden	<p>diabetic medication, incretin-based therapy, or insulin</p> <p>Two primary health care centres in Sweden</p> <p>Follow up points: 6, 12, 24 months</p>	<p>carbohydrates and 30 E% protein</p> <p>Group information used to inform about which food items to choose from, and this was given at baseline, at 2, 6 and 12 months by two different Physicians.</p> <p><b>Age</b>, mean (SD) 61.2 (9.5) years</p> <p><b>Bodyweight</b>: mean (SD) 91.4 (19) kg</p> <p><b>BMI</b>: mean (SD) 31.6 (5.0) kg/m<sup>2</sup></p> <p><b>HbA1c</b>: mean (SD) 7.5 (3.1)%</p> <p><b>Drop out</b>, 17% at 24 months (answered questionee)</p>	<p>1800 kcal for men. Energy content: 30 E% fat (less than 10 E% from saturated fat), 55 to 60 E% carbohydrates and 10 to 15 E% protein.</p> <p><b>Age</b>, mean (SD) 62.7 (11) years</p> <p><b>Bodyweight</b>: mean (SD) 98.8 (21) kg</p> <p><b>BMI</b>: mean (SD) 33.8 (5.7) kg/m<sup>2</sup></p> <p><b>HbA1c</b>: mean (SD) 7.2 (2.9)%</p> <p><b>Drop out</b>, 6% at 24 months (answered questionee)</p>	<p>I mean (SD) 6 months 79.4 (15.6) points, 12 months 83.6 (18.2) points, 24 months 78.7 (19.7) points</p> <p>C mean (SD) 6 months 84.5 (12.1) points, 12 months 83.8 (15.7) points, 24 months 81.6 (17.7) points</p> <p><i>Bodily Pain</i></p> <p>I mean (SD) 6 months 61.0 (25.0) points, 12 months 71.4 (22.1) points, 24 months 60.6 (25.6) points</p> <p>C mean (SD) 6 months 66.2 (22.3) points, 12 months 65.7 (26.5) points, 24 months 61.6 (28.34) points</p> <p><i>General Health</i></p> <p>I mean (SD) 6 months 63.5 (25.6) points, 12 months 70.7 (22.7) points, 24 months 63.8 (26.7) points</p> <p>C mean (SD) 6 months 67.7(18.2) points, 12 months 63.3 (18.4) points, 24 months 66.1 (23.4) points</p> <p><i>Physical component score</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I mean (SD) 6 months 43.2 (12.4) points, 12 months 46.7 (10.5) points, 24 months 41.4 (14.0) points</p> <p>C mean (SD) 6 months 45.8 (8.2) points, 12 months 45.9 (8.9) points, 24 months 43.6 (10.5) points</p> <p><i>Mental component score</i></p> <p>I mean (SD) 6 months 50.0 (13.0) points, 12 months 52.6 (5.3) points, 24 months 53.1 (4.2) points</p> <p>C mean (SD) 6 months 53.5 (10.1) points, 12 months 52.8 (9.5) points, 24 months 52.0 (9.4) points</p> <p>There was an increase in the physical component score of SF-36 from 44.1 (10.0) to 46.7 (10.5) at 12 months in the LCD group. No change occurred in the LFD.</p> <p>At 12 months the physical function, bodily pain and general health scores improved within the LCD group while there was no change within the LFD group.</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Hu et al 2019 [16] China	RCT  Overweight/obese adults with newly diagnosed type 2 diabetes  Outpatient facilities of the Department of Endocrinology and community-based education programmes  6 months follow-up	<b>Intervention A</b>  n=128, 51.6% women  Diet same composition as usual care, but calorie-restricted (-500 kcal/day), aiming for 5-10% weight loss  <b>Age</b> (mean), 53.1 years <b>Bodyweight</b> , (mean), 82.4 kg <b>BMI</b> , Not stated <b>HbA1c</b> , (mean) 62.3 mmol/mol <b>Drop-out</b> , 1.6%  ----- <b>Intervention B</b>  n=128, 49.2% women  Diet + physical activity: same dietary intervention as the diet group (calorie-restricted, aiming for 5-10% weight loss),	n=128, 48.4% women  Usual care: prescribed a standardized diet of 50–60% carbohydrate, 10–15% protein, and 20–30% fat (<7% saturated fat) based on the Dietary Guidelines for Chinese Resident  <b>Age</b> (mean)  50.5 years  <b>Bodyweight</b> , (mean)  82.8 kg  <b>BMI</b>  Not stated  <b>HbA1c</b> , (mean) 62.1 mmol/mol  <b>Drop out</b> , 3%	ITT-analysis of between group differences (95% CI) at 6 months, adjusted for a wide range of baseline covariates  <b>Body weight, kg</b>  IA vs C: -3.83 (-4.32 to -3.33) IB vs C: -3.99 (-4.48 to -3.49) IB vs IA: -0.16 (-0.65 to 0.33)  <b>Waist circumference, cm</b>  IA vs C: -3.42 (-3.97 to -2.87) IB vs C: -3.52 (-4.08, -2.97) IB vs IA: -0.10 (-0.65 to 0.45)  <b>Blood pressure, mmHg</b>  <i>Systolic</i>  IA vs C: 1.01 (-0.94 to 2.96) IB vs C: 0.24 (-1.70 to 2.17) IB vs IA: -0.77 (-2.71 to 1.17)  <i>Diastolic</i>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		plus walking program 30 mins at least 5 days/week <b>Age</b> , (mean, SD) 51.4 <b>Bodyweight</b> , (mean) 83 kg <b>BMI</b> , not stated <b>HbA1c</b> , (mean) 62.4 mmol/mol <b>Drop out</b> , 2.3%		IA vs C: 0.56 (−1.15 to 2.27) IB vs C: 0.74 (−0.96 to 2.44) IB vs IA: 0.18 (−1.52 to 1.89) <b>HbA1c, mmol/mol</b> IA vs C: −2.7 (−3.3 to −2.2) IB vs C: −3.0 (−3.5 to −2.4) IB vs IA: −0.2 (−0.8 to 0.3) <b>Blood lipids, mmol/L</b> <i>Total cholesterol</i> IA vs C: 0.01 (−0.04 to 0.06) IB vs C: −0.02 (−0.07 to 0.03) IB vs IA: −0.03 (−0.08 to 0.02) <i>Triglycerides</i> IA vs C: −0.11 (−0.22 to 0.00) IB vs C: −0.18 (−0.29 to −0.08) IB vs IA: −0.07 (−0.18 to 0.03)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>HDL-C</i></p> <p>IA vs C: 0.02 (−0.05 to 0.10)</p> <p>IB vs C: 0.09 (0.02 to 0.17)</p> <p>IB vs IA: 0.07 (−0.01 to 0.14)</p> <p><i>LDL-C</i></p> <p>IA vs C: −0.01 (−0.13 to 0.11)</p> <p>IB vs C: −0.03 (−0.15 to 0.09)</p> <p>IB vs IA: −0.03 (−0.14 to 0.09)</p> <p><b>Medication use at 6 months</b></p> <p>Odds ratios (95% CI) adjusted for a wide range of baseline covariates</p> <p><i>Glucose-lowering medication</i></p> <p>IA vs C: 0.36 (0.15 to 0.91)</p> <p>IB vs C: 0.44 (0.19 to 1.06)</p> <p>IB vs IA: 1.21 (0.51 to 2.88)</p> <p><i>Lipid-lowering medication</i></p> <p>IA vs C: 0.49 (0.18 to 1.36)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				IB vs C: 0.78 (0.30 to 2.04) IB vs IA: 1.59 (0.58 to 4.38) <i>Blood pressure-lowering medication</i> IA vs C: 0.97 (0.46 to 2.04) IB vs C: 1.49 (0.72 to 3.07) IB vs IA: 1.54 (0.75 to 3.17) <b>Adverse events</b> No differences between groups were observed	
Jenkins et al 2008 [17] Canada	RCT Type 2 diabetes with 6.5–8.0% HbA1c at baseline; not on acarbose; free from clinically significant cardiovascular, renal, or liver disease; not on treatment for cancer	n=104, 39% women High-cereal fibre diet, participants were advised to take the “brown” option (whole grain breads; whole grain break- fast cereals; brown rice; potatoes with skins; and whole wheat bread, crackers, and breakfast cereals), tropical fruit, such as bananas, mangos,	n=106, 39% women Low-GI low-glycemic index breads (including pumpnickel, rye pita, and quinoa and flax- seed) and breakfast cereals (including Red River Cereal (hot cereal made of bulgur and flax), large flake oatmeal, oat bran, and Bran Buds (ready-to-eat cereal made of wheat bran and psyllium fibre), pasta, parboiled rice, beans, peas, lentils, and nuts, temperate fruit was the focus,	<b>HbA1c (%)</b> I: –0.18% (95% CI, –0.29% to –0.07%) C: –0.50% (95% CI, –0.61% to –0.39%) P for difference between groups: <0.001 Mean (SE) I: week 24, 6.89 (0.07) C: week 24, 6.64 (0.07) <b>Body weight (kg) mean (SE)</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Outpatients at university hospital research centre  Follow-up for 6 months	guavas, grapes, raisins, watermelon, and cantaloupe.  <b>Age</b> , mean (SD) 61 (9) years  <b>Bodyweight</b> , mean (SD) 87.8 (19,4) kg  <b>BMI</b> , (mean, SD) 31.2 (5.8) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 7.1 (1.0)%  <b>Drop out</b> , 28% after randomisation, 23% after commencing treatment	including apples, pears, oranges, peaches, cherries, and berries.  <b>Age</b> , mean (SD) 60 (10) years  <b>Bodyweight</b> , mean (SD) 87.0 (20.0) kg  <b>BMI</b> , (mean, SD) 30.6 (6.0) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 7.1 (1.0)%  <b>Drop out</b> , 25% after randomisation, 19% after commencing treatment	I: week 0: 87.8; week 24: 86.2 (1.9) C: week 0: 87.0; week 24: 84.5 (1.8) P for difference between groups: 0.053  <b>Blood pressure (mm Hg) mean (SE)</b> <i>Systolic</i> I: week 0: 127.6; week 24: 125.8 (1.3) C: week 0: 127.4; week 24: 124.7 (1.4) P for difference between groups: 0.52 <i>Diastolic</i> I: week 0: 74.5; week 24: 73.5 (0.9) C: week 0: 73.7; week 24: 72.1 (1.0) P for difference between groups: 0.37  <b>Total cholesterol (mg/dL) mean (SE)</b> I: week 0: 168.4; week 24: 168.4 (5.1) C: week 0: 164.3; week 24: 162.6 (5.1) P for difference between groups: 0.26	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>LDL-C (mg/dL) mean (SE)</b></p> <p>I: week 0: 101.1; week 24: 101.3 (4.0)</p> <p>C: week 0: 96.9; week 24: 95.3 (4.0)</p> <p>P for difference between groups: 0.14</p> <p><b>Triglycerides (mg/dL) mean (SE)</b></p> <p>I: week 0: 122.0; week 24: 122.2 (6.2)</p> <p>C: week 0: 128.1; week 24: 124.6 (10.5)</p> <p>P for difference between groups: &gt;.99</p> <p><b>HDL-C (mg/dL)</b></p> <p>I: -0.2 mg/dL (95% CI, -0.9 to 0.5 mg/dL)</p> <p>C: 1.7 mg/dL (95% CI, 0.8 to 2.6 mg/dL)</p> <p>P for difference between groups: 0.005</p> <p>I: week 24 mean (SE), 42.8 (0.92)</p> <p>C: week 24 mean (SE), 43,6 (1.11)</p> <p><b>Adverse events</b></p> <p>No serious adverse effects, hypoglycemia in 6 low-GI patients</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Johansen et al 2017 [18] Denmark	RCT, Single-centre. Denmark Adult participants with non-insulin-dependent type 2 diabetes who were diagnosed for less than 10 years were included. Duration: 12 months	n=64, 48% women Intensive lifestyle intervention, consisting of 5 to 6 aerobic sessions (duration 30 to 60 min). 2 to 3 of these were combined with resistance training. First 4 months were supervised and performed in groups. Dietary plan (45-60% carbohydrate, 15.20% protein and 20 to 35% fat). <b>Bodyweight</b> , mean (SD) 94.7 (14) kg <b>BMI</b> , mean (SD) 31.4 (3.9) kg/m <sup>2</sup> <b>Age</b> , mean (SD) 53.6 (9.1) years <b>HbA1c</b> , mean (SD) 49.18 (8.74) mmol/mol <b>Drop out</b> , 3%	n=34, 47% women Both groups received standard care (medical counselling, diabetes education and lifestyle advice every 3mon. <b>Bodyweight</b> , mean (SD) 98.1 (15) kg <b>BMI</b> , mean (SD) 32.5 (5.5) kg/m <sup>2</sup> <b>Age</b> , mean (SD) 56.6 (8.1) years <b>HbA1c</b> : mean (SD) 50.17 (9.84) mmol/mol <b>Drop out</b> , 9%	<b>HbA1C</b> Intervention mean difference: -3.34 (95% CI: -4.92 to -1.75) mmol/mol Control mean difference: -0.44 (95% CI: -2.73 to 12.79) mmol/mol Between group difference (IFCC): -2,84 (95% CI: -5,68 to -0.11) mmol/mol <b>Total cholesterol (mmol/l)</b> Intervention mean difference: 0.50 (95% CI: 0.31 to 0.69) Control mean difference: 0.51 (95% CI: 0.22 to 0.79); Between group difference: -0.01 (95% CI: -0.36 to 0.34) <b>LDL cholesterol (mmol/l)</b> Intervention mean difference: 0.33 (95% CI: 0.16 to 0.50) Control mean difference: 0.29 (95% CI: 0.04 to 0.54) Between group difference: 0.04 (95% CI: -0.26 to 0.34)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>HDL cholesterol (mmol/l)</b>  Intervention mean difference: 0.21 (95% CI: 0.16 to 0.27)</p> <p>Control mean difference: 0.14 (95% CI: 0.06 to 0.22)  Between group difference: 0.07 (95% CI: -0.02 to 0.17)</p> <p><b>Triglycerides (mmol/l)</b>  Intervention mean difference: -0.10 (95% CI: -0.16 to -0.03)  Control mean difference: -0.03 (95% CI: -0.12 to 0.06)  Between group difference: -0.07 (95% CI: -0.18 to 0.05)</p> <p><b>Body weight (kg)</b>  Intervention mean difference: -6.11 (95% CI: -7.50 to -4.72); n=64</p> <p>Control mean difference: -1.97 (95% CI: -4.02 to 0.10)  Between group difference: -4.14 (95% CI: -6.63 to -1.66)</p> <p><b>Achieved 5% weight deduction</b>  I: 36 of 62 (56.3%)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: 5 of 31 (14.7%)</p> <p>Between group difference 41.5 (24.5 to 58.6)</p> <p><b>Achieved 10% weight reduction</b></p> <p>I: 20 of 62 (31.3%)</p> <p>C: 1 of 31 (2.9%)</p> <p>Between group difference 28.3 (15.6 to 41.0)</p> <p><b>Body mass index (BMI)</b></p> <p>Intervention mean difference: -2.01 (95% CI: -2.46 to -1.56); n=64</p> <p>Control mean difference: -0.69 (95% CI: -1.35 to -0.02); n=34</p> <p>Between group difference: -1.32 (95% CI: -2.13 to -0.51)</p> <p><b>Systolic blood pressure (mmHg)</b></p> <p>Intervention mean difference: -1.5 (95% CI: -4.0 to 1.0); n=60</p> <p>Control mean difference: -3.7 (95% CI: -7.7 to 0.3); n=24</p> <p>Between group difference: 2.2 (95% CI: -2.6 to 7.0)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Diastolic blood pressure (mmHg)</b>  I: mean difference: -1.4 (95% CI: -3.2 to 0.5); n=60  Control mean difference: -3.4 (95% CI: -6.4 to -0.4); n=24  Between group difference: 2.0 (95% CI: -1.6 to 5.6)</p> <p><b>Proportion of participants with reduction in glucose lowering medication (No of patients (%))</b>  I: mean risk difference: 47/64 (73.5%); n=62  C: mean risk difference: 9/34 (26.4%); n=31  Between group risk difference: 47.1 (95% CI: 28.6 to 65.3)</p> <p>Significantly different</p> <p><b>Proportion of participants with increase in glucose lowering medication (No of patients)</b>  I: 7/64  C:15/34</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Between group risk difference (CI 95%): -33.2 (-51.5 to -14.8)</p> <p>Significantly different</p> <p><b>Proportion of participants with discontinuation in glucose lowering medication (No of patients)</b></p> <p>I: 36/64 C: 5/34</p> <p>Between group risk difference (CI 95%): 41.5 (24.5 to 58.6)</p> <p><b>Proportion of participants with reduction in lipid or blood pressure medication</b></p> <p>Not significant</p>	
Kahleova et al 2011 [19]	RCT, parallel design  Type 2 diabetes treated by oral hypoglycaemic agents. Age 30–70 years, HbA1c between 6 and 11% (42–97 mmol)	n=37, 54% women  Vegetarian diet, calorie-restricted (-500 kcal/d) with calorie intakes based on the measurement of resting energy	n=37, 51% women  Conventional diet, calorie-restricted (-500 kcal/d) based on the indirect calorimetry measurement  <b>Age, mean (SD)</b>	<b>Weight</b>  I mean (CI 95%), 6 months 95.2 (95.9 to 94.5) kg  (-6.2 kg (CI 95%) (-6.6 to -5.3) kg)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Czechia	<p>/mol), BMI between 25 and 53 kg/m<sup>2</sup></p> <p>Study setting not stated</p> <p>Follow up at 6 months</p>	<p>expenditure of each subject by indirect calorimetry.</p> <p>For all participants the second 12 weeks of the diet were combined with aerobic exercise.</p> <p>All meals provided</p> <p><b>Age</b>, mean (SD) 54.6 (7.8) years</p> <p><b>Bodyweight</b>, mean (SD) 101.1 (17.1) kg</p> <p><b>BMI</b>, mean (SD) 35.1 (6.1) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 7.6 (1.4)%</p>	<p>57.7 (4.9) years</p> <p><b>Bodyweight</b>, mean (SD) 100.8 (17.8) kg</p> <p><b>BMI</b>, mean (SD) 35.0 (4.6) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 7.7 (1.2)%</p> <p><b>Drop out</b>, at 6 months 16%</p>	<p>C mean (CI 95%), 6 months 98.0 (98.7 to 97.3)</p> <p>(-3.2 kg (CI 95%) (-3.7 to -2.5)</p> <p>Significant differences between groups</p> <p><b>Waist circumference</b></p> <p>I mean (CI 95%), 6 months 104.6 (105.3 to 103.8) cm</p> <p>(-6.4 cm (CI 95%) (-7.1 to -5.7) cm</p> <p>C mean (CI 95%), 6 months 108.5 (109.2 to 107.8) cm</p> <p>(-5.3 cm (CI 95%) (-5.9 to -4.5) cm)</p> <p><b>BMI</b></p> <p>I mean (SD), baseline 35.1 (6.1) kg/m<sup>2</sup>, change at 6 months -2.18 (2.06) kg/m<sup>2</sup></p> <p>C mean (SD), baseline 35.0 (4.6) kg/m<sup>2</sup>, change at 6 months -0.98 (1.57) kg/m<sup>2</sup></p> <p>Significant differences between groups, p=0.001</p> <p><b>Total cholesterol</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I mean (SD), baseline 4.4 (0.8) mmol/L, change 6 months -0.11 (0.81) mmol/L</p> <p>C mean (SD), baseline 4.2 (0.9) mmol/L, change 6 months -0.04 (0.76) mmol/L</p> <p>No significant differences between groups, p=0.730</p> <p><b>HDL cholesterol</b></p> <p>I mean (SD), baseline 1.07 (0.3) mmol/L, change 6 months -0.01 (0.14) mmol/L</p> <p>C mean (SD), baseline 1.09 (0.2) mmol/L, change 6 months 0.08 (0.14) mmol/L</p> <p>No significant differences between groups, p=0.070</p> <p><b>LDL cholesterol</b></p> <p>I mean (SD), baseline 2.54 (0.6) mmol/L, change 6 months -0.17 (0.68) mmol/L</p> <p>I mean (CI 95%) 6 months 2.25 (2.34 to 2.16) mmol/L</p> <p>C mean (SD), baseline 2.57 (0.8) mmol/L, change 6 months -0.14 (0.68) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C mean (CI 95%) 6 months 2.56 (2.67 to 2.46) mmol/L</p> <p>Significant differences between groups, p=0.050</p> <p><b>Triglycerides</b></p> <p>I mean (SD), baseline 2.1 (0.9) mmol/L, change 6 months -0.27 (0.92) mmol/L</p> <p>C mean (SD), baseline 2.1 (0.9) mmol/L, change 6 months 0.05 (0.63) mmol/L</p> <p>No significant differences between groups, p=0.120</p> <p><b>HbA1c</b></p> <p>I mean (SD), baseline 7.6 (1.4)%, change 6 months -0.65 (0.99)%</p> <p>C mean (SD), baseline 7.7 (1.2)%, change 6 months -0.21 (1.1)%</p> <p>No significant differences between groups, p=0.370</p> <p><b>Quality of life</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Obesity and Weight-Loss Quality-of-Life score</i></p> <p>I mean (SD), baseline 44.85 (23.69) points, change 6 months 11.5 (16) points</p> <p>C mean (SD), baseline 40 (20.4) points, change 6 months 7.3 (14.9) points</p> <p>Significant differences between groups, p=0.010</p> <p><i>Weight-Related Symptoms score</i></p> <p>I mean (SD), baseline 32.29 (26.18) points, change 6 months -13 (20.8) points</p> <p>C mean (SD), baseline 30.77 (18.16) points, change 6 months -8.8 (17.5) points</p> <p>No significant differences between groups, p=0.400</p> <p><b>Medication reduction (due to repeated hypoglycaemia (%))</b></p> <p>I: 43%</p> <p>C: 5%</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>P&lt;0.001</p> <p>Difference between groups: 38 (95% CI, 17-58)%</p> <p>Adverse events not reported</p>	
Krebs et al 2012 [20] New Zealand	<p>RCT, multicentre parallel design, partly blinded (research assessors blinded)</p> <p>Type 2 diabetes (WHO criteria), 30 to 76 years of age, and had a BMI of at least 27 kg/m<sup>2</sup></p> <p>Three centres, primary and secondary care</p> <p>Follow up at 6, 12 and 24 months</p>	<p>n=207, 54% women</p> <p>Very high-protein diet (40% of total energy as carbohydrate, 30% as protein, 30% as fat).</p> <p>Both interventions aim to reduce total energy intake by 2,000 kJ/day (approximately - 500 kcal/day)</p> <p>Both interventions: Group sessions 8 to 12 participants led by dietitians. One-hour meetings were conducted every 2 weeks for the first 6 months, then every month for the second 6 months.</p> <p><b>Age</b>, mean (SD) 57.7 (9.9) years</p>	<p>n=212, 66% women</p> <p>Low-fat diet (55% of total energy as carbohydrate, 15% as protein, 30% as fat)</p> <p><b>Age</b>, mean (SD) 58.0 (9.2) years</p> <p><b>Bodyweight</b>, mean (SD) 101.9 (20.1) kg</p> <p><b>BMI</b>, mean (SD) 36.7 (6.4) kg/m<sup>2</sup></p> <p><b>HbA1</b>, mean (SD) 63,9 (13,1) mmol/mol</p> <p><b>Drop out</b>, (Not attended): 6 months 17%, 12 months 27% and 24 months 29%</p>	<p>Primary</p> <p><b>Weight</b> mean (SD)</p> <p>I: 6 months 100.2 (18.8) kg, 12 months 100.2 (17.8) kg, 24 months 99.5 (17.2) kg</p> <p>C: 6 months 98.7 (19.3) kg, 12 months 99.5 (19.1) kg, 24 months 95.9 (17.1) kg</p> <p>No significant differences between groups over time</p> <p><b>Waist circumferences</b> mean (SD)</p> <p>I: 6 months 111.5 (13.0) cm, 12 months 111.4 (12.8) cm, 24 months 110.1 (14.1) cm</p> <p>C: 6 months 112.1 (13.2) cm, 12 months 112.0 (13.9) cm, 24 months 108.7 (12.1) cm</p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>Bodyweight</b>, mean (SD) 103.4 (19.7) kg</p> <p><b>BMI</b>, mean (SD) 36.6 (6.7) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 65,0 (13,1) mmol/mol</p> <p><b>Drop out</b>, (Not attended): 6 months 16%, 12 months 30% and 24 months 30%</p>		<p>No significant differences between groups over time</p> <p>Secondary</p> <p><b>HbA1c</b> mean (SD)</p> <p>I: 6 months 7.9 (1.3)%, 12 months 8.0 (1.3)%, 24 months 8.2 (1.5)%</p> <p>C: 6 months 7.7 (1.1)%, 12 months 7.8 (1.3)%, 24 months 8.1 (1.4)%</p> <p>No significant differences between groups over time</p> <p><b>Total cholesterol</b> mean (SD)</p> <p>I: 6 months 4.75 (1.01) mmol/L, 12 months 4.67 (0.95) mmol/L, 24 months 4.53 (0.98) mmol/L</p> <p>C: 6 months 4.49 (0.95) mmol/L, 12 months 4.57 (1.01) mmol/L, 24 months 4.44 (1.07) mmol/L</p> <p>Significantly different between groups over time (0.02 mmol/L, adjusted for</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>baseline value and trial centre as covariate)</p> <p><b>LDL cholesterol</b> mean (SD)</p> <p>I: 6 months 2.77 (1.01) mmol/L, 12 months 2.68 (0.94) mmol/L, 24 months 2.57 (0.92) mmol/L</p> <p>C: 6 months 2.59 (0.88) mmol/L, 12 months 2.59 (0.88) mmol/L, 24 months 2.47 (0.93) mmol/L</p> <p>No significant differences between groups over time</p> <p><b>Triacylglycerols</b> median (interquartile range)</p> <p>I: 6 months 1.63 (1.30 to 2.18) mmol/L, 12 months 1.63 (1.21 to 2.29) mmol/L, 24 months 1.70 (1.34 to 2.14) mmol/L</p> <p>C: 6 months 1.57 (1.19 to 2.10) mmol/L, 12 months 1.63 (1.16 to 2.38) mmol/L, 24 months 1.60 (1.15 to 2.28) mmol/L</p> <p>Significant differences between groups over time (0.07 mmol/L, adjusted for</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>baseline value and trial centre as covariate)</p> <p><b>HDL cholesterol</b> mean (SD)</p> <p>I: 6 months 1.11 (0.29) mmol/L, 12 months 1.12 (0.31) mmol/L, 24 months 1.08 (0.30) mmol/L</p> <p>C: 6 months 1.10 (0.31) mmol/L, 12 months 1.13 (0.29) mmol/L, 24 months 1.13 (0.32) mmol/L</p> <p>No significant differences between groups over time</p> <p><b>Systolic blood pressure</b> mean (SD)</p> <p>I: 6 months 130.5 (17.2) mmHg, 12 months 130.9 (17.3) mmHg, 24 months 133.3 (24.0) mmHg</p> <p>C: 6 months 129.3 (16.4) mmHg, 12 months 129.3 (17.2) mmHg, 24 months 131.6 (20.2) mmHg</p> <p>No significant differences between groups over time</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Diastolic blood pressure</b> mean (SD)</p> <p>I: 6 months 76.4 (10.5) mmHg, 12 months 76.7 (11.0) mmHg, 24 months 76.5 (11.1) mmHg</p> <p>C: 6 months 75.9 (10.4) mmHg, 12 months 76.1 (10.7) mmHg, 24 months 76.2 (11.6) mmHg</p> <p>No significant differences between groups over time</p> <p><b>Quality of life</b> mean (SD)</p> <p><i>SF-36 physical</i></p> <p>I: 6 months 46.2 (8.7) points, 12 months 46.1 (9.0) points, 24 months 43.9 (9.9) points</p> <p>C: 6 months 46.1 (9.4) points, 12 months 45.5 (9.4) points, 24 months 45.8 (9.3) points</p> <p>No significant differences between groups over time</p> <p><i>SF-36 Mental</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 6 months 53.0 (9.1) points, 12 months 53.4 (9.2) points, 24 months 52.7 (9.2) points</p> <p>C: 6 months 50.8 (11.1) points, 12 months 52.3 (9.2) points, 24 months 52.1 (11.0) points</p> <p>No significant differences between groups over time</p> <p>There were no important adverse effects</p>	
Larsen et al 2011 [21] Australia	<p>RCT (block randomisation and random block sizes) 1:1, single centre.</p> <p>Type 2 diabetes</p> <p>Aged 30 to 75 years, BMI 27 to 40 kg/m<sup>2</sup> and HbA1c 6.5 to 10%.</p> <p>Recruitment from diabetes clinic and local community. conducted</p>	<p>n=53, 43% women</p> <p>High protein, low fat. E 30% protein (a combination of lean meat, chicken, and fish) and E 40% carbohydrate. E 30% fat (7% saturated fat, 10% polyunsaturated fat, 13% monounsaturated fat). Carbohydrates of low glycaemic index recommended</p>	<p>n=46, 61% women</p> <p>High carbohydrate, low fat. E 15% protein and E 55% carbohydrate. E 30% fat (7% saturated fat, 10% polyunsaturated fat, 13% monounsaturated fat). Carbohydrates of low glycaemic index recommended.</p> <p><b>Age</b>, mean (CI 95%) 58.8 (55.8 to 61.7) years</p> <p><b>Bodyweight</b>, mean (95% CI) 95.5 (91.5 to 99.6) kg</p>	<p>Primary</p> <p><b>HbA1c</b> group difference 12 months mean (95% CI) 0.04 (-0.37 to 0.46)%</p> <p>Secondary</p> <p><b>Weight</b> group difference 12 months mean (95% CI) -0.07 (-1.67 to 1.54) kg</p> <p><b>Waist circumference</b> group difference 12 months mean (95% CI)</p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	at Baker IDI Heart and Diabetes Institute  Follow time points 3, 12 months	Both diets: Two dietary periods: a 3-month energy restrictive period (about 6,400 kJ/day or 30% energy restriction), followed by 9 months of energy balance.  <b>Age:</b> mean (CI 95%) 59.6 (57 to 61.8) years  <b>Bodyweight,</b> mean (CI 95%) 94.6 (90.5 to 98.8) kg  <b>BMI,</b> not given  <b>HbA1c,</b> mean (CI 95%): 62.74 (59.90 to 65.58) mmol/mol  <b>Drop out,</b> 9% (7% changed mind before starting innovation and was excluded from the ITT analysis)	<b>BMI</b> not given  <b>HbA1c,</b> mean (CI 95%) 61.54 (58.48 to 64.49) mmol/mol  <b>Drop out</b> 2% (10% changed mind before starting innovation and was excluded from the ITT analysis)	-0.19 (-2.08, 1.69) cm  <b>Total cholesterol</b> group difference 12 months mean (95% CI) -0.16 (-0.51, 0.18) mmol/L  <b>LDL cholesterol</b> group difference 12 months mean (95% CI) -0.10 (-0.37 to 0.17) mmol/L  <b>HDL cholesterol</b> group difference 12 months mean (95% CI) 0.01 (-0.10 to 0.11) mmol/L  <b>Triacylglycerol</b> group difference 12 months mean (95% CI) -0.17 (-0.65 to 0.32) mmol/L  <b>Systolic blood pressure</b> group difference 12 months mean (95% CI) -4.26 (-8.80, 0.27) mmHg  <b>Diastolic blood pressure</b> group difference 12 months mean (95% CI) -0.44 (-4.95, 4.06) mmHg	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Weighted% change in diabetes medication</b> group difference 12 months mean (95% CI)</p> <p>(precent dose change for each diabetes medication/ number of different diabetes medication</p> <p>-12.72 (-28.18, 2.73)%</p> <p>Adverse events not reported</p>	
Lasa et al 2014 [22] Spain	<p>Multicentre RCT</p> <p>Post hoc analysis to the PREDIMED study, including only those with data from baseline and 1 year</p> <p>People with type 2 diabetes, free from cardiovascular disease, but meeting at least two coronary heart disease risk factors</p>	<p><b>Intervention A</b></p> <p>n=74, 61%, women</p> <p>Mediterranean diet supplemented with virgin olive oil (free of cost)</p> <p><b>Age</b>, mean (SD) 67.4 (6.3) years</p> <p><b>Bodyweight</b>, mean, (SD) 75.2 (11.4) kg</p> <p><b>BMI</b>, mean (SD) 29.4 (2.9) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, not stated</p>	<p>n=67, 52% women</p> <p>Low-fat diet</p> <p><b>Age</b>, mean (SD) 67.2 (6.8) years</p> <p><b>Bodyweight</b>, mean (SD) 77.5 (10.9) kg</p> <p><b>BMI</b>, mean (SD) 29.8 (2.8) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, not stated</p> <p><b>Drop out</b>, no dropouts</p>	<p>Adjusted ANCOVA analysis of within-group mean change (SD) and p-value for between-group differences at 1 year</p> <p><b>Body weight (kg)</b></p> <p>IA: -0.81 (2.22)</p> <p>IB: -0.71 (2.41)</p> <p>C: -0.29 (2.71)</p> <p>No significant between-group difference, p=0,447</p> <p><b>Waist circumference (cm)</b></p> <p><i>Men</i></p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Using oral anti-diabetic medications, but not insulin  Outpatients  12 months follow-up	<b>Drop out</b> , no dropouts  ----- <b>Intervention B</b> n=50, 68% women  Mediterranean diet supplemented with mixed nuts (free of cost)  <b>Age</b> , mean (SD) 67.1 (4.8) years  <b>Bodyweight</b> , mean, (SD) 75.2 (11.5) kg  <b>BMI</b> , mean (SD) 30.1 (3.1) kg/m <sup>2</sup>  <b>HbA1c</b> , not stated  <b>Drop out</b> , no dropouts		IA: -2.79 (5.04)  IB: -1.31 (7.17)  C: -1.68 (5.55)  No significant between-group difference, p=0.476  <i>Women</i>  IA: -4.20 (6.65)  IB: -4.84 (7.50)  C: -3.06 (7.19)  No significant between-group difference, p=0.621  <b>BMI (kg/m<sup>2</sup>)</b>  IA: -0.16 (0.95)  IB: -2.41 (1.05)  C: -0.15 (1.11)  No significant between-group difference, p=0.806	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<b>Adverse effects</b> No relevant diet-related adverse effects were reported	
Lazo et al 2010 [23] USA	RCT; ancillary study within the Look AHEAD trial  Overweight or obese adults, mean (SD) age 61.6 (6.7) years, with type 2 diabetes and alcohol consumption $\leq 1$ drink/day for women and $\leq 2$ drinks/day for men and no other potential causes of liver disease (n=96)  University hospital  12 months	n=46, 59% women  Intensive lifestyle Intervention (ILI) with goals of 10% weight loss at 12 months, $\geq 175$ mins moderate intensity physical activity/week, moderate calorie restricted $<30\%$ fat diet with $<10\%$ from saturated fat  First 6 months, weekly meetings; months 7-12, monthly sessions  (p=0.06)  <b>Age</b> Not reported per group  <b>Bodyweight, (mean, <math>\pm</math>SD)</b> 98.1 $\pm$ 16.6 kg	n=50, 40% women  Diabetes support and education (DSE) with three group sessions/year, provided general information on nutrition, physical activity, and social support  <b>Age</b> , Not reported per group  <b>Bodyweight, (mean, SEM)</b> 104.8 $\pm$ 16.7 kg  <b>BMI, (mean, SEM)</b> 35.3 $\pm$ 4.7 kg/m <sup>2</sup>  <b>HbA1c, (mean, SEM)</b> 56.29 $\pm$ 10.93 mmol/mol  <b>Drop out*</b> , 5.7% (*excluded: alcohol consumption)	Completers analysis, adjusted for sex, baseline weight and baseline hepatic steatosis  Data are means $\pm$ SEM, median (interquartile range), or frequency (%)  <b>Weight (kg)</b> I: 1 year: 90.6 $\pm$ 14.9; absolute change: -8.5 $\pm$ 8.3 C: 1 year: 104.7 $\pm$ 16.9; absolute change: -0.05 $\pm$ 5.7  Significant difference ILI vs DSE (ILI decreased more)  <b>Waist circumference (cm)</b> I: Baseline: 112.0 $\pm$ 11.7; 1 year: 102.4 $\pm$ 11.7; absolute change: -9.9 $\pm$ 11.1 C: Baseline: 115.0 $\pm$ 11.8; 1 year: 113.5 $\pm$ 12.4; absolute change: -1.8 $\pm$ 6.5	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>BMI</b>, (mean, SEM) 34.7±5.4 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SEM) 54.10±10.93 mmol/mol</p> <p><b>Drop out*</b>, 6.1%</p> <p>(*excluded: alcohol consumption or hepatitis B)</p>		<p>Significant difference ILI vs DSE (ILI decreased more)</p> <p><b>BMI, kg/m<sup>2</sup></b></p> <p>I: 1 year: 32.1±5.2; absolute change: -2.6±2.6</p> <p>C: 1 year: 35.3±4.8; absolute change: -0.02±2.0</p> <p>Significant difference ILI vs DSE (ILI decreased more)</p> <p><b>Incident NAFLD (non-alcoholic fatty liver disease) among participants with baseline steatosis &lt;5.5%</b></p> <p>I: 1 of 31 (3%)</p> <p>C: 6 of 23 (26%)</p> <p>Odds ratio 0.07 (95% CI 0.007-0.71)</p> <p><b>HbA1c (IFCC)</b></p> <p>I: 1 year: 47.55±9.84; absolute change: -7.65±12.02</p> <p>mmol/mol</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: 1 year: 54.10±10,93; absolute change: -2,19±8,74 mmol/mol</p> <p>Significant difference ILI vs DSE (ILI decreased more)</p> <p><b>Blood lipids (mmol/l)</b></p> <p><i>HDL-C</i></p> <p>I: Baseline: 1.24±0.30; 1 year: 1.36±0.31; absolute change: 0.11±0.18</p> <p>C: Baseline: 1.11±0.31; 1 year: 1.14±0.29; absolute change: 0.05±0.17</p> <p>No significant difference in change between groups</p> <p><i>LDL-C</i></p> <p>I: Baseline: 3.05±0.89; 1 year: 2.77±0.78; absolute change: -0.24±0.60</p> <p>C: Baseline: 2.84±0.77; 1 year: 2.54±0.71; absolute change: -0.32±0.65</p> <p>No significant difference in change between groups</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Triglycerides</i></p> <p>I: Baseline: Md 1.26 (IQR 0.99-1.91); 1 year: 1.21 (0.75-1.57); absolute change: -0.06 (-0.52 to 0.20)</p> <p>C: Baseline: Md 1.38 (IQR 1.03-2.19); 1 year: 1.37 (0.98-2.15); absolute change: -0.06 (-0.35 to 0.23)</p> <p>No significant difference in change between groups</p> <p><b>Medication use</b></p> <p><i>Number of diabetes medications</i></p> <p>I: Baseline: 1.3±0.8; 1 year: 1.2±0.9; absolute change: -0.1±0.5</p> <p>C: Baseline: 1.4±0.8; 1 year: 1.5±0.8; absolute change: 0.1±0.6</p> <p>No significant difference in change between groups</p> <p><i>Use of insulin (%)</i></p> <p>I: Baseline: 13; 1 year: 11; absolute change: -2</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: Baseline: 10; 1 year: 8; absolute change: -2</p> <p>No significant difference in change between groups</p> <p><i>Use of metformin (%)</i></p> <p>I: Baseline: 52.2; 1 year: 45.7; absolute change: -6.5</p> <p>C: Baseline: 48; 1 year: 54.2; absolute change: 6.2</p> <p>No significant difference in change between groups</p> <p><i>Use of thiazolidinedione (%)</i></p> <p>I: Baseline: 28.3; 1 year: 23.9; absolute change: -4.4</p> <p>C: Baseline: 34; 1 year: 30; absolute change: -4</p> <p>No significant difference in change between groups</p> <p><i>Use of lipid-lowering drug (%)</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: Baseline: 41.3; 1 year: 45.7; absolute change: 4.4</p> <p>C: Baseline: 70; 1 year: 70.8; absolute change: 0.8</p> <p>No significant difference in change between groups</p>	
Lean et al 2018  [24]  UK (England, Scotland)	<p>open-label, cluster-randomised trial</p> <p>Intention-to-treat analysis</p> <p>49 primary care practices in Scotland and the Tyneside region of England</p> <p>Individuals aged 20–65 years who had been diagnosed with type 2 diabetes within the past 6 years, had a body-mass index of 27–45</p>	<p><b>Intervention:</b> Counterweight-Plus weight management Programme. Withdrawal of antidiabetic and antihypertensive drugs, total diet replacement phase using a low energy formula diet (825–853 kcal/day; 59% carbohydrate, 13% fat, 26% protein, 2% fibre) for 3 months (extendable up to 5 months if wished by participant), followed by structured food reintroduction of 2–8 weeks (about 50% carbohydrate,</p>	<p><b>Control:</b> Diabetes care under current guidelines and standards from the National Institute of Health and Care Excellence in England and the Scottish Intercollegiate Guidelines Network in Scotland.</p> <p><b>Participants:</b> N=149 Female: 56 (38%)</p> <p><b>Age</b>, mean (SD): 55.9 (7.3) <b>Weight</b> (kg), mean (SD): 98.8 (16.1) <b>BMI</b>, mean (SD): 34.2 (4.3) <b>HbAc1</b> (mmol/mol), mean (SD): 58 (11.5)</p>	<p>Co-Primary outcomes: <b>Weight reduction ≥15kg:</b> I: 24.2%, C: 0.0% Fisher’s exact test: p&lt;0.0001 Per kg weight loss, OR: 1.32 (95% CI, 1.23 to 1.41), p&lt;0.0001</p> <p><b>Remission at 12 months</b> (HbA1c less than &lt;48 mmol/mol): I: 45.6%, C: 4.0% OR: 19.7 (95% CI, 7.8 to 49.8), p&lt;0.0001</p> <p>Secondary outcomes (assessed at 12 months): <b>Weight</b>, mean (SD): Intervention (n=137): baseline 100.4 (16.5); 12 months: 90.4 (16.4); change: –10.0 (8.0)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	<p>kg/m<sup>2</sup>, and were not receiving insulin.</p> <p>Follow up: 12 months</p>	<p>35% total fat, and 15% protein), and an ongoing structured programme with monthly visits for long-term weight loss maintenance.</p> <p><b>Participants:</b> N=149 Female: 66 (44%)</p> <p><b>Age</b>, mean (SD): 52.9 (7.6) <b>Weight</b> (kg), mean (SD): 101.0 (16.7) <b>BMI</b>, mean (SD): 35.1 (4.5) <b>HbAc1</b> (mmol/mol), mean (SD): 60 (13.7)</p> <p><b>Dropouts:</b> 21% (n=32)</p>	<p><b>Dropouts:</b> 0% (0)</p>	<p>Control (n=148): Baseline: 98.7 (16.1); 12 months: 97.7 (16.4); change: -1.0 (3.7) <i>Intervention effect: -8.8 (-10.3 to -7.3)</i> <i>p&lt;0.0001</i></p> <p><b>BMI</b>, mean (SD): Intervention (n=137): Baseline: 35.0 (4.5); 12 months: 31.5 (4.9); change: -3.5 (2.8) Control (n=148): Baseline: 34.2 (4.3); 12 months: 33.8 (4.5); change: -0.4 (1.3) <i>Intervention effect: -3.0 (-3.5 to -2.5)</i> <i>p&lt;0.0001</i></p> <p><b>HbA1c</b> (mmol/mol), mean (SD): Intervention (n=138): Baseline: 60.2 (12.7); 12 months: 50.6 (13.3); change: -9.6 (15.4) Control (n=148): Baseline: 58.2 (11.6); 12 months: 59.6 (12.1); change: 1.4 (11.6) <i>Intervention effect: -9.3 (-12.1 to -6.5)</i> <i>p&lt;0.0001</i></p> <p><b>Medication:</b> <u>Number of prescribed oral antidiabetic medications</u></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Intervention (n=148): Baseline: 1.1 (0.9); 12 months: 0.4 (0.7); change: -0.8 (0.8)  Control (n=148): Baseline: 1.1 (0.8); 12 months: 1.3 (0.9); change: 0.2 (0.5)  <i>Intervention effect: -0.97 (-1.11 to -0.84), p&lt;0.0001</i></p> <p><u>Number of prescribed antihypertensive medications:</u>  Intervention (n=148): Baseline: 1.0 (1.2); 12 months: 0.5 (0.7); change: -0.6 (1.0)  Control (n=148): Baseline: 1.0 (1.1); 12 months: 1.0 (1.0), change: 0.1 (0.5)  <i>Intervention effect: -0.58 (-0.75 to -0.42) p=0.0001</i></p> <p><u>Number of other prescribed medications (not oral antidiabetic or antihypertensive):</u>  Intervention (n=148): Baseline: 3.5 (3.0); 12 months: 4.0 (3.9); change: 0.5 (2.0)  Control (n=148): Baseline: 3.6 (3.4), 12 months: 4.2 (3.7); change: 0.6 (1.4)  <i>Intervention effect: -0.08 (-0.49, 0.33) p=0.7036</i></p> <p><b>Systolic blood pressure</b> (mm Hg), mean (SD):</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Intervention (n=128): Baseline: 134.3 (17.6); 12 months: 133.0 (16.3); change: -1.3 (18.3)</p> <p>Control (n=147): Baseline: 137.5 (15.8); 12 months: 135.8 (14.6); change: -1.7 (13.7)</p> <p><i>Intervention effect: -0.6 (-4.5 to 3.3)</i></p> <p><i>p=0.7710</i></p> <p><b>Diastolic blood pressure</b> (mmHg), mean (SD):</p> <p>Intervention (n=128): Baseline: 84.8 (10.2); 12 months: 83.5 (9.5); change: -1.3 (10.3)</p> <p>Control (n=147): Baseline: 85.5 (8.8); 12 months: 84.5 (8.9); change: -1.1 (10.1)</p> <p><i>Intervention effect: -0.4 (-2.5, 1.6)</i></p> <p><i>p=0.6863</i></p> <p><b>Quality of Life</b>, mean (SD):</p> <p><u>EuroQol 5 Dimensions (EQ-5D):</u></p> <p>Intervention (n=125): Baseline: 66.4 (19.2); 12 months: 73.7 (19.0); change: 7.2 (21.3)</p> <p>Control (n=147): Baseline: 72.0 (16.9); 12 months: 69.1 (15.6); change: -2.9 (15.5)</p> <p><i>Intervention effect: 6.4 (2.5 to 10.3)</i></p> <p><i>p=0.0012</i></p> <p><u>EQ-5D health utility score:</u></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Intervention (n=125): Baseline: 0.806 (0.279); 12 months: 0.793 (0.278); change: -0.013 (0.211)</p> <p>Control (n=147): Baseline: 0.799 (0.282); 12 months: 0.759 (0.302); change: -0.040 (0.203)</p> <p><i>Intervention effect: 0.025 (-0.023, 0.073)</i> <i>p=0.3146</i></p> <p><b>Total cholesterol</b> (mmol/l), mean (SD): Intervention (n=121): Baseline: 4.3 (1.1); 12 months: 4.5 (1.3); change: 0.23 (1.36) Control (n=147): Baseline: 4.3 (1.1); 12 months: 4.3 (1.1); change: 0.07 (0.87) <i>Intervention effect: 1.03 (0.97, 1.10)</i> <i>p=0.2874</i></p> <p><b>HDL-cholesterol</b> (mmol/l), mean (SD): Intervention (n=121): Baseline: 1.1 (0.3); 12 months: 1.2 (0.4); change: 0.13 (0.25) Control (n=147): Baseline: 1.2 (0.3); 12 months: 1.2 (0.3); change: 0.04 (0.21) <i>Intervention effect: 1.06 (1.00, 1.13)</i> <i>p=0.0563</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Triglycerides</b> (mmol/l), mean (SD):  Intervention (n=121): Baseline: 2.1 (1.4);  12 months: 1.7 (1.4); change: -0.31 (1.33)  Control (n=147): Baseline: 1.9 (0.9); 12  months:  2.0 (1.2); change: 0.09 (0.92)  <i>Intervention effect: 0.80 (0.72, 0.89)</i>  <i>p&lt;0.0001</i></p> <p><b>Number of serious adverse events:</b>  Intervention (n=157): 9 (7 participants,  4%)  Control (n=149): 2 (2 participants, 1%)</p>	
Lean et al 2019 [25] UK (England, Scotland)	open-label, cluster- randomised trial  Intention-to-treat analysis  49 primary care practices in Scotland and the Tyneside region of England	<b>Intervention:</b> Counterweight- Plus weight management Programme. Withdrawal of antidiabetic and antihypertensive drugs, total diet replacement phase using a low energy formula diet (825–853 kcal/day; 59% carbohydrate, 13% fat, 26% protein, 2% fibre) for 3 months (extendable up to	<b>Control:</b> Diabetes care under current guidelines and standards from the National Institute of Health and Care Excellence in England and the Scottish Intercollegiate Guidelines Network in Scotland.  <b>Participants:</b> N=149 Female: 56 (38%)	<p><u>Co-Primary outcomes:</u>  <b>Weight reduction ≥15kg:</b>  I: 11.4% (n=17), C: 2.0% (n=3)  OR: 7.49 (95% CI 2.05–27.32; p=0.0023)  Per kg weight loss, OR: 1.25 (95% CI 1.16–  1.35), p&lt;0.0001)</p> <p><b>Remission at 24 months</b> (HbA1c less than  &lt;48 mmol/mol):  I: 35.6% (n=53), C: 3.4% (n=5)  OR: 25.82 (95% CI 8.25–80.84), p&lt;0.0001</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	<p>Individuals aged 20–65 years who had been diagnosed with type 2 diabetes within the past 6 years, had a body-mass index of 27–45 kg/m<sup>2</sup>, and were not receiving insulin.</p> <p>Follow up: 12 and 24 months</p>	<p>5 months if wished by participant), followed by structured food reintroduction of 2–8 weeks (about 50% carbohydrate, 35% total fat, and 15% protein), and an ongoing structured programme with monthly visits for long-term weight loss maintenance.</p> <p><b>Participants:</b> N=149 Female: 66 (44%)</p> <p><b>Age</b>, mean (SD): 52.9 (7.6) <b>Weight (kg)</b>, mean (SD): 101.0 (16.7) <b>BMI</b>, mean (SD): 35.1 (4.5) <b>HbAc1 (mmol/mol)</b>, mean (SD): 60 (13.7)</p> <p><b>Dropouts:</b> 32% (n=32+16)</p>	<p><b>Age</b>, mean (SD): 55.9 (7.3) <b>Weight (kg)</b>, mean (SD): 98.8 (16.1) <b>BMI</b>, mean (SD): 34.2 (4.3) <b>HbAc1 (mmol/mol)</b>, mean (SD): 58 (11.5)</p> <p><b>Dropouts:</b> 0% (0)</p>	<p><u>Secondary outcomes (assessed at 24 months):</u> <b>Weight</b>, mean (SD): Intervention (n=129): Baseline: 101.0 (16.7); 12 months: 90.4 (16.4); 24 months: 93.2 (17.2); change (baseline to 24 months): –7.6 (6.5) Control (n=143): Baseline: 98.8 (16.1); 12 months: 97.7(16.4); 24 months: 96.4 (16.3); change (baseline to 24 months): –2.3 (5.2) <i>Intervention effect (at 24 months): –5.43 (–6.87 to –3.99; p&lt;0.0001)</i></p> <p><b>HbA1c</b> (mmol/mol), mean (SD): Intervention (n=129): Baseline: 60.4 (13.7); 12 months: 50.6 (13.3); 24 months: 54.4 (15.9); change (baseline to 24 months): –5.2 (16.4) Control (n=143): Baseline: 58.2 (11.5); 12 months: 59.6 (12.1); 24 months: 58.6 (14.4); change (baseline to 24 months): 0.4 (15.5) <i>Intervention effect (at 24 months): –4.82 (–8.28 to –1.36; p=0.0063)</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><u>Medication:</u></p> <p><b>Number of prescribed oral antidiabetic medications</b>  Intervention (n=129): Baseline: 1.1 (0.9); 12 months: 0.4 (0.7); 24 months: 0.6 (0.9); change (baseline to 24 months): -0.6 (0.8)  Control (n=143): Baseline: 1.1 (0.8); 12 months: 1.3 (0.9); 24 months: 1.3 (1.0); change (baseline to 24 months): 0.3 (0.6)  <i>Intervention effect (at 24 months): -0.86 (-1.02 to -0.69; p&lt;0.0001)</i></p> <p><b>Number of prescribed antihypertensive medications:</b>  Intervention (n=129): Baseline: 1.0 (1.2); 12 months: 0.5 (0.7); 24 months: 0.7 (0.9); change (baseline to 24 months): -0.3 (0.9)  Control (n=143): Baseline: 1.0 (1.1); 12 months: 1.0 (1.0); 24 months: 1.1 (1.1); change (baseline to 24 months): 0.1 (0.5)  <i>Intervention effect (at 24 months): -0.36 (-0.53 to -0.19; p&lt;0.0001)</i></p> <p><b>Number of participants on any antidiabetes drugs (binary outcome):</b>  Intervention (n=129): Baseline: 111/149 (74%); 12 months: 39/148 (26%); 24 months: 51/129 (40%)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Control (n=143): Baseline: 115/149 (77%), 12 months: 121/148 (82%); 24 months: 120/143 (84%)  <i>Intervention effect (at 24 months): 0.03 (0.01 to 0.08; p&lt;0.0001)</i></p> <p><b>Systolic blood pressure</b> (mm Hg), mean (SD):  Intervention (n=113): Baseline: 132.7 (17.5); 12 months: 133.0 (16.3); 24 months: 130.3 (13.6); change (baseline to 24 months): -4.3 (18.7)  Control (n=140): Baseline: 137.2 (16.0); 12 months: 135.8 (14.6); 24 months: 135.4 (14.0); change (baseline to 24 months): -1.4 (13.4)  <i>Intervention effect (at 24 months): -3.43 (-6.70 to -0.16; p=0.040)</i></p> <p>Quality of Life, mean (SD):  <b>Quality of life (EQ-5D VAS):</b>  Intervention (n=113): Baseline: 65.8 (19.1); 12 months: 73.7 (19.0); 24 months: 75.2 (17.3); change (baseline to 24 months): 8.2 (20.1)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Control (n=140): Baseline: 72.1 (19.6); 12 months: 69.1 (15.6); 24 months: 74.0 (16.8); change (baseline to 24 months): 1.7 (15.1)</p> <p><i>Intervention effect (at 24 months): 4.64 (0.39 to 8.89; p=0.032)</i></p> <p><b>EQ-5D health utility score:</b></p> <p>Intervention (n=113): Baseline: 0.798 (0.288); 12 months: 0.793 (0.278); 24 months: 0.819 (0.268); change (baseline to 24 months): -0.002 (0.205)</p> <p>Control (n=140): Baseline: 0.802 (0.281); 12 months: 0.759 (0.302); 24 months: 0.788 (0.253); change (baseline to 24 months): -0.013 (0.194)</p> <p><i>Intervention effect (at 24 months): 0.024 (-0.021 to 0.070; p=0.29)</i></p> <p><b>Total cholesterol (mmol/l), mean (SD):</b></p> <p>Intervention (n=105): Baseline: 4.3 (1.2); 12 months: 4.5 (1.3); 24 months: 4.7 (1.2); change (baseline to 24 months): 0.4 (1.3)</p> <p>Control (n=138): Baseline: 4.3 (1.2); 12 months: 4.3 (1.1); 24 months: 4.4 (1.2); change (baseline to 24 months): 0.1 (0.9)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Intervention effect (at 24 months): 0.30 (0.01 to 0.60; p=0.045)</i></p> <p><b>HDL-cholesterol</b> (mmol/l), mean (SD):  Intervention (n=105): Baseline: 1.1 (0.3); 12 months: 1.2 (0.3); 24 months: 1.3 (0.4); change (baseline to 24 months): 0.2 (0.3)  Control (n=138): Baseline: 1.2 (0.3); 12 months: 1.2 (0.3); 24 months: 1.3 (0.4); change (baseline to 24 months): 0.1 (0.2)  <i>Intervention effect (at 24 months): 0.09 (0.02 to 0.16; p=0.013)</i></p> <p><b>Triglycerides</b> (mmol/l), mean (SD):  Intervention (n=105): Baseline: 2.1 (1.4); 12 months: 1.7 (1.4); 24 months: 1.6 (1.0); change (baseline to 24 months): -0.4 (1.2)  Control (n=138): Baseline: 1.9 (0.9); 12 months: 2.0 (1.2); 24 months: 1.7 (0.9); change (baseline to 24 months): -0.2 (0.7)  <i>Intervention effect (at 24 months): -0.14 (-0.23 to -0.04; p=0.0055)</i></p> <p><b>Number of serious adverse events:</b>  Intervention (n=157): 15 (11 participants, 7%)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				Control (n=149): 25 (19 participants, 13%)	
Liss et al 2018 [26] USA	RCT (encouragement trial design)  Adults aged ≥18 years with type 2 diabetes and body mass index ≥24 kg/m <sup>2</sup> (n=331)  Two community-based YMCA sites in metropolitan Chicago  Follow-up at 6 and 12 months	n=164, 51.8% women  Standard care (at baseline, 6 and 12 months) plus free-of-charge group-based lifestyle intervention (GLI) with goals of 10% weight loss, ≥175 mins moderate physical activity/week over 2 years, advise of low-calorie, <30% fat diet  Wellness instructors offered  1) 24 weekly group sessions; 2) a 12-session transition phase over 6 months; 3) 24-session maintenance phase year 2  <b>Age</b> , mean (SD) 57.1 (10.6) years  <b>Bodyweight</b> , mean, (SD) 101.2 (24.5) kg	n=167, 48.5% women  Standard care: brief dietary and lifestyle counselling at baseline, 6 and 12 months  <b>Age</b> , mean (SD) 56.6 (12.2) years  <b>Bodyweight</b> , mean (SD) 98.3 (23.9) kg  <b>BMI</b> , mean (SD) 34.9 (7.3) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 54 (14) mmol/mol  <b>Drop out</b> : at 12 months 21.3%	ITT-analysis with multiple imputation for all missing data, effect of randomization to the GLI study arm (I) (95% CI)  <b>Body weight (kg)</b>  6 months: -1.09 (-1.91 to -0.27)  12 months: -1.42 (-2.63 to -0.21)  Significant group effects  <b>Body weight (percent)</b>  6 months: -0.95 (-1.77, -0.13)  12 months: -1.20 (-2.36, -0.05)  Significant group effects  <b>Body weight (odds ratio of 5% weight loss in I vs C)</b>  6 months: 2.96 (0.95, 9.24), p=0.06  12 months: 1.71 (0.85, 3.47), p=0.13  <b>HbA1c (mmol/mol)</b>	Low risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>BMI</b>, mean (SD) 36.2 (7.8) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 56 (13) mmol/mol</p> <p><b>Drop out:</b> at 12 months 23.3%</p>		<p>6 months: -2.0 (-4.9 to 1.0)</p> <p>12 months: -3.3 (-6.7 to 0.1)</p> <p>NS group effect at 6 months, borderline significance at 12 months</p> <p><b>Systolic blood pressure (mmHg)</b></p> <p>6 months: 1.02 (-2.75 to 4.79)</p> <p>12 months: -1.36 (-5.30 to 2.59)</p> <p>NS group effects</p> <p><b>Blood lipids (mmol/L)</b></p> <p><i>Total cholesterol</i></p> <p>6 months: -0.13 (-0.34 to 0.09)</p> <p>12 months: -0.15 (-0.36 to 0.06)</p> <p>NS group effects</p> <p><i>HDL-cholesterol</i></p> <p>6 months: 0.01 (-0.05 to 0.06)</p> <p>12 months: 0.04 (-0.008 to 0.09)</p> <p>NS group effects</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Madjd et al 2017 [27] Iran	RCT ITT Overweight and obese female adults with type 2 diabetes (n=81) 24 weeks follow-up	n=41 women Water instead of diet beverages during weight loss program designed to enable weight loss of 7% to 10% of initial body weight, at a rate of 0.5 to 1 kg/wk. over 24 weeks Physical activity goal 60 mins moderate activity 5 days/week for both groups <b>Age</b> , mean (SD) 34.15 (6.99) years <b>Body weight</b> , mean (SD) 83.92 (4.42) kg <b>BMI</b> , mean (SD) 32.86 (1.67) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SD) 52.7 (8.4) mmol/mol <b>Drop out</b> , 19.5%	n=40 women Diet beverage (low calorie) five times/week during weight loss program <b>Age</b> , mean (SD) 35.45 (7.45) years <b>Body weight</b> , mean (SD) 84.70 (7.43) kg <b>BMI</b> , mean (SD) 33.19 (2.25) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SD) 52.5 (2.2) mmol/mol <b>Drop out</b> , 20.0%	Outcome at 24 weeks mean (SD) <b>Weight</b> I: 77.52 (4.95) kg C: 79.45 (6.99) kg <b>BMI</b> I: 30.36 (2.06) kg/m <sup>2</sup> C: 31.14 (2.12) kg/m <sup>2</sup> <b>Waist circumference</b> I: 97 (7) cm C: 97 (6) cm <b>Insulin</b> I: 14.27 (3.81) mU/l C: 17.36 (3.43) mU/l <b>HbA1c</b> I: 39.89 (8.96) mmol/mol	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				C: 47.87 (1.75) mmol/mol <b>LDL cholesterol</b> I: 2.22 (0.46) mmol/l C: 2.24 (0.35) mmol/l <b>HDL cholesterol</b> I: 1.33 (0.17) mmol/l C: 1.33 (0.16) mmol/l <b>Triglycerides</b> I: 1.63 (0.27) mmol/l C: 1.62 (0.19) mmol/l <b>Total cholesterol</b> I: 4.29 (0.41) mmol/l C: 4.31 (0.33) mmol/l	
Maiorino et al 2016	RCT People with newly diagnosed type 2 diabetes	n=108, 50% women Mediterranean diet: ≤50% of calories from carbohydrates and ≥30%	n=107, 51.4% women Low-fat diet: ≤30% of calories from fat, ≤10% of	Adjusted within-group change (95% CI), and between-group difference (95% CI) in change at end-of-trial*  *All participants in the low-fat group remained in the trial 6.1 years, while those	Moderate risk for bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[28] Italy	Outpatients  Follow-up of 8,1 years, until last participant reached primary endpoint (need of diabetes drug: see Esposito 2009, 2014)	calories from fat, with the main source of added fat 30–50 g olive oil  Both dietary interventions restricted energy intake to 1500 kcal/day for women and 1800 kcal/day for men  <b>Age, mean (SD)</b>  Men: 53.1 (9.5) years  Women: 50.9 (9.2) years  <b>Bodyweight, mean, (SD)</b>  Men 89.3 (10.4) kg  Women 82.3 (9.9) kg  <b>BMI, not stated</b>  <b>HbA1c, (mean)</b>  Men: 61 mmol/mol  Women: 62 mmol/mol  <b>Drop out, not stated</b>	calories from saturated fat  <b>Age, mean (SD)</b>  Men 52.9 (9.2) years  Women 51.2 (9.3) years  <b>Bodyweight, mean, (SD)</b>  Men: 88.8 (10.8) kg  Women: 82.9 (9.6) kg  <b>BMI, not stated</b>  <b>HbA1c, (mean)</b>  Men: 61 mmol/mol  Women: 61 mmol/mol  <b>Drop out, not stated</b>	in the Mediterranean group remained 8.1 years.  <b>Sexual function</b>  <i>Men</i>  IIEF (International Index of Erectile Function) over the past 6 months (higher scores indicate better function):  I: -1.22 (-1.64 to -0.8)  C: -2.23 (-2.82 to -1.6)  I decreased less than C: 1.16 (0.15 to 2.16), p=0.024  <i>Women</i>  FSFI (Female Sexual Function Index) over the past 4 weeks (higher scores indicate better function):  I: -1.13 (-2.16 to -0.29)  C: -2.25 (-2.9 to -1.62)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				I decreased less than C: 1.18 (0.18 to 2.16), p=0.019  <b>Secondary:</b> Weight, waist circumference, HbA1c, TC, SBP (see Esposito 2014 for pooled analysis men/women)	
Mayer-Davis et al 2004 [29] USA	RCT.  Procedure of randomisation not described  Clinically verified type 2 diabetes, age ≥45 years, and had a BMI of at least 25 kg/m <sup>2</sup>  Two primary health care centres  6 and 12 months follow-up for primary outcome, 6 months for secondary, but data not	<b>Intervention 1</b>  n=49, 78% women  Intensive-lifestyle intervention based on DPP consisting of 16 structured individual sessions  <b>Age</b> , mean (SD) 59.7 (8.6) years  <b>Weight</b> , mean (SD) 99.5 (17.1) kg  <b>BMI</b> , mean (SD) 37.6 (6.5) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 87.99 (27.3) mmol/mol  <b>Drop out</b>	n=56, 79% women  Usual care consisting of one 1-hour individual information session based on materials from the American Diabetes Association  <b>Age</b> , mean (SD) 62.4 (9.5) years  <b>Weight</b> , mean (SD) 93.4 (20.3) kg  <b>BMI</b> , mean (SD) 35.2 (7.5) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 81.43 (31.7) mmol/mol  <b>Drop out</b>  Data not shown. Given that 1/3 were allocated to each group: 5% dropout	Change in body weight (BW) was the primary outcome. At 6 but not 12 months BW significantly lower in I1 than C, but I2 not different from C  In all groups lower HbA1c at 6 months, but no difference between groups. No difference between groups in plasma lipids  Primary  <b>Weight</b> mean change from baseline  I1: 6 months x kg, 12 months x kg  I2: 6 months x kg, 12 months x kg  C: 6 months x kg, 12 months x kg	Moderate risk of bias  No description of randomisation or method of dietary measurement.

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	presented for 12 months.	<p>Data not shown. Given that 1/3 were allocated to each group: 21% dropout</p> <p>-----</p> <p><b>Intervention 2</b></p> <p>n=47, 85% women</p> <p>I2: Low fat diet based on DPP consisting of 3 group sessions and 1 individual session</p> <p><b>Age</b>, mean (SD) 58.9 (7.8) years</p> <p><b>Bodyweight</b>, mean (SD) 100.0 (19.8) kg</p> <p><b>BMI</b>, mean (SD) 37.5 (6.7) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 82.52 (33.88) mmol/mol</p> <p><b>Drop out</b></p> <p>Data not shown. Given that 1/3 were allocated to each group: 24% dropout</p>		<p>Significant between I1 and C, but not between I2 and C at 6 months. For 12 months, data not presented.</p> <p>Secondary</p> <p><b>HbA1c</b> mean change from baseline mmol/mol</p> <p>I1: 6 months -17.05</p> <p>I2: 6 months -9.18</p> <p>C: 6 months -12.24</p> <p>No significant differences compared to control (C)</p> <p><b>Total cholesterol</b> mean change from baseline</p> <p>I1: 6 months 0.00 mmol/L</p> <p>I2: 6 months 0.00 mmol/L</p> <p>C: 6 months -0.16 mmol/L</p> <p>No significant differences compared to control (C)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		All groups, participants were given a weight goal of achieving and maintaining a 10% weight loss over 12 months, with a diet goal of 25 E% fat and a minimum of 150 minutes of physical activity per week similar in intensity to brisk walking.		<p><b>LDL cholesterol</b> mean change from baseline</p> <p>I1: 6 months -0.09 mmol/L</p> <p>I2: 6 months -0.04 mmol/L</p> <p>C: 6 months -0.18 mmol/L</p> <p>No significant differences compared to control (C)</p> <p><b>Triacylglycerols</b> mean change from baseline</p> <p>I1: 6 months 0.01 mmol/L</p> <p>I2: 6 months 0.00 mmol/L</p> <p>C: 6 months 0.01 mmol/L</p> <p>No significant differences compared to control (C)</p> <p><b>HDL cholesterol</b> mean change from baseline</p> <p>I1: 6 months 0.02 mmol/L</p> <p>I2: 6 months 0.04 mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: 6 months -0.03 mmol/L</p> <p>No significant differences compared to control (C)</p> <p><b>Systolic blood pressure</b> mean change from baseline</p> <p>I1: 6 months -3.3 mmHg</p> <p>I2: 6 months -4.3 mmHg</p> <p>C: 6 months -9.5 mmHg</p> <p>No significant differences between groups over time</p> <p><b>Diastolic blood pressure</b> mean change from baseline</p> <p>I1: 6 months -0.5 mmHg</p> <p>I2: 6 months -0.1 mmHg</p> <p>C: 6 months -2.6 mmHg</p> <p>No significant differences compared to control (C)</p> <p>No adverse reactions reported in the study</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Mitri et al 2020 [30] USA	RCT, single centre  Assigned in a 1:1:1 ratio (no change; low-fat; high fat)  Patients diagnosed with type 2 diabetes between 18 and 75 years with a BMI > 25 kg/m <sup>2</sup> .  Follow-up 6 months	n=37, 51.4% women  High fat diet (HF) with focus on dairy products  Nutritional counseling aiming at maintaining baseline energy intake and body weight and individual counseling by dietitian in how to increase isocaloric dairy intake  Instructed to consume milk, yogurt, and/or cheese as part of their 3+ servings/d of dairy products. A serving size of dairy was defined as: 237 mL of milk and yogurt, 42.5 g hard cheese or 256.7 g of processed cheese  <b>Age, (mean, SD)</b> 58.4 ± 9.8 years  <b>Body weight, (mean, SD)</b> 91.4 ± 18.4 kg	<b>Control 1</b>  n=36, 44.4% women  Low fat (LF)  Nutritional counseling aiming at maintaining baseline energy intake and body weight  To increase dairy consumption to 3 servings/d without modifying daily total energy intake (TEI), participants in the LF group were asked to substitute other foods in their daily diets with LF dairy products  ----- <b>Control 2</b>  n=38, 44.7% women  No change (NC)  No change group were asked to maintain their baseline dairy intake  <b>Age, (mean, SD)</b>	<b>HbA1c, mmol/mol. Mean difference (95% CI)</b>  High fat: 2.5 (-12.7 to 6.6)  Low fat: 4.0 (-0.2 to 8.4)  No change: 0.2 (-3.7 to 4.3)  Between-group difference: p=0.32  <b>Body weight, kg Mean difference (95% CI)</b>  High fat: 1 (0.1 to 1.8)  Low fat: -0.2 (-1 to 0.6)  No change: 0.7 (-0.1 to 1.6)  Between-group difference: p=0.25  <b>BMI, kg/m<sup>2</sup>. Mean difference (95% CI)</b>  High fat: 0.32 (0.04 to 0.61)  Low fat: -0.09 (-0.37 to 0.2)  No change: 0.23 (-0.03 to 0.5)  Between-group difference: p=0.54	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<b>BMI</b> , (mean, SD) 32.09 ± 4.46 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 66.2 ± 12.5 mmol/mol <b>Drop out</b> , 30%	LF: 58.7 ± 7.6 years NC: 58.3 ± 9.3 years <b>Body weight</b> , (mean, SD) LF: 91.0 ± 17.5 kg NC: 97.3 ± 20.5 kg <b>BMI</b> , (mean, SD) LF: 32.06 ± 6.47 kg/m <sup>2</sup> NC: 33.24 ± 5.99 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) LF: 64.9 ± 8.3 mmol/mol NC: 63.8 ± 10.3 mmol/mol <b>Drop out</b> LF: 39% NC: 26%	<b>Waist circumference, cm. Mean difference (95% CI)</b> High fat: 0.6 (-1.9 to 3.0) Low fat: -0.4 (-3.0 to 2.2) No change: 2.0 (-0.3 to 4.4) Between group-difference: p=0.6 <b>Systolic blood pressure, mmHg. Mean difference (95% CI)</b> High fat: 1 (-5 to 6) Low fat: -1 (-7 to 5) No change: -5 (-10 to 1) Between group-difference: p=0.8 <b>Diastolic blood pressure, mmHg. Mean difference (95% CI)</b> High fat: -1 (-4 to 3) Low fat: 2 (-1 to 5) No change: -2 (-5 to 1)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Between group-difference: p=0.75</p> <p><b>Total cholesterol, mmol/L. Mean difference (95% CI)</b></p> <p>High fat: 0.34 (0.05 to 0.62)</p> <p>Low fat: 0.10 (-0.21 to 0.39)</p> <p>No change: 0.03 (-0.26 to 0.28)</p> <p>Between group-difference: p=0.22</p> <p><b>HDL-C, mmol/L. Mean difference (95% CI)</b></p> <p>High fat: 0.03 (-0.05 to 0.08)</p> <p>Low fat: -0.03 (-0.08 to 0.03)</p> <p>No change: 0 (-0.05 to 0.05)</p> <p>Between group-difference: p=0.9</p> <p><b>LDL-C, mmol/L. Mean difference (95% CI)</b></p> <p>High fat: 0.18 (-0.08 to 0.47)</p> <p>Low fat: 0.13 (-0.18 to 0.41)</p> <p>No change: 0 (-0.28 to 0.26)</p> <p>Between group-difference: p=0.23</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<b>Triglycerides, mmol/L. Mean difference (95% CI)</b> High fat: 0.08 (-0.11 to 0.51) Low fat: 0.11 (-0.21 to 0.44) No change: 0.19 (-0.11 to 0.49) Between group-difference: p=0.66	
O'Neil et al 2016 [31] USA	RCT, prospective, parallel-group, 16 U.S. sites across 13 states Type 2 diabetes, HbA1c 53 to 96.7 mmol/mol; fasting blood glucose <240 mg/dL (13.3 mmol/L); BMI 27 to 50 kg/m <sup>2</sup> ; age 18 to 70 years; diabetes management by a non-study physician; stable regimen of medications for 3 months	Weight Watchers program. Free access to ongoing, weekly, in-person Weight Watchers meetings in their communities and the standard online tools. n=279, 72% women <b>Age</b> not given <b>Bodyweight</b> , mean (SD): 104.0 (19.4) kg <b>BMI</b> not given	n=284, 70% women American Diabetes Association. Nutrition recommendations and interventions for diabetes (2008). At baseline visit in person with a dietitian. Instructions hypocaloric (-500 kcal/day deficit), carbohydrate-controlled, fibre-rich diet, with nutritional guidance for diabetes control. <b>Age</b> , not given <b>Bodyweight</b> , mean (SD) 106.2 (19.9) kg <b>BMI</b> , not given	Primary <b>HbA1c</b> mean (SD) 6, 9 and 12 months I: 61 (15.2) mmol/mol, 61.4 (14.5) mmol/mol, 64 (15.4) mmol/mol C: 67.2 (16.3) mmol/mol, 67.3 (15.8) mmol/mol, 68.3 (16.4) mmol/mol Secondary <b>Weight</b> mean (SD) 6, 9 and 12 months I: 99.7 (20.1) kg, 99.8 (20.1) kg 99.6 (19.3) kg C: 104.6 (19.7) kg, 103.7 (19.9) kg, 104.4 (20.1) kg	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Follow up at 6, 9 and 12 months	<p><b>HbA1c</b>, mean (SD) 68 (11.1) mmol/mol</p> <p><b>Drop out</b>, 20%</p>	<p><b>HbA1c</b>, mean (SD) 67 (10.9) mmol/mol</p> <p><b>Drop out</b>, 12%</p>	<p>At 12 months, 34.3% in I lost <math>\geq</math>5% in weight, vs 18.1% in C (<math>p &lt; 0.001</math>)</p> <p><b>Waist circumference</b> mean (SD) 6, 9 and 12 months</p> <p>I: 112.50 (14.34) cm, 112.59 (14.17) cm, 112.57 (14.51) cm</p> <p>C: 115.22 (14.36) cm, 114.61 (14.36) cm, 115.23 (14.85) cm</p> <p><b>HDL cholesterol</b> mean (SD) 6, 9 and 12 months</p> <p>I: 1.30 (0.34) mmol/L 1.29 (0.33) mmol/L 1.34 (0.35) mmol/L</p> <p>C: 1.32 (0.35) mmol/L, 1.32 (0.36) mmol/L, 1.32 (0.34) mmol/L</p> <p><b>LDL cholesterol</b> mean (SD) 6, 9 and 12 months</p> <p>I: 2.58 (0.85) mmol/L, 2.53 (0.78) mmol/L, 2.58 (0.81) mmol/L</p> <p>C: 2.61 (0.82) mmol/L, 2.53 (0.83) mmol/L, 2.52 (0.83) mmol/L</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Triglycerides</b> mean (SD) 6, 9 and 12 months</p> <p>I: 1.62 (0.81) mmol/L, 1.79 (1.04) mmol/L, 1.85 (1.9) mmol/L</p> <p>C: 1.66 (0.97) mmol/L, 1.64 (0.96) mmol/L, 1.67 (1.18) mmol/L</p> <p><b>Total cholesterol</b> mean (SD) 6, 9 and 12 months</p> <p>I: 4.6 (1.0) mmol/L, 4.66 (0.98) mmol/L, 4.73 (1.04) mmol/L</p> <p>C: 4.69 (1.01) mmol/L, 4.59 (0.1) mmol/L, 4.58 (0.96) mmol/L</p> <p><b>Diastolic blood pressure</b> mean (SD) 6, 9 and 12 months</p> <p>I: 76.0 (9.8) mmHg, 79.6 (51.2) mmHg, 75.7 (10.1) mmHg</p> <p>C: 77.6 (9.6) mmHg, 77.7 (10.0) mmHg, 77.7 (9.8) mmHg</p> <p><b>Systolic blood pressure</b> mean (SD) 6, 9 and 12 months</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 125.1 (16.0) mmHg, 125.3 (16.0) mmHg, 125.9 (15.8) mmHg</p> <p>C: 129.2 (15.8) mmHg, 128.4 (16.6) mmHg, 128.5 (16.4) mmHg</p> <p>Serious adverse events over the trial, n:</p> <p>I: 11 (18%) (One hypoglycemia case that required hospitalization was considered study related)</p> <p>C: 10 (16%)</p>	
Pi-Sunyer et al 2007 [32] USA	<p>RCT</p> <p>Overweight or obese adults with type 2 diabetes (n=5,145)</p> <p>Report of 1-year feasibility criteria within the Look AHEAD study, a long-term clinical trial at 16 centres</p> <p>Follow up at 12 months</p>	<p>n=2,570, 59.3% women</p> <p>Intensive lifestyle Intervention (ILI) with goals of minimum 7% weight loss, ≥175 mins moderate physical activity/week</p> <p>Moderate calorie restricted diet prescribed (≤30E% fat, max 10E% saturated, min 15E% protein) including use of meal-replacement products</p>	<p>n=2,575, 59.6% women</p> <p>Usual care: diabetes support and education (DSE) with three group sessions/year, providing general information on nutrition, physical activity, and social support</p> <p><b>Age</b>, (mean ± SD) 58.9 ± 6.9 years</p> <p><b>Bodyweight</b>, (mean ± SD)</p> <p>Women 95.4 ± 17.3 kg</p> <p>Men 109.0± 18.0 kg</p>	<p>Completers analysis of group differences at baseline, at 1 year, and change 1 year-baseline (mean ± SE)</p> <p><b>HbA1c (IFCC)</b></p> <p>I: Baseline: 55.74 ± 0.22; 1 year: 48.75 ± 0.22; change: -7.0 ± 0.22 mmol/mol</p> <p>C: Baseline: 56.18 ± 0.22; 1 year: 54.56 ± 0.22; change: -1.53 ± 0.22 mmol/mol</p> <p>No difference at baseline. Significant differences at year 1 and in change (ILI decreased more)</p>	<p>Moderate risk of bias</p> <p>Primary study to [33] Redmon</p>

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p>First year frequent individual and group meetings with dietitians, behaviour psychologists, and exercise specialists</p> <p>After 6 months additional behaviour strategies and use of weight loss medication (orlistat) for participants with difficulty meeting study goals</p> <p><b>Age</b>, (mean <math>\pm</math> SD) 58.6 <math>\pm</math> 6.8 years</p> <p><b>Bodyweight</b>, (mean <math>\pm</math> SD)</p> <p>Women 94.8 <math>\pm</math> 17.9 kg</p> <p>Men 108.9 <math>\pm</math> 19.0 kg</p> <p><b>BMI</b>, (mean <math>\pm</math> SD)</p> <p>Women 36.3 <math>\pm</math> 6.2 kg/m<sup>2</sup></p> <p>Men 35.3 <math>\pm</math> 5.7 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean <math>\pm</math> SD) 55.74 <math>\pm</math> 0.22 mmol/mol</p>	<p><b>BMI</b>, (mean <math>\pm</math> SD)</p> <p>Women 36.6 <math>\pm</math> 6.6 kg/m<sup>2</sup></p> <p>Men 35.1 <math>\pm</math> 5.2 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean <math>\pm</math> SD)</p> <p>56.18 <math>\pm</math> 0.22 mmol/mol</p> <p><b>Drop out</b>, 4.3%</p>	<p><b>Blood pressure (mmHg)</b></p> <p><i>Systolic</i></p> <p>I: Baseline: 129.4 <math>\pm</math> 0.3; 1 year: 126.6 <math>\pm</math> 0.4; change: -6.8 <math>\pm</math> 0.4</p> <p>C: Baseline: 128.2 <math>\pm</math> 0.4; 1 year: 128.2 <math>\pm</math> 0.4; change: -2.8 <math>\pm</math> 0.3</p> <p>Significant differences at baseline, at year 1 and in change (ILI decreased more)</p> <p><i>Diastolic</i></p> <p>I: Baseline: 69.0 <math>\pm</math> 0.2; 1 year: 67.0 <math>\pm</math> 0.2; change: -3.0 <math>\pm</math> 0.2</p> <p>C: Baseline: 70.4 <math>\pm</math> 0.2; 1 year: 68.6 <math>\pm</math> 0.2; change: -1.8 <math>\pm</math> 0.2</p> <p>No difference at baseline. Significant differences at year 1 and in change (ILI decreased more)</p> <p><b>Blood lipids (mmol/l)</b></p> <p><i>LDL-C</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		Drop out, 2.9%		<p>I: Baseline: <math>2.90 \pm 0.01</math>; 1 year: <math>2.77 \pm 0.016</math>; change: <math>-0.13 \pm 0.02</math></p> <p>C: Baseline: <math>2.91 \pm 0.02</math>; 1 year: <math>2.76 \pm 0.018</math>; change: <math>-0.15 \pm 0.02</math></p> <p>No differences at baseline, at year 1 or in change</p> <p><i>HDL-C</i></p> <p>I: Baseline: <math>1.13 \pm 0.005</math>; 1 year: <math>1.21 \pm 0.008</math>; change: <math>0.09 \pm 0.005</math></p> <p>C: Baseline: <math>1.13 \pm 0.005</math>; 1 year: <math>1.16 \pm 0.005</math>; change: <math>0.036 \pm 0.003</math></p> <p>No difference at baseline. Significant differences at year 1 and in change (ILI increased more)</p> <p><i>Triglycerides</i></p> <p>I: Baseline: <math>2.06 \pm 0.026</math>; 1 year: <math>1.72 \pm 0.020</math>; change: <math>-0.34 \pm 0.023</math></p> <p>C: Baseline: <math>2.03 \pm 0.027</math>; 1 year: <math>1.87 \pm 0.021</math>; change: <math>-0.165 \pm 0.020</math></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No difference at baseline. Significant differences at year 1 and in change (ILI decreased more)</p> <p><b>Weight loss (%)</b></p> <p>I: Change: <math>8.6 \pm 6.9</math></p> <p>C: Change: <math>0.7 \pm 4.8</math></p> <p>Significant difference in change (ILI decreased more)</p> <p><b>Waist circumference (cm)</b></p> <p>I: Change: <math>6.2 \pm 10.2</math></p> <p>C: Change: <math>0.5 \pm 8.5</math></p> <p>Significant difference in change (ILI decreased more)</p> <p><b>Medication use (%)</b></p> <p><i>Use of diabetes medicines (%)</i></p> <p>I: Baseline: <math>86.5 \pm 0.7</math>; 1 year: <math>78.6 \pm 0.8</math>; change: <math>-7.8 \pm 0.6</math></p> <p>C: Baseline: <math>86.5 \pm 0.7</math>; 1 year: <math>88.7 \pm 0.6</math>; change: <math>2.2 \pm 0.5</math></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Significant difference in change (ILI decreased more)</p> <p><i>Use of hypertensive medicines (%)</i></p> <p>I: Baseline: 75.3 ± 0.9; 1 year: 75.2 ± 0.9; change: -0.1 ± 0.6</p> <p>C: Baseline: 73.7 ± 0.9; 1 year: 75.9 ± 0.9; change: 2.2 ± 0.6</p> <p>Significant difference in change (ILI decreased more)</p> <p><i>Use of lipid-lowering medicines (%)</i></p> <p>I: Baseline: 49.4 ± 1.0; 1 year: 53.0 ± 1.0; change: 3.7 ± 0.8</p> <p>C: Baseline: 48.4 ± 1.0; 1 year: 57.8 ± 1.0; change: 9.4 ± 0.8</p> <p>Significant difference in change (ILI increased less)</p>	
Pownall, et al. 2015	Multicentre RCT People with type 2 diabetes and overweight/obesity	n=506, 60% women Intensive lifestyle intervention (ILI) designed to achieve and maintain weight loss of ≥7%	n=513, 57% women General information related to healthy eating and physical activity but did not receive the	Analysis adjusted for randomization group, clinic, gender, age, race/ethnicity, HbA1c and baseline body composition measure <b>Overall changes in weight (mean, SE)</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[34] USA	A subset (n=1,019) within the Look AHEAD study with at least one follow-up measure of body composition with DXA (dual-energy x-ray absorptiometry)  Follow-up at 1, 4 and 8 years	Caloric intake goal of 1200–1500 or 1500–1800 kcal/day depending on initial weight, and advised 175 minutes/week of physical activity  <b>Age</b> , mean (SD) 58.6 (7) years  <b>Body weight</b> , mean (SD) 98.8 (15.9) kg  <b>BMI</b> , mean (SD) 35.3 (5.4) kg/m <sup>2</sup>  <b>HbA1c</b> , Not stated  <b>Drop out</b>  At 1 year: 2% At 4 years: 9% At 8 years: 19%	comprehensive components of the intervention nor specific strategies for weight loss  <b>Age</b> , mean (SD) 58.9 (6.7) years  <b>Body weight</b> , mean, (SD) 100.4 (15.1) kg  <b>BMI</b> , mean (SD) 35.6 (5.1) kg/m <sup>2</sup>  <b>HbA1c</b> , Not stated  <b>Drop out</b>  At 1 year: 3% At 4 years: 8% At 8 years: 15%	I: 1 year: -7.9 (0.3); 4 years: -3.7 (0.4); 8 years: -4.0 (0.4)  C: 1 year: -0.5 (0.3); 4 years: -1.2 (0.4); 8 years: -2.3 (0.4)  Groups are different at 1, 4 and 8 years: p<0.05  Overall treatment effect: p<0.0001	
Redmon et al 2010 [33]	RCT  Overweight or obese adults with type 2 diabetes, aged 45–76 years (n=4,998)	n=2,496, 59% women  Intensive lifestyle Intervention (ILI)  with goals of minimum 7% weight loss, ≥175 mins	n=2,502, 60% women  Usual care: diabetes support and education (DSE) with three group sessions/year, providing general	Completers analysis of between-group differences at 12 months (mean ± SD); groups did not differ at baseline  <b>Number of prescribed medications to treat CVD risk factors</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
USA	<p>The Look AHEAD study, a clinical trial at 16 centres</p> <p>Changes in medication were primarily made by participants' primary physicians, with the exception of temporary reductions in hyperglycemic medications during periods of intensive weight loss intervention for the ILI cohort</p> <p>12 months</p>	<p>moderate physical activity/week</p> <p>Moderate calorie restricted diet prescribed including use of meal-replacement products</p> <p>First year frequent individual and group meetings with dietitians, behaviour psychologists, and exercise specialists</p> <p>After 6 months additional behaviour strategies and use of weight loss medication (orlistat) for participants with difficulty meeting study goals</p> <p><b>Age</b> (mean <math>\pm</math> SD), 59 <math>\pm</math> 7 years</p> <p><b>Bodyweight</b>, Not stated</p> <p><b>BMI</b>, (mean <math>\pm</math> SD) 35.9 <math>\pm</math> 6.0 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean <math>\pm</math> SD) 7.3 <math>\pm</math> 1.1%</p> <p><b>Drop out</b>, 13%</p>	<p>information on nutrition, physical activity, and social support</p> <p><b>Age</b>, (mean <math>\pm</math> SD) 59<math>\pm</math>7 years</p> <p><b>Bodyweight</b>, Not stated</p> <p><b>BMI</b>, (mean <math>\pm</math> SD) 36.0 <math>\pm</math> 5.8 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean <math>\pm</math> SD) 7.3 <math>\pm</math> 1.2%</p> <p><b>Drop out</b>, 12%</p>	<p><i>Diabetes medications</i></p> <p>I: Baseline: 1.5 <math>\pm</math> 0.9; 12 months: 1.2 <math>\pm</math> 0.9</p> <p>C: Baseline: 1.5 <math>\pm</math> 0.9; 12 months: 1.6 <math>\pm</math> 0.9</p> <p>Significant difference at 12 months (ILI lower)</p> <p><i>Blood pressure medications</i></p> <p>I: Baseline: 1.3 <math>\pm</math> 1.2; 12 months: 1.3 <math>\pm</math> 1.1</p> <p>C: Baseline: 1.3 <math>\pm</math> 1.1; 12 months: 1.4 <math>\pm</math> 1.1</p> <p>No significant difference at 12 months</p> <p><i>Lipid medications</i></p> <p>I: Baseline: 0.5 <math>\pm</math> 0.6; 12 months: 0.5 <math>\pm</math> 0.6</p> <p>C: Baseline: 0.5 <math>\pm</math> 0.6; 12 months: 0.6 <math>\pm</math> 0.6</p> <p>Significant difference at 12 months (ILI lower)</p> <p><i>Total medications</i></p> <p>I: Baseline: 3.3 <math>\pm</math> 1.8; 12 months: 3.1 <math>\pm</math> 1.8</p> <p>C: Baseline: 3.3 <math>\pm</math> 1.8; 12 months: 3.6 <math>\pm</math> 1.8</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				Significant difference at 12 months (ILI lower)	
Rock et al 2014 [35] USA	RCT  Overweight or obese adults (24-75 years) with type 2 diabetes (n=227)  Two university medical centres  Follow-up at 6 and 12 months	IA: n=74, 47.3% women IB: n=77, 48.1% women  Two commercial weight loss study arms, with prepacked foods provided free of charge during an initial weight loss phase (months 1-6), thereafter gradually phased out.  Weekly counselling visits on basic diabetes self-management strategies and physical activity (30 mins ≥5 days/week) first 9 months, thereafter biweekly or monthly  <b>Intervention A (IA)</b>  As above with high-carbohydrate (60E%) low-fat	n=76, 57.9% women  Usual care: two counselling sessions with advice for 500-1000 kcal/d deficit and dietary guidelines of 55E% carbohydrates, 30E% fat, 15E% protein  Monthly contacts through e-mail or telephone calls; checklist of basic diabetes self-management strategies  <b>Age</b> , (mean, SD) 56.8 (9.3) years <b>Bodyweight</b> , mean (SD) 104.6 (16.9) kg <b>BMI</b> , mean (SD) 36.3 (4.4) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SD) 57 (12) mmol/mol <b>Drop out</b> at 12 months	ITT-analysis for weight, BMI, and waist data; blood pressure, QoL and laboratory measurements analysed for those with available data (mean, SD)  <b>Body weight change (%)</b>  IA: 6 months: -8.6 (5.9); 12 months: -7.4 (7.6) IB: 6 months: -10.4 (6.9); 12 months: -9.0 (8.4) C: 6 months: -2.3 (4.2); 12 months: -2.5 (5.5.)  Significant differences at 6 and 12 months between C (UC) and aggregated weight loss programs (smaller changes in UC)  <b>Body weight (kg)</b>  IA: 6 months: 96.5 (17.5); 12 months: 97.7 (18.0)	Moderate risk for bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p>(20E%) diet (LF), protein 20E%, energy reduced</p> <p><b>Intervention B (IB)</b></p> <p>As above with low-carbohydrate (45E%), high-fat (30E%) diet (LC), protein 25E%, energy reduced</p> <p><b>Age, mean (SD)</b></p> <p>IA: 55.5 (9.2) years</p> <p>IB: 57.3 (8.6) years</p> <p><b>Bodyweight, mean (SD)</b></p> <p>IA: 105.4 (17.8) kg</p> <p>IB: 106.4 (18.3) kg</p> <p><b>BMI, mean (SD)</b></p> <p>IA: 36.2 (4.3) kg/m<sup>2</sup></p> <p>IB: 36.2 (4.7) kg/m<sup>2</sup></p>	10.5%	<p>IB: 6 months: 95.0 (17.9); 12 months: 96.7 (19.7)</p> <p>C: 6 months: 102.2 (17.3); 12 months: 101.9 (17.4)</p> <p>Significant differences at 6 and 12 months between C (UC) and aggregated weight loss programs (higher in UC)</p> <p><b>BMI (kg/m<sup>2</sup>)</b></p> <p>IA: 6 months: 33.2 (4.4); 12 months: 33.5 (4.7)</p> <p>IB: 6 months: 32.4 (4.8); 12 months: 33.0 (5.5)</p> <p>C: 6 months: 35.5 (4.7); 12 months: 35.4 (4.6)</p> <p>Significant differences at 6 and 12 months between C (UC) and aggregated weight loss programs (higher in UC)</p> <p><b>Waist circumference (cm)</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, mean (SD)</p> <p>IA: 58 (13) mmol/mol</p> <p>IB: 56 (15) mmol/mol</p> <p><b>Drop out</b>, at 12 months</p> <p>IA: 6.8%</p> <p>IB: 13%</p>		<p>IA: Baseline: 119.9 (11.5); 6 months: 112.7 (11.8); 12 months: 113.2 (13.3)</p> <p>IB: Baseline: 121.3 (12.3); 6 months: 111.8 (13.3); 12 months: 112.3 (14.6)</p> <p>C: Baseline: 119.9 (11.9); 6 months: 117.7 (13.1); 12 months: 117.1 (13.0)</p> <p>Significant differences at 6 and 12 months between C (UC) and aggregated weight loss programs (larger in UC)</p> <p><b>Blood pressure (mmHg)</b></p> <p><i>Systolic</i></p> <p>IA: Baseline: 133 (15); 6 months: 125 (14); 12 months: 127 (16)</p> <p>IB: Baseline: 131 (19); 6 months: 125 (17); 12 months: 127 (15)</p> <p>C: Baseline: 133 (15); 6 months: 129 (16); 12 months: 126 (14)</p> <p>Significant differences at 6 months between C (UC) and aggregated weight loss programs (higher in UC)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Diastolic</i></p> <p>IA: Baseline: 84 (11); 6 months: 77 (9); 12 months: 77 (10)</p> <p>IB: Baseline: 82 (12); 6 months: 76 (11); 12 months: 78 (11)</p> <p>C: Baseline: 83 (11); 6 months: 82 (12); 12 months: 78 (12)</p> <p>Significant differences at 6 months between C (UC) and aggregated weight loss programs (higher in UC)</p> <p><b>Quality of life (SF-36)</b></p> <p><i>Physical</i></p> <p>IA: Baseline: 78 (15); 6 months: 80 (17); 12 months: 82 (15)</p> <p>IB: Baseline: 80 (15); 6 months: 80 (19); 12 months: 80 (21)</p> <p>C: Baseline: 80 (15); 6 months: 72 (22); 12 months: 80 (16)</p> <p><i>Mental</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>IA: Baseline: 80 (16); 6 months: 82 (14); 12 months: 82 (14)</p> <p>IB: Baseline: 79 (17); 6 months: 79 (18); 12 months: 74 (20)</p> <p>C: Baseline: 82 (16); 6 months: 80 (17); 12 months: 80 (18)</p> <p>Significant differences at 6 months between C (UC) and aggregated weight loss programs on Physical and Mental parts of SF-36 (lower in UC)</p> <p><b>HbA1c (mmol/mol)</b></p> <p>IA: Baseline: 58 (13); 6 months: 50 (11); 12 months: 55 (16)</p> <p>IB: Baseline: 56 (15); 6 months: 44 (9); 12 months: 49 (11)</p> <p>C: Baseline: 57 (12); 6 months: 55 (16); 12 months: 58 (16)</p> <p>Significant differences at 6 and 12 months between LC and LF (higher in LF), and at 6 and 12 months between C (UC) and</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				aggregated weight loss programs (higher in UC)  <b>Blood lipids (mmol/l)</b>  <i>Total cholesterol</i>  IA: Baseline: 4.01 (0.89); 6 months: 4.10 (1.06); 12 months: 4.34 (0.98)  IB: Baseline: 3.96 (0.93); 6 months: 4.06 (1.01); 12 months: 4.24 (0.93)  C: Baseline: 4.16 (1.03); 6 months: 4.34 (1.01); 12 months: 4.40 (0.98)  No significant differences between groups  <i>LDL-C</i>  IA: Baseline: 2.07 (0.88); 6 months: 2.12 (0.91); 12 months: 2.22 (0.78)  IB: Baseline: 2.04 (0.93); 6 months: 2.09 (0.85); 12 months: 2.15 (0.83)  C: Baseline: 2.15 (1.01); 6 months: 2.22 (0.88); 12 months: 2.09 (0.96)  No significant differences between groups	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>HDL-C</i></p> <p>IA: Baseline: 0.96 (0.21); 6 months: 1.19 (0.26); 12 months: 1.32 (0.31)</p> <p>IB: Baseline: 1.01 (0.26); 6 months: 1.24 (0.28); 12 months: 1.40 (0.28)</p> <p>C: Baseline: 1.01 (0.28); 6 months: 1.19 (0.36); 12 months: 1.27 (0.36)</p> <p>Significant differences at 12 months between C (UC) and aggregated weight loss programs (lower in UC)</p> <p><i>Triglyceride</i></p> <p>IA: Baseline: 1.94 (1.08); 6 months: 1.69 (0.98); 12 months: 1.76 (1.08)</p> <p>IB: Baseline: 2.00 (1.12); 6 months: 1.55 (0.88); 12 months: 1.58 (0.82)</p> <p>C: Baseline: 2.04 (1.05); 6 months: 2.04 (0.94); 12 months: 2.30 (1.39)</p> <p>Significant differences at 6 and 12 months between C (UC) and aggregated weight loss programs (higher in UC)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Diabetes medication use (n of participants)</b></p> <p><i>Insulin</i></p> <p>IA: Baseline: 19; stopped/decreased at 12 months: 12; started/increased at 12 months: 2</p> <p>IB: Baseline: 10; stopped/decreased at 12 months: 9; started/increased at 12 months: 0</p> <p>C: Baseline: 12; stopped/decreased at 12 months: 1; started/increased at 12 months: 3</p> <p>Significantly less decrease in UC vs weight loss programs</p> <p><i>Oral hypoglycemic</i></p> <p>IA: Baseline: 62; stopped/decreased at 12 months: 24; started/increased at 12 months: 6</p> <p>IB: Baseline: 69; stopped/decreased at 12 months: 22; started/increased at 12 months: 6</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: Baseline: 62; stopped/decreased at 12 months: 10; started/increased at 12 months: 8</p> <p>Significantly less decrease in UC vs weight loss programs</p> <p><i>Cholesterol</i></p> <p>IA: Baseline: 49; stopped/decreased at 12 months: 10; started/increased at 12 months: 4</p> <p>IB: Baseline: 52; stopped/decreased at 12 months: 11; started/increased at 12 months: 3</p> <p>C: Baseline: 57; stopped/decreased at 12 months: 4; started/increased at 12 months: 4</p> <p><i>Hypertension</i></p> <p>IA: Baseline: 52; stopped/decreased at 12 months: 13; started/increased at 12 months: 3</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>IB: Baseline: 65; stopped/decreased at 12 months: 18; started/increased at 12 months: 1</p> <p>C: Baseline: 60; stopped/decreased at 12 months: 7; started/increased at 12 months: 6</p>	
Rubin et al 2014 [36]  USA  The Look AHEAD Trial,  16 study centers in the United States	<p>RCT</p> <p>Overweight or obese adults with type 2 diabetes (n=5,145)</p> <p>Follow-up 8 years. Median follow-up was 9.6 years. Planned maximum follow-up was 13.5 years, but study was terminated prematurely after a futility analysis. All data were censored on this date.</p>	<p><b>Intervention (ILI):</b> The intensive lifestyle intervention was aimed at achieving and maintaining weight loss of at least 7% by focusing on reduced caloric intake and increased physical activity. The program included both group and individual counseling sessions, occurring weekly during the first 6 months, with decreasing frequency over the course of the trial. Specific intervention strategies included a calorie goal of 1200 to 1800 kcal per day (with &lt;30% of</p>	<p><b>Control (DSE):</b> Diabetes support and education featured three group sessions per year focused on diet, exercise, and social support during years 1 through 4. In subsequent years, the frequency was reduced to one session annually.</p> <p><b>Participants:</b> N= 2 575 Female: 1 537 (59.7%)</p> <p><b>Age, mean (SD):</b> 58.9 (6.9) <b>Weight (kg), mean (SD):</b> male 109 (18) Female 95.4 (17.3)</p>	<p>Quality of Life</p> <p>I vs C (ILI vs DSE)</p> <p>mean difference between groups = 0.93; SE = 0.2; P &lt; 0.001.</p> <p>Differences were statistically significant (P &lt; 0.01 for all comparisons) at every year through the first 8 years of follow up.</p> <p>During these 8 years, the physical component summary scores in ILI were 3.2% higher than those in DSE. In contrast, there were no significant</p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	ITT-analysis	<p>calories from fat and &gt;15% from protein), the use of meal-replacement products, and at least 175 minutes of moderate-intensity physical activity per week.</p> <p><b>Participants:</b> N= 2 570 Female: 1 526 (59.4%)</p> <p><b>Age, mean (SD):</b> 58.6 (6.8) <b>Weight (kg), mean (SD):</b> Male 109 (19.1) Female 94.8 (17.9) <b>BMI, mean (SD):</b> male 35.3 (5.7) Female 36.3 (6.2) <b>HbAc1 (mmol/mol), mean (SD):</b> 56 (12)</p> <p><b>Dropouts:</b> 3.5% (90 lost to follow-up) Sample size: 8 years: -14% 9 years: -30% 10 years:-63%</p>	<p><b>BMI, mean (SD):</b> male 35.1 (5.2) female 36.6 (6.0) <b>HbAc1 (mmol/mol), mean (SD):</b> 56 (13)</p> <p><b>Dropouts:</b> 3.2% (82 lost to follow-up) Sample size: 8 years: -16% 9 years: -31% 10 years:-63%</p>	<p>differences between treatment arms in SF-36 mental component summary scores over the 10 years (all years) (P = 0.361)</p> <p>Estimated from figure in table at 8 years, MCS data and transferred SD form baseline: -0.20 (-0.65, 0.25) Points</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Ruggenenti et al 2017 [37] Italy	RCT  People with type 2 diabetes and abdominal obesity (waist circumference >94 cm in men and >80 cm in women), n=74  Outpatients at clinical research centre for rare diseases  6 months follow-up	n=36, 24,3% women  Calorie restricted diet (CR), decreased daily calorie intake by 25%  Nutrient composition for both diets 45–50 E% carbohydrates, 30–35 E% fat, and 15–20 E% proteins, 20 g/day of fibre, and 300 mg/day of cholesterol.  Patients were encouraged to consume moderate and low glycemic index and nutrient-dense foods.  <b>Age</b> , mean (SD) 59.8 (7.1) years  <b>Bodyweight</b> , mean (SD) 87.2 (13.7) kg  <b>BMI</b> , mean (SD) 30.0 (3.9) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 50.7 (11.1) mmol/mol  <b>Drop out</b> , 5.6%	n=38, 24,3% women  Usual care (UC) and some support  <b>Age</b> , mean (SD) 59.8 (7.1) years  <b>Bodyweight</b> , mean (SD) 83.4 (15.0) kg  <b>BMI</b> , mean (SD) 29.6 (3.8) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 48.4 (8.1) mmol/mol  <b>Drop out</b>  5.3%	p is changes in the CR compared with the UC group at 6 months after adjustment for baseline values by ANCOVA.  <b>Body weight at 6 months (kg)</b>  CR: Baseline=87.2 (13.7); 6 months=82.5 (13.2)  UC: Baseline=83.4 (15.0); 6 months=82.8 (14.7) p=<0.0001  <b>BMI at 6 months (kg/m<sup>2</sup>)</b>  CR: Baseline=30.0 (3.9); 6 months=28.4 (3.8)  UC: Baseline=29.6 (3.8); 6 months=29.3 (3.7) p=<0.0001  <b>Waist circumference at 6 months (cm)</b>  CR: Baseline=104.1 (9.4); 6 months=98.2 (10.7)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>UC: Baseline=102.3 (10.2); 6 months=100.7 (9.9) p=0.0001</p> <p><b>Systolic blood pressure at 6 months (mmHg)</b></p> <p>CR: Baseline=127.8 (9.7); 6 months=121.1 (9.9)</p> <p>UC: Baseline=129.3 (9.1); 6 months=126.1 (8.6) p=0.0322</p> <p><b>Diastolic blood pressure at 6 months (mmHg)</b></p> <p>CR: Baseline=80.5 (7.1); 6 months=75.3 (7.1)</p> <p>UC: Baseline=79.6 (7.3); 6 months=77.6 (7.3) p=0.0349</p> <p><b>HbA1c at 6 months (mmol/mol)</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>CR: Baseline=50.7 (11.1); 6 months=44.9 (7.6)</p> <p>UC: Baseline=48.4 (8.1); 6 months=51.3 (10.9)</p> <p>p=&lt;0.0001</p> <p><b>Total cholesterol at 6 months (mmol/L)</b></p> <p>CR: Baseline=4.43 (0.70); 6 months=4.33 (0.71)</p> <p>UC: Baseline=4.43 (0.76); 6 months=4.47 (0.91)</p> <p>p=0.3384</p> <p><b>HDL at 6 months (mmol/L)</b></p> <p>CR: Baseline=1.06 (0.29); 6 months=1.12 (0.28).</p> <p>UC: Baseline=1.08 (0.29); 6 months=1.06 (0.28)</p> <p>p=0.0501</p> <p><b>LDL at 6 months (mmol/L)</b></p> <p>CR: Baseline=2.76 (0.68); 6 months=2.67 (0.72).</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>UC: Baseline=2.74 (0.79); 6 months=2.76 (0.83). p=0.3718</p> <p><b>Triglycerides at 6 months (mmol/L)</b></p> <p>CR: Baseline=1.12 (0.40); 6 months=0.96 (0.39)</p> <p>UC: Baseline=1.33 (0.79); 6 months=1.49 (1.43) p=0.1182</p> <p><b>Hypoglycaemic agents at 6 months (any)</b></p> <p>CR: Baseline=19; 6 months=29</p> <p>UC: Baseline=18; 6 months=29</p> <p><b>Antihypertensive agents at 6 months (any)</b></p> <p>CR: Baseline=12; 6 months=12</p> <p>UC: Baseline=11; 6 months=13</p> <p><b>Lipid-lowering agents at 6 months (any)</b></p> <p>CR: Baseline=10; 6 months=10</p> <p>UC: Baseline=21; 6 months=19</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Samaha et al 2003 [38] USA	RCT  People with severe obesity (mean BMI 43), high prevalence of diabetes (39%) or the metabolic syndrome (43%)  Philadelphia Veterans Affairs Medical Center  Follow-up at 6 months	n=64 (26 with diabetes)  20% women  Carbohydrate-restricted (low-carbohydrate) diet  Intake of carbohydrates restricted to ≤30 g/day, no restriction of total fat intake, vegetables, and fruits with high ratios of fiber to carbohydrate were recommended.  <b>Age</b> , mean (SD) 53 (9) years  <b>Bodyweight</b> , mean, (SD): 130 (22.7) kg  <b>BMI</b> , mean (SD) 42.9 (6.6) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 61,75 (13,12) mmol/mol  <b>Drop out</b> , 33%	n=68 (26 with diabetes)  15% women  Calorie- and fat-restricted (low-fat) diet.  Instructions in accordance with the obesity-management guidelines of the National Heart, Lung, and Blood Institute, including caloric restriction of 500 calories per day, with ≤30 E% from fat  <b>Age</b> , mean (SD) 54 (9) years  <b>Bodyweight</b> , mean (SD) 131.8 (27.3) kg  <b>BMI</b> , mean (SD) 42.9 (7.7) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 57.38 (16.40) mmol/mol  <b>Drop out</b> , 47%	Only HbA1c reported separately for those with diabetes.  Mean (SD) at 6 months  <b>HbA1c (mmol/mol)</b> I: 55.20 (18.58), p=0.42 C: 57.38 (19,67), p=0.06	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Sato J, et al. 2017 [39] Japan	RCT  Type 2 diabetes patients with HbA1c >7.5% after repeated education programs on calorie restricted diet (n=66)  Outpatient clinic at university hospital  6 months follow-up	n=33, 23.3% women  Baseline values of completers (n=30):  Low-carbohydrate diet (LCD): target carbohydrate intake was 130 g/day, and recommendation on unsaturated rather than saturated fat, apart from that no specific restrictions.  Both groups: Five 30-minutes personal nutritional education meetings with a dietician over 6 months  <b>Age</b> , (mean, SD) 60.5 ± 10.5 years  <b>Bodyweight</b> , (median, IQR) 74.0 (66.2 to 86.4) kg  <b>BMI</b> , (median, IQR) 26.7 (25.0 to 30.0) kg/m <sup>2</sup>	n=33, 25% women  Baseline values of completers (n=32):  Calorie restricted diet (CRD): target total calorie intake was ideal body weight x 28 kcal/kg, 50 to 60% carbohydrate, protein 1.0 to 1.2 g/kg, calory balance covered by fat.  <b>Age</b> , (mean, SD) 58.4 ± 10.0 years  <b>Bodyweight</b> , (median, IQR) 73.6 (68.1 to 88.0) kg  <b>BMI</b> , (median, IQR) 26.5 (24.6 to 30.1) kg/m <sup>2</sup>  <b>HbA1c</b> , (median, IQR) 67.2 (63.9 to 78.1) mmol/mol  (The DCCT scale were assumed before conversion to the IFCC scale)  <b>Drop out</b> , 3% (n=1)	Per-protocol analysis at 6 months, median (IQR) change  <b>HbA1c (mmol/mol)</b> I: -7.10 (-16.72 to -1,09) C: 0.00 (7,43 to 4,37)  HbA1c decreased significantly more in the LCH group  <b>Body weight (kg)</b> I: -1.60 (-4.2 to -0.43) C: -0.60 (-1.45 to 0.68)  Body weight decreased significantly more in the LCH group  <b>BMI (kg/m<sup>2</sup>)</b> I: -0.58 (-1.51 to -0.16) C: -0.22 (-0.58 to 0.24)  BMI decreased significantly more in the LCH group	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, (median, IQR) 63.9 (59.6 to 73.8) mmol/mol</p> <p>(The DCCT scale were assumed before conversion to the IFCC scale)</p> <p><b>Drop out</b>, 9.1% (n=3)</p>		<p><b>Blood lipids (mmol/L)</b></p> <p><i>LDL-C</i></p> <p>I: -0.1293 (0.556 to 0.137)</p> <p>C: 0.0776 (-0.305 to 0.207)</p> <p><i>HDL-C</i></p> <p>I: 0.0259 (-0.0595 to 0.1293)</p> <p>C: 0.0259 (-0.0776 to 0.1034)</p> <p><i>Triglyceride</i></p> <p>I: - 0.225 (-0.810 to 0.3443)</p> <p>C: - 0.00564 (-0.3872 to 0.819)</p> <p>Changes in LDL-C, HDL-C, and triglycerides were not significantly different between groups.</p> <p><b>Perception of hypoglycemia</b> (lower score indicates more ideal glucose level)</p> <p>I: 0.0 (-0.3 to 1.0)</p> <p>C: 0.0 (0.0 to 0.8)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Changes were not significantly different between groups.</p> <p><b>Reduction of diabetes medications</b> (n of participants):</p> <p>I: 8 C: 1</p> <p><b>Change in insulin dosage</b> (n of participants):</p> <p><i>Increase</i></p> <p>I: 0 C: 2</p> <p><i>Decrease</i></p> <p>I: 3 C: 3</p>	
Shirai et al 2013	Multicentre RCT Obese adults (BMI >25 kg/m <sup>2</sup> ) with type 2	n=120, 62% women Baseline values of completers (n=119):	n=120, 64% women Baseline values of completers (n=110):	<p>Completers only analysis at 24 weeks, mean changes ± SD:</p> <p><b>Body weight, kg</b></p> <p>I: -3.5±4.0</p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[40] Japan	diabetes, aged 20 to 69 years 11 hospitals in Japan 24 weeks follow-up	Low-caloric diet with partial use of formula diet (FD): one pack of MicroDiet (240 kcal/meal) and 2 conventional Japanese low-caloric meals/day, protein 18E%, fat 30E%, carbohydrate 52E%. Guidance on lifestyle improvements by dieticians and/or nurses at the clinic every 4 weeks  <b>Age</b> , (mean, SD) 50.5±11.8 years  <b>Bodyweight</b> , (mean, SD) 79.9±17.8 kg  <b>BMI</b> , (mean, SD) 30.8±5.8 kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 64.4±15.1 mmol/mol  <b>Drop out</b> , 0.8%	Isocaloric conventional low-calorie diet (CD): classical Japanese low-caloric meals x 3/day: protein 15E%, fat 25E%, carbohydrate 60E%.  Guidance on lifestyle improvements by dieticians and/or nurses at the clinic every 4 weeks  <b>Age</b> , (mean, SD) 51.7±10.9 years  <b>Bodyweight</b> , (mean, SD) 77.9±14.9 kg  <b>BMI</b> , (mean, SD) 30.0±4.6 kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 64.4±14.0 mmol/mol  <b>Drop out</b> , 8.3%	C: -1.4±3.4  Mean weight reduction was significantly greater in FD than in CD  <b>BMI, kg/m<sup>2</sup></b> I: -1.4±1.5 C: -0.6±1.3  Mean BMI reduction was significantly greater in FD than in CD  <b>Blood pressure, mmHg</b> <i>Systolic</i> I: -5.9±16.2 C: -1.1±15.5  Mean SBP reduction was significantly greater in FD than in CD  <i>Diastolic</i> I: -1.1±9.0 C: -0.3±11.3	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No significant difference between groups</p> <p><b>HbA1c (mmol/mol)</b></p> <p>I: <math>-6.5 \pm 11.9</math></p> <p>C: <math>-2.2 \pm 8.6</math></p> <p>Mean HbA1c reduction was significantly greater in FD than in CD</p> <p><b>Blood lipids (mmol/L)</b></p> <p><i>LDL-C</i></p> <p>I: <math>-0.08 \pm 0.68</math></p> <p>C: <math>-0.07 \pm 0.57</math></p> <p>No significant difference between groups</p> <p><i>HDL-C</i></p> <p>I: <math>-0.08 \pm 0.19</math></p> <p>C: <math>-0.02 \pm 0.18</math></p> <p>The changes in HDL-C in FD was significantly different from that in CD</p> <p><i>Triglycerides</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: <math>-0.26 \pm 0.68</math></p> <p>C: <math>-0.02 \pm 0.92</math></p> <p>The changes in triglyceride were significantly greater in FD than in CD</p> <p><b>Use of glucose-lowering drugs</b></p> <p><i>Sulfonylureas</i></p> <p>Discontinued cases were 3/51 in CD, and 20/57 in FD (<math>p &lt; 0.02</math>), reduced cases were 3/51 in CD, and 11/57 in FD (<math>p &lt; 0.05</math>)</p> <p><i>Thiazolidine</i></p> <p>Discontinued cases were 4/24 in CD, and 12/27 in FD (<math>p &lt; 0.02</math>)</p> <p>Changes in insulin, biguanides, glinides and alfa glucosidase inhibitors were not significantly different between groups</p> <p><b>Use of antihypertensive drugs</b></p> <p>Changes in statins, fibrates and eicosapentaenoic acid glucosidase inhibitors were not significantly different between groups</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Use of lipid-lowering drugs</b></p> <p>Changes in angiotensin converting enzyme inhibitor, angiotensin II receptor blockers and calcium channel blockers were not significantly different between groups</p> <p><b>Adverse events</b>, None observed</p>	
Taheri et al 2020 [41] Qatar	<p>Randomized controlled trial, parallel group.</p> <p>Assigned in a 1:1 ratio with computer-generated randomization.</p> <p>Patients newly (within 3 years) diagnosed with type 2 diabetes between 18 and 50 years with a BMI over 27 kg/m<sup>2</sup>.</p> <p>12 months follow-up</p>	<p>n=70, 30% women</p> <p>Intensive lifestyle intervention. Supported by a team of dietitians, personal trainers, and physicians.</p> <p>12 week of diet replacement phase including a low-energy (800-820 kcal/day) diet meal replacement products (57% CHO, 14% fat and 26% protein) followed by a 12-week structured food reintroduction phase. Thereafter participants managed their own energy restricted food intake and lifestyle changes for 6 months.</p>	<p>n=77, 25% women</p> <p>Usual medical care according to clinical guidelines. Standard diet and activity advice, and diabetes education were provided. Participants were seen by a physician at baseline and once every month.</p> <p><b>Age</b>, (mean, SD) 42.3 ± 5.8 years</p> <p><b>Bodyweight</b>, (mean, SD) 101.7 ± 19.3 kg</p> <p><b>BMI</b>, (mean, SD) 34.8 ± 5.8 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 52.5 ± 13.3 mmol/mol</p>	<p><b>Weight, kg. Adjusted mean difference (95% CI)</b></p> <p>-6.08 (-8.37 to -3.79)</p> <p>I change at 12 mon: -11.98 (SD 9.46)</p> <p>C change at 12 mon: -3.98 (SD 5.29)</p> <p><b>Waist circumference, cm. Adjusted mean difference (95% CI)</b> -6.97 (-9.86 to -4.10)</p> <p>I change at 12 mon: -11.44 (SD 9.90)</p> <p>C change at 12 mon: -4.03 (SD 5.68)</p> <p><b>HbA1c, mmol/mol. Adjusted mean difference (95% CI)</b></p> <p>-6.77 (-10.09 to -3.46)</p>	Low risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p>Participants were advised to aim for low-GI carbohydrates.</p> <p>Meal replacement products were provided at no cost.</p> <p><b>Age</b>, (mean, SD) 41.9 ± 5.4 years</p> <p><b>Bodyweight</b>, (mean, SD) 100.6 ± 19.5 kg</p> <p><b>BMI</b>, (mean, SD) 35 ± 5.2 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 52.5 ± 15.3 mmol/mol</p> <p><b>Drop out</b>, 21%</p>	<p><b>Drop out</b>, 13%</p>	<p>I change at 12 mon: -9.50 (SD 11.31)</p> <p>C change at 12 mon: -3.46 (SD 14.70)</p> <p><b>Total cholesterol, mmol/L. Adjusted mean difference (95% CI)</b></p> <p>0.86 (0.52 to 1.18)</p> <p>I change at 12 mon: 0.23 (SD 1.21)</p> <p>C change at 12 mon: -0.43 (SD 1.03)</p> <p><b>Triglycerides, mmol/L. Adjusted mean difference (95% CI)</b></p> <p>-0.02 (-0.05 to 0.05)</p> <p>I change at 12 mon: -0.50 (SD 1.50)</p> <p>C change at 12 mon: -0.13 (SD 0.92)</p> <p><b>HDL, mmol/L. Adjusted mean difference (95% CI)</b></p> <p>0.08 (0.01 to 0.15)</p> <p>I change at 12 mon: 0.03 (SD 0.40)</p> <p>C change at 12 mon: 0.03 (SD 0.11)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>LDL, mmol/L. Adjusted mean difference (95% CI)</b>  0.82 (0.51 to 1.13)  I change at 12 mon: 0.30 (SD 1.10)  C change at 12 mon: -0.36 (SD 0.94)</p> <p><b>Systolic blood pressure, mmHg. Adjusted mean difference (95% CI)</b>  -0.36 (-3.63 to 2.92)  I change at 12 mon: -8.19 (SD 12.66)  C change at 12 mon: -4.41 (SD 11.44)</p> <p><b>Diastolic blood pressure, mmHg. Adjusted mean difference (95% CI)</b>  -1.49 (-3.68 to 0.68)  I change at 12 mon: -5.60 (SD 7.34)  C change at 12 mon: -2.24 (SD 7.88)</p> <p><b>Quality of life, EQ-5D-score. Adjusted mean difference (95% CI)</b>  4.03 (-1.12 to 9.19)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I change at 12 months: 4.32 (SD 16.80)</p> <p>C change at 12 months: -1.03 (SD 16.51)</p> <p><b>Number of diabetes medications. Adjusted mean difference (95% CI)</b></p> <p>-1.54 (-1.84 to -1.24)</p> <p>I change at 12 months: -1.38 (SD 1.03)</p> <p>C change at 12 months: 0.06 (SD 1.19)</p> <p><b>Number of antihypertensive medications. Adjusted mean difference (95% CI)</b></p> <p>-0.36 (-0.58 to -0.14)</p> <p>I change at 12 months: -0.24 (SD 0.84)</p> <p>C change at 12 months: 0.15 (0.54)</p> <p><b>Diabetes remission (HbA1c &lt;48 mmol/mol and receiving no pharmacological therapy for diabetes for at least 3 months).</b></p> <p>I: 61%</p> <p>C: 12%</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				OR (95% CI) 12.03 (5.17 to 28.03)  <b>Adverse events, number</b>  I: 0  C: 5	
Tay et al 2014 [42] Australia	RCT  Overweight and obese adults with type 2 diabetes, aged 35 to 68 years with HbA1c ≥ 7.0% and/or using diabetes medication including insulin), (n=131 randomised, n=115 allocated and enrolled)  Outpatient research clinic  24 weeks follow-up	n=58, 36% women  Very-low-carbohydrate, low-saturated fat diet, hypocaloric (LC): 14E% CHO (<50 g/day), 28E% protein, 58E% fat (<10E% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) [data from 24w)  Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly.  <b>Age</b> , (mean, SD) 58±7 years  <b>Bodyweight</b> , (mean, SD) 101.7±14.4 kg	n=57, 49% women  Low-fat, high-carbohydrate, low-glycaemic index diet, hypocaloric (HC): 53E% CHO, 17E% protein, <30E% fat (<10E% saturated, 15E% monounsaturated, 9 E% polyunsaturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week)  Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly.  <b>Age</b> , (mean, SD) 58±7 years  <b>Bodyweight</b> , (mean, SD) 101.6±15.8 kg	Adjusted (baseline and sex) completers only analysis of between-group differences at 6 months, mean changes (SD):  <b>HbA1c, mmol/mol</b>  The LC diet reduced HbA1c to a greater extent among participants with baseline HbA1c >62 mmol/mol, with no diet effect in participants with baseline HbA1c ≤62 mmol/mol  I: -28.4 (10.9) mmol/mol, C: -20.8 (13.1) mmol/mol  Significant differences between groups (P=0.002)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>BMI</b>, (mean, SD) 34.2±4.5 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 56.29±12.02 mmol/mol</p> <p><b>Drop out</b>, 20.7%.</p>	<p><b>BMI</b>, (mean, SD) 35.1±4.1 kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 57.38±12.02 mmol/mol</p> <p><b>Drop out</b>, 17.5%</p>	<p><b>Antiglycemic medication effect score (MES)</b></p> <p>I: -0.5 (0.5), C: -0.2 (0.5)</p> <p>The LC diet achieved a greater reduction than did the HC diet (p=0.003)</p> <p>Significantly (p&lt;0.005) more LC participants showed a ≥20% reduction in diabetes medication:</p> <p>I: 67.4%, C: 27.7%</p> <p>More LC participants showed a ≥50% reduction in diabetes medication (p=0.05):</p> <p>I: 34.8%, C: 17.0%</p> <p><b>Lipid-lowering medication</b></p> <p><i>Number of participants who reduced medication</i></p> <p>I: n=4, C: n=2</p> <p><i>Number of participants who increased medication</i></p> <p>I: n=3, C: n=2</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Antihypertensive medication</b></p> <p><i>Number of participants who reduced medication</i></p> <p>I: n=10, C: n=1</p> <p><i>Number of participants who increased medication</i></p> <p>I: n=3, C: n=3</p> <p><b>Body weight, kg</b></p> <p>I: -12.0 (6.3), C: -11.5 (5.5)</p> <p>Changes did not differ between groups, p=0.57</p> <p><b>BMI, kg/m<sup>2</sup></b></p> <p>I: -4.0 (2.0)</p> <p>C: -4.0 (1.8)</p> <p>Changes did not differ between groups, p=0.74</p> <p><b>Waist circumference, cm</b></p> <p>I: -10.6 (7.1)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: -9.1 (6.4)</p> <p>Changes did not differ between groups, p=0.25</p> <p><b>Blood pressure, mmHg</b></p> <p><i>Systolic</i></p> <p>I: -11.0 (10.6)</p> <p>C: - 8.7 (12.5)</p> <p>p=0.26</p> <p>Calculated difference I-C=-2.3</p> <p>SE calculated to 2.03</p> <p><i>Diastolic</i></p> <p>I: -8.2 (5.6)</p> <p>C: -6.4 (7.8)</p> <p>Calculated difference -1,8</p> <p>and DBP p=0.10 did not differ between groups</p> <p>SE calculated to 1.09</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Blood lipids, mmol/L</b></p> <p><i>Total cholesterol</i></p> <p>I: -0.3 (0.7)</p> <p>C: -0.3 (0.9)</p> <p>p=0.89</p> <p><i>LDL-C</i></p> <p>I: -0.3 (0.5)</p> <p>C: -0.3 (0.7)</p> <p>p=0.81</p> <p>Changes in total cholesterol and LDL-C did not differ between groups</p> <p><i>Triglycerides</i></p> <p>I: -0.5 (0.5)</p> <p>C: -0.1 (0.5)</p> <p>P= 0.001</p> <p>Significantly greater reductions of TG with the LC diet</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Tay et al 2015 [43] Australia	RCT  Overweight and obese adults with type 2 diabetes, aged 35 to 68 years with HbA1c $\geq$ 7.0% and/or using diabetes medication including insulin), (n=115)  Outpatient research clinic  1 year follow-up	n=58, 36% women  Very-low-carbohydrate, low-saturated fat diet, hypocaloric (LC): 14E% CHO, 28E% protein, 58E% fat (<10% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) for 2 years.  Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly.  <b>Age</b> , (mean, SD) 58 $\pm$ 7 years  <b>Bodyweight</b> , (mean, SD) 101.7 $\pm$ 14.4 kg  <b>BMI</b> , (mean, SD) 34.2 $\pm$ 4.5 kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 56.3 $\pm$ 12.0 mmol/mol	n=57, 49% women  Low-fat, high-carbohydrate, low-glycaemic index diet, hypocaloric (HC): 53E% CHO, 17E% protein, 30E% fat (<10% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) for 2 years.  Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly.  <b>Age</b> , (mean, SD) 58 $\pm$ 7 years  <b>Bodyweight</b> , (mean, SD) 101.6 $\pm$ 15.8 kg  <b>BMI</b> , (mean, SD) 35.1 $\pm$ 4.1 kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 57.4 $\pm$ 12.0 mmol/mol  <b>Drop out</b> , 35.1%.	ITT-analysis at 1-year, mean changes (95% CI):  <b>Hba1c mmol/mol</b> I: -10.9 (-13.2 to -7.7) C: -10.9 (-14.2 to -8.8) Difference (CI 95%) 1.1 (-3.3, 5.5)  Changes did not differ between groups (p=0.65).  Both diet groups spent a comparable proportion of time in the hypoglycemic range (p= 0.33)  <b>Antiglycemic medication effects score (MES)</b> I: -0.5 (-0.7 to -0.4) C: -0.2 (-0.4 to -0.06) Difference (CI 95%) -0.3 (-0.6, -0.05)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		Drop out, 29.3%.		<p>The LC diet achieved a greater reduction than did the HC diet (p=0.02)</p> <p>Significantly more LC participants showed a <math>\geq 20\%</math> reduction in diabetes medication:</p> <p>I: 52%</p> <p>C: 21%</p> <p><b>Lipid-lowering medication</b></p> <p><i>Number of participants who reduced medication</i></p> <p>I: n=4</p> <p>C: n=6</p> <p><i>Number of participants who increased medication</i></p> <p>I: n=3</p> <p>C: n=1</p> <p><b>Antihypertensive medication</b></p> <p><i>Number of participants who reduced medication</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				I: n=13 C: n=8 <i>Number of participants who increased medication</i> I: n=2 C: n=1 <b>Body weight, kg</b> <b>BMI, kg/m<sup>2</sup></b> I: -3.2 (-3.9 to -2.6) C: -3.5 (-4.2 to -2.9) Difference (CI 95%) 0.3 (-0.6, 1.2) Changes did not differ between groups (p=0.31) <b>Waist circumference, cm</b> I: -9.8 (-11.9 to -7.7) C: -9.1 (-11.2 to -7.0)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				Difference (CI 95%) -0.7 (-3.7, 2.3) Changes did not differ between groups (p=0.36) <b>Blood pressure, mmHg</b> <i>Systolic</i> I: -7.1 (-10.6 to -3.7) C: -5.8 (-9.4 to -2.2) Difference (CI 95%) -1.3 (-6.3, 3.7) (p=0.81) <i>Diastolic</i> I: -6.2 (-8.2 to -4.1) C: -6.4 (-8.4 to -4.3) Difference (CI 95%) 0.2 (-2.7, 3.1) (p=0.38) Similar reductions in both groups <b>Blood lipids, mmol/L</b>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Total cholesterol</i></p> <p>I: -0.1 (-0.3 to 0.1)</p> <p>C: -0.1 (-0.3 to 0.1)</p> <p>Difference (CI 95%)</p> <p>-0.02 (-0.3, 0.3) (p=0.97)</p> <p><i>LDL-C</i></p> <p>I: -0.1 (-0.3 to 0.1)</p> <p>C: -0.2 (-0.4 to 0.03)</p> <p>Difference (CI 95%)</p> <p>0.1 (-0.2, 0.4) (p=0.76)</p> <p>Changes did not differ between groups for TC and LDL-C</p> <p><i>HDL-C</i></p> <p>I: 0.1 (0.1 to 0.2)</p> <p>C: 0.06 (-0.01 to 0.1)</p> <p>Difference (CI 95%)</p> <p>0.1 (-0.03, 0.2)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>HDL-C levels increased more with the LC compared to the HC diet (p= 0.002)</p> <p><i>Triglycerides</i></p> <p>I: -0.4 (-0.5 to -0.2)</p> <p>C: 0.01 (-0.2 to 0.2)</p> <p>Difference (CI 95%)</p> <p>-0.4 (-0.6, -0.1)</p> <p>TG decreased more with the LC compared to HC diet, p=0.001).</p> <p><b>Adverse events</b></p> <p>One LC-diet (I) participant had a non-hospitalized hypoglycemia incident</p>	
Tay et al 2018 [44] Australia	RCT  Overweight and obese adults with type 2 diabetes, aged 35 to 68 years with HbA1c ≥ 7.0% and/or using diabetes medication	n=58 (or 61 according to abstract) 36% women  Very-low-carbohydrate, low-saturated fat diet, hypocaloric (LC): 14E% CHO, 28E% protein, 58E% fat (<10% saturated fat). Combined with supervised	n=57, 49% women  Low-fat, high-carbohydrate, low-glycaemic index diet, hypocaloric (HC): 53E% CHO, 17E% protein, 30E% fat (<10% saturated fat). Combined with supervised aerobic/resistance exercise (1 hour, 3 days/week) for 2 years.	ITT-analysis at 2 years, mean changes (95% CI):  HbA1c reductions were similar in both groups: -7.7 (-10.9, -5.5) mmol/mol,  Difference I-C calculated to -6.5 mmol/mol  p=0.52	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	including insulin), (n=115) Outpatient research clinic 2 years follow-up	aerobic/resistance exercise (1 hour, 3 days/week) for 2 years. Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly. <b>Age</b> , (mean, range) 58 (56 to 60) years <b>Bodyweight</b> , (mean, range) 101.7 (97.8 to 105.7) kg <b>BMI</b> , (mean, range) 34.2 (33.1 to 35.3) kg/m <sup>2</sup> <b>HbA1c</b> , Not stated (same as in other publications) <b>Drop out</b> , 43.1%	Individual instructions from a dietitian every 2 week for 12 weeks, thereafter monthly. <b>Age</b> , (mean, range) 58 (56 to 60) years <b>Bodyweight</b> , (mean, range) 101.6 (97.6 to 105.6) kg <b>BMI</b> , (mean, range) 35.1 (34.0 to 36.2) kg/m <sup>2</sup> <b>HbA1c</b> , Not stated (same as in other publications) <b>Drop out</b> , 50.9%	SE calculated to 10.07 <b>Antiglycemic medication effects score (MES)</b> I: -0.5 (-0.6 to -0.3) C: -0.2 (-0.4 to -0.02) Difference (CI 95%) -0.2 (-0.5 to 0.04) The LC group maintained greater reductions in diabetes medication requirements (p=0.03) Significantly more LC participants showed a ≥20% reduction in diabetes medication: I: n=22 (38%) C: n=9 (16%) The number of participants with ≥50% reduction in diabetes medication did not differ between groups: I: n=12 (21%)	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: n=8 (14%)</p> <p><b>Lipid-lowering medication</b></p> <p><i>Number of participants who reduced medication</i></p> <p>I: n=3</p> <p>C: n=2</p> <p><i>Number of participants who increased medication</i></p> <p>I: n=1</p> <p>C: n=2</p> <p><b>Antihypertensive medication</b></p> <p><i>Number of participants who reduced medication</i></p> <p>I: n=10</p> <p>C: n=5</p> <p><i>Number of participants who increased medication</i></p> <p>I: n=3</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: n=2</p> <p><b>Body weight, kg</b></p> <p>I: -6.8 (-8.8 to -4.7)</p> <p>C: -6.6 (-8.8 to -4.5)</p> <p>Difference (CI 95%)</p> <p>-0.1 (-3.1 to 2.8)</p> <p>Changes did not differ between groups (p=0.26)</p> <p><b>BMI, kg/m<sup>2</sup></b></p> <p>I: -2.1 (-2.8 to -1.5)</p> <p>C: -2.3 (-3.0 to -1.6)</p> <p>Difference (CI 95%)</p> <p>0.1 (-0.8 to 1.1)</p> <p>Changes did not differ between groups (p=0.33)</p> <p><b>Waist circumference (cm)</b></p> <p>I: -7.9 (-10.0 to -5.7)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: -7.2 (-9.5 to -5.0)</p> <p>Difference (CI 95%)</p> <p>-0.6 (-3.7 to 2.5)</p> <p>Changes did not differ between groups (p=0.54)</p> <p><b>Blood pressure (mmHg)</b></p> <p><i>Systolic</i></p> <p>I: -2.0 (-5.9 to 1.8)</p> <p>C: -3.2 (-7.3 to 0.9)</p> <p>Difference (CI 95%)</p> <p>1.1 (-4.5 to 6.8) (p=0.76)</p> <p><i>Diastolic</i></p> <p>I: -1.2 (-3.6 to 1.2)</p> <p>C: -2.0 (-4.5 to 0.5)</p> <p>Difference (CI 95%)</p> <p>0.8 (-2.7 to 4.2)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Similar changes between groups for both (p=0.44)</p> <p><b>Blood lipids, mmol/L</b></p> <p><i>Total cholesterol</i></p> <p>I: 0.2 (-0.1 to 0.6)</p> <p>C: 0.1 (-0.3 to 0.4)</p> <p>Difference (CI 95%)</p> <p>0.2 (-0.3 to 0.7) (p=0.85)</p> <p><i>LDL-C</i></p> <p>I: 0.2 (-0.1 to 0.5)</p> <p>C: 0.1 (-0.2 to 0.4)</p> <p>Difference (CI 95%)</p> <p>0.1 (-0.3 to 0.5) (p=0.85)</p> <p>Changes similar between groups for TC and LDL-C</p> <p><i>HDL-C</i></p> <p>I: 0.02 (-0.05 to 0.1)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				C: -0.1 (-0.1 to 0.01) Difference (CI 95%) 0.1 (-0.02 to 0.2) HDL-C levels were maintained with the LC compared to the HC diet (p≤ 0.004) <i>Triglycerides</i> I: -0.1 (-0.3 to 0.2) C: 0.1 (-0.2 to 0.3) Difference (CI 95%) -0.2 (-0.5 to 0.2) TG decreased to a greater degree with the LC compared to HC diet, (p=0.001).	
Wing et al 2013 [45]	RCT  Overweight or obese adults with type 2 diabetes (n=5,145)  Median follow-up was 9.6 years.	<b>Intervention:</b> The intensive lifestyle intervention was aimed at achieving and maintaining weight loss of at least 7% by focusing on reduced caloric intake and increased physical activity. The	<b>Control:</b> Diabetes support and education featured three group sessions per year focused on diet, exercise, and social support during years 1 through 4. In subsequent years, the frequency was reduced to one session annually.	<u>Primary outcome:</u> <b>Death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina:</b> Patients with events: 821 C: 418 (1.92 per 100 person-yr) I: 403 (1.83 per 100 person-yr)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
The Look AHEAD Research Group 16 study centers in the United States	Planned maximum follow-up was 13.5 years, but study was terminated prematurely after a futility analysis. All data were censored on this date.  ITT-analysis	program included both group and individual counseling sessions, occurring weekly during the first 6 months, with decreasing frequency over the course of the trial. Specific intervention strategies included a calorie goal of 1200 to 1800 kcal per day (with <30% of calories from fat and >15% from protein), the use of meal-replacement products, and at least 175 minutes of moderate-intensity physical activity per week. <b>Participants:</b> N= 2570 Female: 1,526 (59.4%)  <b>Age</b> , mean (SD): 58.6 (6.8) <b>Weight (kg)</b> , mean (SD): 101 (20) <b>BMI</b> , mean (SD): 35.9 (6.0) <b>HbAc1 (mmol/mol)</b> , mean (SD): 55.20 (12.02)	<b>Participants:</b> n= 2,575 Female: 1,537 (59.7 %)  <b>Age</b> , mean (SD): 58.9 (6.9) <b>Weight (kg)</b> , mean (SD): 101 (19) <b>BMI</b> , mean (SD): 36.0 (5.8) <b>HbAc1 (mmol/mol)</b> , mean (SD): 56.29 (13.12)  <b>Dropouts:</b> 3.8% (99 lost to follow-up)	HR (95% CI): 0.95 (0.83–1.09), p-value: 0.51  <u>Secondary outcomes:</u> <b>Death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke:</b> Patients with events: 550 C: 283 (1.25 per 100 person-yr) I: 267 (1.17 per 100 person-yr) HR (95% CI): 0.93 (0.79–1.10), p-value: 0.42  <b>Death from any cause, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina:</b> Patients with events: 1,025 C: 529 (2.43 per 100 person-yr) I: 496 (2.25 per 100 person-yr) HR (95% CI): 0.93 (0.82–1.05), p-value: 0.23  <b>Death from any cause, nonfatal myocardial infarction, nonfatal stroke, hospitalization for angina, CABG, PCI,</b>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		Dropouts: 3.5% (89 lost to follow-up)		<p><b>hospitalization for heart failure, carotid endarterectomy, or peripheral vascular disease:</b></p> <p>Patients with events: 1,177  C: 600 (2.81 per 100 person-yr)  I: 577 (2.67 per 100 person-yr)  HR (95% CI): 0.94 (0.84–1.05), p-value: 0.29</p> <p><b>Death, any cause:</b></p> <p>Patients with events: 376  C: 202 (0.86 per 100 person-yr)  I: 174 (0.73 per 100 person-yr)  HR (95% CI): 0.85 (0.69–1.04), p-value: 0.11</p> <p><b>Death, cardiovascular cause:</b></p> <p>Patients with events: 109  C: 57 (0.24 per 100 person-yr)  I: 52 (0.22 per 100 person-yr)  HR (95% CI): 0.88 (0.61–1.29), p-value: 0.52</p> <p><u>Myocardial infarction:</u></p> <p><b>Fatal or non-fatal:</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>Patients with events: 354  C: 191 (0.84 per 100 person-yr)  I: 163 (0.71 per 100 person-yr)  HR (95% CI): 0.84 (0.68–1.04), p-value: 0.11</p> <p><b>Fatal:</b>  Patients with events: 16  C: 11 (0.05 per 100 person-yr)  I: 5 (&lt;0.02 per 100 person-yr)  HR (95% CI): 0.44 (0.15–1.26), p-value: 0.13</p> <p><b>Non-fatal:</b>  Patients with events: 342  C: 183 (0.80 per 100 person-yr)  I: 159 (0.69 per 100 person-yr)  HR (95% CI): 0.86 (0.69–1.06), p-value: 0.16</p> <p>Stroke:  Patients with events: 165  C: 80 (0.34 per 100 person-yr)  I: 85 (0.36 per 100 person-yr)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>HR (95% CI): 1.05 (0.77–1.42), p-value: 0.78</p> <p><b>Weight</b> (kg), mean (95% CI)  C: baseline: 101 (100, 101), end of study: 96.2 (95.4, 97)  I: baseline: 100 (99.7, 101), end of study: 93.6 (92.8, 94.4)</p> <p><b>Waist circumference</b> (cm), mean (95% CI)  C: baseline: 114 (114, 115), end of study: 113 (113, 114)  I: baseline: 114 (113, 114), end of study: 112 (111, 112)</p> <p><b>HbA1c</b> (mmol/mol), mean (95% CI)  C: baseline: 56,5 (56,0, 56,9), end of study: 57,8 (57,1, 58,7)  I: baseline: 55,9 (55,3, 56,3), end of study: 56,6 (55,7, 57,5)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><b>Systolic blood pressure</b> (mmHg), mean (95% CI)  C: baseline: 129 (129, 130), end of study: 127 (127, 128)  I: baseline: 128 (128, 129), end of study: 126 (125, 127)</p> <p><b>Diastolic blood pressure</b> (mmHg), mean (95% CI)  C: baseline: 70.4 (70, 70.7), end of study: 65.9 (65.5, 66.4)  I: baseline: 70 (69.6, 70.3), end of study: 66.3 (65.8, 66.8)</p> <p><b>HDL cholesterol</b> (mg/dl), mean (95% CI)  C: baseline: 1.125 (1.1146, 1.1378), end of study: 1.236 (1.2206, 1.2542)  I: baseline: 1.125 (1.112, 1.1353), end of study: 1.2594 (1.2413, 1.275)</p> <p><b>Triglycerides</b> (mg/dl), mean (95% CI)  C: baseline: 1.7387 (1.7048, 1.7725), end of study: 1.4 (1.366, 1.4225)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: baseline: 1.7725 (1.7387, 1.8064), end of study: 1.4225 (1.3887, 1.4564)</p> <p><b>LDL cholesterol (mg/dl), mean (95% CI)</b>  C: baseline: 2.8963 (2.8705, 2.922), end of study: 2.2834 (2.2395, 2.3274)  I: baseline: 2.8963 (2.8705, 2.922), end of study: 2.3145 (2.2705, 2.356)</p> <p><b>Use of specific medications (%)</b>, mean (95% CI)  <u>Hypertension medications:</u>  C: baseline: 0.72 (0.7, 0.74), end of study: 0.88 (0.86, 0.89)  I: baseline: 0.73 (0.71, 0.74), end of study: 0.87 (0.85, 0.88)</p> <p><u>Insulin</u>  C: baseline: 0.16 (0.15, 0.18), end of study: 0.41 (0.38, 0.43)  I: baseline: 0.15 (0.14, 0.16), end of study: 0.36 (0.33, 0.38)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Uusitupa et al 1993 [46] Finland	n=86  Randomized controlled trial, multicentre, parallel  Newly diagnosed (mean 60 days) non-insulin-dependent (type 2) diabetes, age 40-64  108 patients were contacted, 22 did not fulfil the inclusion criteria or were not willing to participate  5 rural and 1 urban health centres  Follow up at 3, 9, 15 and 27 months  Intervention between 3 and 15 months, observation between 15 and 27 months.	n=40, 48% women  Intensified diet education. The goals of the diet were individually planned energy restriction, restriction of the intake of total fat ( $\leq 30\%$ of total energy), saturated fatty acids ( $< 10\%$ of energy) and dietary cholesterol ( $< 250-300$ mg/day), a moderate increment of unsaturated fatty acids and increased intake of foods containing unrefined carbohydrates and regular eating patterns. The diet was individually tailored based on knowledge from food records.  <b>Age, mean (SD)</b> 50.7 (6.7) years  <b>Bodyweight:</b> mean (SD) 98.1 (13.0) kg  <b>BMI:</b> mean (SD) 32.6 (3.9) kg/m <sup>2</sup>	n=46, 39% women  Patients were advised to visit the local health centres regularly at 2-3 months intervals  <b>Age, mean (SD):</b> 54.0 (6.6) years  <b>Bodyweight, mean (SD)</b> 97.7 (12.7) kg  <b>BMI, mean (SD)</b> 32.0 (3.4) kg/m <sup>2</sup>  <b>HbA1c, (mean, SD)</b> HbA1c (all) 74.87 (28.42) mmol/mol  <b>Drop out, 4%</b>	<b>BMI, kg/m<sup>2</sup> mean (SD)</b>  I: 3 months 32.0 (5.2), 9 months 31.8 (5.3), 15 months 31.4 (5.0), 27 months 31.9 (5.0)  C: 3 months 31.6 (4.8), 9 months 31.8 (4.6), 15 months 31.9 (4.6), 27 months 32.2 (4.5)  <b>Weight difference, mean (95% CI)</b>  3 vs 15 months: I: -1.8 (-3.0 to -0.5) kg, C: 1.0 (-0.1 to 2.2) kg, I vs C: p=0.001  0 vs 15 months: I: -6.9 (-8.6 to -5.1) kg, C: -3.8 (-5.7 to -1.9) kg, p(I vs C)=0.022  <b>HbA1c, mmol/mol mean (SD)</b>  3 months: I: 54.10 (19.7), C: 61.75 (21.86)  9 months: I: 50.82 (17.49), C: 61.75 (21.86)  15 months: I: 48.64 (17.49), C: 58.48 (18.58)  27 months: I: 55.20 (20.77), C: 63.94 (17.49)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>BMI</b>, (mean, SD) BMI (all): 33.2 (5.5) kg/m</p> <p><b>HbA1c</b>, (mean, SD) HbA1c (all): 65.03 (24.05) mmol/mol</p> <p><b>Drop out</b>, 5%.</p>		<p>HbA1c difference 3 vs 15 months, mean (95% CI)</p> <p>I: -6.59 (-13.12 to -0.92), C: -3.28 (-9.84 to 3.28), I vs C: p=NS</p> <p>Participants with HbA1c ≤53.01 mmol/mol</p> <p>0 months: I: 33.3%, C: 28.3%</p> <p>15 months: I: 74.4%, 47.8%, p=0.005</p> <p>27 months: 55.3%, C: 31.8%, p=0.016</p> <p><b>Systolic blood pressure (mmHg), mean (SD)</b></p> <p>0 months: I 148 (18), C: 149 (23)</p> <p>3 months: I: 140 (16), C: 143 (19)</p> <p>9 months: I: 140 (14), C: 145 (21)</p> <p>15 months: I: 137 (16), C: 144 (18)</p> <p>27 months: I: 146 (19), C: 150 (22)</p> <p>Systolic bp difference 3 vs 15 months, mean (95% CI)</p> <p>I: -3 (-7 to -0), p=0.082</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>C: 1 (-2 to 4)</p> <p><b>Diastolic blood pressure (mmHg), mean (SD)</b></p> <p>0 months: I: 91 (13), C: 88 (12)</p> <p>3 months: I: 87 (11), C: 86 (9)</p> <p>9 months: I: 84 (9), C: 87 (10)</p> <p>15 months: I: 83 (9), C: 85 (9)</p> <p>27 months: I: 88 (10), C: 87 (9)</p> <p>Diastolic bp difference 3 vs 15 months, mean (95% CI)</p> <p>I: -4 (-6 to -1), p=0.084</p> <p>C: -1 (-3 to 1)</p> <p><b>Total Cholesterol (mmol/l), mean (SD)</b></p> <p>0 months: I: 6.3 (1.4), C: 6.5 (1.1)</p> <p>3 months: I: 6.1 (1.2), C: 6.3 (1.0)</p> <p>9 months: I: 6.1 (1.3), C: 6.5 (1.1)</p> <p>15 months: I: 6.0 (1.0), C: 6.4 (1.0)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>27 months: I: 6.4 (1.3), C: 6.5±1.1</p> <p>Participants with Total Cholesterol &lt; 6.5 mmol/l at 15 months: I: 77.5%, C: 58.7%, p=0.03</p> <p><b>HDL cholesterol (mmol/l), mean (SD)</b></p> <p>0 months: I: 1.07 (0.32), C: 1.12 (0.26)</p> <p>3 months: I: 1.07 (0.25), C: 1.17 (0.29)</p> <p>9 months: I: 1.13 (0.27), C: 1.18 (0.32)</p> <p>15 months: I: 1.20 (0.29), C: 1.21 (0.28)</p> <p>27 months: I: 1.17 (0.24), C: 1.19 (0.29)</p> <p>HDL difference 3 vs 15 months, mean (95% CI)</p> <p>I: 0.12 (0.086 to 0.18), p&lt;0.001</p> <p>C: 0.046 (-0.012 to 0.010)</p> <p>Participants with HDL Cholesterol &gt;0.9 mmol/l at 15 months: I: 82.5%, C: 88.9%</p> <p><b>Triglycerides (mmol/l)</b></p> <p>0 months: I: 2.76 (1.60), C: 2.88 (1.67)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				3 months: I: 2.50 (1.44), C: 2.26 (1.33) 9 months: I: 2.42 (1.30), C: 2.27 (1.20) 15 months: I: 1.96 (0.89), C: 2.33 (1.19) 27 months: I: 2.34 (1.19), C: 2.25 (1.25) Triglyceride difference 3 vs 15 months, mean (95% CI) I: -0.53 (-0.91 to -0.15), p=0.003 C: 0.07 (-0.22 to 0.37) Participants with Triglycerides < 2.2 mmol/l at 15 months: I: 67.5%, C: 52.2%	
Wadden et al 2014 [47]	RCT  Overweight or obese adults with type 2 diabetes (n=5,145)  Follow up at 8 years ITT-analysis	<b>Intervention:</b> The intensive lifestyle intervention was aimed at achieving and maintaining weight loss of at least 7% by focusing on reduced caloric intake and increased physical activity. The program included both group and individual counseling sessions, occurring weekly during the first 6 months,	<b>Control:</b> Diabetes support and education featured three group sessions per year focused on diet, exercise, and social support during years 1 through 4. In subsequent years, the frequency was reduced to one session annually.  <b>Participants:</b> n= 2,575	Primary outcome: <b>Weight</b> (kg), mean loss from baseline ( $\pm$ SE) at end of study (based on 101 kg baseline weight) At 4 years I: -4.4 (0.2) % (kg) C: -0.7 (0.2) % (kg) p<0.001 At 8 years I: -4.7 (0.2) % (kg) C: -2.1 (0.2) % (kg)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
centers in the United States		<p>with decreasing frequency over the course of the trial. Specific intervention strategies included a calorie goal of 1200 to 1800 kcal per day (with &lt;30% of calories from fat and &gt;15% from protein), the use of meal-replacement products, and at least 175 minutes of moderate-intensity physical activity per week.</p> <p><b>Participants:</b> n= 2,570 Female: 1,526 (59.3 %)</p> <p><b>Age</b>, mean (SD): 58.6 (6.8) <b>Weight (kg)</b>, mean (SD): 101 (20) <b>BMI</b>, mean (SD): 35.9 (6.0) <b>HbAc1 (mmol/mol)</b>, mean (SD): 55.20 (12.02)</p> <p><b>Dropouts:</b> 10.1 % (not a complete outcome)</p>	<p>Female: 1,537 (59.6 %)</p> <p><b>Age</b>, mean (SD): 58.9 (6.9) <b>Weight (kg)</b>, mean (SD): 101 (19) <b>BMI</b>, mean (SD): 36.0 (5.8) <b>HbAc1 (mmol/mol)</b>, mean (SD): 56.29 (13.12)</p> <p><b>Dropouts:</b> 11.7 % (not a complete outcome)</p>	<p>p&lt;0.001)</p> <p>I vs C with ≥5% weight loss (50.3% vs 35.7%), p&lt;0.001)</p> <p>I vs C with 10% weight loss (26.9% vs 17.2%), p&lt;0.001)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Watson et al 2016 [48] Australia	RCT Overweight/obese adults with type 2 diabetes (n=61) Aged 18-70 years Outpatients 6 months follow-up	n=32, 47% women Higher-protein diet (HD), plus moderate intensive exercise 150 min/week Energy restricted weeks 0-12, weight maintenance weeks 12-24 32E% protein, 33E% carbohydrate, and 30E% total fat (<10% as saturated fat) <b>Age</b> , (mean, SD) 54±8 years <b>Bodyweight</b> , (mean, SD) 97.3±17.1 kg <b>BMI</b> , (mean, SD) 34.3±5.4 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 63.94±14.20 mmol/mol <b>Drop out</b> 28.1% (n=9)	n=29, 45% women Higher-carbohydrate diet (HC), plus moderate intensive exercise 150 min/week Energy restricted weeks 0-12, weight maintenance weeks 12-24 22E% protein, 51E% carbohydrate, and 22E% total fat (<10% as saturated fat). <b>Age</b> , (mean, SD) 55± 8 years <b>Bodyweight</b> , (mean, SD) 101.5±16.6 kg <b>BMI</b> , (mean, SD) 34.4±4.7 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 65.03±16,40 mmol/mol <b>Drop out</b> , 27.6% (n=8)	Outcomes at week 24 and overall change (means ± SEM): <b>HbA1c (mmol/mol)</b> I: 49,73±2,19 C: 48,64±2,19 Decreased significantly in both groups, no difference between groups <b>Waist circumference (cm)</b> I: 103.2±2.2; -9.6±1.2 C: 105.0±2.3; -7.5±1.2 Decreased significantly in both groups, no difference between groups <b>Blood pressure (mmHg)</b> <i>Systolic</i> I: 119.5±2.3; -12.3±1.8 C: 125.2±2.3; -9.8±1.9 <i>Diastolic</i>	Moderate risk of bias  Same study as references 1488 and 1488 and 1489

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 70.7±1.6; -7.7±1.4</p> <p>C: 74.1±1.6; -4.9±1.4</p> <p>SBP and DBP decreased significantly in both groups, no difference between groups</p> <p><b>Body weight (kg)</b></p> <p>I: 88.4±2.8; -8.9±1.3</p> <p>C: 93.8±2.9; -7.7±1.3</p> <p>Decreased significantly in both groups, no difference between groups</p> <p><b>Blood lipids (mmol/L)</b></p> <p><i>Total cholesterol</i></p> <p>I: 4.3±0.2; -0.4±0.1</p> <p>C: 4.4±0.2; -0.03±0.1</p> <p>LDL-C</p> <p>I: 2.4±0.2; -0.3±0.1</p> <p>C: 2.5±0.2; -0.004±0.1</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>HDL-C</p> <p>I: 1.2±0.05; 0.03±0.03</p> <p>C: 1.3±0.06; 0.1±0.03</p> <p>Triglycerides</p> <p>I: 1.6±0.2; -0.4±0.2</p> <p>C: 1.5±0.2; -0.6±0.2</p> <p>Total cholesterol decreased significantly in the HP diet, but not in the HC diet.</p> <p>LDL-C did not change from baseline in either diet. HDL-C increased slightly, with no significant differences between diets.</p> <p>Triglycerides decreased significantly, with no differences between diets.</p> <p><b>Medication effect score (MES)</b></p> <p>I: 0.97±0.15</p> <p>C: 1.13±0.16</p> <p>P for effect of diet: 0.43</p> <p><b>Lipid-lowering medication</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p><i>Number of participants who reduced dose</i></p> <p>I: n=1</p> <p>C: n=3</p> <p><i>Number of participants who increased dose</i></p> <p>I: n=1</p> <p>C: n=0</p> <p><b>Antihypertensive medication</b></p> <p><i>Number of participants who reduced dose</i></p> <p>I: n=5</p> <p>C: n=2</p> <p><i>Number of participants who increased dose</i></p> <p>I: n=0</p> <p>C: n=1</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Watson et al 2018 [49] Australia	RCT Adults with type 2 diabetes and obesity (n=61) Follow-up at 24 weeks	n=32, 47% women Low-fat diet, high in protein (HP): Aiming for 32% protein, 33% carbohydrate, 30% fat In both groups: moderate intensity exercise, for 12 weeks of weight loss and 12 weeks of weight maintenance <b>Age</b> , (mean, SD) 54±8 years <b>Bodyweight</b> , (mean, SD) 97.3±17.1 kg <b>BMI</b> , (mean, SD) 34.3±5.4 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 8.0±1.3% <b>Drop out</b> , 28.1% (n=9).	n=29, 45% women Low-fat diet, high in carbohydrates (HC): Aiming for 22% protein, 51% carbohydrate, 22% fat <b>Age</b> , (mean, SD) 55± 8 years <b>Bodyweight</b> , (mean, SD) 101.5±16.6 kg <b>BMI</b> , (mean, SD) 34.4±4.7 kg/m <sup>2</sup> <b>HbA1c</b> , (mean, SD) 8.1±1.5% <b>Drop out</b> , 27.6% (n=8)	HRQoL, psychological wellbeing means ± SEM <b>D-39 Overall Quality of life (0 to 7)</b> HP: Baseline=4.67±0.23; 6 months=5.02±0.23 HC: Baseline=4.89±0.24; 6 months=5.20±0.24 <b>D-39 Severity of diabetes (0 to 7)</b> HP: Baseline=3.41±0.29; 6 months=2.95±0.28 HC: Baseline=3.69±0.31; 6 months=3.01±0.29 <b>SF-36 Physical functioning</b> HP: Baseline=80.44±2.68; 6 months=84.73±3.04 HC: Baseline=72.00±3.42; 6 months=83.18±3.18 <b>SF-36 Social functioning</b>	Moderate risk of bias  Same study as reference 632

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>HP: Baseline=87.90±3.31; 6 months=84.22±3.78</p> <p>HC: Baseline=86.21±3.45; 6 months=84.80±3.96</p> <p><b>SF-36 Role limitations due to physical health</b></p> <p>HP: Baseline=82.64±3.01; 6 months=84.35±3.75</p> <p>HC: Baseline=86.21±3.14; 6 months=82.77±3.92</p> <p><b>SF-36 Role limitations due to emotional problems</b></p> <p>HP: Baseline=87.65±2.84; 6 months=85.26±3.78</p> <p>HC: Baseline=86.08±2.99; 6 months=83.85±3.95</p> <p><b>SF-36 Mental health</b></p> <p>HP: Baseline=76.59±2.83; 6 months=76.97±2.89</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>HC: Baseline=74.77±2.98; 6 months=76.27±3.02</p> <p><b>SF-36 Bodily pain</b></p> <p>HP: Baseline=69.43±3.66; 6 months=63.13±4.43</p> <p>HC: Baseline=68.75±3.84; 6 months=64.53±4.64</p> <p><b>SF-36 Vitality</b></p> <p>HP: Baseline=56.09±3.20; 6 months=63.10±3.43</p> <p>HC: Baseline=58.71±3.36; 6 months=64.45±3.59</p> <p><b>SF-36 General health</b></p> <p>HP: Baseline=59.77±3.52; 6 months=68.05±3.50</p> <p>HC: Baseline=60.66±3.67; 6 months=68.60±3.65</p> <p><b>SF-36 Physical component summary</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				HP: Baseline=49.04±0.95; 6 months=50.32±1.27. HC: Baseline=49.80±1.00; 6 months=50.31±1.33. <b>SF-36 Mental component summary</b> HP: Baseline=51.80±1.49; 6 months=51.48±1.53 HC: Baseline=51.03±1.57; 6 months=51.56±1.60	
Wien, Oda and Sabate 2014 [50] USA	RCT, prospective parallel-group ITT Type 2 diabetes for at least 6 months and HbA1c less than 9.0% Recruited through advertisements on the Loma Linda University campus and surrounding communities	n=30, 57% women Approximately 20% E from peanuts into individualised ADA meal plan (35% total fat (15% MUFA), 45% carbohydrate and 20% protein); BMI above 25 kg/m <sup>2</sup> and with energy restriction <b>Age</b> , mean (SD) 59 (13) years <b>Bodyweight</b> , mean (SD) 86.0 (24.8) kg	n=30, 43% women Individualised ADA meal plan (35% total fat (15% MUFA), 45% carbohydrate and 20% protein); BMI above 25 kg/m <sup>2</sup> and with energy restriction <b>Age</b> , mean (SD) 64 (12) years <b>Bodyweight</b> , mean (SD) 90.4 (19.3) kg	Outcome at 24 weeks (Least squares mean/adjusted for baseline data) and (CI 95%) <b>Weight</b> I: 85.2 (77.6 to 92.8) kg C: 89.7 (81.9 to 97.4) kg <b>BMI</b> I: 30.8 (28.4 to 33.2) kg/m <sup>2</sup> C: 33.1 (30.7 to 35.6) kg/m <sup>2</sup>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Follow up 24-weeks	<b>BMI</b> , mean (SD) 31.1 (6.9) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SD) 6.6 (0.6)% <b>Drop out</b> , 3.3%	<b>BMI</b> , mean (SD): 33.4 (6.8) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SD): 6.6 (0.6)% Drop out: 6.6%	<b>Waist circumference</b> I: 102.6 (95.9 to 109.4) cm C: 109.8 (103.0 to 116.5) cm <b>Total cholesterol</b> I: 4.27 (3.94 to 4.61) mmol/l C: 4.22 (3.88 to 4.53) mmol/l <b>LDL cholesterol</b> I: 2.20 (1.94 to 2.49) mmol/l C: 2.15 (1.86 to 2.43) mmol/l <b>HDL cholesterol</b> I: 1.30 (1.16 to 1.45) mmol/l C: 1.22 (1.09 to 1.35) mmol/l <b>Triglycerides</b> I: 1.36 (1.12 to 1.64) mmol/l C: 1.54 (1.27 to 1.85) mmol/l <b>HbA1c</b>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 49.84 (46.78 to 52.90) mmol/mol</p> <p>C: 47.87 (44.81 to 50.93) mmol/mol</p> <p>Significant improvement in weight, BMI, and waist circumference in both groups, but not difference between groups. All other variables unchanged.</p>	
Williamson et al 2009 [51] USA	<p>Randomized controlled trial, multicentre</p> <p>Overweight adults with type 2 diabetes. Age 45-74 years. BMI <math>\geq 25</math> or <math>\geq 27</math> if currently taking insulin. Exclusion of HbA1c <math>&gt;11\%</math>, blood pressure <math>&gt;160/100</math> mmHg, Triglycerides <math>&gt;6.78</math> mmol/l.</p> <p>n=5,145 60% women: 16 outpatient research centres</p>	<p>n=2,570, 59.3% women</p> <p>The treatment protocol combined multiple diet and exercise approaches. The 2 principal intervention goals were to induce a mean loss of at least 7% of initial weight and to increase participants' moderately intense physical activity to at least 175 minutes per week. For the first 6 months, participants attended 1 individual and 3 group sessions per month and were encouraged to replace 2 meals and 1 snack each day with liquid shakes and meal</p>	<p>n=2,575, 59.6% women</p> <p>The Diabetes Support and Education (DSE) control arm involved 3 educational group sessions per year that each focused on 1 of the following 3 topics: nutrition, physical activity, and support. Participants assigned to the DSE arm was not given goals for weight loss or caloric intake, were not instructed to monitor energy intake or physical activity, and were not weighed at group meetings.</p> <p><b>Age</b>, mean (SD) 58.85 (6.86) years</p> <p><b>Bodyweight</b>, mean, (SD) 100.86 (18.83) kg</p>	<p><b>SF-36 physical component summary</b></p> <p>Difference from baseline after 1 year, mean (SE)</p> <p>I: 1.65 (7.94), <math>p&lt;0.001</math></p> <p>C: -1.27 (7.44), <math>&lt;0.001</math></p> <p>I vs C mean change (99% CI): -2.91 (-3.44 to -2.37), <math>p&lt;0.001</math></p> <p><b>SF-36 mental health component summary</b></p> <p>Difference from baseline after 1 year, mean (SE)</p> <p>I: 0.03 (8.75), <math>p=0.21</math></p> <p>C: -0.60 (8.32), <math>p=0.13</math></p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Duration of follow-up: 1 year	<p>bars. From months 7 to 12, they attended 1 individual and 2 group meetings per month and continued to replace 1 meal per day.</p> <p>Participants were instructed to self-monitor energy intake and physical activity, and their body weight was measured at each individual and group counseling session. Participants counted calories and fat grams with the aid of a</p> <p>booklet provided. They were prescribed &lt; 30% of calories from fat, with &lt; 10% from saturated fat.</p> <p><b>Age</b>, mean (SD) 58.55 (6.77) years</p> <p><b>Bodyweight</b>, (mean, SD) 100.54 (19.65) kg</p> <p><b>BMI</b>, mean (SD) 35.89 (6.01) kg/m<sup>2</sup></p>	<p><b>BMI</b>, mean (SD) 36.00 (5.76) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 7.31 (1.20)%</p> <p><b>Drop out</b> 4%</p>	<p>I vs C mean change (99% CI): -0.46 (-1.04 to 0.12), p&gt;0.05</p> <p><b>Body weight, kg</b></p> <p>Reported in ref 1807</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<b>HbA1c</b> , (mean, SD) 7.25 (1.14)% <b>Drop out</b> , 3%			
Wolever 2008 [52] Canada	RCT Type 2 diabetes managed on diet alone with HbA1c ≤130% of “upper limit of normal” (5.8%) and BMI 24 to 40 kg/m <sup>2</sup> Outpatients at 6 centres Follow up 1 year	<b>Intervention 1</b> n=52, 50% women High-GI diet In all three study-arms, exchange of diet items for choices of 16-21 listed and free of charge-provided key foods For high-GI and low-GI diets, key foods were starchy carbohydrates with determined GI, providing 20-25 E% Estimated GI difference of about 10 between high-GI and low-GI diets <b>Age</b> , mean (SE) 60.4 (1.1) years <b>Weight</b> , mean (SE) 84.4 (2.5) kg <b>BMI</b> , mean (SE) 30.1 (0.6) kg/m <sup>2</sup>	n=54, 47% women Low-CHO diet Key foods consisted of olive or canola oils or spreads, nuts, and other foods low in SFAs and high in MUFAs <b>Age</b> , mean (SE) 58.6 (1.2) years <b>Weight</b> , mean (SE) 84.7 (2.6) kg <b>BMI</b> , mean (SE) 31.1 (0.6) kg/m <sup>2</sup> <b>HbA1c</b> , mean (SE) 43.2 (9.8) mmol/mol <b>Drop out</b> , 19 to 24%.	Means adjusted for baseline values and significant confounders <b>Weight</b> , kg mean (SE) High-GI: 84.3 (0.2) Low-GI: 83.9 (0.2) Low-CHO: 84.3 (0.2) p=0.062 <b>Waist circumference</b> , cm mean (SE) High-GI: 103.1 (0.8) Low-GI: 104.9 (0.8) Low-CHO: 103.1 (0.8) p=NS <b>HbA1c</b> , mmol/mol mean (SE) High-GI: 45.8 (0.5) Low-GI: 45.8 (0.5)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, mean (SE) 44.3 (10.9) mmol/mol</p> <p><b>Drop out</b>, 21 to 31%</p> <p>-----</p> <p><b>Intervention 2</b></p> <p>n=56, 66% women</p> <p>Low-GI diet</p> <p><b>Age, mean (SE)</b> 60.6 (1.0) years</p> <p><b>Weight</b>, mean (SE) 81.1 (2.5) kg</p> <p><b>BMI</b>, mean (SE) 31.6 (0.6) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SE) 44.3 (8.7) mmol/mol</p> <p><b>Drop out</b>, 20 to 32%</p>		<p>Low-CHO: 45.9 (0.5)</p> <p>p=NS</p> <p><b>Total Cholesterol, mmol/l mean (SE)</b></p> <p>High-GI: 5.04 (0.08)</p> <p>Low-GI: 5.04 (0.08)</p> <p>Low-CHO: 4.99 (0.08)</p> <p>p=NS</p> <p><b>LDL Cholesterol, mmol/l mean (SE)</b></p> <p>High-GI: 3.00 (0.08)</p> <p>Low-GI: 2.92 (0.05)</p> <p>Low-CHO: 2.89 (0.05)</p> <p>p=NS</p> <p><b>HDL Cholesterol, mmol/l mean (SE)</b></p> <p>High-GI: 1.19 (0.03)</p> <p>Low-GI: 1.16 (0.03)</p> <p>Low-CHO: 1.21 (0.03)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>p=0.033 (ANOVA)</p> <p><b>Triacylglycerol (triglycerides), mmol/l</b> mean (SE)</p> <p>High-GI: 2.00 (0.07)</p> <p>Low-GI: 2.17 (0.07)</p> <p>Low-CHO: 1.93 (0.06)</p> <p>p=0.034 (ANOVA)</p> <p><b>Systolic blood pressure, mmHg</b> mean (SE)</p> <p>High-GI: 128 (1)</p> <p>Low-GI: 129 (1)</p> <p>Low-CHO: 127 (1)</p>	
Wycherley et al 2016 [53] Australia	RCT  Overweight or obese patients with type 2 diabetes (n=131 randomised, n=115 allocated and enrolled)	n=58, 36% women  Very-low carbohydrate diet (LowCHO), combined with supervised exercise program (60 min, 3 days/week)	n=57, 49% women  Low-fat diet (HighCHO), combined with supervised exercise program (60 min, 3 days/week)	<p><b>Body weight</b>, means <math>\pm</math> SEM</p> <p>Week 52:</p> <p>I: 90.4 <math>\pm</math> 1.9 kg (change -10.4 kg)</p> <p>C: 91.1 <math>\pm</math> 2.0 kg (change -10.9 kg)</p> <p>No significant differences between groups</p>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Outpatient research clinic 12 months	Energy reduced, 14E% carbohydrate, 28E% protein, 58E% fat (<10% saturated) <b>Age</b> , (mean, SEM), 58.5±1.0 years <b>Bodyweight</b> , (mean, SEM) 100.8±1.8 kg <b>BMI</b> , Not reported <b>HbA1c</b> , (mean, SEM) 7.26±0.14% <b>Drop out</b> 36 to 29.3%	Energy reduced, 53E% carbohydrate, 17E% protein, 30E% fat (<10% saturated) <b>Age</b> , (mean, SEM) 58.4±0.9 years <b>Bodyweight</b> , (mean, SEM) 102.0±1.8 kg <b>BMI</b> , Not reported <b>HbA1c</b> , (mean, SEM) 7.42±0.15% <b>Drop out</b> , 46 to 35.1%		
Yancy et al 2019 [54] USA	RCT People (89% men) with uncontrolled type 2 diabetes and BMI ≥27 Outpatients enrolled from Veterans Affairs Medical Center clinics	n=127, 13% women Group medical visits combined with intensive weight management, low-carbohydrate diet, and initial medication reduction followed by optimization for glycemic control; visits every 2 weeks for	n=136, 8% women Group medical visits focused on diabetes counseling and medication optimization for glycemic control; visits every 4 weeks for 16 weeks, thereafter every 8 weeks (in total 9 visits)	Estimated mean differences (95% CI) <b>HbA1c, mmol/mol</b> 32 weeks: -5.5 (-8.1 to -1.1) 48 weeks: -1.1 (-5.5 to 2.2) <b>Weight, kg</b>	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
	Follow-up at 32 and 48 weeks.	<p>16 weeks, thereafter every 8 weeks (in total 13 visits)</p> <p>Carbohydrate intake was initially restricted to 20 to 30 g/day with no specified caloric restriction, adding daily carbohydrate intake gradually as participants approached their weight goal</p> <p><b>Age</b>, (mean, SD) 61.0 (8.1) years</p> <p><b>Bodyweight</b>, (mean, SD) 109.1 (20.7) kg</p> <p><b>BMI</b>, (mean, SD) 35.6 (5.1) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 74.9 (14.2) mmol/mol</p> <p><b>Drop out</b>, 14%</p>	<p><b>Age</b>, (mean, SD) 60.4 (8.3) years</p> <p><b>Bodyweight</b>, (mean, SD) 107.3 (18.5) kg</p> <p><b>BMI</b>, (mean, SD) 35.0 (4.8) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, (mean, SD) 77.1 (14.2) mmol/mol</p> <p><b>Drop out</b>, 14%.</p>	<p>32 weeks: -6.2 (-7.6 to -4.9)</p> <p>48 weeks: -3.7 (-5.5 to -1.9)</p> <p><b>Diabetes medication use (Medication effect score)</b></p> <p>32 weeks: -0.5 (-0.7 to -0.3)</p> <p>48 weeks: -0.5 (-0.6 to -0.3)</p> <p><b>Hypoglycemic events (mean number, 95% CI)</b></p> <p>I: Individuals in need of assistance from family (n=7) or medical personnel (n=0)</p> <p>C: Individuals in need of assistance from family (n=9) or medical personnel (n=6)</p>	

Included RCT diabetes type 1

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Amiel et al 2002 [55] England	Multicentre RCT with crossover design  Adults (+18) with type 1 patients, diabetes duration for more than 2 years, moderate or poor glycaemic control  Three secondary care diabetes clinics  Follow up at 6 months (crossover design, controls were given the intervention after 6 months)	n=69 (84 randomized but without baseline assessment) Women, not stated per arm, overall 56%  Carbohydrate counting and flexible insulin adjustment on a meal-to-meal basis  Training course for 5 days in groups of six to eight participants Teaching by diabetes specialist nurses and dietitians  <b>Age</b> , mean (SD), Not stated per arm, overall, 40 (9) years  <b>Bodyweight</b> , (mean, SD) 80.5 (16.7) kg  <b>BMI</b> , Not reported	n=72 (85 randomized but without baseline assessment) Women, not stated per arm, overall, 56%  Usual care  <b>Age</b> , mean (SD) Not stated per arm, overall, 40 (9) years  <b>Bodyweight</b> , (mean, SD) 77.4 (13.4) kg  <b>BMI</b> , Not reported  <b>HbA1c</b> , (mean, SD) 78.15 (12.02) mmol/mol  <b>Drop-outs</b> , 20%.	Primary  <b>HbA1c</b> mean (SD) at 6 months I: 68.31 (13.12) mmol/mol C: 79.24 (14.21) mmol/mol  C vs I mean (CI 95%): 10.93 (5.47 to 15.30) mmol/mol  <b>Quality of life</b> Audit of diabetes dependent quality of life (ADDQoL)  Weighted impact of diabetes on <i>Freedom to eat as I wish</i> , scale from -9 (negative) to +9 (positive), mean (SD) I: -1.8 (2.3) C: -4.0 (2.8)  I vs C mean (CI 95%): 2.2 (1.3 to 3.1)  Average weighted impact of diabetes on <i>Overall quality of life</i> , scale from -9 (negative) to +9 (positive), mean (SD) I: -1.6 (1.6) C: -1.9 (1.4)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>HbA1c</b>, (mean, SD) 79.24 (13.12) mmol/mol</p> <p><b>Drop-outs</b>, 19%.</p>		<p>I vs C mean (CI 95%): 0.4 (-0.1 to 0.9)</p> <p><i>Present quality of life</i>, scale from -3 (extremely bad) to +3 (excellent), mean (SD)</p> <p>I: 1.3 (0.9)</p> <p>C: 1.0 (1.1)</p> <p>I vs C mean (CI 95%): 0.3 (-0.1 to 0.6)</p> <p><b>Severe hypoglycemia</b> within 6 months</p> <p>I: 12 of 67 participants (18%)</p> <p>C: 11 of 72 participants (15%)</p> <p>No significant difference between groups</p> <p>Secondary</p> <p><b>Weight</b>, mean (SD)</p> <p>I: 81.5 (16.9) kg</p> <p>C: 77.3 (13.4) kg</p> <p>I vs C mean (CI 95%): 4.18 (-0.90 to 9.27) kg</p> <p><b>Total cholesterol</b>, mean (SD)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 5.1 (0.8) mmol/L  C: 5.0 (1.0) mmol/L  I vs C mean (CI 95%): 0.15 (-0.16 to 0.45) mmol/L</p> <p><b>HDL cholesterol, mean (SD)</b>  I: 1.6 (0.4) mmol/L  C: 1.5 (0.3) mmol/L  I vs C mean (CI 95%): 0.09 (-0.01 to 0.22) mmol/L</p> <p><b>Triglycerides, mean (SD)</b>  I: 1.4 (0.7) mmol/L  C: 1.5 (0.9) mmol/L  I vs C mean (CI 95%): 0.12 (-0.41 to 0.17) mmol/L</p>	
Laurenzi et al 2011 [56]	RCT Adults (18-65 yrs.) with type 1 diabetes who are receiving CSII (continuous	n=28 after early drop-out (n=30 randomized) 46.4% women  Carbohydrate counting following steps in the	n=28 after early drop-out (n=31 randomized) 67.9% women	ITT-analysis of within-group changes (Md, IQR) at 24 weeks, and p-value for difference between groups  <b>HbA1c,%</b>  No difference between groups, p=0.252 (data not shown)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Italy	subcutaneous insulin infusion) Outpatients at a CSII clinic 24 weeks follow-up	Complete Guide to Carb Counting, (2 <sup>nd</sup> ed); 12 weeks of individual training (4-5 sessions) on carbohydrate counting and bolus calculation with a dietitian and a diabetologist  <b>Age</b> , (mean, SD) 41.2 (10.0) years  <b>Bodyweight</b> , Not stated  <b>BMI</b> , (mean, IQR) 23.7 (21-25.2) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 62.8 (9.8) mmol/mol  <b>Drop out</b> , Not stated per group, overall 8.2%.	Continued estimating pre-meal insulin dose in the usual empirical way  <b>Age</b> , (mean, SD) 39.8 (9.8) years  <b>Bodyweight</b> , Not stated  <b>BMI</b> , (mean, IQR) 23.8 (20.8-26.8) kg/m <sup>2</sup>  <b>HbA1c</b> , (mean, SD) 65.0 (16.4) mmol/mol  <b>Drop out</b> , Not stated per group, overall 8.2%.	<b>BMI, kg/m<sup>2</sup></b> I: -0.32 (-0.65 to 0) C: 0.15 (0 to 0.40) More reduced in the intervention group, p=0.003  <b>Waist circumference, cm</b> I: -1 (-2 to 0) C: 0 (0-2) More reduced in the intervention group, p=0.002  <b>Insulin dose</b> No difference between groups (data not shown)  <b>Diabetes-Specific Quality-of-Life Scale (DSQOLS)</b>  <i>Social relations</i> I: 2 (-2.5 to 3.5) C: 0 (-1.5 to 5) p=0.993  <i>Leisure-time flexibility</i>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: -0.5 (-2 to 1)  C: 0 (-2 to 3)  p=0.413</p> <p><i>Physical complaints</i></p> <p>I: 2 (0 to 4.5)  C: 2 (-0.5 to 5)  p=0.483</p> <p><i>Worries about future</i></p> <p>I: 1 (-1 to 4)  C: 0 (-1.5 till 3)  p=0.466</p> <p><i>Diet restrictions</i></p> <p>I: 5.5 (0.5 to 8.5)  C: 0 (-2 to 3.5)  p=0.008 (more increased in intervention group)</p> <p><i>Daily hassles</i></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>I: 1.5 (-2.5 to 6)</p> <p>C: 2 (-1.5 to 3.5)</p> <p>p=0.488</p> <p><i>Fears about hypoglycemia</i></p> <p>I: 0.5 (-2 to 7.5)</p> <p>C: 1 (-5.5 to 5.5)</p> <p>p=0.643</p> <p><b>Adverse events</b></p> <p><i>Hypoglycemic episodes (&lt;2.8 mmol/L)</i></p> <p>Similar frequency in the two groups, no episodes requiring assistance from a third party were observed</p>	
Sterner Isaksson et al 2021	RCT, multicentre in 9 Swedish diabetes specialist centres	n=60 (analysed 53) 58.5% women  Carbohydrate counting and flexible insulin adjustment on a meal-to-meal basis, and	n=60 (analysed 51) 52.9% women,  <b>Control 1 (C1)</b>  Group training without carbohydrate counting	<b>HbA1c (mmol/mol) at 6 months</b>  I: 60.8 (8.5) C1: 62.9 (10.3) C2: 62.9 (6.7)	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
[57] Sweden	Adults 20 to 70 years with type 1 diabetes for at least 3 years.  HbA1c 57 to 78 mmol/mol (7.4%–9.3%), BMI) ≤35 kg/m <sup>2</sup> .  Follow up at 1 year (and at 6 months for HbA1c)	correction doses. Group training led by diabetes specialist nurses. Ten sessions of 3 hours each with home assignments in groups of ≤8 participants. Weekly meetings the first 8 weeks, two follow-up meetings at 6 and 9 months  <b>Age</b> , mean (SD) 49.1 (11.9) years  <b>Bodyweight</b> , mean (SD) 77.8 (13.0) kg  <b>BMI</b> , mean (SD) 26.3 (3.5) kg/m <sup>2</sup>  <b>HbA1c</b> , mean (SD) 63.1 (8.0) mmol/mol  <b>Drop out</b> , Did not receive allocated intervention: 12%. From start of	led by dietitians using a food-based approach to incorporate fish, nuts and seeds, vegetables, legumes, fruit, berries and whole grains with low GI in diet. Ten sessions of 3 hours each with home assignments in groups of ≤8 participants. Weekly meetings the first 8 weeks, two follow-up meetings at 6 and 9 months  <b>Age</b> , mean (SD) 47.7 (11.5) years  <b>Bodyweight</b> , mean (SD) 79.7 (14.5) kg  <b>BMI</b> , mean (SD) 26.2 (3.4) kg/m <sup>2</sup>	Mean difference (SD) at 12 months, and p-value for difference between groups (ITT-analysis)  <b>HbA1c</b> I vs C1 -0.4 (0.3) mmol/mol (p=0.754) I vs C2 -0.8 (1.2) mmol/mol (p=0.522)  <b>Bodyweight</b> I vs C1 -0.05 (0.56) kg (p=0.935) I vs C2 -0.22 (0.60) kg (p=0.713)  <b>Systolic blood pressure</b> I vs C1 -0.12 (1.34) mmHg (p=0.928) I vs C2	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		intervention to analysis (lost during follow up): 23%	<p><b>HbA1c</b>, mean (SD) 64.8 (9.0) mmol/mol</p> <p><b>Drop out</b>, did not receive allocated intervention: 15%. From start of intervention to analysis (lost during follow up): 30%</p> <p>-----</p> <p><b>Control 2 (C2)</b></p> <p>n=61 (analysed 55) 61.8% women,</p> <p>Individually tailored according to routine care, four education sessions with specialist nurse, 1 hour each, after baseline, 3, 6 and 9 months</p> <p><b>Age</b>, mean (SD) 48.9 (12.6) years</p>	<p>-0.14 (1.24) mmHg (p=0.913)</p> <p><b>Diastolic blood pressure</b></p> <p>I vs C1</p> <p>-0.12 (0.88) mmHg (p=0.888)</p> <p>I vs C2</p> <p>-0.14 (0.84) mmHg (p=0.867)</p> <p><b>Total cholesterol</b></p> <p>I vs C1</p> <p>-0.01 (0.06) mmol/L (p=0.846)</p> <p>I vs C2</p> <p>0.05 (0.06) mmol/L (p=0.376)</p> <p><b>HDL cholesterol</b></p> <p>I vs C1</p> <p>0.01 (0.02) mmol/L (p=0.547)</p> <p>I vs C2</p> <p>0.00 (0.02) mmol/L (p=0.962)</p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
			<p><b>Bodyweight</b>, mean (SD) 79.3 (14.7) kg</p> <p><b>BMI</b>, mean (SD) 26.8 (3.8) kg/m<sup>2</sup></p> <p><b>HbA1c</b>, mean (SD) 63.7 (6.7) mmol/mol</p> <p><b>Drop out</b>, did not receive allocated intervention: 10%. From start of intervention to analysis (lost during follow up): 23%</p>	<p><b>LDL cholesterol</b></p> <p>I vs C1 0.04 (0.05) mmol/L (p=0.400)</p> <p>I vs C2 0.07 (0.05) mmol/L (p=0.159)</p> <p><b>Triglycerides</b></p> <p>I vs C1 -0.05 (0.04) mmol/L (p=0.194)</p> <p>I vs C2 -0.08 (0.04) mmol/L (p=0.054)</p> <p><b>Insulin dose</b></p> <p>I vs C1 -0.03 (0.02) IU/kg bodyweight (p=0.161)</p> <p>I vs C2 0.01 (0.02) IU/kg bodyweight (p=0.625)</p> <p><b>Quality of life (ADDQoL)</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<p>No statistically significant differences between groups in '<i>present quality of life</i>' or in the '<i>overall quality of life</i>' score at 3, 6 or 12 months, data not shown</p> <p><b>Hypoglycemia</b></p> <p>Only mild self-reported hypo-glycemic events reported</p>	

Included RCT on gestational diabetes type 1 and type 2 diabetes

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Jamilian and Asemi  2015  [58]  USA	RCT  Women with gestational diabetes mellitus diagnosed by a “one-step” 2-hour 75-g oral glucose tolerance test and aged 18–40 years (at week 24–28 of gestation). A diagnosis of GDM (one-step) was based on the American Diabetes Association criteria.  Length of study at least 6 weeks	n=34  Soy diet: 0.8 g/kg protein (35% animal protein, 35% soy protein and 30% other plant protein)	n=34  0.8 g/kg protein (70% animal and 30%plant proteins)	Soy protein consumption significantly improved the glucose homeostasis parameters, triglycerides, as well as reductions in the incidence of new-born hyperbilirubinemia and hospitalizations  Outcomes:  Body weight  BMI  FPG (mg/dL)  HOMA -IR  Insulin levels (μIU/mL)  HDL  LDL  Triglycerides  Preeclampsia	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				Need to insulin therapy after intervention Caesarean section New-borns' weight Maternal hospitalization Preterm delivery Macrosomia 1-min Apgar score 5-min Apgar score New-born hyperbilirubinemia, n (%) Newborn hospitalization, n (%) Nåsborna hypoglycemia, n (%)	
Landon et al	RCT, multicentre	n=485	n=440 Usual prenatal care	Primary	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
2009 [59] USA	Mild gestational diabetes mellitus (i.e., an abnormal result on an oral glucose-tolerance test but a fasting glucose level below 95 mg per decilitre (5.3 mmol per litre))  Length of study at least 6 weeks	Dietary intervention, self-monitoring of blood glucose, and insulin therapy, if necessary.  American Diabetes Association Nutrition recommendations and interventions for diabetes (2008)		Composite of stillbirth or perinatal death and neonatal complications, including hyperbilirubinemia, hypoglycemia, hyperinsulinemia, and birth trauma  Secondary  <b>Birth weight,</b>  <b>Neonatal fat mass,</b>  <b>Frequency of large/small-for-gestational age infants,</b> <b>Birth weight greater than 4000 g,</b>  <b>Admission to the neonatal intensive care unit,</b>  <b>Respiratory distress syndrome,</b>  <b>Mothers weight gain from the time of enrolment to delivery,</b>	

First author Year Reference Country	Study design Population Setting Duration of follow-up	Intervention (I) Participant characteristics at baseline Drop-outs	Control (C) Participant characteristics at baseline Drop-outs	Results Effects/Side effects	Risk of bias Comments
				<b>Shoulder dystocia,</b> <b>Labour induction</b> <b>Caesarean delivery,</b> <b>Preeclampsia and</b> <b>Gestational hypertension</b>	
Louie et al 2011 [60] Australia	RCT Women aged 18–45 years diagnosed with gestational diabetes mellitus by a 75-g oral glucose tolerance test at 20–32 weeks' gestation. Length of study at least 6 weeks	n=47 Low glycemic index (target glycemic index (GI) ~50) (Dietary GL/total daily available carbohydrate) x 100 Dietary intake was assessed by 3-day food records.	n=45 Conventional high-fibre diet and moderate-GI diet, target GI ~60	<b>Birth weight</b> mean (SD) I: 3.3 (0.1) kg C: 3.3 (0.1 kg); P=0.619), <b>Birth weight centile</b> mean (SD) I: 52.5 (4.3) C: 52.2(4.0); P=0.969) <b>Prevalence of macrosomia</b> I: 2.1% vs. C: 6.7%; P=0.157), <b>Insulin treatment</b> I: 53% v	Low risk of bias

First author Year Reference Country	Study design Population Setting Duration of follow-up	Intervention (I) Participant characteristics at baseline Drop-outs	Control (C) Participant characteristics at baseline Drop-outs	Results Effects/Side effects	Risk of bias Comments
				C: 65%; P=0.251), <b>Adverse pregnancy outcomes</b> No significant differences <i>Outcomes included</i> <b>Fasting blood glucose levels,</b> <b>Insulin</b> <b>HOMA-2 IR</b> <b>HbA1c</b> <i>Pregnancy outcomes</i> <b>Gestational age,</b> <b>Birth weight,</b> <b>Birth weight centile,</b> <b>Large/small for gestational age,</b> <b>Macrosomia</b>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				<b>Ponderal index,</b> <b>Maternal weight gain,</b> <b>Insulin treatment,</b> <b>Final daily insulin dose,</b> <b>Infant length,</b> <b>Infant head circumference,</b> <b>Need for emergency caesarean section.</b>	
Louie et al 2015 [61] Australia	RCT  Women aged 18–45 years diagnosed with gestational diabetes mellitus by a 75-g oral glucose tolerance test at 20–32 weeks' gestation.  Follow up 3 months after birth (postpartum)	n=33  Low glycaemic index  Dietary intake was assessed by 3-day food records.	n=25  Conventional high-fibre diet and moderate-GI	The glycaemic index of the antenatal diets differed modestly (mean (SD): 46.8 (5.4) vs. 52.4 (4.4); $P < 0.001$ ), but there were no significant differences in any of the post-natal outcomes.  <b>Maternal outcomes</b>  Fasting blood glucose levels,	Moderate risk for bias  Follow up on study [60]  All individuals from the original study not included in the analysis.

<b>First author</b> <b>Year</b> <b>Reference</b> <b>Country</b>	<b>Study design</b> <b>Population</b> <b>Setting</b> <b>Duration of follow-up</b>	<b>Intervention (I)</b> <b>Participant characteristics at baseline</b> <b>Drop-outs</b>	<b>Control (C)</b> <b>Participant characteristics at baseline</b> <b>Drop-outs</b>	<b>Results</b> <b>Effects/Side effects</b>	<b>Risk of bias</b> <b>Comments</b>
				Insulin, HOMA2-IR, HbA1c, Total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglyceride, Weight, BMI, Waist circumference. <b>Infant outcomes</b> Weight for age percentile, Length for age percentile, Weight for length percentile, Weight gain per day.	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
Ma et al 2015 [62] China	RCT, parallel design  Per protocol analysis Gestational diabetes mellitus  Length of study 12 to 14 weeks	n=41  Low glycemic load  Both groups received a one-on-one general dietary intervention every two weeks according to the guidelines recommended by the Chinese Medical Association	n=42  General dietary intervention.  Detailed advice and the provision of sample daily menus that mainly targeted limitations on starches and fat and encouraged appropriate macronutrient proportion ranges. The recommended daily energy intake was approximately 146 kJ (35 kcal)/kg per d for individuals with a normal weight and 104 kJ (25 kcal)/kg per d for obese women (BMI≥28 kg/m <sup>2</sup> ) according to their pre-pregnancy weight.	Significantly greater decreases in fasting plasma glucose and 2 h postprandial glucose for the low GI group.  The increases in TC, TG and the decrease in HDL cholesterol were significantly lower (p < 0.05) in the low GI group compared with the higher GI group.  There were no significant differences in body weight gain, birth weight or other maternal–fetal perinatal outcomes between the two groups  Fasting plasma glucose 2 h postprandial glucose HbA1c Total cholesterol	Moderate risk for bias

First author Year Reference Country	Study design Population Setting Duration of follow-up	Intervention (I) Participant characteristics at baseline Drop-outs	Control (C) Participant characteristics at baseline Drop-outs	Results Effects/Side effects	Risk of bias Comments
				HDL cholesterol LDL cholesterol Birth weight, Preterm delivery Macrosomia Intra-uterine asphyxia Eclampsia Postpartum haemorrhage Infection	
Mijatovic et al 2020 [63] Australia	Randomized controlled trial, parallel design. Pregnant women (18 to 45 years) between 24 and 32 weeks of gestation with gestational diabetes confirmed by a 75-g oral-glucose tolerance test. Follow-up: 6 weeks	Low carbohydrate (LC) diet with a target of 135g carbohydrates a day without energy restriction. n=21 <b>Age (mean, SD)</b> 32.5 ± 0.9 years <b>Body weight, (mean, SD)</b> 91.4 ± 18.4 kg	Routine care (RC) diet with a target of 180 to 200 g carbohydrates a day. n=24 <b>Age (mean, SD)</b> 34.2 ± 0.9 years <b>Body weight, (mean, SD)</b> 91.4 ± 18.4 kg	<b>Weight gain, kg. mean ± standard error of mean.</b> LC: 10.9 ± 0.9, RC: 8.2 ± 1.5 Between group-difference: p=0.21 <b>Gestational age, wk. mean ± standard error of mean.</b> LC: 38.7 ± 0.2, RC: 38.6 ± 0.2	Moderate risk of bias

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
		<p><b>Pre pregnancy BMI, (mean, SD)</b> 25.8 ± 1.0 kg/m<sup>2</sup></p> <p><b>HbA1c, (mean, SD)</b> 32.2 ± 1.1 mmol/mol</p> <p><b>Drop-out, 4.</b></p>	<p><b>Pre pregnancy BMI, (mean, SD)</b> 27.8 ± 1.5 kg/m<sup>2</sup></p> <p><b>HbA1c, (mean, SD)</b> 31.2 ± 1.1 mmol/mol</p> <p><b>Drop-out, 8.</b></p>	<p>Between group-difference: p=0.97</p> <p><b>Emergency caesarean, number. N (%)</b> LC: 4 (16.7), RC: 2 (9.5)</p> <p>Between group-difference: p=0.48</p> <p><b>Birth weight, g. mean ± standard error of mean.</b> LC: 3125 ± 101, RC: 3278 ± 79</p> <p>Between group difference: p=0.25</p> <p><b>Small-for-gestational-age, number. N (%).</b> LC: 6 (25.0) RC: 3 (14.3)</p> <p>Between group-difference: p=0.25</p> <p><b>Large-for-gestational-age, number. N (%).</b></p>	

First author	Study design	Intervention (I)	Control (C)	Results	Risk of bias
Year	Population	Participant characteristics at baseline	Participant characteristics at baseline	Effects/Side effects	Comments
Reference	Setting	Drop-outs	Drop-outs		
Country	Duration of follow-up				
				LC: 0 (0) RC: 1 (4.8) Between group-difference: p=0.28  <b>Macrosomia, number. N (%)</b>  LC: 1 (4.2) RC: 1 (4.8) Between group-difference: p=0.55	
Moreno-Castilla et al 2013 [64]	Randomized controlled trial, open, parallel  Gestational diabetes mellitus, aged 18 to 45 years (inclusive), singleton pregnancies and a gestational age $\leq$ 35 weeks  Length of study unclear (about 6 weeks)	low carbohydrate diet (40% of the total diet energy content as CHO) Assessed by 3-day food records  n=75	high carbohydrate diet (55% of the total diet energy content as CHO)  n=75	The rate of women requiring insulin was not significantly different between the treatment groups (low CHO 54.7% vs. control 54.7%; P=1). Daily food records confirmed a difference in the amount of CHO consumed between the groups (P=0.0001). No differences were found in the obstetric and perinatal outcomes between the treatment groups.	Moderate risk of bias

<b>First author</b> <b>Year</b> <b>Reference</b> <b>Country</b>	<b>Study design</b> <b>Population</b> <b>Setting</b> <b>Duration of follow-up</b>	<b>Intervention (I)</b> <b>Participant characteristics at baseline</b> <b>Drop-outs</b>	<b>Control (C)</b> <b>Participant characteristics at baseline</b> <b>Drop-outs</b>	<b>Results</b> <b>Effects/Side effects</b>	<b>Risk of bias</b> <b>Comments</b>
				<b>Gestational age at delivery</b> <b>Insulin <u>treatment</u></b> <b>Final insulin dose/kg body weight</b> <b>Maternal weight gain</b> <b>Ketonuria (mild/absent or moderate-high)</b> <b>Caesarean sections</b> <b>Small/large for gestational age</b> <b>Macrosomia</b> <b>New-born hypoglycemia</b>	

Included prospective cohort studies

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
Altorf-van der Kuil et al  2013 [65]  16 European countries	Clinic-based prospective cohort study  Type 1-diabetes without hypertension  EURODIAB PCS  Average follow-up of 7 years (range: 5 to 9 years)	<b>Number included</b> n=1,045  <b>Gender</b> 49% women  <b>Mean age (SD)</b> 30.9 years (9.0)  <b>BMI mean (SD)</b> 23.3 kg/m <sup>2</sup> (2.6)  <b>Insulin use</b>  100%	Energy percentage of total protein intake (%)/ tertiles  T1 mean (range): 14.1 (9.4–16.0) n=439  T2 mean (range): 17.3 (16.0–18.8) n=440  T3 mean (range): 21.5 (18.8–42.6) n=440	3-day food diary. Data were converted into intake of protein. Reproducibility was tested on a selected sample. 3 weeks after completing the first 3-day record a new standardized 3-day food diary was filled in.  No repeated measurements (validation study)  Model 1: Adjusted for age and sex.  Model 2: Adjusted for age, sex, diabetes duration, HbA1c, BMI, total energy, fat and carbohydrate intakes, alcohol intake (3 categories), smoking (3 categories), physical activity (4 categories).	<b>Hypertension</b>  Model 2 (n=1,296):  Total, animal and plant protein intakes were not related to incident of hypertension (298 cases). OR's (95% CI) across increasing tertiles (T1 to T3).  For total protein: 1 (ref), 0.86 (0.60–1.25) and 0.91 (0.59 to 1.43). P for trend=0.71.  Animal protein: 1 (ref), 0.88 (0.61 to 1.27) and 0.92 (0.59 to 1.44). P for trend=0.72  Plant protein (298 cases): 1 (ref), 1.40 (0.97 to 2.01) and 1.27 (0.83 to 1.93). P for trend=0.26.  Not significant with model A  Protein exchanged for fat or carbohydrates: not significant  Number of cases: n=298  Excluded:	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					Missing data on covariates in Model 2: n=23  Lost to follow-up: 14% of original cohort (n=3,250), 70% of the remaining n=2,685 attended examinations at follow-up	
Bidel et al  2006  [66]  Finland	Prospective cohort study  Type 2 diabetes.  Individuals with diabetes within six population-based cohorts.  Mean follow-up 20.8 years	<b>Number included</b> n=3,837 at baseline  <b>Gender</b> Approx. 50% women  <b>Mean age</b> Approx. 48 years  <b>Mean BMI</b> 29.8 kg/m <sup>2</sup>  <b>Insulin use</b> Not stated	Coffee: number of cups  0–2 cups/day: n=644  3–4 cups/day: n=1,041  5–6 cups/day: n=1,356  ≥7 cups/day: n=796	Questionnaire at Baseline  No repeated measurements  Adjustment for age, sex, study year, BMI, blood pressure, total cholesterol, education, alcohol and tea consumption and smoking status.	<b>Total mortality</b> 0-2: HR 1.00 3-4 cups: HR 0.77 (95% CI 0.65–0.91) 5-6 cups: 0.68 (95% CI 0.58-0.80) ≥7 cups: HR 0.70 (95%CI 0.59–0.85) p-trend <0.001  <b>CVD mortality</b> 0-2: HR 1.00 3-4 cups: HR 0.79 (95% CI 0.64–0.97) 5-6 cups: 0.70 (95% CI 0.57-0.86) ≥7 cups: HR 0.71 (95% CI 0.56–0.90) p-trend 0.006	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><b>CHD mortality</b></p> <p>0-2: HR 1.00</p> <p>3-4 cups: HR 0.78 (95% CI 0.60-1.01)</p> <p>5-6 cups: HR 0.70 (95% CI 0.54-0.90)</p> <p>&gt;=7 cups: HR 0.63 (0.47-0.84)</p> <p>p-trend 0.01</p> <p><b>Stroke mortality</b></p> <p>0-2: HR 1.00</p> <p>3-4 cups: HR 0.77 (0.50-1.19)</p> <p>5-6 cups: HR 0.64 (95% CI 0.41-0.99)</p> <p>&gt;=7 cups: HR 0.90 (0.56-1.45)</p> <p>None lost to follow-up</p> <p>1,471 deaths</p> <p>909 CVD deaths</p> <p>598 CHD deaths</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					210 stroke deaths	
Bonaccio et al 2016 [67] Italy	Prospective population-based cohort  Type 2-diabetes (antidiabetic treatment or blood glucose more than or equal to 126 mg/dl). Individuals with Type 1-diabetes were excluded.  Conducted in the Molise region  Part of the MOLI-SANI study  Median follow-up 4 years	<b>Number included</b> n=1,995  <b>Gender</b> 33.9% women, (66.1%)  <b>Mean age (SD)</b> 62.6 years (10.2)  <b>Mean BMI</b> Normal (BMI less than 25): 10.6% Overweight (BMI 25 to 30): 37.6% Obese (BMI more than 30): 51.8%  <b>Insulin use</b>	Adherence to the Mediterranean diet  Poor (0–3) 30.1% Average (4–5) 44.1%  High (more than or equal to 6) 25.8%	Questionnaire of food intake during the year before enrolment according to European project investigation into cancer and nutrition food frequency questionnaire (188 food items/ 45 predefined food groups). Adherence to the traditional Mediterranean Diet calculated by using the Mediterranean Diet Score.  No repeated measurements  Adjustment for age, sex, education, total energy intake, leisure-time physical activity, smoking, years from diagnosis of diabetes, blood glucose and hypercholesterolaemia	A 2-unit increase in Mediterranean diet score was associated with lower  <b>Overall mortality</b> 37% (95% CI 19% to 51%).  Data remained unchanged when restricted to those being on a hypoglycaemic diet or on antidiabetic drug treatment.  <b>Cardiovascular mortality</b> HR=0.66 (95% CI 0.46 to 0.95).  A Mediterranean diet-like pattern, originated from principal factor analysis, indicated a reduced risk of <b>overall death</b>  Fully controlled model HR: 0.81 (0.62 to 1.07).  The effect of Mediterranean diet score was mainly contributed by moderate alcohol drinking (14.7% in the reduction of the	Moderate risk of bias

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		Drug treatment for diabetes: 50%  Insulin alone not stated.			effect), dairy products (13.4%, high intake of cereals (12.2%), vegetables (5.8%) and reduced consumption of meat products (3.4%).	
Burger et al  2012  [68]  Europa	Prospective multicentre cohort study (EPIC)  Patients with Type 2-diabetes between 35 to 70 years old.  Data collected from ten European countries between 1992 and 2000.	<b>Number included</b> n=6,192  <b>Gender</b> 45.8% women  <b>Mean age (SD)</b> 57.4 years (6.7)  <b>Mean BMI</b> 28.8 kg/m <sup>2</sup> (4.9)  <b>Insulin use</b> 22.3%	Investigated the exposure of fibre intake, carbohydrate quality and quantity on the risk for all-cause and CVD mortality.  Included the following exposures: Higher dietary fibre, carbohydrate, sugar, glycemic index, glycemic load and starch	Baseline data were collected through either self-administered country specific questionnaires or semi quantitative FFQ.  Models were adjusted for: Smoking, smoking duration, BMI, waist-to-hip ratio, physical activity, alcohol intake, menopausal status, hormone replacement therapy, diabetes duration, insulin use, glycated haemoglobin level, total energy, vitamin C, saturated fat, monosaturated fat, polyunsaturated fat, dietary fibre, and carbohydrates.	<b>All-cause mortality</b> HR (95% CI) Fibre: 0.83 (0.75 to 0.91) GL 1.01 (0.89 to 1.14) GI: 0.99 (0.91 to 1.07) CHO: 1.03 (0.89 to 1.19) Sugar: 1.04 (0.91 to 1.19) Starch: 0.93 (0.80 to 1.07) <b>CVD mortality</b> HR (95% CI) Fibre: 0.76 (0.64 to 0.89) GL: 0.95 (0.78 to 1.15)	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					GI: 0.96 (0.85 to 1.10) CHO: 0.97 (0.77 to 1.23) Sugar: 0.96 (0.78 to 1.18) Starch: 0.89 (0.71 to 1.12)	
Campmans-Kuijpers et al 2016 [69] Denmark, Germany, Italy, Netherlands, Spain, Sweden,	Cohort study Type 2-diabetes (confirmed). 15 cohorts of the European Prospective Investigation into Cancer and Nutrition (EPIC) Mean (SD) follow up 9.2 years (2.3)	<b>Number included</b> n=6,152 <b>Gender</b> 45.8% women <b>Mean age (SD)</b> 57.4 years (6.7) <b>Mean BMI (SD)</b> 28.8 kg/m <sup>2</sup> (4.9) <b>Insulin use</b> 22.3%	Substituting 10 g of carbohydrates by 10 g total fat, 10 g saturated fatty acids, 10 g mono-unsaturated fatty acids or 10 g poly-unsaturated fatty acids	Dietary intake assessed at recruitment with country-specific food-frequency questionnaires.  Adjusted for energy intake, protein intake, alcohol intake, age, body mass index, duration of diabetes, insulin use, education level, physical activity index, tobacco status, sex, and country	<b>All-cause mortality</b> Hazard ratios (95% CI) for substituting 10 g of carbohydrates by: Total fat: 1.07 (1.02 to 1.13) Saturated fat: 1.25 (1.11 to 1.40) Monounsaturated fat: 0.89 (0.77 to 1.02) Polyunsaturated fat: 1.13 (0.97 to 1.32) <b>Cardiovascular (CVD) mortality</b> Total fat: 1.06 (0.96 to 1.16) Saturated fat: 1.22 (1.00 to 1.49) Monounsaturated fat: 0.85 (0.67 to 1.08) Polyunsaturated fat: 1.29 (1.02 to 1.63)	Moderate risk of bias for total and CVD mortality  High risk of bias for body weight and waist circumference: outcomes self-reported at follow-up

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					Loss to follow up Total deaths 791 CVD deaths 268	
Diez-Espino et al 2017 [70] Spanien	Prospective cohort study based on data from the randomized control study PREDIMED.  Among the recruited patients 48.9% (n=3,527) had type 2 diabetes.  Participants enrolled from primary care centres between	Data were not available specific for participants with diabetes and the following characteristics are therefore from the full cohort  <b>&lt;2 eggs a week</b> n=2,509  <b>Gender</b> 70.7% women  <b>Mean age (SD)</b> 67.1 kg/m <sup>2</sup> (6.1)  <b>Mean BMI (SD)</b>	Participants were grouped according to their reported egg consumption per week.  <b>&lt;2 eggs a week,</b> n =1,193  <b>2 to 4 eggs a week</b> n=2,225  <b>&gt; 4 eggs a week</b> n=109  The group with the lowest consumption (<2	Baseline dietary intake was ascertained with a 137-item semi-quantitative food-frequency questionnaire (FFQ). The FFQ were then administered yearly during the trial.  Model A: Adjusted for age, sex, BMI, and intervention group (from original study where a Mediterranean diet were compared to a low-fat diet).  smoking status (3 categories), physical activity	<b>Incidence of CVD event (myocardial infarction, stroke, and death from CVD)</b>  Hazard Ratio (95% CI) 2-4 eggs: 0.86 (0.65 to 1.14) >4 eggs: 1.33 (0.75 to 2.46), P for trend=0.89  1.18 (0.90-1.55) per 500 egg of cumulative consumption  Number of events: 225	Moderate risk of bias

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	<p>2003 and 2009 in Spain.</p> <p>Mean follow-up was 5.8 years.</p>	<p>30 kg/m<sup>2</sup> (3.9)</p> <p><b>Insulin use</b> 5.2%</p> <p><b>2 to 4 eggs a week</b></p> <p><b>Number included</b> n=4,493</p> <p><b>Gender</b> 56.7% women</p> <p><b>Mean age (SD)</b> 67 years (6.3)</p> <p><b>Mean BMI (SD)</b> 29.9 kg/m<sup>2</sup> (3.8)</p> <p><b>Insulin use</b> 5.3%</p> <p><b>&gt; 4 eggs a week</b></p> <p><b>Number included</b></p>	<p>eggs/week) were used as reference.</p>	<p>during leisure time and education (3 categories).</p> <p>diabetes, family history of premature coronary heart disease.</p> <p>Mediterranean diet score, alcohol intake and total energy intake.</p>		

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		n=214 <b>Gender</b> 34.6% women <b>Mean age (SD)</b> 65.6 years (5.8) <b>Mean BMI (SD)</b> 0.3 (3.7) kg/m <sup>2</sup> <b>Insulin use</b> 2.8%				
He et al 2010 [71] USA	Prospective cohort study Women with type 2-diabetes diagnosed 1976 to 2006, without history of CVD or cancer at inclusion	<b>Number included</b> n=7,822 <b>Gender</b> 100% women <b>Mean age</b> In quintiles of whole grain intake:	Whole grains, and the subcomponents cereal fibre, bran, and germ  Quintiles (Q1 – Q5) reflecting lower to higher intakes (grams/day)	Semi-quantitative FFQs in 1980, 1984, 1986, 1990, 1994, 1998 and 2002 were used to calculate cumulative averages  Medical history, lifestyle information and disease diagnosis updated every 2 years	<b>Number of events</b> All-cause death: n=852 CVD-deaths: n=295 <b>All-cause mortality</b> In Model 1, RR(95% CI) across fifths of intake were:  Whole-grain: Q1 (Md 4.8 g/day) 1.0 (reference); Q2 (Md 10.5 g/day) 1.24(1.00–	Moderate and Low risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	Nurses' Health Study (NHS) Up to 26 years of follow-up	Q1: 46 years Q2: 47 years Q3: 46 years Q4: 47 years Q5: 49 years  <b>Mean BMI</b> Q1: 30.3 kg/m <sup>2</sup> Q2: 30.2 kg/m <sup>2</sup> Q3: 30.2 kg/m <sup>2</sup> Q4: 29.8 kg/m <sup>2</sup> Q5: 28.5 kg/m <sup>2</sup>  <b>Insulin use</b> Not stated		Model 1 adjusted for age, smoking status, BMI, alcohol intake, physical activity, parental history of MI, menopausal status, use of hormone therapy, and duration of diabetes.	1.54); Q3 (Md 14.4 g/day) 0.84(0.67–1.06); Q4 (Md 20.6 g/day) 0.91(0.73–1.14); Q5 (Md 32.6 g/day)0.89(0.71–1.11), P for trend =0.06  <b>Cereal fibre</b> Q1 (Md 1.9 g/day) 1.0 (reference); Q2 (Md 2.99 g/day) 1.03(0.82–1.29); Q3 (Md 3.8 g/day) 0.99(0.78–1.25); Q4 (4.7 g/day) 0.88(0.70–1.12); Q5 (Md 6.29 g/day) 0.81(0.64–1.03), P for trend=0.02  <b>Bran</b> Q1 (Md 0.8 g/day) 1.0 (reference); Q2 (Md 1.88 g/day) 0.95(0.76–1.18); Q3 (Md 3.22 g/day) 0.85(0.68–1.05); Q4 (Md 5.16 g/day) 0.86(0.68–1.07); Q5 (Md 9.73 g/day) 0.75(0.60–0.95), P for trend=0.01  <b>Germ</b> Q1 (Md 0.2 g/day) 1.0 (reference); Q2 (Md 0.46 g/day) 1.13(0.91–1.40); Q3 (Md 0.61 g/day) 0.92(0.74–1.14); Q4 (Md 0.9 g/day) 0.89(0.71–1.12), P for trend=0.35	

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					<p><b>CVD-specific mortality</b></p> <p>In Model 1, RR(95% CI) across fifths of intake were:</p> <p><b>Whole grain</b></p> <p>Q1 1.0 (reference); Q2 1.10(0.78–1.57); Q3 0.73(0.50–1.07); Q4 0.88(0.61–1.27); Q5 0.81(0.56–1.19) P for trend=0.21</p> <p><b>Cereal fibre</b></p> <p>Q1 1.0 (reference); Q2 1.08(0.74–1.57); Q3 1.04(0.70–1.54); Q4 1.00(0.68–1.49); Q5 0.85(0.56–1.29), P for trend=0.31</p> <p><b>Bran</b></p> <p>Q1 1.0 (reference); Q2 0.98(0.68–1.42); Q3 0.88(0.62–1.27); Q4 0.86(0.58–1.25); Q5 0.78(0.53–1.15), P for trend=0.18</p> <p><b>Germ</b></p> <p>Q1 1.0 (reference); Q2 0.98(0.69–1.39); Q3 0.77(0.54–1.11); Q4 0.66(0.45–0.97); Q5 0.91(0.64–1.31), P for trend=0.50</p>	

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					Follow-ups for death >98% complete	
Hirahatake et al 2019 [72] USA	Prospective cohort study (population-based) Type 2 diabetes Women's Health Initiative WHI Mean follow up 12.4 years	<b>Number included</b> n=5,809 <b>Gender</b> 100% women <b>Mean age (SD)</b> 64.0 years (6.9) <b>Mean BMI (SD)</b> 31.9 kg/m <sup>2</sup> (6.8) <b>Insulin use</b> Insulin users between 74.1% to 76.9%	Mediterranean, Dietary Approach to Stop Hypertension (DASH), Palaeolithic, and American Diabetes Association (ADA) dietary patterns  Examine the association between diet quality and CVD risk  Quintile rankings (1 to 5), higher score indicating a more beneficial rank to diet.	Dietary intake was assessed with a validated food questionnaire (past 3 months). Three sections: 122 composite and single food line items, which included questions on the frequency of consumption and portion sizes.  Questionnaires were collected at baseline -all subjects. Specified follow-up visits on a rotating basis for a subsample of the cohort each year.  <b>Model 1</b> adjusted for age, race/ethnicity, education, income, marital status, physical activity, cigarette smoking, BMI, geographical region, and WHI study arm.	During mean 12.4 years of follow-up, 1,454 (25%) incident cardiovascular disease cases were documented. Women with higher alternate Mediterranean, DASH, and ADA dietary pattern scores had a lower risk of CVD compared with women with lower scores (Q5 v Q1).  Model 2, Q5, hazard ratio (HR) (95% CI) <b>Mediterranean</b> Cardiovascular Disease 0.77 (0.65 to 0.93) Coronary Heart Disease 0.69 (0.53 to 0.91) Stroke Risk 0.67 (0.47 to 0.96) <b>DASH</b> Cardiovascular Disease 0.69 (0.58 to 0.83) Coronary Heart Disease 0.75 (0.57 to 0.98) Stroke Risk 0.56 (0.40 to 0.80) <b>ADA</b>	Moderate risk of bias

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				<b>Model 2</b> additionally adjusted for age at diabetes mellitus diagnosis, energy intake, insulin use, systolic and diastolic blood pressures, and history of high cholesterol requiring medication	Cardiovascular Disease 0.71 (0.59 to 0.86) Coronary Heart Disease 0.57 (0.42 to 0.76) Stroke Risk 0.74 (0.51 to 1.09) <b>Palaeolithic</b> Cardiovascular Disease 0.91 (0.75 to 1.09) Coronary Heart Disease 1.04 (0.78 to 1.39) Stroke Risk 0.84 (0.58 to 1.21)	
Hodge et al 2011 [73] Australia	Prospective cohort study Type 1 or 2-diabetes unclear proportions Recruitment from the Melbourne metropolitan area between 1990 and 1994 via the Electoral Rolls, advertisements,	<b>Number included</b> n=666+1,484 Unknown diabetes (NDM) n=666 Known diabetes (KDM) n=1,484 <b>Gender</b> NDM: 38% women KDM: 49% women	Adherence to Mediterranean diet Reflected by calculated Mediterranean diet score	Data from a validated 121-item food frequency questionnaire. Adjustment of confounding for data that we are interested in is unclear	<b>Hazards ratios per unit increase of Mediterranean Diet Score:</b> <b>Total mortality (CI 95%)</b> Men: 0.96 (0.93 to 0.99) Women: 0.94 (0.92 to 0.97) <b>Cardiovascular mortality</b> Men: 0.94 (0.89 to 0.99) Women: 0.94 (0.87 to 1.01) <b>Dropout rate</b>	Moderate risk of bias

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	and community announcements. 25% were born in Greece or Italy, and 2150 had previously been diagnosed with diabetes or had elevated blood glucose at baseline (1990 to 94). Average follow-up 12.3 years	<b>Mean age (SD)</b> NDM: 59.4 years (7.2) KDM: 60.5 years (6.9) <b>Mean BMI (SD)</b> NDM: 29.5 kg/m <sup>2</sup> (4.0) KDM: 28.9 kg/m <sup>2</sup> (4.0) <b>Insulin use</b> Not stated			Not stated	
Horikawa et al 2014 [74]	Multicentre prospective study Type 2 diabetes, aged 40 to 70 years with	<b>Number included</b> n=1,588 Q1: n=397 Q2: n=397 Q3: n=396	Sodium intake at registration Mean (SD) Q1: 2.8 (0.4) g Q2: 3.8 (0.2) g	Data assessed by the food frequency questionnaire based on food groups (FFQg) at baseline and 5 years after registration. In brief, the FFQg elicited information on the average intake per week	Q1 were used as reference point. <b>CVD</b> (adjustment for confounders) hazard ratios (95% CI) Q2 vs Q1: 1.70 (0.98 to 2.93), p=0.06	Moderate risk of bias

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Japan	<p>haemoglobin A1c (HbA1c) <math>\geq 6.5\%</math></p> <p>Part of the Japan Diabetes Complications Study (JDCS) to study incidence of and risk factors for macro- and microvascular complications among Japanese patients with Type 2-diabetes from outpatient clinics in 59 university and general hospitals.</p> <p>Patient were followed for 8 years</p>	<p>Q4: n=398</p> <p><b>Gender:</b> women</p> <p>Q1: 49.6% women Q2: 51.4% women Q3: 47.2% women Q4: 42.0% women</p> <p><b>Mean age (SD)</b> Q1: 58.1 years (7.4) Q2: 58.6 years (6.9) Q3: 59.0 years (6.8) Q4: 59.1 years (6.4)</p> <p><b>Mean BMI (SD)</b></p>	<p>Q3: 4.5 (0.2) g Q4: 5.9 (0.8) g</p> <p>Sodium intake after 5 years</p> <p>Q1: 3.3 (1.2) g Q2: 3.8 (1.3) g Q3: 4.4 (1.5) g Q4: 4.6 (1.8) g</p>	<p>of 29 food groups and 10 kinds of cookery in commonly used units or portion sizes.</p> <p>Adjusted by to models Model A: age, sex, BMI, HbA1c, diabetes duration, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, log-transformed triglycerides, treatment by insulin, treatment by lipid-lowering agents, current smoking, alcohol intake, energy intake, and physical activity.</p> <p>Model B: Further adjusted for systolic BP and antihypertensive agents.</p>	<p>Q3 vs Q1: 1.47 (0.82 to 2.62), <math>p=0.20</math> Q4 vs Q1: 2.07(1.16 to 3.71), P for trend=0.03</p> <p><b>Overt nephropathy,</b> <b>Diabetic retinopathy,</b> <b>All-cause mortality</b></p> <p>Not significantly associated with sodium intake.</p>	

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		Q1: 22.8 kg/m <sup>2</sup> (2.9) Q2: 23.1 kg/m <sup>2</sup> (3.1) Q3: 23.0 kg/m <sup>2</sup> (2.9) Q4: 23.0 kg/m <sup>2</sup> (2.9) <b>Insulin use</b> Q1: 23.2% Q2: 23.2% Q3: 19.7% Q4: 16.3%				
Hu et al 2003 [75] USA	Prospective cohort study  Women with Type 2-diabetes diagnosed 1976-1994 from the	<b>Number included</b> n=5,103  <b>Gender</b> 100% women	Food ad libitum.  Cohort (5 103 women at baseline) divided in 5 groups reflecting average	Repeated semi-quantitative food frequency questionnaires  1980, 1984, 1986, 1990, 1994.	RR (95% CI) of CHD or death "Fish <1/week" or "ω-3. 0.04 g/day", Fish 1 to 3/months	Moderate risk of bias

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	<p>Nurses' Health Study</p> <p>End points CHD incidence and all-cause mortality</p> <p>1980–1996</p> <p>Sub cohort of; recruited during 1976–1994</p> <p>16 years follow-up</p>	<p><b>Age</b> and <b>BMI</b>, not stated for complete cohort</p> <p>For 1,097 patients recruited in 1980</p> <p><b>Mean age</b> 48 years</p> <p><b>Mean BMI</b> 28.1 kg/m<sup>2</sup></p> <p><b>Insulin use</b> Not stated</p>	<p>frequency of fish or <math>\omega</math>-3 FA intake.</p> <p>Fish &lt;1/month,</p> <p>F 1–3/months</p> <p>1/week</p> <p>2–4/week</p> <p>&gt;5/week</p> <p>N3 FA: Quintile 1 (0.04 g/day), Q2 (0.06 g/d), Q3 (0.09 g/d), Q4 (0.15 g/d), Q5 0.25 g/d)</p>	<p>Intake of long-chain <math>\omega</math>-3 FA computed with a view to fish species differences</p> <p>Computed <math>\omega</math>-3 intake correlated with EPA in adipose tissue</p> <p>Adjustments for age, time intervals, smoking, BMI, alcohol, parental history of myocardial infarction, menopausal status, postmenopausal hormone use, physical activity, aspirin use, multivitamin supplement use, vitamin E supplement use, history of hypertension, hypercholesterolemia, diabetes duration, hypoglycemic medication, trans fat, PUFA:SFA ratio, dietary fibre.</p>	<p>CHD: 0.70 (0.48 to 1.03)</p> <p>Death: 0.75 (0.53 to 1.07)</p> <p>Fish 1/week</p> <p>CHD: 0.60 (0.42 to 0.85)</p> <p>Death: 0.66 (0.48 to 0.92)</p> <p>Fish 2–4/week</p> <p>CHD: 0.64 (0.42 to 0.99)</p> <p>Death: 0.67 (0.45 to 1.01)</p> <p>Fish &gt;5/week</p> <p>CHD: 0.36 (0.20 to 0.66)</p> <p>Death: 0.48 (0.29 to 0.80)</p> <p>Trend in fish intake data: <math>p=0.002</math> (CHD) or <math>0.005</math> (death)</p> <p><b>Dropout rate</b> Not stated.</p>	

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Jiao et al 2019 [76] USA	Prospective, longitudinal cohort study  Type 2-diabetes in the  Nurses' Health Study (1980-2014) (NHS) and Health Professionals Follow-Up Study (1986-2014) (HPFS).	<b>Number included</b> n=11,264 (HNS n=9,053 and HPFS=2,211)  <b>Gender</b> 80% women= (HNS 100% and HPFS 0%)  <b>Age</b> according to quarters of polyunsaturated fat intake (% energy). Four Quarters  NHS (n=2,358, n=2,275, n=2,224, n=2,196): mean (SD) (69.7 (10.6) 72.6 (8.4) 73.1 (7.3) 73.6 (7.2) years	Quarters of <b>polyunsaturated fat</b> intake Median (range)% energy 4.48 (≤5.06) 5.50 (5.07 to 5.97) 6.39 (5.98 to 7.06) 7.95 (≥7.07)  Quarters of <b>Monounsaturated fatty acids</b> intake Median (range)% energy 9.51 (≤10.77) 11.66 (10.78 to 12.61) 13.37 (12.62 to 14.64) 16.01 (≥14.65)  Quarters of <b>Saturated fatty acids</b> intake Median (range) 8.03 (≤9.28) 10.03 (9.29 to 11.09)	Information on non-dietary lifestyle factors, medical history, and incident diseases was collected every two years through validated questionnaires  Adjusted for model 1 och model 2  Model 1: age (in months), sex, and survey period.  Model 2: Further adjusted for ethnicity, BMI at diagnosis, physical activity, smoking status, alcohol consumption, multivitamin use, family, history of myocardial infarction, family history of diabetes, history of hypercholesterolemia, history of hypertension, duration of diabetes, dietary cholesterol, and percentage of energy from dietary	<b>Quarter intake of fat</b>  <b>Polyunsaturated fat intake</b>  <b>CVD mortality</b> <u>Model 1:</u> HR (96% CI): 1.00 0.98 (0.79 to 1.20) 0.84 (0.67 to 1.04) 0.74 (0.59 to 0.93), P for trend=0.004  <u>Model 2:</u> HR (96% CI):1.00 0.99 (0.80 to 1.23) 0.85 (0.67 to 1.08) 0.76 (0.58 to 0.99), P for trend=0.03  <b>Total mortality</b> <u>Model 1:</u> HR (96% CI): 1.00 0.81 (0.73 to 0.90) 0.78 (0.70 to 0.86) 0.61 (0.55 to 0.69), P for trend <0.001  <u>Model 2:</u> HR (96% CI): 1.00 0.86 (0.77 to 0.95) 0.83 (0.74 to 0.94) 0.68 (0.60 to 0.78), P for trend <0.001  <b>Cancer mortality</b> <u>Model 1:</u> HR (95% CI) 1.00 0.76 (0.59, 0.99) 0.91 (0.71, 1.17) 0.75 (0.58, 0.98), P for trend=0.09	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
		<p>HPFS (n=476, n=539, n=582, n=614): 75.0 (9.9) 74.1 (9.3) 72.1 (8.0) 71.8 (6.4) years</p> <p><b>BMI</b> age adjusted, according to quarters of polyunsaturated fat intake (% energy)</p> <p>HNS: 29.4 (6.8) 29.3 (7.1) 30.3 (6.4) 28.9 (5.5) kg/m<sup>2</sup></p> <p>HPFS: mean (SD)</p> <p>26.9 (3.9) 29.3 (4.7) 27.9 (4.5) 27.9 (4.1) kg/m<sup>2</sup></p> <p><b>Hypoglycemic drug use:</b></p>	<p>11.69 (11.10 to 13.18) 14.34 (≥13.19)</p> <p>Quarters of <b>Trans fatty acids</b> intake Median (range)% energy</p> <p>0.94 (≤1.16) 1.37 (1.17 to 1.53) 1.71 (1.54 to 1.95) 2.24 (≥1.96)</p> <p>Quarters of <b>Marine n-3 PUFAs</b> intake Median (range)% energy</p> <p>0.03 (≤0.05) 0.07 (0.06 to 0.09) 0.13 (0.10 to 0.17) 0.25 (≥0.17)</p>	<p>protein and remaining fatty acids where appropriate.</p>	<p><u>Model 2</u>: HR (95% CI)<sup>†</sup> 1.00 0.81 (0.62, 1.06) 0.95 (0.72, 1.25) 0.74 (0.55, 1.01), P for trend=0.11</p> <p><b>Monounsaturated fatty acids</b></p> <p><b>CVD mortality</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 1.08 (0.87 to 1.35) 1.05 (0.84 to 1.32) 1.31 (1.05 to 1.64), P for trend=0.02</p> <p><u>Model 2</u>: HR (96% CI): 1.00 0.96 (0.74 to 1.24) 0.85 (0.63 to 1.15) 0.99 (0.70 to 1.39), P for trend=0.97</p> <p><b>Total mortality</b></p> <p><u>Model 1</u>/Quarter, HR (96% CI): 1.00 1.01 (0.90 to 1.12) 0.97 (0.87 to 1.09) 1.08 (0.97 to 1.21), P for trend=0.23</p> <p><u>Model 2</u> /Quarter, HR (96% CI): 1.00 0.93 (0.82 to 1.05) 0.83 (0.72 to 0.96) 0.90 (0.76 to 1.06), P for trend=0.21</p> <p><b>Cancer mortality</b></p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
		<p>HNS:</p> <p>1,205 (51.1%)</p> <p>1,413 (62.1%)</p> <p>1,466 (65.9%)</p> <p>1,377 (62.7%)</p> <p>HPFS:</p> <p>153 (32.2%)</p> <p>156 (29.0%)</p> <p>177 (30.4%)</p> <p>279 (45.4%)</p>			<p><u>Model 1</u>: HR (95% CI)* 1.00 0.81 (0.62, 1.06) 0.93 (0.71, 1.21) 1.06 (0.82, 1.37), P for trend=0.48</p> <p><u>Model 2</u>: HR (95% CI)† 1.00 0.88 (0.64, 1.19) 0.98 (0.70, 1.39) 1.09 (0.74, 1.60), P for trend=0.49</p> <p><b>Saturated fatty acids</b></p> <p><b>CVD mortality</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 1.30 (1.03 to 1.64) 1.26 (1.00 to 1.59) 1.71 (1.37 to 2.14), P for trend &lt;0.00</p> <p><u>Model 2</u>: HR (96% CI): 1.00 1.14 (0.88 to 1.48) 0.98 (0.73 to 1.33) 1.13 (0.80 to 1.59), P for trend=0.62</p> <p><b>Total mortality</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 1.14 (1.02 to 1.28) 1.21 (1.08 to 1.36) 1.39 (1.24 to 1.56) P for trend &lt;0.001</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><u>Model 2</u> /Quarter, HR (96% CI): 1.00 1.05 (0.92 to 1.19) 1.03 (0.89 to 1.19) 1.00 (0.85 to 1.19), P for trend=0.88</p> <p><b>Cancer mortality</b></p> <p><u>Model 1</u>: HR (95% CI) 1.00 1.01 (0.78, 1.31) 1.00 (0.76, 1.30) 1.16 (0.89, 1.50), P for trend=0.29</p> <p><u>Model 2</u>: HR (95% CI)<sup>†</sup> 1.00 1.04 (0.77, 1.40) 0.96 (0.67, 1.35) 0.99 (0.67, 1.47), P for trend=0.90</p> <p><b>Trans fatty acids</b></p> <p><b>CVD mortality</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 1.10 (0.87 to 1.39) 1.25 (0.99 to 1.57) 1.49 (1.19 to 1.86), P for trend &lt;0.001</p> <p><u>Model 2</u>: HR (96% CI): 1.00 0.97 (0.76 to 1.25) 1.03 (0.80 to 1.34) 1.13 (0.86 to 1.50), P for trend=0.28</p> <p><b>Total mortality</b></p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><u>Model 1</u>: HR (96% CI): 1.00 1.06 (0.94 to 1.19) 1.21 (1.08 to 1.36) 1.42 (1.27 to 1.58), P for trend &lt;0.001</p> <p><u>Model 2</u>: HR (96% CI): 1.00 0.93 (0.82 to 1.06) 1.01 (0.88 to 1.15) 1.08 (0.94 to 1.25), P for trend=0.11</p> <p><b>Cancer mortality</b></p> <p><u>Model 1</u>: HR (95% CI)* 1.00 0.74 (0.57, 0.97) 0.80 (0.62, 1.04) 0.93 (0.72, 1.19), P for trend=0.68</p> <p><u>Model 2</u>: HR (95% CI)† 1.00 0.69 (0.52, 0.91) 0.72 (0.54, 0.97) 0.74 (0.54, 1.01), P for trend=0.11</p> <p><b>Marine n-3 PUFAs:</b></p> <p><b>CVD mortality:</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 0.83 (0.67 to 1.02) 0.78 (0.63 to 0.97) 0.54 (0.42 to 0.68), P for trend &lt;0.001</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><u>Model 2</u>: HR (96% CI): 1.00 0.92 (0.74 to 1.14) 0.91 (0.72 to 1.14) 0.69 (0.52 to 0.90), P for trend=0.007</p> <p><b>Total mortality</b></p> <p><u>Model 1</u>: HR (96% CI): 1.00 0.89 (0.80 to 0.98) 0.77 (0.69 to 0.85) 0.52 (0.46 to 0.59), P for trend &lt;0.001</p> <p><u>Model 2</u>: HR (96% CI): 1.00 0.99 (0.89 to 1.10) 0.91 (0.81 to 1.03) 0.71 (0.62 to 0.82), P for trend &lt;0.001</p> <p><b>Cancer mortality</b></p> <p><u>Model 1</u>: HR (95% CI) 1.00 0.95 (0.74, 1.23) 0.94 (0.73, 1.22) 0.63 (0.48, 0.84), P for trend &lt;0.001</p> <p><u>Model 2</u>: HR (95% CI) 1.00 1.02 (0.78, 1.33) 1.02 (0.78, 1.35) 0.72 (0.53, 0.99), P for trend=0.03</p>	
Komorita et al 2020	Prospective multicenter study	<b>Number included</b> n=4,923 <b>Gender</b>	Green tea None: n=607	The dietary survey, including green tea and coffee consumption, was conducted using a self-	<b>All-cause mortality</b> HR (95% CI) <i>Green tea</i> (multivariate adjusted including coffee consumption)	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
[77] Japan	Type 2 diabetes aged 20 years or older  The Fukuoka Diabetes Registry (UMIN Clinical Trial Registry 000002627)  Annual follow-up during their survival.  Median follow up time was 5.3 years.	43% women  Green tea  None: 39.7%, ≤1cup/d: 35.7% 2-3cups/d: 39.5% ≥4cups/d: 52.4%  Coffee  None: 49.4% ≤1cup/d: 45.3% 2-1cup/d: 46.7% ≥2cups/d: 36.1%  <b>Mean age (SD)</b>  Green tea  None: 64.6 (10.2) ≤1cup/d: 62.5 (10.8) 2-3cups/d: 65.7 (9.8)	≤1cup/d: n=1,143  2-3cups/d: n=1,389 ≥4cups/d: n=1,784  Coffee  None: n=994  ≤1cup/d: n=1,306 1cup/d: n=963 ≥2cups/d: n=1,660	administered brief diet history questionnaire (Gender Medical Research Inc., Tokyo) regarding the frequency of 58 food items and supplements. This was only assessed once.  Participants received an annual follow-up during their survival through interviews, medical records, letters, telephone calls, and municipal registration of residence.  Adjustments for age, sex, BMI, diabetes duration, current smoking habit, current alcohol intake, leisure-time physical activity (LTPA), sleep duration, HbA1c, UACR, systolic blood	None: 1.0 (ref.) ≤1cup/d: 0.88 (0.61–1.26) 2-3cups/d: 0.73 (0.51–1.03) ≥4cups/d: 0.60 (0.42–0.85) P for trend=0.001  <b>Coffee</b> (multivariate adjusted including tea consumption)  None: 1.0 (ref.) ≤1cup/d: 0.88 (0.66–1.18) 1cup/d: 0.81 (0.58–1.13) ≥2cups/d: 0.58 (0.42–0.81) P for trend=0.002  <b>Green tea and coffee</b> (multivariate adjusted)  None & None: 1.0 (ref.) None & <1cup/day: 0.95 (0.45–2.04) None & 1cup/day: 1.17 (0.53–2.59)	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
		<p>≥4cups/d: 67.3 (9.7)</p> <p>Coffee</p> <p>None: 69.0 (10.0)</p> <p>≤1cup/d: 66.4 (10.2)</p> <p>1cup/d: 65.6 (10.1)</p> <p>≥2cups/d: 62.3 (9.5)</p> <p><b>Mean BMI (SD)</b></p> <p>Green tea</p> <p>None: 23.9 kg/m<sup>2</sup> (3.4)</p> <p>≤1cup/d: 24.1 kg/m<sup>2</sup> (3.8)</p> <p>2-3cups/d: 23.5 kg/m<sup>2</sup> (3.7)</p>		<p>pressure, LDL cholesterol, history of CVD, and cancer. Further adjustment for the coffee-drinking habit to analyse the association between green tea and mortality, and vice versa.</p>	<p>None &amp; ≥2cups/day: 0.76 (0.35–1.66)</p> <p>≤1cup/day &amp; None: 0.93 (0.45–1.92)</p> <p>≤1cup/day &amp; &lt;1cup/day: 0.95 (0.48–1.86)</p> <p>≤1cup/day &amp; 1cup/day: 0.85 (0.41–1.77)</p> <p>≤1cup/day &amp; ≥2cups/day: 0.62 (0.31–1.23)</p> <p>2-3cups/d &amp; None: 0.98 (0.52–1.86)</p> <p>2-3cups/d &amp; &lt;1cup/day: 0.59 (0.30–1.16)</p> <p>2-3cups/d &amp; 1cup/day: 0.81 (0.40–1.64)</p> <p>2-3cups/d &amp; ≥2cups/day: 0.49 (0.24–0.99)</p> <p>≥4cups/d &amp; None: 0.72 (0.38–1.35)</p> <p>≥4cups/d &amp; &lt;1cup/day: 0.74 (0.40–1.38)</p> <p>≥4cups/d &amp; 1cup/day: 0.42 (0.20–0.88)</p> <p>≥4cups/d &amp; ≥2cups/day: 0.37 (0.18–0.77)</p> <p><b>CVD mortality</b></p> <p><b>Green tea</b> (multivariate adjusted including coffee consumption)</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
		<p>≥4cups/d: 23.7 kg/m<sup>2</sup> (3.9)</p> <p>Coffee</p> <p>None: 23.7 kg/m<sup>2</sup> (3.7)</p> <p>≤1cup/d: 23.9 kg/m<sup>2</sup> (3.8)</p> <p>2-1cup/d: 23.9 kg/m<sup>2</sup> (4.0)</p> <p>≥2cups/d: 23.6 kg/m<sup>2</sup> (3.6)</p> <p><b>Insulin use</b></p> <p>Green tea</p> <p>None: 32.8</p> <p>≤1cup/d: 27.7</p> <p>2-3cups/d: 27.0</p> <p>≥4cups/d: 29.6</p> <p>Coffee</p>			<p>None: 1.0 (ref.)</p> <p>≤1cup/d: 1.06 (0.53–2.12)</p> <p>2-3cups/d: 0.54 (0.25–1.14)</p> <p>≥4cups/d: 0.65 (0.33–1.29)</p> <p>P for trend=0.08</p> <p><b>Coffee</b> (multivariate adjusted including tea consumption)</p> <p>None: 1.0 (ref.)</p> <p>≤1cup/d: 0.92 (0.51–1.64)</p> <p>1cup/d: 0.82 (0.42–1.61)</p> <p>≥2cups/d: 0.52 (0.26–1.02)</p> <p>P for trend=0.055</p> <p><b>Dropout rate</b></p> <p>0.5%</p>	

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		None: 30.4 ≤1cup/d: 24.9 1cup/d: 28.7 ≥2cups/d: 31.1				
Li et al 2009 [78] USA	Prospective cohort study Women with Type 2 diabetic from Nurses' Health diagnosed 1980-2002 Study without CVD or cancer at entry End points Total CVD and MI alone Follow up 54,656 person-years	<b>Number included</b> n=6,309 <b>Gender</b> 100% women <b>Mean age</b> 57 years <b>Mean BMI</b> 29.8 kg/m <sup>2</sup> <b>Insulin use</b> Not stated	Food ad libitum. Cohort of 6 309 patients divided in 4 groups reflecting cumulative mean frequency of servings of nuts or peanut butter (1 serving=16 g of nuts or 28 g of peanut butter): Almost never: 613	Repeated semi-quantitative food frequency questionnaires 1980, 1984, 1986, 1990, 1994, 1998 adjusted for age, BMI, physical activity, alcohol consumption, family history of MI, hormone use and menopausal status, smoking, aspirin intake, duration of diabetes, hypertension,	634 cases of CVD HR (95% CI) of total CVD or MI alone compared with: "Almost never" and 1-3 servings/month to 1 serving/week CVD: 0.72 (0.50 to -1.02) MI: 0.63 (0.41 to -0.96) 2-4 servings/week CVD: 0.80 (0.56 to -1.14) MI: 0.74 (0.49 to -1.13) ≥5 servings/week	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
			1–3 servings per month to 1 serving a week: 2,275 2–4 servings a week: 2,725 ≥5 servings/week: 696	hypercholesterolemia, total energy intake, cereal fibre, glycemic load, saturated fat, and trans fat	CVD: 0.56 (0.36 to –0.89) MI: 0.56 (0.33 to –0.97) p-trend CVD: 0.44 MI: 0.85	
Lindberg et al 2013 [79] Norway	Cohort study Type 2-diabetes (newly diagnosed). Previously unidentified individuals. Nord-Trøndelag	<b>Number included</b> n=323 <b>Gender</b> 48% women: <b>Mean age (SD)</b> 68.2 years (9.8) <b>Mean BMI (SD)</b>	To investigate the association between plasma phospholipid fatty acid relative concentrations expressed as weight percentage and total mortality	Phospholipid fatty acid measured from plasma blood samples. Multivariate model was adjusted for major risk factors of death in the general population (age, sex, BMI, total cholesterol, HbA1c, mean blood pressure, education,	After 10 years of follow-up, EPA in the diabetic population was negatively associated with total mortality, with an HR at the fifth quintile of 0.47 (95% CI 0.25 to 0.90) compared with the first quintile. In contrast, DHA was positively associated with total mortality, with an HR at the fifth quintile of 2.87 (95% CI 1.45 to 5.66). After 10 years of follow-up	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	Health (HUNT)/ NUNT1-surway  Follow up 10 years	29.3 kg/m <sup>2</sup> (4.85)  <b>Insulin use</b> Not stated	Divided into quintiles (Q1 to Q5). Q5 contains most of the omega-3 eicosapentaenoic acid (EPA), omega-3 fats docosahexaenoic acid (DHA) or phospholipid n-3 (PLN3)	exercise, current smoking and estimated glomerular filtration rate)	Mortality, hazard ratio (HR) (95% CI) fifth quintile (Q5)  <b>EPA</b> HR: 0.47 (0.25 to 0.90)  <b>DHA</b> HR: 2.87 (1.45 to 5.66)  <b>PLN3</b> HR: 1.34 (0.84 to 2.13)	
Liu et al 2019 [80] USA	Prospective cohort study  Type 2-diabetes  Nurses' Health Study (NHS) 1980-2014 (female nurses)  Health Professionals	<b>Number included</b> n=16,217  <b>Gender</b> 74% women  <b>Age (range)</b> NHS between 30 to 55 years	Total and specific types of nuts, including tree nuts and peanuts  Serving size: 28 g (1 ounce)	Validated semi-quantitative food frequency questionnaire containing 131 food items administered every 2-4 years.  Serval factors adjusted: Time-varying covariates were considered in the multivariate models. Age	Higher total nut consumption, especially tree nuts, was associated with a lower risk of CVD incidence and mortality.  The multivariate-adjusted hazard ratios (HR) (95% confidence intervals) for participants who consumed ≥5 servings of total nuts per week, compared with those who consumed less than 1 serving per month, were  <b>Total CVD incidence:</b>	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	<p>Follow-Up Study: 1986-2014) (male health (HPFS) professionals)</p> <p>Up to 34 (women) and 28 years (men) follow-up (223,682 and 254,923 person-years)</p>	<p>HPFS: 40 to 75 years</p> <p><b>BMI</b> Not given for the cohort(s).</p> <p><b>Insulin use</b> Not given for the cohort(s).</p>	<p>&lt; 1 serving/month (105,778 person-years)</p> <p>&lt;1 serving/week (35,828 person-years)</p> <p>1 serving/week (29,121 person-years)</p> <p>2-4 servings/week (34,593 person-years)</p> <p>≥5 servings/week (18,362 person-years)</p>	<p>(continuous), diabetes duration, sex, Caucasian, BMI at diagnosis (five categories), physical activity (five categories), smoking (four categories), alcohol consumption (four categories), family history of MI or cancer, current aspirin use, presence of hypertension, use of lipid-lowering medication, diabetes medication use (three categories) and intake of total energy, red or processed meat, fruits, and vegetables.</p>	<p>HR: 0.83 (0.71-0.98), P trend=0.01</p> <p><b>CHD incidence</b> HR: 0.80 (0.67-0.96), P for trend =0.005</p> <p><b>Stroke incidence</b> 0.93 (0.68-1.29), P for trend 0.74</p> <p><b>CVD mortality</b> 0.66 (0.52-0.84), P for trend&lt;0.001</p> <p><b>All-cause mortality</b> 0.69 (0.61-0.77; P trend&lt;0.001)</p> <p><b>Higher tree nut consumption</b> was associated with lower risk of total CVD, CHD incidence, and mortality due to CVD, cancer, and all causes, while <b>peanut consumption</b> was associated with lower all-cause mortality only (all P trend&lt;0.001).</p> <p>There were 3,336 incident CVD cases and 5,682 deaths.</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					Follow-up rate was over 90% in each 2-year cycle for both cohorts.	
Nöthlings et al 2008 [81] France, Germany, Greece, Italy, The Netherlands, Spain, United Kingdom, Sweden, Denmark, and Norway	Prospective cohort study Mixed type 1 diabetes and type 2 diabetes sub cohort European Prospective Investigation into Cancer and Nutrition (EPIC) Follow-up mean 9 years (range <1 to >14 years)	<b>Number included</b> n=10,449 <b>Gender</b> 54% women <b>Mean age</b> 58 years <b>Mean BMI</b> 28.8 kg/m <sup>2</sup> <b>Insulin use</b> Range in quartiles 16% to 32%	Food intake ad libitum. Cohort divided in quartiles of self-reported consumption of vegetables, legumes, and fruit Total n=10,449 at baseline. Deaths 1,346 all causes 517 circulatory disease 319 cancer 323 other specific causes	Dietary intake during 12 months before baseline by questionnaire, in part combined with food records 24-hour dietary recall for 8% of cohort, used for calibrating questionnaire data No other repeated measurement All models are stratified on age and study centre, and adjusted for sex, smoking status, self-reported heart attack at baseline, self-reported hypertension at baseline, self-reported cancer at baseline, WHR (continuous), insulin treatment, age at diabetes diagnosis (continuous),	<b>All-cause mortality</b> 1) Inversely related to intake of total vegetables, legumes and fruit. An intake increment by 80 g/day yielded RR=0.95 in men (95% CI 0.89 to 1.00), 0.93 in women (95% CI 0.85 to 1.03), 0.94 in all patients (0.90 to 0.98), and 0.95 (95% CI 0.90 to 1.00) in 8 408 patients diagnosed as diabetics at 40 years or older (type 2 diabetes sub cohort) 2) Inversely related to vegetables( p<0.03) or legumes (p<0.02) alone 3) Not significantly related to fruit alone <b>CVD mortality, non-CVD/ non-cancer mortality,</b> but not cancer mortality,	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
			187 unknown cause  Total number at baseline used for RR of all-causes deaths.	energy intake (continuous), alcohol intake (continuous).	significantly inversely related to intake of total vegetables, legumes and fruit  Adherence to baseline dietary pattern not ascertained  <b>Number of dropouts</b>  Not stated.	
Schoenaker et al 2012 [82] Europa	Clinic/based prospective cohort study (EURODIAB PCS).  Patients with type 1-diabetes.  Data were collected from 16 European countries between 1989 and 1991.	<b>Number included</b> n=3,250 (1,151 loss to follow-up)  <b>Gender</b> 48.7% women  <b>Age (mean, IQR)</b> 31 years (25 to 38)  <b>Mean BMI</b> 23.5 kg/m <sup>2</sup> (2.8)	Investigates the risk associated with different saturated fatty acid intakes (SFA) and dietary fibre intakes.  Results were presented stratified in tertiles, lowest tertiles were used as reference.	Dietary intake at baseline were determined from a standardised 3-day dietary records.  Model was adjusted for the following confounders: Age, sex, total energy, diabetes duration, HbA1C, smoking, physical activity, alcohol, systolic blood pressure, total/HDL-cholesterol ratio and BMI.	<b>Fatal and non-fatal CVD HR (95% CI)</b>  Saturated fatty acid (SFA)  Tertiles 2: 0.95 (0.62 to 1.46)  Tertiles 3: 0.84 (0.53 to 1.32)  P for trend=0.43  Per 10g/day: 0.85 (0.69 to 1.05)  Total fibre  Tertiles 2: 1.09 (0.78 to 1.70)	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	Median follow-up: 7.4 years	<b>Insulin use</b> 100%			Tertiles 3: 0.69 (0.43 to 1.11), P for trend=0.05 Per 2g/day: 0.93 (0.87 to 0.98) Per 5g/day: 0.84 (0.72 to 0.98) <b>All-cause mortality</b> HR (95% CI) Total fibre Per 2g/day: 0.87 (0.78 to 0.97) Per 5g/day: 0.72 (0.55 to 0.95)	
Sluik et al 2014 [83] Europe	Multicentre prospective cohort study  People with confirmed type 1 or type 2 diabetes  Sub-cohort within EPIC (European Prospective Investigation into Cancer and Nutrition)	<b>Number included</b> n=6,384  <b>Gender</b> 46% women,  <b>Age (mean, SD)</b> 57.4 (6,7)  <b>Mean BMI</b> 28.9 kg/m <sup>2</sup> (4,9)	Exposure to 26 food groups or items, e.g. fruits, legumes, nuts, dairy, grains, meat, fish and shellfish, eggs, fats, sugar and confectionery, and non-alcoholic beverages	dietary intake during the preceding 12 months was assessed at baseline with country-specific quantitative dietary questionnaires (up to 300-500 items), semi-quantitative FFQs and combined dietary methods of food records and questionnaires. Intake of 26 meaningful food groups was adjusted for energy.	<b>Number of events</b> All-cause mortality, n=830 (13%) HR (95% CI) of all-cause mortality per unit increase of intake:  <b>Vegetables (per 100 g)</b> 0.74 (0.64, 0.86)  <b>Fruit (per 100 g)</b> 0.85 (0.79, 0.92)	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	recruited from 1992 to 2000  Median follow-up 9.9 years	<b>Insulin use</b>  Not stated		Age- and centre-stratified analysis adjusted for sex, prevalence of heart disease, cancer or stroke, educational attainment, diabetes medication use, alcohol consumption, smoking behaviour, and physical activity	<b>Legumes (per 10 g)</b> 0.88 (0.81, 0.96) <b>Nuts and seeds (per g)</b> 0.94 (0.90, 0.97) <b>Pasta (per 10 g)</b> 0.93 (0.90, 0.96) <b>Poultry (per 10 g)</b> 0.89 (0.83, 0.96) <b>Fish and shellfish (per 10 g)</b> 0.99 (0.96, 1.02) <b>Eggs (per 10 g)</b> 1.04 (0.96, 1.12) <b>Vegetable oil (per g)</b> 0.97 (0.96, 0.98) <b>Butter and margarine (per g)</b> 1.05 (1.02, 1.09)	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<b>Tee (per 100 g)</b> 0.99 (0.97, 1.02) <b>Coffee (per 100 g)</b> 0.99 (0.97, 1.01) <b>Drop-outs</b> Not stated	
Tanasescu et al 2004 [84] USA	Prospective cohort study Women with type 2-diabetes Sub-cohort of Nurses' Health Study (NHS), recruited during 1980–1996, excluding those with a history of MI, angina, coronary	<b>Number included</b> n=5,674 <b>Gender</b> 100% women, <b>Mean age</b> Not clear, approx. 48 years <b>Mean BMI</b> Not clear, approx. 28 kg/m <sup>2</sup>	Intake of total and specific types of fat, analysed divided into quintiles of each fat (expressed as percentage of energy) and also as continuous variables	Repeated food questionnaires (including 116 food items) in 1980, 1984, 1986, 1990, and 1994, rendered cumulative averages used in the analyses  Confounders (updated every 2 years) adjusted for: age, alcohol, smoking, family history of MI, vitamin supplements, total caloric	<b>Number of events</b> Total CVD: n=619 <i>Including</i> Non-fatal MI: n=268 Fatal MI: n=183 Strokes: n=168 Relative risks (95% CI) of CVD for quintile 5 compared to quintile 1 in the multivariate model adjusted for fat subclasses and fiber intake:	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
	revascularization, stroke, or cancer at baseline  16 years of follow-up	<b>Insulin use</b> Not clear, approx. 34,5%		intake, dietary fibres, protein intake, physical activity, diabetes medication, BMI, menopausal status	<b>Total fat</b> (47% of energy vs 29,3%) 1.09 (0.81 to 1.47), P for trend=0.56 <b>Animal fat</b> (38% of energy vs 18.1%) 1.00 (0.70 to 1.43), P for trend=0.63 <b>Vegetable fat</b> (16.7% of energy vs 4.5%) 0.75 (0.53 to 1.06), P for trend=0.12 <b>Saturated fat</b> (19,1% of energy vs 10.8%) 1.29 (0.85 to 1.98), P for trend=0.16 <b>Monounsaturated fat</b> (19.9% of energy vs 11.1%) 1.10 (0.82 to 1.46), P for trend=0.23 <b>Polyunsaturated fat</b>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p>(6.5% of energy vs 2.8%) 1.46) 0.96 (0.70 to 1.31), P for trend=0.92</p> <p><b>Trans unsaturated fat</b> (3% of energy vs 1.3%) 1.03 (0.73 to 1.44), P for trend=0.74</p> <p><b>Cholesterol</b> (298.2 mg/1000 kcal vs 139.6) 1.39 (1.04 to 1.88), P for trend=0.01</p> <p>Only cholesterol intake was significantly associated with CVD risk in the analysis of quintiles</p> <p>Multivariate analyses of fat intakes as continuous variables showed also saturated fat to be significantly associated with CVD risk:</p> <p>For each increase of 5% of energy from saturated fat, the RR for CVD was 1.29 (1.02 to 1.63), p=0,04</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p>For each increase of 200 mg/1000 kcal of cholesterol, the RR for CVD was 1.37 (1.12 to 1.68), p0,003</p> <p>Non-significant associations for the other types of fat</p> <p><b>Drop-outs</b> Not stated</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
Trichopoulou et al 2006 [85] USA	Prospective cohort (from EPIC). From the Greek EPIC cohort of 28,572 volunteers. Follow-up 2–114 months (mean 4.5 years)	<b>Number included</b> n =1,013 <b>Gender</b> 58% women <b>Age</b> Less than 55,% =15 55 to 65,% =32 65 to 74,% =47 More than 75 ,% =6 <b>Mean BMI</b> More than 30 kg/m <sup>2</sup> , =48% 25 to 30 kg/m <sup>2</sup> =40% Less than 25,% =13	Consumption of 16 different food groups, nutrients, or beverages where analysed. n=1,013 <b>Food groups:</b> Vegetables Legumes and potatoes Fruits and nuts Dairy products Cereals Meat and products Fish and Sea food Olive oil	Dietary intake was assessed through an interviewer administered FFQ (150 items). Nutrient intakes were calculated through a good composition database adjusted to the Greek diet. Model II adjustment for gender, educational level, smoking, waist-height, METscore, insulin-, hypertension-, lipid lowering treatment, baseline dietary risk factors other food groups but not energy intake	<b>All-cause mortality</b> 80 deaths. Of all food items only egg consumption was correlated to all-cause mortality Egg (increment 10 gram). HR: 1.31 (95% CI 1.07 to 1.60) p=0.01 (model II) Vegetables (increment 210 gram) HR: 1.10 (95% CI 0.80 to 1.52) p=0.56 (model II) Fish and seafood (increment 18 gram) HR: 1.06 (95% CI 0.82 to 1.37) p=0.64 (model II) Soft drinks and juices (increment 85 gram) HR: 0.83 (95% CI 0.58 to 1.20) p=0.32 (model II) Soft drinks and juices (increment 150 gram)	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
		<p><b>Insulin use</b> 20%</p>	<p>Eggs Sugar and confectionery Soft drinks and juices Tea and coffee Ethanol intake Olive oil</p>	<p>Model III also adjusted for other lipids</p>	<p>HR: 0.75 (95% CI 0.52 to 1.09) p=0.13 (model II)</p> <p>Monounsaturated lipids (increment 16 gram). HR: 1.28 (95% CI 0.76 to 2.16) (model III), p=0.35</p> <p>Saturated lipids (increment 10 gram). HR: 1.82 (95% CI 1.14 to 2.9) (model III), p=0.01</p> <p>Polyunsaturated lipids (increment 9 gram). HR: 1.44 (95% CI 1.06 to 1.96) (model III), p=0.02</p> <p>Physical activity – MET score (per quintile) Ratio:0.76 (95% CI 0.63 to 0.92), p=0.004</p> <p><b>CVD mortality</b></p> <p>46 CVD deaths</p> <p>Saturated fat (increment 10 gram). HR: 1.93 (95% CI 1.08 to 3.42), p=0.01</p>	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
Wallin et al 2018	Prospective cohort study	<b>Number included</b> n=2,225	Total fish consumption (servings, median),	Retrospective dietary habits were queried with a food	<b>Number of events</b> Myocardial infarction (MI), n=333	Moderate risk of bias

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
[86] Sweden	Women and men (aged 45-84 years) with type 2 diabetes  Two population-based cohorts: the Swedish Mammography Cohort (SMC) and the Cohort of Swedish Men (COSM)  Followed from 1998, up to 15 years of follow-up (mean 11.8 years for morbidity, and mean 13.2 years for mortality)	<b>Gender</b> 41% women  <b>Age (mean, range)</b> 64.5 (45-84)  <b>Mean BMI</b> 27.8 kg/m <sup>2</sup>  <b>Insulin use</b> Not stated	divided into four groups:  ≤3/months (n=232)  1 to <2/week (n=911)  2 to 3/week (n=716)  >3/week (n=366)	frequency questionnaire (FFQ) including 96-items  No repeated measurements  Adjusted for age, sex, time since diabetes diagnosis, BMI, physical activity, education, smoking, total energy intake, alcohol, history of high cholesterol, history of hypertension, and DASH diet component score	Stroke, n=321  Total mortality, n=771  CHD mortality, n=154  HR (95% CI) compared with total fish consumption ≤3 servings/months:  <b>1 to &lt;2/week</b> MI: 0.66 (0.47 to 0.92) Stroke: 1.02 (0.68 to 1.51)  Total mortality: 0.82 (0.64 to 1.04)  CHD mortality: 0.53 (0.32 to 0.90)  <b>2 to 3/week</b> MI: 0.67 (0.47 to 0.96) Stroke: 0.89 (0.58 to 1.35)  Total mortality: 0.79 (0.61 to 1.01)  CHD mortality: 0.75 (0.45-1.27)CHD mortality: 0.75 (0.45 to 1.27)	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><b>&gt;3/week</b></p> <p>MI: 0.60 (0.39 to 0.92)</p> <p>Stroke: 1.04 (0.66 to 1,64)</p> <p>Total mortality: 0.90 (0,69 to 1.18)</p> <p>CHD mortality: 0.77 (0,43 to 1.40)</p> <p>Fish consumption was inversely and significantly associated with MI incidence (restricted to the age group <math>\geq 65</math> years), and at 1 to &lt;2 servings also with CHD-related mortality. No significant association were found with stroke and total mortality.</p> <p>No significant p-values for trend for any outcome.</p> <p><b>Drop-outs,%</b> not stated</p> <p><b>Effects/side effects</b></p> <p>Not stated</p>	
Zhang et al. 2009	Prospective cohort study	<b>Number included</b>	Caffeinated coffee, cups	Validated semi-quantitative FFQ	RR's (95% CI) by caffeinated coffee consumption group compared to intake <1 cup/month (Model II):	Moderate risk of bias



First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
			Q3 204-316 mg/d: n=104, 4,801 person-years  Q4 317-450 mg/d: n=75, 4,845 person-years  Q5 >450 mg/d: n=82, 4,818 person-years		1/month to 4/week: RR 0.69 (0.47–1.02) 5-7/week: RR 0.89 (0.63–1.26) 2-3/day: RR 0.71 (0.47–1.06) ≥4/day: RR 0.80 (0.41–1.54), P for trend 0.45 No significant associations for exposure by quintiles of caffeine intake. <b>Number of events</b> Total cardiovascular events, n=435 CHD events (defined as non-fatal MI or fatal CHD), n=324 Stroke events, 111 All-cause deaths, n=538 <b>Drop-outs (%)</b> Not stated	

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
Zhang et al. 2009 [88] USA	Prospective cohort study Type 2-diabetes (women only), free of CVD at baseline Women's Health Study Mean follow-up 8.7 years	<b>Number included</b> n=7,170 <b>Gender</b> 100% women (registered nurses) <b>Age (mean)</b> 48,5 <b>Mean BMI</b> 29.7 kg/m <sup>2</sup> <b>Insulin use</b> Not stated	Coffee intake divided into five groups: <1 cup/month, n=1,451 1 cup/month to 4/week, n=1,076 5–7 cups/week, n=2,302 2–3 cups/day, n=1,717 ≥4 cups/day, n=624	Validated FFQ used to repeatedly (every two years) self-report average coffee consumption the past year between 1980 to 2002  Adjusting for age, smoking status, BMI, alcohol intake, family history of myocardial infarction, hypertension, hypercholesterolemia, menopausal status, use of hormone therapy, physical activity, multivitamin use, vitamin E supplement use, total energy intake, duration of diabetes and diabetes therapy	<b>Number of events</b> Total cardiovascular events, n=658 Total CHD (non-fatal and fatal), n=434 Non-fatal MI, n=217 Fatal CHD, n=217 Stroke, n=224 All-cause mortality, n=734 RRs (95% CI) by caffeinated coffee consumption group compared to intake <1 cup/month: <b>Total cardiovascular events</b> 1/month to 4/week: 1.04 (0.80–1.36) 5 to 7/week: 1.14 (0.91–1.44) 2 to 3/day: 0.92 (0.70–1.20) ≥4/day: 0.76 (0.50–1.14), P for trend =0.09	Moderate risk of bias  Differences in socioeconomic status assumed to be modest  The relevance is compromised due to coffee consumption pattern that is different from that in Sweden

First author Year Reference Country	Study design Population Study design Duration of follow-up	Participant characteristics at baseline	Exposure Number per group at baseline	Dietary assessment method Repeated measurements Confounders adjusted for	Results Effects/side effects Number of events Drop-outs	Risk of bias Comments
					<p><b>Total CHD</b></p> <p>1/month to 4/week: 0.94 (0.67–1.30)</p> <p>5–7/week: 1.14 (0.86–1.50)</p> <p>2–3/day: 0.80 (0.57–1.12)</p> <p>≥4/day: 0.70 (0.43–1.14), P for trend 0.06</p> <p><b>Non-fatal MI</b></p> <p>1/month to 4/week: 0.60 (0.36–1.00)</p> <p>5–7/week: 1.16 (0.79–1.70)</p> <p>2–3/day: 0.69 (0.43–1.13)</p> <p>≥4/day: 0.74 (0.38–1.45), P for trend 0.06</p> <p><b>Fatal CHD</b></p> <p>1/month to 4/week: 1.41 (0.90–2.22)</p> <p>5–7/week: 1.12 (0.74–1.69)</p> <p>2–3/day: 0.91 (0.56–1.46)</p> <p>≥4/day: 0.67 (0.33–1.36), P for trend 0.07</p>	

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					<p><b>Stroke</b></p> <p>1/month to 4/week: 1.24 (0.80–1.93)</p> <p>5–7/week: 1.13 (0.76–1.70)</p> <p>2–3/day: 1.16 (0.73–1.85)</p> <p>≥4/day: 0.86 (0.40–1.84), P for trend 0.74</p> <p><b>All-cause mortality</b></p> <p>1/month to 4/week: 1.10 (0.86–1.40)</p> <p>5–7/week: 1.04 (0.84–1.30)</p> <p>2–3/day: 0.87 (0.67–1.12)</p> <p>≥4/day: 0.80 (0.55–1.14), P for trend 0.05</p> <p><b>Drop-outs</b> not stated</p>	

## Included health economic studies

Table 1. Economic evaluation comparing the Counterweight-Plus weight management programme with usual care for patients with type 2 diabetes.

<b>Author</b>	Xin et al.
<b>Year</b>	2020
<b>Reference</b>	[89]
<b>Country</b>	UK
<b>Study design</b>	1. RCT-based within-trial CEA. Time frame: two years 2. Model-based CEA in which RCT outcomes were extrapolated over lifetime
<b>Population</b>	Individuals with type 2 diabetes (n=298). Intervention group mean (SD) age 52.9 (7.6) years, 44% women. Control group mean (SD) age 55.9 (7.3) years, 38% women.
<b>Setting</b>	Primary care
<b>Perspective</b>	UK National Health Service
<b>Intervention</b>	The Counterweight-Plus weight management programme (Low-energy formula diet for 12-20 weeks followed by structured food reintroduction for 2-8 weeks and a subsequent longer-term programme of weight loss maintenance) (n=149)
<b>vs control</b>	vs Usual care, given under current clinical guidelines (n=149)
<b>Incremental cost</b>	<u>2-year analysis</u> : incremental cost 616 GBP (95% CI -45, 1269) <u>Lifetime analysis</u> : incremental cost -1337 GBP (95% CI -2081, -674)  Costs reported in GBP year 2018
<b>Incremental effect</b>	<u>2-year analysis</u> : proportion of remission 35.6% in intervention group versus 3.4% in control group. Difference 32.3% (95% CI 23.5, 40.3) <u>Lifetime analysis</u> : 0.13 life-years gained (95% CI 0.09, 0.20); 0.06 QALYs gained (95% CI 0.04, 0.09)
<b>ICER</b>	Cost saving, intervention dominates

<b>Study quality with respect to economic aspects and transferability*</b>	High quality with respect to economic aspects High transferability to Swedish context
<b>Further information</b>	
<b>Comments</b>	Missing data were minimal, as all resource use data were obtained directly from participating GP practices.

\* Assessed using SBU's checklist for model-based health economic studies ([https://www.sbu.se/globalassets/ebm/metodbok/checklist\\_modelbased-economic-study.pdf](https://www.sbu.se/globalassets/ebm/metodbok/checklist_modelbased-economic-study.pdf))

**ICER** = Incremental cost-effectiveness ratio; **QALY** = Quality-adjusted life-years; **RCT** = randomized controlled trial.

Table 2. Economic evaluation comparing intensive lifestyle intervention with standard diabetes support and education for patients with overweight/obesity and type 2 diabetes.

<b>Author</b>	Zhang et al.
<b>Year</b>	2020
<b>Reference</b>	[90]
<b>Country</b>	USA
<b>Study design</b>	RCT-based within-trial CEA. Time frame: nine years
<b>Population</b>	Adults with overweight/obesity and type 2 diabetes (n=4,827). Age 45-76 years. 58,4% women in the intervention group and 58,5% women in the control group.
<b>Setting</b>	Clinical centres using multidisciplinary treatment teams
<b>Perspective</b>	Health care system
<b>Intervention</b>	Intensive lifestyle intervention (ILI) comprising one individual and three group sessions per month in combination with replacement of two meals and one snack a day with liquid shakes and meal bars for the first 6 months. During the second 6 months, the participants received one individual and two group meetings per month and continued to replace one meal per day. In years 2-4, treatment was provided mainly on an individual basis including at least one on-site visit per month and a second contact by telephone, mail, or e-mail. In subsequent years, the participants were offered monthly individual visits, and a refresher group session and one campaign a year. Total median follow-up time was 9.6 years (n=2,411)
<b>vs control</b>	vs Standard diabetes support and education (DSE). The participants were offered three group sessions each year focusing on diet, physical activity, and social support (n=2,436)
<b>Incremental cost</b>	9-year incremental cost of ILI vs DSE was 6 666 USD (95% CI USD 4 082, USD 9 203) Costs reported in USD year 2012
<b>Incremental effect</b>	9-year incremental QALYs of ILI vs DSE measured were 0.07 (95% CI 0.02, 0.12) when measured with SF-6D and 0.15 (95% CI 0.10, 0.21) when measured with FT

<b>ICER</b>	Cost per QALY gained based on SF-6D: 96 458 USD (95% CI 41 597 USD, 295 448 USD) Cost per QALY gained based on FT: 43 169 USD (95% CI 23 053 USD, 76 588 USD)
<b>Study quality and transferability*</b> <b>Further information</b> <b>Comments</b>	Moderate quality Moderate transferability to Sweden

\* Assessed using SBU's checklist for trial-based health economic studies ([https://www.sbu.se/globalassets/ebm/metodbok/checklist\\_modelbased-economic-study.pdf](https://www.sbu.se/globalassets/ebm/metodbok/checklist_modelbased-economic-study.pdf))

**DSE** = diabetes support and education; **FT** = Feeling Thermometer; **ILI** = Intensive lifestyle intervention; **RCT** = randomized controlled trial; **USD** = United States dollar; **QALY** = Quality adjusted life years; **ICER** = Incremental cost-effectiveness ratio; **SF-6D** = Short-Form 6D;

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