Table I Dietary interventions in obesity (RCTs); Dietary exposure (Observational studies).

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Brehm et al 2003 [14] USA American Heart Association University of Cincinnati NIH	RCT 1 academic medical centre 6 mo Repeated 3-day food records	Healthy women 53/11 **LF+ER** (3 mo, 6 mo) (27/7) At baseline: Age: 43.10±8.56 yrs BMI: 34.04±1.83 kg/m^2 Weight: 92.31±6.0 kg **LCHO** (3 mo, 6 mo) (26/4) At baseline: 44.22±6.84 yrs BMI: 33.17±1.83 kg/m^2 Weight: 91.20±8.4 kg Mean ± SD	**LF+ER** Low fat calorie-restricted diet: ≈30% of the calories as fat, ≈55% from carbohydrates, and ≈15% from protein **LCHO** Low carbohydrate diet: ≤20 gram/d for 2 wks, then 40–60 gram/d		**LF+ER**	**LCHO**	Moderate risk of bias Small groups
				Weight, kg (change) 3 mo: 6 mo: Means ± standard error. * P-values indicates values different from the low fat group (ie significant interaction of time and diet), p<0,001	 –4.2±0.8 –3.9±1.0	 –7.6±0.7* –8.5±1.0*	

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Brehm et al 2009 [32] USA ADA Cincinnati Medical Clinical Research Center NCT00622960	RCT Single centre 52 wks + 18 mo follow-up after completion of the 1 yr intervention Adherence was measured with no difference between dietician and participant ratings: 6.45±0.21 vs 6.67±0.20 for the high-MUFA group and 6.31±0.16 vs 6.41±0.16 for the high-CHO group	Type 2 diabetics, obese, and overweight (124/29) **High-MUFA** N=43 (completers) 39.5% men (4 m, 8 m, 12 m) **High-CHO** N=52 (completers) 32.7% men (4 m, 8 m, 12 m) Age: 56.5±0.8 yrs BMI: 35.9±0.3 kg/m^2 Mean ± SEM	**High-MUFA** CHO: 45 E% Protein: 15 E% Fat: 40 E% (20% MUFA) **High-CHO** CHO: 60 E% Protein: 15 E% Fat: 25 E% Both diets included similar amounts of saturated fats. –200–300 kcal/d based on daily energy requirements (Harris-Benedict formula). Average energy intake was approximately 1 550 kcal/d Dieticians adjusted caloric prescription. Meal plans: starches, fruits, vegetables, low-fat dairy products, meat/meat substitutes, fat. Maintain habitual level of physical activity or 30 min walking/d		**High-MUFA**	**High-CHO**	Moderate risk of bias Results based on completers, only. According to the authors the ITT analyses yielded similar results No significant differences between the groups in any of the measured variables at 1 yr or 18 mo after completion of 1 yr study Retention rate: 77%. Retention rate High-MUFA: 69%. Retention rate: High-CHO: 84%. (χ^2=3.65, p=0.06)
				Mean±SEM Weight, kg* BL: 4 mo: 8 mo: 12 mo:	103.7±2.8 99.2±2.8 99.3±2.9 99.7±3.0	102.1±2.0 98.2±2.0 98.3±2.1 98.3±2.0	
				Body fat, kg* BL: 4 mo: 8 mo: 12 mo:	38.8±1.3 35.6±1.6 36.3±1.4 36.9±1.4	38.9±1.0 36.5±1.1 36.3±1.1 37.1±1.1	
				*p<0.01 for change over time			
				High-MUFA: Adherence: dietitian vs participants: 6.45±0.21 vs 6.67±0.20 (ns)			
				High-CHO: Adherence: dietitian vs participants: 6.31±0.16 vs 6.41±0.16 (ns)			
				High-MUFA: Those participants with higher adherence were 50 more likely to complete the study than those with lower adherence (OR: 1.5, p=0.012). The analysis was adjusted for diet group sex, race and age			

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Brinkworth et al 2004 [28] CIRO Health Science and Nutrition, Adelaide, Australia National Health and Medical Research Grant, Dairy Research and Development Corporation Grant	RCT Single-centre, CSIRO clinic 68 wks Weighed daily diet checklists of all foods, assessed by the same dietician at 2-wk intervals. Three consecutive days (one weekend and 2 weekdays) of the checklist from each 2-week period were analysed Adherence was measured with urea/creatinine ratio	Obese, hyperinsulinemic participants (outpatients) (58/15) 16 wks, 68 wks **High protein (HP)** (29/7) Age: 52.0±2.6 yrs BMI: 34.6±0.9 kg/m^2 **Standard protein (SP)** (29/8) Age: 51.5±1.6 yrs BMI: 33.6±0.8 kg/m^2 Data on completers **Drop-out HP (n=8)** Age: 46.3±3.8 yrs BMI: 33.0±1.2 kg/m^2 **Drop-out SP (n=7)** Age: 45.3±5.3 yrs BMI: 34.4±1.8 kg/m^2 No information when participants dropped out	12 wks energy restriction period **HP** Protein: 30 E% (≈110 g/d) Fat: 30 E% (≈50 g/d) CHO: 40 E% (≈140 g/d) **SP** Protein: 15 E% (≈60 g/d) Fat: 30 E% (≈50 g/d) CHO: 55 E% (200 g/d) Thereafter 4 wks energy balance period with an increase in caloric intake by approximately 30%. Then keeping the diet for 12 mo Meetings with dietician every 2 wks till 16 wks. No dietary counseling from 4 to 12 mo follow-up All subjects were provided with key food that made up to 60% of their energy intake during the initial 16 wks. See: Farnsworth et al [44]	Mean±SEM	**HP**	**SP**	Low risk for bias Completers analyses. ITT analyses with LOCF for body weight No significant differences between those who completed the study and those who dropped out regarding baseline characteristics 74% (n=43) completed the 68-wk study protocol. Attrition: SP: 24.1% (n=7) HP: 27.6% (n=8)
				Weight, kg			
				0 wks:	94.0±3.4	94.0±3.2	
				Weight loss, %			
				68 wks:	–4.1±5.8	–2.9±3.6	
				Body fat, kg			
				0 wks:	41.8±8.1	40.6±1.9	
				68 wks:	34.0±2.0	38.0±2.1	
				% change:	–9.4±2.4	–7.0±1.5	
				Diet compliance was equally poor in both studies measured with urinary urea/creatinine ratio			

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Buckland et al 2011 [36] Spain Numerous Sources: Among them; European commission (DG-SANCO), International agency for research on cancer (IARC), Spanish Ministry of Health and funding from several Spanish Regional governmental research funds	Multi-centre RCT (EPIC study) The present study includes only the EPIC-Spain cohort Academic and various Public Health Institutes Recruitment 1992–1996 and follow-up December 2006 to June 2009; approximately 14 yrs follow-up The relative Mediterranean diet score	41 438 healthy volunteers 37.7% males Age: 29–69 yrs 816 participants were excluded due to implausible dietary data or death (n=56). In our analysis only the following two groups were evaluated; men >102 cm and women >88 cm, n=17 222 (230 164 person yrs) and persons with BMI >30 kg/m^2 (153 231 person yrs)	Exposure to Mediterranean diets was estimated by interviews in person and the usual food intake over the previous yr was estimated using a computerized validated question-naire. The relative Mediterranean diet score (rMED) used in all EPIC studies was used to measure exposure. A score from 0 to 18 units measured adherence to Mediterranean diet from the lowest to the highest level. The analysis was based on a categorical variable	Hazard ratio (95% CI) for the three rMED scores **Total mortality (BMI >30 kg/m^2)** Low (reference): 1 Medium: 0.94 (0.78; 1.14) High: 0.79 (0.63; 1.0) p<0.048 **Total mortality (WC >102 cm men, >88 cm women)** Low (reference): 1 Medium: 0.99 (0.84; 1.17) High: 0.81 (0.66; 0.99) p<0.032 **The levels of adherence** Low: 0–6 Medium: 7–10 High: 11–18 units	High risk of bias

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Dansinger et al 2005 [1] USA NIH US Dep of Agriculture Agency for Healthcare Research and Quality Different sources of funding: public, non-profit	RCT Single centre, academic medical centre 1 yr Self-reported dietary adherence with 3-d food records and 10-points scale (none=1 to perfect=10) 3-d food record	Overweight or obese subjects (160/67) 2 mo, 6 mo, 12 mo **Atkins diet** N=40, 53% women 47±12 yrs 35±3.5 kg/m^2 **Zone diet** N=40, 50% women 51±9 yrs 34±4.5 kg/m^2 **WW diet** N=40, 58% women 49±10 yrs 35±3.8 kg/m^2 **Ornish diet** N=40, 43% women 49±12 yrs 35±3.9 kg/m^2	**Atkins diet** Less than 20 g CHO/d and gradual increase to 50 CHO/d **Zone diet** CHO: 40 E% Fat: 30 E% Protein: 30 E% **WW diet** Daily "points". Each point was roughly 50 kcal. Aim: 24–32 points/d. Lists with point values of common foods were provided **Ornish diet** Vegetarian diet with 10 E% fat	**Weight, kg** BL: 100±14 99±18 97±14 103±15 6 mo: –3.2±4.9 –3.4±5.7 –3.5±5.6 –3.6±6.7 12 mo: –2.1±4.8 –3.2±6.0 –3.0±4.9 –3.3±7.3 **WC, cm** BL: 109±11 108±13 108±11 111±13 6 mo: –3.2±4.9 –2.9±5.2 –3.5±5.9 –2.5±5.3 12 mo: –2.5±4.5 –2.9±5.3 –3–3±5.4 –2.2±5.5 **Atkins diet** **Zone diet** **WW diet** **Ornish diet**	Moderate risk of bias

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Table I continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Elhayany et al 2010 [2] Israel IDNCT00520182	RCT Primary care clinics 1 yr Repeated 24-h recall and FFQ	Individuals with type 2 diabetes (259/80) **LCHO-MD** (3 mo, 6 mo, 12 mo) (85/14, 16, 24) 51% male 55.5±6.5 yrs BMI: 31.4±2.8 kg/m^2 Weight: 86.7±14.3 kg WC: 112.7±9.6 cm **MD** (3 mo, 6 mo, 12 mo) (89/13, 21, 26) At baseline: 55% male 57.4±6.1 yrs BMI: 31.1±2.8 kg/m^2 Weight: 85.5±10.6 kg WC: 111.1±9.1 cm **ADAD (LF)** (3 mo, 6 mo, 12 mo) (85/15,26,30) At baseline: 49% male 56.0±6.1 yrs BMI: 31.8±3.3 kg/m^2 Weight: 87.9±13.7 kg WC: 113.4±10.0 cm	**LCHO-MD** 35% LGI carbohydrates, 45% fat high in monounsaturated fat, 15–20% protein **MD** 50–55% LGI carbohydrates, 30% fat high in monounsaturated fat, 15–20% protein **ADAD (LF)** 50–55% carbohydrates, 30% fat, 20% protein	At 12 mo: **LCHO-MD** / **MD** / **ADAD (LF)** Weight, kg: 77.8±13.1‡ / 78.1±9.9 / 80.2±13.2 BMI: 28.1±2.8‡ / 28.5±2.9 / 29.0±3.3 WC: 102.2±10.2‡ / 101.6±8.0 / 104.0±10.2 ‡ P-values for change over time. Result did not change when 80 people with missing data at 12 months follow-up were included, using the latest available data from 3-, 6- or 9-months follow-up data.	Moderate risk of bias

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Estruch et al 2013 [34] 1. Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain) (ref: G03/140) 2. Communal Patrimony Olivarero Foundation (Fundación Patrimonio Comunal Olivarero) (Spain) 3. Hojiblanca SA (Spain) 4. Borges SA (Spain) 5. Morella Nuts SA (Spain) 6. California Walnut Commission (USA) IRCTN35739639	RCT Mainly at academic centres The trial ws stopped after a median follow-up of 4.8 yrs The adherence to a Mediterranean diet was followed by a 14 item Mediterranean diet screener and with biomarker for intake of olive oil and nuts. The diet groups were well separated throughout the study. On the basis of an interim analysis the trial was stopped after a median follow-up of 4.8 yrs	7 447 subjects at high cardiovascular risk were enrolled Hypertension (82.1–83.7%); Type 2 diabetes (46.6–50.4%); Dyslipidaemia (71.6–73.3%) Drop outs: After initial assessment 2.8% did not attend further assessment but were followed by medical records. By the end of the study the drop-out rate in the control and Mediterranean diet groups were 11.3% and 4.9%, respectively BMI >30 kg/m^2 (44.3–49.0%) n=2 282 (nuts+olive oil groups), N=1 201 (control group)	Mediterranean diet supplemented with extra-virgin olive oil, 1 liter/wk Mediterranean diet supplemented with nuts. Recieved 30 g mixed nuts/d (walnut, almonds and hazelnuts) Control diet	Primary end-point Hazard ratio (95% CI) The whole study (n=7 447) Control diet: 1.0 (ref) Med diet (olive oil): 0.70 (0.53; 0.91) p=0.009 Med diet (nuts): 0.70 (0.53; 0.94) p=0.02 Crude event rate in the three groups were: 96 (oil), 83 (nuts) and 109 (control) Crude rate per 1 000 person yrs: 8.1 (6.6–9.9) (oil), 8.0 (6.4–9.9) (nuts) and 11.2 (9.2–13.5) (control) Primary end-point Hazard ratio (95% CI) Obese persons (n=3 483) BMI >30 kg/m^2 HR 0.51 (0.37, 0.71) The two Mediterranean diets groups together vs the control group	Moderate risk of bias Low number of events Interruption when significance for primary end-point was reached has a risk to overestimate the difference between the diets In the first half of the study (2003–2006) the intensity of follow-up and instructions was more intense in the two intervention groups compared to controls. This bias was adjusted in the later part of the study (2006–2010)

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence			Comments
Fabricatore et al 2011 [24] USA NIDDK Public NCT00729196	RCT Centre for weight and eating disorders in Philadelphia, US 1 academic medical centre 40 wks Repeated 3-day food records	Obese persons with diabetes type 2 79/29 **LF** (BL/20 wks/40 wks) (39/8/13) 20% male at baseline 52.5±1.3 yrs BMI: 35.8±0.7 kg/m^2 Weight: 99.1±2.3 kg WC: 111.6±1.6 cm **LGL** (BL/20 wks/40 wks) (40/11/16) 20% male at baseline 52.8±1.4 yrs BMI: 36.7±0.8 kg/m^2 Weight: 102.3±2.7 kg WC: 114.2±1.7 cm Mean ± SEM	**LF** Low-fat diet based on low fat pyramid aiming at ≤30 E% from fat **LGL** Low Glycemic Load diet based on "low GL pyramid" aiming at consuming ≤3 and 1 serving/d of moderate GL and high GL items, respectively		**LF**	**LGL**	Low risk of bias Several grants from the industry
				Weight, kg			
				20 wks:	−5.7±3.7	−6.7±4.4	
				40 wks:	−4.5±7.5	−6.4±8.2	
				WC, cm			
				20 wks:	−6.2±0.7	− 6.6±0.7	
				40 wks:	−6.4±1.4	−7.1±1.4	
				Means ± standard error			
Foster et al 2003 [3] USA NIH	Multicentre RCT 3 academic medical centres 1 yr Measurement of adherence not stated	Obese persons without diabetes type 2 **LCHO** (33/5/9/13) (BL/3 mo/6 mo/12 mo) 36% male 44.0±9.4 yrs 33.9±3.8 kg/m^2 98.7±19.5 **LF** (30/9/38/14) (BL/3 mo/6 mo/12 mo) 27% male 44.2±7.0 yrs 34.4±3.1 kg/m^2 98.3±16.4	**LCHO diet** Based on "Dr Atkins New Diet Revolution" (20 g CHO/d for the first two wks, thereafter gradually increased until a stable and desired weight was achieved) **LF diet** (25 E% from fats) and approximately 60 E% from CHO with limited energy intake (1 200–1 800 kcal/d) LEARN diet	% change: Weight, kg 6 mo: 12 mo: ¥ Significant differences from baseline	**LCHO** −7.0±6.5¥ −4.4±6.7¥	**LF** −3.2±5.6¥ −2.5±6.3¥	High risk of bias High dropout rate at 12 mo

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Foster et al 2010 [4] USA NIH NCT00143936	RCT 3 academic medical centres 2 yrs Measurement of adherence not stated	Obese men and women **LCHO** (153/4/7/41) (BL/6 mo/12 mo/24 mo) 33% male 46.2±9.2 yrs 36.1±3.59 kg/m^2 **LF** (154/10/16/36) (BL/6 mo/12 mo/24 mo) 32% male 44.9±10.2 yrs 36.1±3.46 kg/m^2	**LCHO diet** Limited CHO intake in the form of low GI vegetables (20 g CHO/d). After 3 mo amount of CHO was increased **LF diet** (≤30 E% from fats) with limitation of energy intake (1 200–1 800 kcal/d)		**LF**	**LCHO**	Moderate risk of bias
				Weight, kg			
				6 mo:	–11.3 (–12; –10)	–12.2 (–13; –11)	
				12 mo:	–10.8 (–12; –9.3)	–10.9 (–12; –9.7)	
				24 mo:	–7.4 (–9.1; –5.6)	–6.3 (–8.0; –4.6)	

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Table I continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Goldstein et al 2011 [15] Israel Hebrew University-Hadassah Jerusalem, Israel	RCT University 12 mo Body-weight	52 type 2 diabetes patients, aged 35–75, BMI 30–39.9 kg/m^2, HbA_{1c} >7%, treated by diet or oral medication Of 52 randomised (13/26 were men in Atkins group, and 12/26 in ADA-diet group) data were available at 12 mo on 21 in Atkins group and 20 in ADA-diet group	All patients were initially placed on a 4-wk personalized diet containing 80% of their caloric requirements based on the DASH-diet. A modified Atkins diet (ATK) unrestricted calorie intake containing up to 25 g of carbohydrates daily for 6 wks. Thereafter increasing to a ceiling of 40 g daily A standard American Diabetes Association calorie-restricted diet. 10–20 E% intake from protein. 80 E% divided between fats (18–20% of calories as MUFA, 8–10% as PUFA and 9–10% as SFA), carbohydrates and 35 g of fiber. Men were allowed up to 1 500 kcal/d and women 1 200 kcal/d	Weight (kg) ± SD **LCHO (ATK)** **LF (ADA)** BL* 91.7±10.2 92.2±13.7 6 mo: –5.9±4.9 –4.7±4.7 12 mo: –3.4±4.0 –5.4±5.7 No difference in weight loss between groups at any time point Blood pressure, lab variables only given including DASH induced changes * After initial DASH diet	Moderate risk of bias HbA_{1c} data and glucose entered wrongly in Table 4

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**		**Comments**
Iqbal et al 2010 [16] USA Grant support: VA Merit Review Entry Program NCT00108459 Funding source: non-profit	RCT Single-centre. The Philadelphia Veterans Affairs Medical Center 24 mo 24-h recalls	**Low-CHO** (70/42) (6 mo, 12 mo, 24 mo) Male gender: 94.6% White: 51.4% African-American: 44.6% Other: 4.1% Age: 60.0±8.9 yrs BMI: 36.9±5.3 kg/m^2 **Low-fat** (74/34) (6 mo, 12 mo, 24 mo) Male gender: 84.3% White: 34.4% African-American: 62.9% Other: 2.8% Age: 60.0±9.5 yrs BMI: 38.1±5.5 kg/m^2	**Low-CHO** Target: 30g/CHO/d. Whole grain and high-fibre foods. No caloric or fat intake restriction. Select MUFA and PUFA and limit trans- and saturated fats **Low-fat** Individualized "fat budget" and a calorie goal based on participant's height and weight (500 kcal/d deficit). Extensive education on various types of dietary fats. Limit saturated fat intake to <7% of caloric intake (AHA guide-lines). Limit cholesterol intake to <300 mg/d. Increase intake of fruits and vegetables All participants received hand-outs that were specific to their dietary interventions and CalorieKing Calorie, Fat and Carbohydrate Counter. No individu-alised diet plans were provided	**Low-CHO** Weight, kg BL: 6 mo: 12 mo: 24 mo: **Low-fat** Weight, kg BL: 6 mo: 12 mo: 24 mo:	 118.3±21.3 mean ± SD –2.8 mean ± SE –1.3 1.5 115.5±16.7 mean ± SD –2.0 mean ± SE –1.2 –0.5	Moderate risk of bias Self-reported medical history, 24-h recalls. Energy and macronutrient intake was underreported although not verified with f ex. P- or U-ketones Attrition: 76 patients (52.8%) did not complete the 24 m study. Attrition: Low-CHO: 60.0% Attrition: Low-fat: 46.0%

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Keogh et al 2007 [23] Australia NIH National Health and Medical research Council of Australia	RCT Academic medical centre 52 wks Measurement of adherence not stated	Obese hyperinsulinaemic subjects, BMI 27–40 kg/m^2, Age 20–65 yrs) (73/35, attrition given only for the entire randomised group) **HMF (completers)** 52±8 yrs 93±12 kg BMI: 34±4 kg/m^2 **HP (completers)** 48±13 yrs 99±15 kg BMI: 34±4 kg/m^2	Low CHO, high MU-saturated fat (HMF: 50% fat, 20% protein (67 g/d), 30% CHO) Low CHO, high protein, moderate fat (HP: 30% fat, 40% protein (136 g/d), 30% CHO) Both diets energy target 6 000 kJ/d	Weight, kg 0 wks: 28 wks: 52 wks:	**HMF** 98.8 89.0 91.3	**HP** 91.9 – 86.6	High risk of bias
Krebs et al 2010 [17] USA NIH The National Cattlemen's Beef Association	RCT Weight management clinic in Colorado, US 1 academic medical centre 36 wks Repeated 3-day food records	Obese adolescents **LF** (13 wks, 24 wks, 36 wks) (22/7, 8, 11) 45% male 13.7±0.3 yrs BMI: 40.1±1.8 kg/m^2 BMI-Z: 2.51±0.05 kg/m^2 Weight: 107.1±6.1 kg **LCHOHP** (13 wks, 24 wks, 36 wks) (24/18, 13, 11) 46% male 14.2±0.4 yrs BMI: 38.0±1.2 kg/m^2 BMI-Z: 2.48± 0.06 kg/m^2 Weight: 109.3±4.7 kg Mean ± standard error	**LF** Diet low in fat (30% of calories) **LCHOHP** Diet high in protein, and low in carbo-hydrate (20 g/d)	Weight, kg (change) 24 wks: 36 wks: BMI-Z 24 wks: 36 wks: Means ± standard error. * P-values for the between-group difference	**LF** –1.41 No significant difference between groups –0.14±0.04 –0.15±0.04	**LCHOHP** –6.3* –0.21±0.07* –0.22±0.09*	High risk of bias Small groups High drop-out rate during follow-up

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Larsen et al 2011 [29] Australia ACTRN12605000063617	RCT 1 medical centre 12 mo Measurement of adherence not stated	Type 2 diabetes **High protein (HP)** (53/2/5) (BL/6 mo/12 mo) 57% male 59.6 (57.5, 61.8) yrs 33.9±3.8 kg/m^2 94.6 (90.5, 98.8) **High carbohydrate (HCHO)** (46/1/1) (BL/6 mo/12 mo) 39% male 58.8 (55.8, 61.7) yrs 95.5 (91.5, 99.6)	High protein, low carbohydrate (Protein 30 E%/fat 30 E%/CHO 40 E%) Low protein, high carbohydrate (Protein 15 E%/fat 30 E%/55 E%) HbA_{1c} primary endpoint	12 mo results: Significant differences over time with both diets but not between diets for the following variables: **HP** **HCHO** Weight, kg: –2.23 –2.17 Waist, cm: –3.54 –3.35	Moderate risk of bias

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Krebs et al 2012 [26] New Zealand ACTRN12606000490572 Health Research Council of New Zealand	Multicentre parallel design, blinded randomised controlled trail 3 centres 2 yrs (Intervention: 12 mo, follow-up: 12 mo) Measurement of dietary adherence was estimated from 3-day food diaries completed at baseline, 6 mo, 12 mo and 24 mo Adherence not reported	Overweight or obese men and women with type 2 diabetes **HP** (207/34/62/63) (BL/6 mo/12 mo/24 mo) 46% male 57.7±9.9 yrs 36.6±6.7 kg/m^2 **HCHO** (211/37/58/61) (BL/6 mo/12 mo/24 mo) 34% male 58.0±9.2 yrs 36.7±6.4 kg/m^2	**HP** 40 E% CHO 30 E% protein 30 E% fat **HCHO** 55 E% CHO 15 E% protein 30 E% fat Energy intake reduction with –500 Kcal/d using individualised dietary prescription based on estimated energy requirements for both diet groups Group-based dietary counselling (dieticians) included appropriate intakes of alcohol, saturated fat and fibre, the glycemic index and behaviour change strategies. Weight was monitored at each session ongoing self-recording of food intake was encouraged. No further dietary advice was offered after 12 mo. Participants were asked to follow their prescribed diets on their own in the second yr		**HP**	**HCHO**	Moderate risk of bias
			Mean ± sd				
			Weight, kg				
			BL:	103.4±19.7	101.9±20.1		
			6 mo:	100.2±18.8	98.7±19.3		
			12 mo:	100.2±17.8	99.5±19.1		
			24 mo:	99.5±17.2	95.9±17.1		
			HCHO: Diff between groups in weight change over time (95% CI): 0.00 (–1.20, 1.21), p=0.73				
			Waist circ, cm				
			BL:	114.4±13.7	115.1±13.5		
			6 mo:	111.5±13.0	112.1±13.2		
			12 mo:	111.4±12.8	112.0±13.9		
			24 mo:	110.1±14.1	108.7±12.1		
			HP: Secondary analyses included: HbA_{1c}, total body fat (kg, %), total-cholesterol, LDL-chol, TG, HDL-cholesterol, systolic and diastolic blood pressure, SF-36, S-creatinine, UACR. Energy- and macronutrient intake HP: Side effects were not measured HCHO Waist: Diff between groups in waist change over time (95% CI): 0.46 (–0.77, 1.69), p=0.60			

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Table I continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence				Comments
McAuley et al 2005 [5] New Zealand The Health Research Council of New Zealand	RCT Single centre 6 mo 3-day food records (weighted) at baseline, 8, 16 and 24 wks	Insulin resistant women with overweight/obesity **HF/LCHO diet** (31/0) (BL/6 mo) 45±7.4 yrs 36.0±3.9 kg/m^2 **HP diet** (30/0) (BL/6 mo) 47±4.9 yrs 34.5±5.3 kg/m^2 **HCHO/LF diet** (32/0) (BL/6 mo) 45±7.5 yrs 36.6±5.6 kg/m^2	**LF (control group)** Nutrient composition based on DNSG. The diet used the national healthy eating guidelines with focus on wholegrains, vegetables and fruit, low-fat milk or milk products lean meat, chicken, seafood, eggs, beans, peas or lentils. Advice to reduce dietary fat, salt and sugar **HP diet (Zone diet)** The total energy provided by each meal and snack, 40% from low glycaemic index carbohydrate, 30% from protein and 30% from fat (predominantly monounsaturated). Participants were advised to consume an appreciable amount of protein, fruits and vegetables, and to consume small amounts of fats and oils *Description contiunes on the next page*		**HF/LCHO diet**	**HP diet**	**HCHO diet**	Moderate risk of bias
				Weight, kg				
				0 mo:	96.0±10.8	93.2±14.5	98.0±15.1	
				24 wks:	88.9±10.6	86.3±14.2	93.3±14.5	
				WC, cm				
				0 mo:	99.2±10.9	108.0±11.5	109.1±11.6	
				24 wks:	99.1±9.2	108.9±9.9	102.2±11.8	

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Table I continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
McAuley et al *(continued)*			**LCHO diet** **(Atkins diet)** No specific macronutrient targets were given except for carbohydrates. During the first 2 wks, participants were instructed to consume <20 g of carbohydrate daily. From wk 3 to 8, carbohydrate was reintroduced by the addition of 5 g/d each wk, resulting in 50 g of carbohydrate/d was consumed wk 8		

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Meinert Larsen et al 2010 [25] Europe (8 countries) European Commision NCT00390637	RCT 8 academic centres from Europe 26 wks Measurement of adherence not stated	Overweight subjects BMI 27–45 kg/m^2 938 entered low-calorie phase/ 773 completed 548 completed the intervention (below) **LP/LGI** 42.2±5.7 yrs 88.4±15.7 kg Waist 96.8±11.8 cm **LP/HGI** 42.0±5.9 yrs 86.6±13.8 kg Waist 96.5±10.7 cm **HP/LGI** 42.1±6.5 yrs 88.5±15.6 kg Waist 96.6±11.7 cm **HP/HGI** 42.0±5.7 yrs 89.5±17.1 kg Waist 97.6±12.8 cm **Control** 43.0±6.7 yrs 87.6±15.9 kg Waist 96.9±12.4 cm **Total (548)** 42.3±6.1 yrs 88.1±15.7 kg Waist 96.9±11.9 cm	**Weight reduction phase** Modifast products + up to 400 g vegetables providing 800–1 000 kcal/d) **Intervention diets** LP (13% protein)/LGI LP (13% protein)/HGI HP (25% protein)/LGI HP (25% protein)/HGI **Control diet** Moderate fat content in all diets (25–30%) Difference of 15 GI units (LGI vs HGI)	Mean weight reduction in the low calorie phase was 11.0 kg Fewer participants dropped out in the HP and LGI groups than in the LP (26.4% and 25.6% respectively vs 37.4 5; p=0.02 and p=0.01) **Weight regain** HP vs LP groups –0.93 kg (0.31, 1.55) p=0.003 LGI vs HGI groups –0.95 kg (0.33, 1.57) p=0.003 **Adherence to diets** Dietary intake of energy from protein was 5.4 E% higher and from carbohydrate 7.1 E% lower in the HP groups compared to LP (p<0.001 for both). The mean GI was 5 units lower in the LGI groups compared to the HGI groups, p <0.001)	Low risk of bias

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence			Comments
Papandreou et al 2012 [33] Greece NCT01312558	RCT 1 academic medical centre 6 mo FFQ at baseline, and at 3 and 6 mo visit	Patients with obesity and obstructive sleep apnoea syndrome (OSAS) **MD (Mediterranean diet)** (20/0) (BL/6 mo) 85% male 52.2±10.5 yrs 35.3±3.8 kg/m^2 101.5±12.5 kg Waist: 116.6±9.3 cm AHI: 52.4±33.8 events/h AHI = apnoea-hypopnoea index **PD (Prudent diet)/LF** (20/0) (BL/6 mo) 85% male 45.8±14.2 yrs 37.7±4.6 kg/m^2 108.9±19.8 kg Waist: 119.3±14.4 cm AHI: 58.7±34.9 events/h	Both groups received CPAP, exercise advice (walking ≥30 min/d) and energy reduction (1 200–1 500 kcal/d for females and 1 500–1 800 kcal/d for males) Recommended daily intake in the MD groups of fruits, vegetables, legumes, non-refined cereals and fish was 3 times higher than in PD group. Red meat intake was 1/3 of the PD group. Moderate daily consumption of nuts and alcohol was recommended in the MD group. Exclusion of rapidly absorbed CHO, full cream products, processed meat and carbonated or sugared beverages was advised to both groups		**MD**	**PD/LF**	Low risk of bias
				Weight:	–8.9±3.9	–7.2±4.2	
				BMI:	–3.2±1.5	–2.5±1.4	
				Waist:*	–8.7±3.6	–5.7±3.8	
				Body fat* %:	–4.3±2.5	–2.6±1.7	
				*p<0.05			
				Changes after 6 mo intervention			

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population (N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Salmerón et al 2001 [43] USA National Institutes ofHealth	Longitudinal cohort study Registered nurses 14 yrs Self-reported diabetes, diet assessment by FFQ	Female registered nurses aged 30–55 yrs at enrollment (total population 84 204, separate information on BMI >30 kg/m^2) In women >30 kg/m^2 n=1 213 self-reported cases of diabetes	Women were divided into quintiles by percentage of energy from each type of fatty acid; incidence rates were calculated by dividing the number of events by person-time of follow-up in each quintile. Percentage of energy from protein, and total energy intake. Intakes of specific types of fat and cholesterol were entered into the model simultaneously adjusted for non-dietary covariates: seven 2-yr time periods, age in 5-yr categories smoking status, alcohol consumption (g/d in 4 categories), physical activity, and history of diabetes in a first-degree relative	RR (95% CI) Polyunsaturated fat (5% increase in energy) 0.68 (0.52; 0.88) p=0.004 *trans* Unsaturated fat (2% increase in energy) 1.31 (1.00; 1.72) p=0.05 Cholesterol (23.9-mg/MJ increase) 1.15 (1.07; 1.25) p=0.0005	Moderate risk of bias Dietary intake was self-reported, and so was diabetes diagnosis. Unmeasured confounders due to the observational study design, for example interest in health issues

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Samaha et al 2003 [18] USA Veterans Affairs Healthcare Network Competitive Pilot Project Grant	RCT Philadelphia Veterans Affairs Medical Center 6 mo 24 h recall	Obese men and women (132/53) **Low-CHO** Ethnicity: Caucasian: 42% Afro-Americans: 55% Hispanic: 3% Sex: 20% female, 80% male Age: 53±9 yrs BMI: 42.9±6.6 kg/m^2 **Low-fat** Ethnicity: Caucasian: 34% Afro-Americans: 62% Hispanic: 3% Sex: 155 F, 85% M Age: 54±9 yrs BMI: 42.9±7.7 kg/m^2	**Low-CHO** Restrict carbohydrate intake ≤30 g/d. No instruction on restricting total fat intake. Vegetables and fruits with high ratios of fiber to carbohydrate were recommended **Low-fat** Instructions in accordance with the obesity management guidelines of the National Heart, Lung, and Blood Institute including caloric restriction sufficient to create a deficit of 500 kcal/d, with 30% or less of total calories derived from fat Both groups attended separate 2-h group-teaching sessions/wk for 4 wks. Therafter, one-hour session/mo for five mo; experts led all sessions. Subjects received a diet-overview hand out, instructional nutrition labels, sample menus and recipes, a book on counting calories and carbohydrates. No specific exercise program was recommended	Weight, kg BL: diff, 6 mo:	**LCHO** 130.0±22.7 –5.8±8.6	**LF** 131.8±27.3 –1.9±4.2	Moderate risk of bias **Attrition** *Low-CHO* 1 mo: 38% 3 mo: 44% 6 mo: 47% *Low-fat* 1 mo: 25% 3 mo: 27% 6 mo: 33% 3 mo: I vs C: p=0.03 6 mo: I vs C: p=0.10

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Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Stern et al 2004 [19] USA Veterans Affairs Healthcare Network Competitive Pilot Project Grant	Randomised parallel-group Philadelphia Veterans Affairs Medical Center 1 yr Measurement of adherence not stated	Obese men and women **LCHO (data on weight)** 64/20 (64/2) 80% males 53±9 yrs 42.9±6.6 kg/m^2 White: 42% African American: 55% Hispanic: 3% Diabetes: 42% **Conventional (data on weight)** 68/25 (68/4) 85% male 54±9 yrs 42.9±7.7 kg/m^2 White: 34% African American: 63% Hispanic: 3% Diabetes: 40%	LCHO diet restrict carbohydrate intake to <30 g/d Conventional restrict caloric intake by 500 calories/d with <30% of calories from fat	**LCHO** **Conventional** Weight (kg) 12 mo: –5.1±8.7 –3.1±8.4 Completers, n= 87 Two on LCHO died, none on conventional diet	Moderate risk of bias

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Tinker et al 2008 [30] USA The National Heart Lung and Blood Institute of NIH NCT0000611 Funding source: Public	RCT 40 US clinical centres 6 yrs FFQ designed for WHI	Post-menopausal women 45 887 (of which 16 653 were obese) 1 yr, 6 yrs **Low-fat intervention group LF (I) (40%)** Age: 62.2±6.89 yrs BMI ≥30: 36.3% **Usual diet comparison group UD (C) (60%)** Age: 62.2±6.87 yrs BMI ≥30: 36.3%	**Low-fat intervention group** 20 E% fat ≥5 servings/d of combined vegetables and fruits ≥6 servings/d of whole grains **Usual diet comparison group** A copy of Dietary Guidelines for Americans to each woman in the comparison group 18 group sessions for the intervention group during the first yr followed with four sessions/yr	Number of cases (%) with treated diabetes in women between baseline and 6 yrs **LF (I)** **UD (C)** BMI <25 kg/m²: 136 (0.34) 177 (0.29) BMI 25–30 kg/m²: 347 (0.64) 559 (0.69) BMI ≥30 kg/m²: 814 (1.52) 1 297 (1.62) P for interaction: p=0.74 **Hazards ratio:** BMI <25 kg/m²: 1.15 (0.92; 1.45) BMI 25–30 kg/m²: 0.94 (0.82; 1.07) BMI ≥30 kg/m²: 0.93 (0.85: 1.01)	Moderate risk of bias Self-reported data on incident diabetes treated with oral agents or insulin. Self-reported dietary intake (FFQ)

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Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Interventions	Effects Side effects Adherence	Comments
Westman et al 2008 [22] USA Funding by Robert C Atkins Foundation	RCT Academic centre 24 wks Dietary intake was followed by a 5 day food record at baseline and at wks 4, 12 and 24	Patients with type 2 diabetes and BMI 27–50 kg/m^2 97/13 Baseline characteristics: Age: 51.8±7.3 yrs Females: approximately 80% **The low carbohydrate ketogenic diet group (LCKD)** (38/17) HbA_{1c}: 8.8±1.8% BMI: 37.8±6.7 kg/m^2 **The low glycaemic index diet group (LGID)** (46/17) HbA_{1c}: 8.3±1.9% BMI: 37.9±6.0 kg/m^2	LCKD group were recommended a strict ketogenic low-carbohydrate diet (<20 g/d). They were informed by a dietitian and with a lay-press diet book and handouts without explicitly reducing energy intake A similar strategy was used for the LGID group, with the additional recommendation to reduce energy intake by 500 kcal and aim at a daily carbohydrate intake of 55%	The outcome is given per protocol, and the intention-to-treat analysis is not given The results from baseline to wk 24 were: **LGID** **LCKD** BMI (kg/m^2): –2.7 (p=0.10) –3.9 Body weight (kg): –6.9 (p=0.01) –11.1 For lipids, blood pressure and waist, there were no significant difference between the groups after adjustment. (p values given for comparison between the groups given after adjustment for baseline characteristics)	Moderate risk of bias The treatment groups were not well balanced for some important variables at baseline High drop-out rate

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Table I continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Wycherley et al 2010 [6] Australia Public as well as companies that donated different food products to the study	RCT University, 1 academic medical centre 52 wks 3 d of semi-quantitative food records	Overweight and obese patients **LCHO** (0 wks, 52 wks) (55/16) 31% male Age: 49.9±1.7 yrs BMI: 33.5±0.8 kg/m^2 Weight: 94.1±3.2 kg WC: 111.8±3.9 cm (men), 100.6±2.0 cm (women) **LF** (0 wks, 52 wks) (52/22) 39% male at baseline Age: 50.2±1.4 yrs BMI: 33.9±0.8 kg/m^2 Weight: 97.5±2.7 kg WC: 110.8±1.8 cm (men), 102.0±2.9 cm (women) Mean ± SEM	**LCHO** Low carbohydrate diet, high in saturated fat with 4% of energy coming from carbo-hydrates, 35% as protein and 61% as fat (20% saturated fat). Aiming at restricting intake of carbohydrate to <20 g/d for the first 8 wks, with optional to increase to <40 g/d for the remaining time **LF** Low fat diet high in carbohydrates with 46% of energy as carbohydrate, 24% as protein and 30% as fat (<8% saturated fat), aiming at <10 g of saturated fat/d	52 wks Weight, kg: BMI:	**LCHO** –14.9±2.1 –5.3±0.7	**LF** –11.5±1.5 –3.9±0.5	Moderate risk of bias

ADAD = American Diabetes Association diet; BL = Baseline; BMI = Body Mass Index; C = Control; CHO = Carbohydrate; CI = Confidence interval; E% = Energy percent; CPAP = Continuous Positive Airway Pressure; ER = Energy restricted; d = Day(s); F = Female; FFQ = Food Frequency Questionnaries; GI = Glycemic index; GL = Glycemic load; h = Hour(s); HCHO = High carbohydrate; HF = High fat; HGI = High glycaemic index; HMF = High monounsaturated fat; HP = High protein; HR = Hazard ratio; I = Intervention; ITT = Intention to treat; kcal = Kilocalories; LCHO = Low carbohydrate; LCHOHP =Low carbohydrate/High protein; LCKD = Low carbohydrate ketogenetic diet; LF = Low fat; LGI = Low glycaemic index; LGID = Low glycaemic index diet; LGL = Low glycaemic load; LOCF = Last observation carried forward; LP = Low protein; M = Male; MD = Mediterranian diet; Mo = month(s); MUFA = Monounsaturated fatty acid; n = Number; PD = Prudent diet; PUFA = Polyunsaturated fatty acids; RCT = Randomised controlled trial; rMED = The relative Mediterranean diet score; SEM = Standard error of mean; SFA = Saturated fatty acid; SP = Standard protein; UACR = Urine Albumin-to-Creatinine Ratio; UD = Usual diet; US = United States; WC = Waist circumference; WW = Weight watchers; Yr(s) = Year(s)

Table II.a Interventional studies of specific food items in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population (N/drop-outs)** **Baseline data** **Groups**	**Intervention**	**Effects** **Side effects** **Adherence**	**Comments**
Foster et al 2012 [6] USA The Almond Board of California	RCT 1 academic medical centre 6 and 18 mo No information	Overweight-obese individuals with BMI 27–40 **Intervention group** BL/6 mo/18 mo (61/7/14) 88.5% females Age: 47±12 yrs BW: 94±13.1 kg **Control group** BL/6 mo/18 mo (62/12/17) 93.5% females Age: 46.7±13 yrs BW: 91.5±11.9 kg	**Exposure in both groups** The low-caloric diet provided 1 200–1 500 kcal/d for women and 1 500–1 800 kcal/d for men. From wk 4 encouraged to walk for 20 min 4 times/wk, progressing to 50 min 4 times/wk by wk 19 **Intervention group (almond-enriched, low-calorie diet)** Instructed to consume 56 g almond/d, adhere to the total energy goal and abstain from alternative nut consumption. Were provided with two 28-g packages of almonds/d. The 5 first wk whole, raw almonds, at 6 wk roasted almonds and over time a variety of isocaloric, flavored almonds were used **Control group (nut-free, low-calorie diet)** Instructed to abstain from nut consumption (eg peanuts, peanut butter, cashews, macadamia nuts, walnuts, pistachios)	Ajusted mean change *Significant between group differences **Almond** **Nut-free** Weight 6 mo, kg: –5.5±0.6 –7.4±0.7* Weight 18 mo, kg: –3.7±1.0 –5.9±1.0 Fatmass 6 mo, kg: –3.7±0.5 –5.0±0.5* Fatmass 18 mo, kg: –3.0±0.8 –4.0±0.8	Moderate risk of bias

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Table II.a continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Intervention	Effects Side effects Adherence	Comments
Lapointe et al 2009, 2010 [1–3] Canada Canadian Diabetes Association	RCT 1 academic medical centre 6 mo (article 5 177 and 238) 18 mo (article 92) FFQ	Postmenopausal women (n=68) Age: 45–68 yrs WC: ≥88 cm BMI: ≥28 kg/m^2 **Limit high-fat foods (LOFAT)** BL/6 mo/18 mo (n=33/2/5) Age: 58.1±4.6 yrs BW: 85.8±8.9 **High intake of fruit and vegetables (HIFV)** BL/6 mo/18 mo (n=35/3/7) Age: 56.2±4.4 yrs BW: 85.0±8.9	**LOFAT** Restrictive messages about decreasing high-fat food consumption **HIFV** Positive messages promoting consumption of fruits and vegetables No specific goals for energy restriction 3 group sessions (including cooking lesson) and 10 individual sessions with registered dietitian	Analysis according to the intention-to-treat procedure **LOFAT** **HIFV** **BW change, kg** 3 mo: –1.5±1.8* –0.7±1.7 6 mo: –3.5±2.9* –1.6±2.9* sig 12 mo: appr –3.9*† appr –1.9*† 18 mo: appr –2.7*† appr –1.4 **WC change, cm** 6 mo: appr –4.3*† appr –2.5*† 12 mo: appr –3.1*† appr –2.3† 18 mo: appr –3.0*† appr –2.2† **Dietary restraint** BL: 8.2±4.6 9.6±4.0 3 mo: 11.8±5.0* 9.4±4.9* sig 6 mo: 12.5±4.3* 11.0±4.4* sig 12 mo: 10.8±4.3* 10.2±4.6 18 mo: 11.0±4.4* 10.7±4.7 † = Estimated from figure 2; * = significant from BL; sig = significant between groups	Moderate risk of bias for all 3 publications Low risk of selective reporting. Low risk for conflict of interest. Low risk for publication bias. Acceptable indirectness
Raynor et al 2012 [17] USA The National Institute of Diabetes and Digestive and Kidney Diseases	RCT 1 academic medical centre 6, 12 and 18 mo 24 h-recall x 3 d	Overweight-obese individuals with BMI 27–45 **Intervention group** BL/6 mo/12 mo/18 mo (101/2/4/7) 58.4% females Age: 51.7±8.9 y BMI: 34.5±4.1 kg/m^2 **Control group (lifestyle 1 200–1 500 kcal/d ≤30 E% fat)** BL/6 mo/12 mo/18 mo (103/3/6/7) 57.3% females Age: 51.9±9.0 y BMI: 35.3±4.5 kg/m^2	**Exposure in both groups (lifestyle)** Caloric goal was 1 200 kcal/d for an entry body weight ≤90 kg and 1 500 kcal/d for >90.9 kg. Fat intake was restricted to 30 E%. Physical activity was instructed to gradually increase to ≥40 min/d 5 times/wk and 10 000 steps/d **Intervention group** Lifestyle + limited variety of non-nutrient-dense, energy-dense foods = NND-EDF (eg chips, ice cream, cookies), ie 2 choices. No instructions regarding specific amount or frequency **Control group** Only lifestyle	Weight loss, % **Intervention** **Control** 6 mo: –11.2±7.0 –10.6±7.0 12 mo: –10.9±7.0 –10.6±7.0 18 mo: –9.9±7.6 –9.6±9.2	Moderate risk of bias

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Table II.a continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Method of dietary adherence	Population (N/drop-outs) Baseline data Groups	Intervention	Effects Side effects Adherence	Comments
Venn et al 2010 [8] New Zealand NZ Foundation for Research, Science, and Technology Australian Clinical Trials Registry ACTRN12605000537651	RCT 1 academic medical centre 18 mo 3-day weighed food records at 0, 2, 6, and 12 mo. Daily check sheets every 2 wks during the first 6 mo	Overweight-obese individuals with BMI ≥28 **Intervention group** (53/4/10) (26 wks, 72 wks) 84% males Age: 42±11 yrs BW: 95±17.4 kg **Control group** (55/6/25) (26 wks, 72 wks) 88% males Age: 42±10 yrs BW: 99±20.7 kg	**Intervention group: pulses and whole grains** Instructed to consume 2 servings of pulses as a substitution for 2 servings of breads and cereals, and all other breads and cereals were to be wholegrain. Key foods provided: rolled oats and rye, canned pulses, wholemeal wheat and rye breads **Control group: foods rich in more refined carbohydrates** Key foods provided were cornflakes, cans of fruits and vegetables such as corn and tomatoes, and bread made with refined wheat flour	Between group differences[1], means = Control–Intervention **Interven-tion** / **Control** BL Weight (kg): 100±20,7 / 95±17,7 Weight (kg), 6 mo: 93±21 / 89±18,3 Weight (kg), 18 mo: 94±22,8 / 92±21,8 Baseline WC (cm): 106±14 / 102±12 WC (cm), 6 mo: 99±14 / 96±13 WC (cm), 18 mo: 102±16 / 100±14 [1] Adjusted for baseline values, age, and sex	Moderate risk of bias
Wien et al 2003 [5] USA NIH	RCT 1 academic medical centre 24 wks Food records in specific weekly logbooks	Overweight-obese individuals with BMI 27–55 (n=65/13) Age: 27–79 yrs **Almond group** (32/8) (24 wks) 13/32 male 53±2 yrs 39±1 kg/m^2 **Starchy food group** (33/5) (24 wks) 15/33 male 57±2 yrs 37±1 kg/m^2	**Almonds** Formula-based LCD supplemented with 84 g/d of prepackaged whole unblanched unsalted almonds **Starchy foods** Formula-based LCD supplemented with self-selected starchy foods (peas, maize, potato, pasta, rice, etc) and 2 teaspoons of safflower oil	Estimated from figure 2: Almond-LCD: –20.3 kg CI: –22.4, –18.5 Starch-LCD: –12.5 kg CI: –14.3, 10.5 **Almonds** / **Starchy foods** % change[1] Weight: –18*** / –11 Waist circ: –14* / –9 Fat mass: –30* / –20 Fat free mass: –8 / –4 [1] 24 weeks–0 weeks, adjusted for baseline values. Difference between groups: ***p<0.0001, *p<0.05	Moderate risk of bias

BL = Baseline; BMI = Body Mass Index; CI = Confidence interval; d = Day(s); FFQ = Food Frequency Questionnaries; h = Hour(s); HIFV = High intake of fruit and vegetables; kcal = Kilocalories; LCD = Low-calorie diet; LOFAT = Limit high-fat foods; mo = Month(s); N = Number; RCT = Randomised controlled trial; WC = Waist circumference; yr(s) = Year(s)

Table II.b Observational studies of specific food items in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Fung et al 2002 [9] USA NIH (public), ADA (non-profit)	Prospective cohort study: subgroup analysis of the Health Professionals Follow-up Study Follow-up time: ≤12 yrs Semi-quantitative FFQ: average intake of 'whole grains' (brown rice, dark breads, whole-grain ready-to-eat cereals, cooked cereal, pop-corn, wheat germ, bran, and other grains) (9 possible frequency responses, ranging from "never" to "more than 6 times a day". An algorithm (Jacobs et al. Am J Clin Nutr 1998;68:248) was used for whole-grain classification	Male health professionals with BMI above 30 N=3 234 Lost-to-follow-up: Not reported. Mean BMI: Not stated. Age: 40–75 yrs	Exposure: 'Whole grains' Factors adjusted for in the final model: age, period, physical activity, energy intake, missing FFQ, smoking, family history of diabetes, alcohol intake, fruit intake and vegetable intake	Diabetes incidence: **Servings/d*** **HR (95% CI)** 0.4: 1 0.8: 0.91 (0.69–1.20) 1.3: 0.76 (0.56–1.04) 1.9: 0.94 (0.70–1.26) 3.2: 0.83 (0.60–1.14) * 'whole grains', quintile medians	Moderate risk of bias Self-reported diabetes. Possibility of selective reporting
Halton et al 2006 [11] USA NIH (public)	Prospective cohort study: subgroup analysis of the Nurses' Health Study 20 yrs FFQ	Registered nurses with BMI ≥30 (n=approximately 14 000) Age: 34–59 yrs	Exposure: potatoes, french fries Adjusted for BMI, family history of diabetes, smoking, postmenopausal hormone use, physical activity, trans-fat, ratio of polyunsaturated fat/ saturated fat, cereal fiber, total calories	Multivariate RR for type 2 DM: **Potatoes:** **BMI <30** **BMI ≥30** Q1: 1.0 1.0 Q2: 0.97 (0.84; 1.13) 1.12 (0.98; 1.28) Q3: 1.01 (0.88; 1.17) 1.12 (0.98; 1.27) Q4: 0.98 (0.85; 1.14) 1.20 (1.05; 1.38) Q5: 0.95 (0.82; 1.11) 1.22 (1.06; 1.41) p for trend: 0.58 0.007 Test for interaction showed p=0.01 **French fries:** **BMI <30** **BMI ≥30** Q1: 1.0 1.0 Q2: 1.14 (0.97; 1.33) 0.94 (0.80; 1.09) Q3: 1.17 (1.01; 1.35) 1.16 (1.02; 1.33) Q4: 1.14 (1.00; 1.30) 1.15 (1.01; 1.29) Q5. 1.34 (1.15; 1.55) 1.19 (1.04; 1.36) p for trend: 0.0003 0.003	Moderate risk of bias No information on selective reporting. Low risk for conflicts of interest. Acceptable indirectness. No lack of indirectness. Low effect size. Support of dose-response gradient

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Table II.b continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Jiang et al 2002 [7] USA NIH (public)	Prospective cohort study: subgroup analysis of the Nurses' Health Study 16 yrs FFQ	Registered nurses (n=88 818) Age: 34–59 yrs BMI: ≥30 (n=approximately 8 000)	Exposure: nuts (including peanut butter) Adjusted for age, BMI, family history of diabetes, physical activity, smoking, alcohol use, total energy intake, glycemic load, multivitamin use, polyunsaturated fat, saturated fat, trans-fat, cereal fiber, magnesium, whole grains, vegetables, fruit, fish	Multivariate-adjusted RR for type 2 DM regarding intake of nuts (including peanut butter): **BMI 25–29** / **BMI ≥30** Never: 1.00 / 1.00 <1/wk: 0.83 / 0.96 <1–4/wk: 0.77 / 0.91 ≥5/wk: 0.75 / 0.75 (0.54, 1.05) / 0.56, 0.98) p for trend: 0.01 / 0.02	Moderate risk of bias No information on selective reporting. Low risk for conflicts of interest. Acceptable indirectness. Low effect size. Support of dose-response gradient
Kochar et al 2007 [10] USA NCI and NHLBI (public)	Prospective cohort study: subgroup analysis of the Physicians' Health Study, a placebo-controlled RCT of low-dose aspirin and/or ß-carotene for the primary prevention of cardiovascular disease and cancer. Follow-up time: 19.1 yrs Abbreviated, simple semi-quantitative FFQ: average intake of breakfast cereals (7 responses ranging from rarely/never to ≥2 cups/d). In addition, the brand of cereals consumed was queried at baseline. An algorithm (Jacobs et al. Am J Clin Nutr 1998;68:248) was used for whole-grain classification. Breakfast cereals that contain at least 25% of oat or bran were classified as whole grain	Physicians with BMI >30 N approximately 1 000 (incident cases of diabetes 174) Lost-to-follow-up: Not reported. Mean BMI: Not stated Mean age: Approximately 55 yrs	Exposure: Whole-grain breakfast cereals Factors adjusted for in the final model: age, smoking (never, past, current smokers), vitamin intake, alcohol consumption (<1, 1 to 4, 5 to 6, ≥7 drinks/w), vegetable consumption (<3, 3 to 4, 5 to 6, 7 to 13, 14+ servings/w), and physical activity (<1, 1+/w) (p=0.38 for interaction between whole-grain cereals and BMI category)	Diabetes incidence: **Servings/d** / **Cases, N** / **HR (95% CI)** 0: 97 1.0 ≤1: 29 0.84 (0.55–1.28) 2–6: 36 0.89 (0.60–1.32) ≥7: 12 0.75 (0.41–1.40) p for trend: 0.31	Moderate risk of bias Self-reported diabetes Possibility of selective reporting

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Table II.b continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Morimoto et al 2011 [12] USA (Hawaii) National Cancer Institute (public)	Prospective cohort study: subgroup analysis of the Multiethnic Cohort Study 14 yrs FFQ	Native Hawaiians, Japanese Americans, Caucasians N=11 624 Lost-to follow-up: Not reported. Age: 45–75 yrs	Exposure: soy (tofu, miso soup, vegetarian meat products) Factors adjusted for in the final model: adjusted for age, ethnicity, BMI, physical activity, education, energy intake, smoking status, and intakes of alcohol, dietary fiber, and processed red meat	Diabetes incidence: **Soy, g/d — Cases, N — HR (95% CI)** ***Males*** <5: 572 1.00 5–10: 313 1.09 (0.94–1.27) ≥10: 775 1.23 (1.08–1.40) p for trend: 0.002 ***Females*** <5: 511 1.00 5–10: 331 1.14 (0.98–1.32) ≥10: 1 443 1.13 (0.98–1.30) p for trend: 0.10	Moderate risk of bias Dose-response gradient in males (and in overweight males and females). No significant effect in females
Schulze et al 2003 [15] USA NIH (public)	Prospective cohort study (Nurses' Health Study) 8 yrs FFQ	Registered nurses (n=91 246) Age: 26–46 yrs BMI: ≥30 (n=approximately 15 000)	Exposure: Processed meat Adjusted for lifestyle (BMI) and dietary variables	Multivariate-adjusted RR for type 2 DM regarding intake of processed meat ≥2 times/wk vs <1 times/wk: BMI <30: 1.14 (0.72, 1.82) BMI ≥30: 1.44 (1.08, 1.90) Test for interaction showed p=0.34	Moderate risk of bias No information of selective reporting Low risk for conflicts och interest Acceptable indirectness Low effect size No support of dose-response gradient for obese subjects (but for all subjects)

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Table II.b continued

Author Year Reference Country Funding source Protocol registration	Study design Setting Follow-up time Measurement of exposure Method of dietary adherence	Population (N/drop-outs) Baseline data	Exposure Factors adjusted for in the final model	Effects		Comments
Vergnaud et al 2012 [4] 10 European countries Fundings from European Union in the framework of the Public Health Programme as well as from about 35 other national sources	Prospective cohort study: subgroup analysis of the EPIC-PANACEA Study 5 yrs FFQ	Men (n=103 455) and women (n=270 348) Age: 25–70 yrs BMI: ≥30 (n=approximately 60 000)	Exposure: fruit and vegetable intakes Adjusted for age, fruit/vegetable consumption (No/Yes), educational level, physical activity level, change in smoking status, BMI at baseline, follow-up time, energy intake, alcohol intake and plausibility of diet misreporting	Weight change, g/yr (95% CI), per 100 g of: **Total fruit** BMI* <25: BMI 25–29: BMI ≥30: **Total vegetables** BMI <25: BMI 25–29: BMI ≥30: *At baseline	 –11 (–16, –6), p<0.001 0 (–6, 6), p=0.9 4 (–13, 4), p=0.3 –2 (–15, 10), p=0.7 27 (15, 40), p<0.001 10 (–4, 24), p=0.17	Moderate risk of bias No information on selective reporting. Low risk of conflicts of interest. Acceptable indirectness. Low effect size. No support of dose-response gradient
Vergnaud et al 2010 [16] 10 European countries Fundings from European Union in the framework of the Public Health Programme as well as from about 35 other national sources	Prospective cohort study: subgroup analysis of the EPIC-PANACEA Study 5 yrs FFQ	Men (n=103 455) and women (n=270 348) Age: 25–70 yrs BMI: ≥30 (n=approximately 60 000)	Exposure: meat, red meat, poultry, processed meat Adjusted for sex, age, meat consumption (No/Yes), initial BMI, follow-up time, educational level, physical activity index, smoking status, total energy intake, energy from alcohol, and indicated plausibility of energy intake reporting	Weight change, g/yr (95% CI), per 100 kcal from: **Total meat** BMI <25: BMI 25–29: BMI ≥30: **Red meat** BMI <25: BMI 25–29: BMI ≥30: **Poultry** BMI <25: BMI 25–29: BMI ≥30: **Processed meat** BMI <25: BMI 25–29: BMI ≥30:	 37 (30, 44), p<0.0001 14 (7, 21), p<0.0001 6 (–2, 15), p=0.12 28 (13, 42), p=0.0002 1 (–14, 16), p=0.9 4 (–13, 21), p=0.6 67 (48, 87), p<0.0001 62 (43, 81), p<0.0001 –44 (–68, –19), p=0.0004 44 (35, 53), p<0.0001 9 (0, 18), p=0.04 7 (–4, 17), p=0.22	Moderate risk of bias No information on selective reporting. Low risk of conflicts of interest. Acceptable indirectness. Low effect size. No support of dose-response gradient

BMI = Body Mass Index; CI = Confidence interval; d = Day(s); DM = Diabetes mellitus; FFQ = Food Frequency Questionnaries; HR = Hazard ratio; kcal = Kilocalories; N = Number; Q = Quintiles; RCT = Randomised controlled trial; RR = Risk ratio; yr(s) = Year(s)

Table III.a Beverages. Observational studies of sweet beverage intake in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol Registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Chen et al 2010 [2] USA National Heart Lung and Blood Institute, NIH, University	Prospective cohort study of participants in the 18 mo PREMIER multicenter interventional study Dietary intake measured by multiple unannounced 24 h recalls	810 overweight and obese men and women Females 61,5% BMI: 33,1±5,8 kg/m^2 WC: 107,6±15,2 cm SSB intake: 10,5±11,9 fl oz/d (approximately 300 ml)	Change in sugar sweetened beverages (SSB) intake from baseline to follow-up visits Adjusted for gender, race, baseline age, alcohol intake, randomization assignment, study sites, baseline physical activity and change in physical activity, baseline fitness and change in fitness, baseline SSB consumption, baseline dietary intakes of selected foods and nutrients, baseline BMI and change in weight Main outcome: blood pressure	SSB quartile weight reduction/SSB intake (lb/fl oz) 1. –3.9/+9.5 2. –6.4/–0.9 3. –10.9/–15.3 Tertiles of change in SSB intake at 18 mo (mean±SD) **1** **2** **3** SSB-intake (fl oz/d): 9.5±7.4 –0.9±1.6 –15.3±9.9 Body weight (lb): –3.9±9.2 –6.4±12.7 –10.9±16.4 SBP (mmHg): –7.2±4.3 –8±4.3 –9.5±4.3	Secondary objective. No mixed model analysis. No conflict of interest. Small effects. Dos response gradient
Palmer et al 2008 [3] USA National Cancer Institute, National Institute of Diabetes and Digestive and Kidney Diseases	Prospective cohort study 7 yrs follow-up Dietary intake measured by a validated 68 item FFQ at baseline in 1995 and in 2001 after 6 yr follow-up	43 960 African American women aged 21–69 yrs without diabetes, MI, stroke, cancer at baseline Mean BMI approximately 28 kg/m^2 Baseline data not reported for the obese subpopulation	Number of drinks: <1/mo, 1–7/mo, 2–6/wk, ≥1/d Model adjusted for age, questionnaire cycle, education, physical activity, smoking status, family history of diabetes, intake of red meat, processed meat, cereal fiber, and coffee; glycemic index, each of the other 2 types of drinks. BMI dietary factors from 1995 to 2001	Incidence risk ratio (95% CI) of diabetes in the obese subpopulation (BMI>30): Sugar sweetened soft drink <1/mo: 1 (reference) 1–7/mo: 0.92 (0.80; 1.06) 2–6/wk: 0.99 (0.85; 1.14) ≥1/d: 1.05 (0.90; 1.23) Sugar sweetened fruit drink <1/mo: 1 (reference) 1–7/mo: 1.00 (0.86; 1.17) 2–6/wk: 1.04 (0.86; 1.18) ≥1/d: 1.30 (1.11; 1.52) In the general population, the absolute risk of diabetes was 0.76%/person year (733/96 266) and 0.83%/person year for the lowest consumers of sugar sweetened soft drinks and sweetened fruit drinks	Diabetes risk evaluation based on self-reported incidence. Weight gain not evaluated in the obese group. No major conflict of interest. Fruit drinks increase the risk more than sweetened soft drinks (a possible selection effect)

BMI = Body Mass Index; CI = Confidence interval; d = Day(s); FFQ = Food Frequency Questionnaries; h = Hour(s); lb/fl oz = Pounds/fluid ounzes; MI = Myocardial infarction; mo = Month(s); N (n) = Number; SD = Standard deviation; SSB = Sugar-sweetened beverages; WC = Waist circumference; wk(s) = Week(s); yr(s) = Year(s)

Table III.b Beverages. Interventional studies of sweet beverage intake in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Blackburn et al 1997 [1] USA Boston Biostatistics Research Foundation Human Performance Laboratory, University of Nebraska Kearney Nutrasweet Company, Deerfield IL Centre for Nutritional Research, Charitable Trust, Boston	RCT (stratified by body weight and clinic site) 19 wk weight reduction program (including 3 wks run-in period). 1 yr weight maintenance (71 wks), 2 yr follow-up (175 wks) Aspartame intake and body weight change measured at follow-up Aspartame intake measured by 7 d food records at 19, 71 and 175 wks	163 obese women randomised to aspartame (Asp) or no-aspartame (No-Asp) (n/19 wks/71 wks/175 wks) Asp (n=82/11/21/41) No-Asp (n=81/16/17/36) **BMI** Asp: 37.4±5.1 kg/m^2 No-Asp: 37.2± 4.6 kg/m^2 **Baseline aspartame intake** Asp: 233±223 mg/d No-Asp: 239±229 mg/d	Addition of aspartame to a multidisciplinary weight loss program (LF diet with ER, aerobic exercise, weekly group sessions) Asp group provided with aspartame sweetened beverages and tabletop sweetener No-Asp group told to avoid products sweetened with any low-energy sweetener and to use instead up to 50 g sugar or honey daily. Provided with non energy-containing flavored seltzer water	Body weight change (kg, mean±SD) **Asp** **No-Asp** 19 wks: –9,9±6.1 –9,8±6,5 71 wks: –8,1±9,4 –5,1±9,3 175 wks: –5,1±9,6 0±11,4 Aspartame intake (mg/d, mean±SD) **Asp** **No-Asp** BL: 233±223 239±229 71 wks*: 279±178 172±146 175 wks*: 293±231 192±164 * statistically significant difference between groups 3 SAE in each group. One study related (low blood pressure due to weight loss)	Recruitment by advertisements and doctors referral. Industrial support

Asp = Aspartame; BL = Baseline; BMI = Body Mass Index; d = Day(s); ER = Energy restriction; LF = Low fat; N (n) = Number; RCT = Randomised controlled trial; SAE = Serious adverse events; wk(s) = Week(s)

Table III.c Beverages. Interventional studies of dairy product/beverage intake in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Kelishadi et al 2009 [7] Iran Isfahan Cardiovascular Research Centre (WHO collaborating centre)	RCT Preschool screening 36 mo 3-day dietary record	Obese children (median age: 5.5 yrs) 120/21 **BMI (>IOTF 30)** 1: 40/4, BMI 22.1±0.9 2: 40/9, BMI 22.7±0.8 3: 40/8, BMI 22.4±0.5 **Body fat (>95th)** 1: 39.7 2: 39.2 3: 38.9	1. Dairy rich diet (>800 mg Ca/d) 2. Energy restriction for weight 3. Healthy lifestyle advice	BMI SDS no difference at baseline At follow-up 6 mo mean SD delta change 1. –0.01 (0.004) 2. 0.7 (0.01) 3. 0.6 (0.02) At follow-up up 12 mo group 1 sign lower WC (cm) 1. –2 (0.1) 2. –2.5 (0.2) 3. –1.7 (0.2) 24 mo group 1 sign lower Body fat no difference using DXA	No major study limitations. Good adherence
Thompson et al 2005 [8] USA National Dairy Council Mayo General Clinical Research Centre Division of Preventive and Occupational Medicine	RCT 12 mo Food dietary exercise record	Obese men and women (13 men) 90/18 BMI: 1. 35 (3.1) 2. 35 (3.2) 3. 34.5 (3.0) Age: 1: 42±0.8 2: 41.2±9.3 3: 41.1±8.6	Weight loss through 3 different diets and exercise 1. 500 kcal reduction. 2 servings of Ca 2. 500 kcal reduction. 4 servings of Ca 3. As 2 but increased fiber Adherence weight loss 1. 18/29 2. 18/30 3. 17/31 Adherence diet and exercise >75% of wks 1. 26/29 2. 22/30 3. 24/31	No significant effect regarding weight loss (intention to treat), adherer weight loss, completer weight loss, fat loss by DXA, trunk fat loss by DXA, change in WC or hip circumference	One author employed by General Mills, maker of yoghurt. Negative results of the study. No major limitations

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Table III.c continued

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Zemel et al 2004 [9] USA The National Dairy Council	RCT 500 kcal/d deficit all groups. 400–500 mg Ca/d vs 800 mg Ca/d vs 1 200–1 300 mg Ca/d 24 wks follow-up	41/32 randomised to 14/13/14 after drop-outs 19/11/10 (low/medium/high Ca) BMI 30.0–39.9	Supplementation with Ca or placebo. 4–500/800/12–1 300 mg/d	Weight change (% of initial) in each of the three groups is given for low/medium/high Ca 1. 6.4±2.5[a] 2. 8.6±1.1[b] 3. 10.9±1.6 (NS) Fat change (kg) 1. 4.81±1.22[a] 2. 5.61±0.98[b] 3. 7.16±1.22[c] Trunkal fat change (kg) 1. 1.38±0.60[a] 2. 2.94±0.73[b] 3. 3.74±0.64[c] Not matching letter denotes p<0.01	ANOVA in 32 individuals
Zemel et al 2005 [10] USA The National Dairy Council	RCT Setting not given Phase 1: Dairy 3 servings vs control Phase 2: Dairy 3 servings/d vs control and 500 kcal reduction in both groups	34 and 29 Afro-Americans adherence 100% **Phase 1** 24 wks Age: 41.9 BMI: 34.4 **Phase 2** 24 wks Age: 41.7 BMI: 35.5	Diary products with or without calorie restrictions	**Phase 1** No change in body weight. Index vs control Body fat (kg): –2.158 vs –0.169 Trunk fat (kg): –1.206 vs –0.357 WC (cm): –3.9 vs 1.9 **Phase 2** Index vs control Weight (kg): –11.02 vs –5.954 Fat (kg): –9.08 vs –3.97 Trunk fat (kg): –4.177 vs –0.849 WC (cm): –5.4 vs –1.7	Same individuals in phase 1 and 2. Support only by company interests

ANOVA = Analysis of variance; BMI = Body Mass Index; Ca = Calcium; d = Day(s); DXA = Dual-energy X-ray absorptiometry; kcal = Kilocalories; mo = Month(s); N (n) = number; NS = Not significant; RCT = Randomised controlled trial; WC = Waist circumference; wk(s) = Week(s)

Table III.d Beverages. Observational studies of water intake in people with obesity.

Author **Year, Reference** **Country** **Funding source** **Protocol Registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for** **in the final model**	**Effects**	**Comments**
Stookey et al 2008 [15] USA National Institute of Health Community Foundation of Southeastern Michigan Human Health Service Grant, NIH Nestle Waters	Observational study within a RCT (randomization to 4 different diet interventions: Atkins, Zone, LEARN, Ornish) 12 m follow-up Dietary intake data collected at BL, 2, 6 and 12 mo by repeated, unannounced, telephone administrered 24 h recalls	Obese and overweight premenopausal women who reported <1 l drinking water at baseline (n=173/30) (mean±SE) Body weight: 85.5±0.2 kg WC: 95.2±0.2 cm Water intake: 505±30 ml/d	Absolute and relative increases in drinking water Adjustment for age, race/ethnicity, baseline status, diet treatment group, energy expenditure, energy intake from food, food macronutrient and water composition, energy intake from beverages	Regression coefficients from mixed models predicting mean change in body weight and composition over 12 mo associated with drinking ≥1 liter water/d (coefficient±SE) Body weight (kg): –2.2±0.4* WC (cm): –2.1±0.3* Body fat (%): –1.0±0.3* * p<0,05	One author employed by Nestle Waters. High drop-out rate (46% in a yr)

BL = Baseline; d = Day(s); h = Hour(s); N (n) = Number; RCT = Randomised controlled trial; SE = Standard error; WC = Waist circumference; yr(s) = Year(s)

Table III.e Beverages. Interventional studies of water beverage intake in people with obesity.

Author **Year, Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**	**Comments**
Muckelbauer et al 2009 [14] Germany No funding information	Cluster-RCT Elementary school setting 250 d follow-up Cumulated water flow increased in water fountains Children's beverage consumption was self-reported in 24 h recall questionnaires	Second and third graders (n=3 190/240) 40 elementary schools randomised 1:1 to intervention or control 17 intervention schools and 15 control schools completed the study Age: approximately 8 yrs BMI-SDS: approximately 0.25 Obesity: 7.3% Overweight: 17.3%	Intervention schools: water fountains were installed. Children were provided with water bottles. Teachers performed classroom lessions to promote water consumption In control schools no intervention was given	Incidence rate, % **Intervention** **Control** Overweight 3.8 6.0 Obesity 7.1 5.2 Remission rate, % **Intervention** **Control** Overweight: 16.7 14.4 Obesity: 21.6 15.5	Limitations Randomisation on city level

BMI-SDS = Body Mass Index Standard Deviation Score; d = Day(s); h = Hour(s); N (n) = Number; RCT = Randomised controlled trial

Table III.f Beverages. Observational studies of coffee intake in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol Registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Freedman et al 2012 [18] USA NIH	Prospective cohort in 6 US states + 2 metropolitan areas Follow-up: 13.6 yrs (mean) Food frequency questionnaire (validated), single baseline measurement	Members of organization for retired people 50–71 yrs at baseline. Total number in cohort 229 119 men and 173 141 women, but number with BMI ≥30 kg/m^2 not reported (estimated at 60 000). Mean age 62 yrs at study onset (total cohort)	Coffee intake in women with BMI ≥30 kg/m^2: A. No coffee B. ≥4 cups of coffee per day Adjusted for race/ethnic group, education, alcohol consumption, smoking, mariatal status, health status, diabetes, physical activity, intake of energy and several other dietary components, vitamin supplements, postmenopausal hormone therapy	Hazard ratio (95% CIs) for total mortality (B vs A), estimated from figure 1 BMI 30–<35: 0.88 (0.78–0.96) BMI ≥35: 0.87 (0.73–1.00)	Extremely large study with good statistical power. No information on participants lost to follow-up
Giri et al 2011 [25] USA Material obtained from NIH-sponsored study	Prospective cohort Women's Health Initiative Observational Study Follow-up: 7.5 yrs (mean) Food frequency questionnaire (validated), single baseline measurement	Women 50–79 yrs at study onset 10 498 women with BMI ≥30 m/kg^2 Mean age 63 yrs at study onset (total cohort)	Intake of caffeinated coffee, cups/d: A. 0 or <1 B. 1 C. ≥2 Adjusted for age, ethnicity, estrogen and progestin use and smoking	Hazard ratio for endometrial cancer: A. 1.00 (referent category) B. 1.16 (0.75–1.78) C. 0.66 (0.45–0.97) p value C vs A 0.03 (0.05 for trend)	Data for decaffeinated coffee also given. No information on participants lost to follow-up
Hu et al 2006 [20] Finland	Prospective cohort study Three region of Finland Follow-up: 13.4 yrs Self-administered questionnaire (validated), single baseline measurement	Random population sample, stratified Total 10 188 men and 11 197 women. Number with BMI ≥30 kg/m^2 not reported but estimated at 42 800. Mean age 49.8 yrs at study onset (range 25–74 yrs) (total cohort)	Coffee consumption, cups/d in people with BMI ≥30 kg/m^2: A. 0–2 B. 3–6 C. ≥7 Adjusted for age, sex, study yr, education, blood pressure, bread, vegetable, fruit, sausage and tea consumption and smoking	Relative risk (95% CI) for type 2 diabetes vs the subgroup with BMI <25 and coffee intake ≥ 7 cups/d: A. 12.8 B. 8.3 C. 6.3 95% CIs not given, no statistical analysis of differences in relative risks	Large effect with dose–response relationship

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Table III.f continued

Author Year Reference Country Funding source Protocol Registration	Study design Setting Follow-up time Measurement of exposure	Population (N/follow-up) Baseline data	Exposure Factors adjusted for in the final model	Effects	Comments
Hu et al 2008 [24] Finland Finnish Academy City of Oulu	Prospective cohort Six areas of Finland Mean 19.3 yrs Self-administrered questionnaire (validated), single baseline measurement	Random population sample, partly stratified Total 29 286 men and 31 037 women but number with BMI ≥30 kg/m^2 not reported Mean age 44.3 yrs at study onset (range 25–74 yrs) (total cohort)	Coffee consumption, cups per day in persons with BMI ≥30 kg/m^2: A. 0–1 B. 2–3 C. 4–5 D. 6–7 E. ≥8 Adjusted for age, sex, study yr, education, smoking and diabetes	Hazard ratios (95% CI) for liver cancer in persons with BMI >30 kg/m^2 A. 1.00 B. 0.53 (0.19–1.48) C. 0.24 (0.08–0.72) D. 0.29 (0.10–0.85) E. 0.29 (0.09–0.99) p value for trend 0.077	
Larsson et al 2011 [23] Sweden Swedish Research Council FAS	Prospective cohort Women examined by mammography in Västmanlands and Uppsala counties Follow-up: 10.4 yrs (mean) Self-adminisrtrered questionnaire (validated), single baseline measurement	Women 30–75 yrs Total number in cohort 34 670 but number with BMI ≥30 kg/m^2 not reported (estimated at 4 000–5 000) Mean age 61 yrs at study onset (total cohort)	Coffee intake, cups/d in women with BMI ≥30 kg/m^2: A. <1 B. 1–2 C. 3–4 D. ≥5 Adjusted for age, smoking, education, physical activity, diabetes, hypertension, family history of myocardial infarction, intake of total energy, alcohol, red meat, fish, fruits and vegetables	Relative risks (95% CI) for cerebral infarction A. 1.00 B. 0.52 (0.33–0.80) C. 0.71 (0.46–1.09) D. 0.56 (0.32–0.97) p value for trend 0.16	Low correlation of coffee intake between food frequency quationnaire and dietary record (r=0.6). No information on participants lost to follow-up

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Table III.f continued

Author **Year** **Reference** **Country** **Funding source** **Protocol Registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Lopez-Garcia et al 2006 [17] USA NIH American Heart Asoociation	Prospective cohort Nationwide Follow-up: 12 yrs Dietary questionnaire (validated), repeated measurements	Health care staff Total cohort 18 417 men, 36 740 women but number with BMI ≥30 kg/m^2 not reported 51.7±0.1 yrs at study onset (total cohort)	Change in caffeine intake (quintiles) in people with BMI ≥30 kg/m^2: Q1: –294 mg/d Q2: –80 mg/d Q3: –5 mg/d Q4: +36 mg/d Q5: +211 mg/d Adjusted for age, BMI at baseline, smoking, physical acitvity, intake of alcohol, trans fats, fiber, wholegrain, soft drinks, fruit, vegetables intake and glycemic load	Weight change by quintile of change in coffeine intake **Women** Q1: 3.8±0.4 kg Q2: 3.2±0.4 kg Q3: 3.6±0.4 kg Q4: 3.3±0.4 kg Q5: 1.9±0.4 kg p <0.001 for interaction between change in coffee intake and change in weight **Men** Q1: 3.8±0.4 kg Q2: 3.2±0.4 kg Q3: 3.6±0.4 kg Q4: 3.3±0.4 kg Q5: 1.9±0.4 kg p <0.001 for interaction between change in coffee intake and change in weight	Information on participants lost to follow-up not given
Lopez-Garcia et al 2009 [22] USA NIH American Heart Association	Prospective cohort Nationwide Follow-up: 24 yrs Food frequency questionnaire (validated), repeated measurements	Registered nurses Total number in cohort 83 076 but number with BMI ≥30 kg/m^2 not reported (estimated at >9 000 from other reports from Nurses' Health Study) Mean age 56 yrs at study onset (total cohort)	Coffee intake, cups in women with BMI ≥30 kg/m^2: A. <1 per month B. 1 per month–4 per week C. 5–7 per week D. 2–3 per day E. ≥4 per day Adjusted for age, smoking, physical activity, intake of alcohol, total energy, calcium, potassium, sodium, folate, fruits, vegetables and fish, aspirin use, hormone replacement therapy, menopause	Relative risks (95% CI) for stroke A. 1.00 B. 1.14 (0.80–1.62) C. 0.85 (0.61–1.17) D. 0.91 (0.63–1.29) E. 0.62 (0.35–1.10) p value for trend 0.08	Apparent dose–response relationship. Similar relationship in non-obese participants. Information on participants lost to follow-up not given. Relatively few stroke events resulting in insufficient statistical power

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Table III.f continued

Author **Year** **Reference** **Country** **Funding source** **Protocol Registration**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for in the final model**	**Effects**	**Comments**
Salazar-Martinez et al 2004 [19] USA NIH	Prospective cohorts Nationwide Follow-up: 18 yrs (women), 12 yrs (men) Dietary questionnaire (validated), repeated measurements	Health care staff Total cohort 41 934 men, 84 276 women but number with BMI ≥30 kg/m^2 not reported Mean age 53 yrs in men and 46 yrs in women at study onset (total cohort)	Coffee intake (cups) in people with BMI ≥30 kg/m^2: A. 0 B. <1/wk C. 1–3/wk D. 4–5/wk E. ≥6/wk Adjusted for age, famility history of diabetes, smoking, menopausal status, post-menopausal hormone use physical activity, and intakes of energy, glycemic laod, trans fats, PUFA, cereal fibre and magnesium	Relative risks of type 2 diabetes **Men** A. 1.00 B. 0.86 (0.66–1.12) C. 0.92 (0.73–1.18) D. 0.60 (0.37–0.97) E. 0.28 (0.09–0.88) p value for trend 0.04 **Women** A. 1.00 B. 1.15 (1.01–1.31) C. 0.96 (0.86–1.08) D. 0.59 (0.47–0.74) E. 0.79 (0.58–1.07) p value for trend <0.001	Apprarent dose-effect relationship in both men and women. Similar effects of coffee intakt also in non-obese participants
Zhang et al 2011 [21] USA NIH	Prospective cohort The Strong Heart Study (US Indians) Follow-up: 7.6 yrs (mean) Personal interview and 24-h dietary recall, repeated measurements	1 141 men and women 45–74 yrs (US Indians), normal glucose tolerance at baseline. Sex distribution not reported. Mean BMI approximately 28.5, mean waist circumference approximately 99 cm	Coffee intake, cups/d: A. 0 B. 1–2 C. 3–4 D. 5–7 E. 8–11 F. ≥12 Adjusted for age, gender, smoking, alcohol use, family history of diabetes, physical activity, BMI	Hazard ratio (95 % CI) for incident diabetes A. 1.00 B. 0.93 (0.55–1.57) C. 0.87 (0.53–1.44) D. 0.72 (0.43–1.23) E. 0.78 (0.44–1.37) F. 0.33 (0.13–0.81) p value for trend 0.01; hazard ratio decrease 0.05 (0.01–0.09) per additional cup of coffee	High-risk population for diabetes (US Indians). Mean BMI <30 but mean WC indicating abdominal obesity. No information on participants lost to follow-up. Apparent dose–response relationship

BMI = Body Mass Index; CI = Confidence interval; d = Day(s); h = Hour(s); N (n) = number; PUFA = Polyunsaturated fatty acids; Q = Quintile; WC = Waist circumference; yr(s) = Year(s)

Table III.g Beverages. Interventional studies of tea intake in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of dietary adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions** **Exposure**	**Effects** **Side effects** **Adherence**	**Comments**
Matsuyama 2008 [28] Japan No funding reported	Double-blind RCT School children Follow-up: 36 wks	42/29 School children 6–16 yrs, recruited by websites, fliers and announcements in schools Age: 11.1±0.5 29 boys 13 girls Mean BMI 27.3 kg/m^2	A. Catechin-rich beverage (green tea leave extract), 576 kg catechin/day) for 24 weeks B. Control beverage, 75 mg catechin/day, for 24 weeks	Change at 24 wks **Intervention** **Control** BMI: 0.2±0.2 0.6±0.2 WC: 0.2±1.0 1.4±0.9 Significant decrease in LDL/HDL cholesterol ratio ($p<0.01$) in intervention group. No significant changes in other blood lipids, glucose, PAI-1, leptin, CRP, a large number of other laboratory variables and blood pressure levels	Low statistical power. Drop-outs not balanced between the groups

BMI = Body Mass Index; CRP = C-reactive protein; HDL = High density lipoprotein; LDL = Low density lipoprotein; PAI-1 = Plasminogen activator inhibitor-1; RCT = Randomised controlled trial; WC = Waist circumference; yr(s) = Year(s)

Table III.h Beverages. Observational studies of alcohol intake in people with obesity.

Author Year Reference Country Funding source	Study design Setting Follow-up time Measurement of exposure	Population (N/follow-up) Baseline data	Exposure Factors adjusted for in the final model	Effects	Comments
Buckland et al 2011 [34] Spain European Commission (DG-SANCO), International Agency for Research on Cancer (IARC), Health Research Funds (FIS) of the Spanish Ministry of Health and regional non-commercial sources	Prospective cohort Majority blood donors (75%), the remaining 25% industrial workers, civil servants or general population Follow-up: 13.4 yrs (mean) Validated dietary history questionnaire. Single baseline measurement	17 222 participants with WC men ≥102 cm, women ≥88 cm (approximately 37 men). Mean age 49 yrs	Alcohol intake as part of a Mediterranean diet. Intake inside range males 10–50 g/d, females: 5–25 g/d vs outside range Stratified by centre, age and sex and adjusted for BMI, waist circumference, education level, physical activity, smoking status and intensity and total energy intake	Hazard ratio (HR) for total mortality estimated by combining several exposure data in the article. HR for obese participants inside vs outside alcohol intake range 0.89 (CI not possible to estimate)	Main aim to study the relationship between a Mediterranean diet score and mortality; alcohol only one of nine componants analysed
Crandall et al 2009 [36] USA 6 non-commercial sources (eg NIH, American Diabetes Association) and 8 commercial companies	Observational study within a multicentre randomised trial Follow-up 3.2 yrs (mean) Food frequency questionnaire (validated), single baseline measurement	3 175 men and women (sex distribution not given) Mean BMI approximately 34 kg/m^2. Mean age approximately 50 yrs	Alcohol intake, drinks (1 drink = approximately 13 g alcohol) A. <1 per week B. 1–6 per week C. ≥1 per day Adjusted for age, sex, ethnicity, baseline weight, exercise, energy intake, CRP, smoking and a "homeostasis model" (estimation of insulin resistance)	Hazard ratio for diabetes (95% CI): Placebo group A. 1.09 (0.79–1.50) B. 1.08 (0.79–1.47) C. 0.87 (0.47–1.67) p for trend 0.83 Metformin group A. 0.83 (0.57–1.22) B. 0.58 (0.39–0.84) C. 0.46 (0.21–1.01) p for trend 0.001 Lifestyle group A. 0.80 (0.52–1.23) B. 0.64 (0.40–1.05) C. 0.28 (0.07–1.16) p for trend 0.016	Large effect with dose–response relationship in metformin and lifestyle intervention groups

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Table III.h continued

Author Year Reference Country Funding source	Study design Setting Follow-up time Measurement of exposure	Population (N/follow-up) Baseline data	Exposure Factors adjusted for in the final model	Effects	Comments
Lim et al 2007 [38] USA National Cancer Institute	Prospective cohort Mean follow-up 5.2 yrs Dietary questionnaire, single baseline measurement	Members of organization för retired people 50–71 yrs at baseline. Approximately 104 000 participants with BMI ≥30 kg/m^2. Mean age 62 yrs at study onset	Alcohol intake per wk, units divided in 3 groups Adjusted for age, sex, ethnicity, energy intake and smoking	Only descriptive report: "The BMI-non-Hodgkin's lymphoma association did not vary by ... alcohol intake (data not shown)."	Low statistical power
Park et al 2009 [37] United Kingdom Cancer Research UK Medical Research Council	Prospective cohort Participants recruited from a local population register Follow-up: 11 yrs Health and lifestyle questionnaire (validated), single baseline measurement	Total population 11 607 men 14 032 women Number of participants with BMI ≥30 kg/m^2 not reported, but estimated at 4 800. Mean age approximately 58 yrs (all BMI groups together)	Alcohol intake per wk, units (approximately 8 g alcohol per unit) A. 0 B. >0 to <7 C. ≥7 Adjusted for age, sex, smoking, education, physical activity, family history of colorectal cancer, intakes of energy, folate, fibre, fat, calcium, total meat and processed meat	Adjusted hazard ratios (95% CI) for colorectal cancer: A. 1.00 B. 1.17 (0.62–2.21) C. 1.00 (0.46–2.17) p for trend 0.99 p for interaction between BMI and alcohol intake 0.88	Low statistical power Information missing on participants lost to follow-up No significant effect of coffee also in participants with BMI <30
Wannamethee et al 2004 [32] USA NIH Harvard School of Public Health	Prospective cohort Nationwide (14 US states) Follow-up: 8 yrs Food frequency questionnaire (validated), repeated measurements	Registered nurses 6 750 women with BMI ≥30 kg/m^2. Mean age 38 yrs at study onset (all weight groups together)	Alcohol intake/d A. 0 B. 0.1–4.9 g C. 5.0–14.9 g D. 15.0–29.9 E. ≥30 Adjusted for age, intital weight and height, previous weight change, smoking, physical activity, race, spousal education, intakes of energy, protein, carbohydrate, trans fats, scrose, fiber, saturated fat	Adjusted relative risks (95% CI) for weight gain ≥5 kg: A. 1.00 B. 1.15 (1.04–1.29) C. 1.02 (0.74–1.25) D. 1.11 (0.72–1.69) E. 1.37 (0.79–1.32)	

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Table III.h continued

Author **Year** **Reference** **Country** **Funding source**	**Study design** **Setting** **Follow-up time** **Measurement of exposure**	**Population** **(N/follow-up)** **Baseline data**	**Exposure** **Factors adjusted for** **in the final model**	**Effects**	**Comments**
Wannamethee et al 2003 [35] USA NIH	Prospective cohort Nationwide Follow-up: 10 yrs Food frequency questionnaire (validated), repeated measurements	Registered nurses Total cohort 109 690 women Age: 25–42 yrs. Number of women with BMI ≥30 kg/m^2 not reported, but estimated at >10 000. Mean age 34 yrs at study onset (all weight groups together)	Alcohol intake/d A. 0 B. 0.1–4.9 g C. 5.0–14.9 g D. 15.0–29.9 Adjusted for age, smoking, family history of diabetes, physical activity, oral contraceptives, hypertension, use of antihypertensive drugs, cholesterol levels, infertility	Adjusted risk ratio (95% CI) for incident diabetes: A. 1.00 B. 0.83 (0.71–0.98) C. 0.69 (0.51–0.94) D. 0.53 (0.24–1.20) p for trend 0.005	Dose–response relationship. Strong trend observed also in non-obese participants

BMI = Body Mass Index; CI = Confidence interval; CRP = C-reactive protein; d = Day(s); g = Gram; HR = Hazard ratio; N (n) = number; WC = Waist circumference; yr(s)= Year(s)

Table III.i Beverages. Interventional studies of alcohol in people with obesity.

Author **Year** **Reference** **Country** **Funding source** **Protocol registration**	**Study design** **Setting** **Follow-up time** **Method of diet of adherence**	**Population** **(N/drop-outs)** **Baseline data** **Groups**	**Interventions**	**Effects** **Side effects** **Adherence**			**Comments**
Nörgaard et al 2010 [33] Sweden Gorthons fond, Helsingborg	RCT Primary health care Follow-up: 6 mo	Participants 35–65 yrs, moderate alcohol consumption, BMI 27–35 kg/m^2, recruited by newspaper advertisement 41/3 23 men 18 women Mean BMI approximately 32±2 kg/m^2 Mean age 53±6 yrs	A. Advice to abstain from all alcohol during 6 mo B. Advice on low energy intake (1 700 kcal/d) and physical activity (30 min per d)		**Group A**	**Group B**	Groups not balanced at onset. Low statistical power
				BMI BL: 6 mo:	32.3±3.2 30.8±4.2	31.1±2.3 29.1±3.2	
				WC BL: 6 mo:	109±10 104±9	103±9 96±7	
				Changes in BMI and WC from 0 to 6 mo highly significant (p<0.001) in both groups The following outcomes were also measured: Serum GT, ALT, haemoglobin, glucose, creatinine, and SF-12 (quality of life instrument)			

ALT = Alanine transaminase; BL = Baseline; BMI = Body Mass Index; GT = Gamma-glutamyltransferase; RCT = Randomised controlled trial; kcal = Kilocalories; mo = Month(s); WC = Waist circumference; d = Day(s); yr(s) = Year(s)

Table IV.a Systematic reviews of interventional studies of meal replacement and very-low energy diets (VLED) in people with obesity.

Author Year Reference Literature database Date of literature search	Inclusion criteria	Interventions of interest to the present report	Studies that met the inclusion criteria of the present report
Franz et al 2007 [1] PubMed Jan 1997–Sept 2004	English language Overweight or obese adults RCTs with ≥1 yr follow-up	Meal replacements VLED	1 of 7 on meal replacement [3] 2 of 11 on VLED [4,5]
Mulholland et al 2012 [2] PubMed Web of Science Science Direct Jan 2000–Dec 2010	Mean BMI ≥28 kg/m^2 RCTs, non-RCTs and retrospective studies ≥1 yr follow-up	VLED (800 kcal/d or less)	32 studies were included. However, none met the inclusion criteria of the present report

RCT = Randomised controlled trial; VLED = Very low calorie diet

Table IV.b Systematic reviews of interventional studies of exercise in people with obesity.

Author Year Reference Literature database Date of literature search	Inclusion criteria	Interventions of interest to the present report	Studies that met the inclusion criteria of the present report
Shaw et al 2006 [11] MEDLINE SPORT Discus EMBASE Cochrane Library Until Dec 2005	RCTs Overweight or obese Compared exercise with placebo or another non-pharmacological weight loss intervention	Diet + exercise intervention compared to diet intervention Diet vs exercise intervention	2 of 15 on diet + exercise vs diet [13,14] 1 of 7 on exercise vs diet
Wu et al 2009 [12] PubMed Cochrane Library 1966–June 2007	English language RCTs Study duration ≥6 mo Adults	Diet + exercise intervention compared to diet intervention, with the diet intervention identical in both groups	5 of 18, of which 4 [15–18] were not included in Shaw 2006 [11]

RCT = Randomised controlled trial; VLED = Very low calorie diet

Table 5.2 Cost-effectiveness studies.

First author Year Ref Country	Study design Setting	Population No at baseline Male/female Age Drop out rate	Intervention Follow up time	Control Follow up time	Results			Study quality and relevance	Comments
					Incremental costs	Incremental effects	Cost-effectiveness		
Tsai et al 2005 [7] USA	Cost-effectiveness analysis based on a RCT	129 severely obese patients with average BMI=42.9	Low carbohydrate (counseled to consume less than 30g carbohydrates/d), 1 yr	Standard diet (counseled to follow National Cholesterol Education Program Step 1 diet), 1 yr	ΔCosts: –$49 (95% CI –1 388; 1 274)	ΔQALYs: 0.04 (95% CI –0.01; 0.08)	Dominant. 78.6% probability that the low-carbohydrate is cost-effective compared to standard diet at a maximum willingness-to-pay of $100,000 per QALY	Moderate	Over 50% African American and only 17% women, Stern et al. (2004), no significant effects

BMI = Body Mass Index; CI = Confidence Interval; RCT = Randomised Controlled Trial;
QALY = Quality Adjusted Life Year

Table 5.3 Studies investigating the correlation between price and BMI.

Author Year Reference Country	Study design Setting Follow-up time	Population (N/follow-up) Baseline data	Exposure	Factors adjusted for in the final model	Effects	Study limitations
Duffey et al 2010 [12] USA	Multicentre longitudinal cohort Cardio-vascular disease/risk Four US cities (CARDH-study) Young adults 18–30 yrs Follow-up 20 yrs	n = 11 972, after 20 yrs 72 % remained. Baseline data published elsewhere	Increase in price of food and beverages on (A) total energy intake, (B) body weight, (C) insulin resistance (HOMA-IR)	Age, education, income, family structure, physical activity, cost of living	A 1.00 $ increase in soda price was associated with lower daily energy intake –124 kcal (95% CI –4.00; –0.68). A 1.00 $ increase in both soda and pizza was associated with lower daily energy intake –181.49 kcal (–247.79; –115.18), body weight –3.66 lbs (–5.19; –2.14) and –0.45 HOMA-IR (–0.59; –0.31)	Increasing drop-out over time
Goldman et al 2009 [14] USA	Longitudinal cohort (Health and Retirement Study) Ages 50+ yrs Follow-up 10 yrs	n = 9 733 (n = 3 111) BMI: 28.65 Age at interview: 61.4 Male: 46.6 % Less than high school: 21.6 % Working for pay: 51.4 %	Price per calorie (based on 59 standardized items), price of cigarettes and price of gasoline	Age, sex, household income, suburb/rural area, smoking, health conditions, economic conditions, married, health insurance	Very modest short-term effects of price per calorie on body weight: A 10% reduction in price per calorie would lead to a BMI increase of 0.22 units or 0.6%	High attrition
Han et al 2011 [13] USA	Longitudinal survey Individual data for 11 yrs Young adults (20 yrs) n = 26 400	n = 11 861 Age: 20.6 yrs Male: 45.1% Obese: 10% of women, 8% of men College or more: 54.1–54.5%	Fast food prices Prices of fruit and vegetables Price of soft drinks	Age, gender, race, marital status, school enrolment, highest grade completed, parents degree, mother's working status, distance	Limited effect from food prices on obesity, no results significant in multivariate analyses. +10% on fast food prices decreased the probability of obesity with 18.8% for women	High attrition
Powell et al 2009 [11] USA	Longitudinal panel data (NLSY97-study) Adolescents 12–17 yrs Follow-up 4 yrs	n = 5 215 (n at follow up not given) Age: 15.48 yrs Male: 51.7 % Youth lives with one parent: 26% Mother does not work: 20.3%	Fast food prices Fast food restaurant availability	Age, race, gender, income, family structure, hours of work, mother's education, area indicators, physical activities facilities	Fast food price increase of +1$ reduces adolescent BMI by 0.646 units. Larger price elasticities for fast food prices for low- and middle-SES-populations	Attrition rate not given
Sturm et al 2005 [10] USA	Nationally representative longitudinal cohort of kindergarten children (ECLS-K study) Children 6 yrs old at start Follow-up 3 yrs	n = 13 282 (n = 6 916) Age in mo: 74.6 Birth weight: 7.38 pounds Girls: 49.6 % Days per wk that child gets exercise that causes rapid breathing: 3.85	Food prices based on 63 items, weighted according to consumption of meats, diary, fruits, vegetables and fast food	Birth weight, real family income, gender, mother's educational achievement, ethnicity	Lower real prices for vegetables and fruits predicted lower gain in BMI between kindergarten and 3rd grade. +1SD of price of fruit and vegetables would raise BMI by 0.11 units by 3rd grade. No significant effects for diary and fast-food prices on BMI	High attrition

$ = US dollar; BMI = Body mass index; CI = Confidence interval; d = Day(s); ECLS-K = Early Childhood Longitudinal Study – Kindergarten Class; HOMA-IR = Homeostatic model assessment insulin resistance; n = number; NLSY97 = National Longitudinal Survey of Youth 1979; QALY = Quality adjusted life year; RCT = Randomised controlled trial; SES = Socioeconomic status; Yr(s) = Year(s)