

**Bilaga till rapport** Mat vid diabetes, rapport 345 (2022)

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## RCT

First author Year Reference Country	Study design Population Setting Duration of follow-up	Intervention (I) Participant characteristics at baseline Drop-outs	Control (C) Participant characteristics at baseline Drop-outs	Results Effects/Side effects	Risk of bias Comments
Petersen, et al.	RCT	I: Increased	C: Usual diet	Carotid intima media thickness progression,	Moderate risk of
2015	People with	fruit, vegetables, and	n=73	HbA1c, LDL, HDL, TG, total cholesterol, weight, SBP, DBP	bias
[1]	type 1 or type 2 diabetes for	dairy intakes Fruit (+1			
Australia	any duration managed with diet, oral hypoglycemic agents, and/or insulin (n=146) 12 months follow-up	serving; 150 g/d), vegetable (+2 servings; 150 g/d), and dairy (+1 serving; 200– 250 g/d) n=73			
Trento M, et al.	RCT	I: Carbohydrate	C: Continuing	Quality of life	Moderate risk of
2011		counting programme	group care	Weight BMI	bias

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[2] Italy	People (age <70) with type 1 diabetes	(CCP) in combination with group care	education without CCP n=29	Episodes of hypoglycaemia HbA1c Blood lipids Insulin dosage	
	<ul> <li>(n=56)</li> <li>Outpatients attending group care sessions every 3-4 months</li> <li>Follow-up at 30 months</li> </ul>	n=27			
Vuksan, et al. 2017	RCT People with	I: 30 g/1000 kcal Salba-chia/day	C: 36 g/1000 kcal oat bran-based	Body weight Waist circumference Blood pressure	Moderate risk of bias
[3]	type 2 diabetes and	n=27	n=31	HbA1c	
Canada	overweight/o besity (n=77)	Calorie- restricted diets for both groups. Both			

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	A Canadian academic centre	supplements were provided in two forms: baked into			
	6 months follow-up	whole-wheat bread and provided as a powder to be sprinkled onto food			

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Balk et al.	Clinic-based prospective	Number included n=1659	Variations in intake of total	Dietary data at baseline was	Baseline intake below the median of vegetable	Moderate risk of bias
2016	cohort study in men and	Sex 47.9% women	energy, carbohydrates,	collected using a standardized 3-day	protein (less than 29 g/day) and dietary fibre (less than	
[4]	women with type 1 diabetes	Age median mean (SD)	total protein, animal	food diary. Records of physical activity,	18 g/day) was associated with higher HbA1c levels.	
16 European countries	collected between 1989 and 1991. EURODIAB PCS	32.5 years (9.8) BMI median mean (SD): 23.6 kg/m2 (2.8) Insulin use	protein, vegetable protein, total fat, SAFA, MUFA, poly-	smoking status and alcohol intake by questionnaires. The records were	Restricted cubic splines showed nonlinear associations with HbA1c levels for vegetable protein (P (nonlinear) = 0.008) and	
	Aged between 15 and 60 years and recruited from 31 hospital centres in 16 European countries.	No information on insulin use (though continuous insulin therapy within 1 year)	inter A, pory unsaturated fatty acids, total dietary fibre, soluble fibre, insoluble fibre and cholesterol	analysed for intake of total energy, carbohydrates, total protein, animal protein, vegetable protein, total fat, SAFA, MUFA, poly-	total dietary fibre (P (nonlinear) = 0.0009). Participants (48%) dropped out from analyses if: they died (n = 82), four centres did not participate in the follow-up	

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	Average follow- up of 7 years			unsaturated fatty acids, total dietary fibre, soluble fibre, insoluble fibre and cholesterol. Energy intake was calculated using Atwater factors. Diet was assessed at baseline and at follow-up (only baseline data used). Adjustment for age, sex, lifestyle and body composition measures, baseline HbA1c, medication use and severe	examination (n = 437) or participants were lost to follow-up because of unknown reasons (n = 840), had missing data on nutritional intake at baseline (n = 142) or HbA1c levels at follow-up (n = 90). This resulted in 1659 participants available for analyses.	

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				hypoglycaemic attacks.		
Campmans- Kuijpers et al 2015 [5] Denmark, Germany, Italy, Netherlands, Spain, Sweden.	Cohort study Type 2 diabetes (confirmed- Type 1 excluded) European Prospective Investigation into Cancer and Nutrition (EPIC) Mean (SD) follow up 9.2 years (2.3)	n=6,107 (15 cohorts) Note missing data (based on 4082 individuals) <b>Sex</b> Women=44.8% <b>Age</b> mean (SD): 57.5 (6.4) years <b>BMI</b> mean (SD): Male 28.4 (4.1) kg/m <sup>2</sup> Female 29.3 (5.4) kg/m <sup>2</sup> <b>Insulin use</b> 20.9%	Investigating the association between dietary substitution of carbohydrates with (animal and plant) protein	Dietary intake assessed at recruitment with country-specific food-frequency questionnaires. Model 1: Hazard ratio (HR) respectively Beta, adjusted for energy intake, protein intake (per 10 g / 5 energy %), alcohol intake (per 10 gram / 5 energy%), age at recruitment, BMI, duration of	After a mean follow-up of 9.2 (SD 2.3) years, 787 (13%) participants had died, of which 266 (4%) deaths were due to CVD All-cause mortality or cardiovascular mortality (CVD), Hazard ratio Substitution of 10 gram dietary carbohydrate with: Total Protein (10 g) All Model 1: 0.96 [0.92 to 1.01] All Model 2: 0.99 [0.94 to 1.03] CVD Model 1: 0.95 [0.88 to 1.03]	Moderate risk of bias for total and CVD mortality High risk of bias for body weight and waist circumference: outcomes self- reported at follow-up Note: Recruitment base refers to Nothlings 2011 [6]

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				diabetes, insulin use (no/yes), education level (four categories), physical activity index (four categories), smoking status (three categories), sex, and country. Model 2: is model 1 with additional adjustments for healthy diet by including vitamin C and fiber in the model.	CVD Model 2: 1.00 [0.92 to 1.08] Animal Protein (10 g) All Model 1: 0.99 [0.95 to 1.04], All Model 2: 1.00 [0.95 to 1.04] CVD Model 1: 0.99 [0.92 to 1.07] CVD Model 1: 0.99 [0.93 to 1.09] Plant Protein (10 g) All Model 1: 0.71 [0.61 to 0.82], All Model 2: 0.79 [0.64 to 0.97] CVD Model 1: 0.69 [0.54 to 0.90] CVD Model 2: 1.03 [0.72 to 1.47]	
Cooper et al.	Cohort study	Number included	Computed dietary score	A validated 130- item	Dietary change over 1 year among patients prescribed	

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2014	Newly	n= 574	consistent	semiquantitative	and not prescribed cardio-	
[7]	diagnosed type 2 diabetes	Sex Women=36%	with American Diabetes	food frequency questionnaire	protective medication after baseline was associated	
United Kingdom	patients	Age mean (SD): Men: 60.4 (7.4)	Association and Diabetes	(FFQ)20 was used to assess dietary intake for the	with comparative (p-interaction $ x  > 0.05$ ) reductions in	
	ADDITION- Cambridge	years Women: 62.3 (6.3)	UK Recommendat ions (note low	preceding 12 months	all ≥0.95) reductions in diastolic blood pressure (–2.38 vs – 2.93mmHg,	
	Follow up after one year	<b>BMI</b> mean (SD): Men: 32.3 (5.1)	fat).	A:Models adjusted	respectively) and triglycerides	
		kg/m <sup>2</sup> Women: 34.1 (5.5) kg/m <sup>2</sup>	Comparative longitudinal associations of	for age, randomisation group, sex,	(–0.31 vs – 0.21 mmol/l, respectively), independent of potential confounding	
		Insulin use not stated	baseline diet and change in	occupational socio- economic class,	factors and change from baseline to follow-up in	
		Prescribed glucose-lowering medication	diet over 1 year with	baseline prescription for	physical activity and smoking status.	
		(basline), n (%): Men: 1 (0.27%)	change in blood	anti-hypertensive medications,	Systolic blood pressure (mm	
		Women: 1 (0.48%)	pressure, HbA1c and lipids.	glucose-lowering medications or lipidlowering	Hg)	

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				medications (as appropriate), the baseline cardiovascular risk factor under study and baseline and change from baseline for PAEE and smoking status. B: Models adjusted as before but also including baseline diet	Prescribed medication, No/Yes (number of participants) No (186) $-5.53$ ( $-9.82$ to $-1.24$ ) P=0.01 Yes (388) $-1.03$ ( $-5.02$ to 2.96) p=0.61 Diastolic blood pressure (mm Hg) No (186) $-2.93$ ( $-5.55$ to $-0.32$ ) p=0.03 Yes (388) $-2.38$ ( $-4.35$ to $-0.41$ ) p=0.02 HbA1c (%) No (401) $-0.38$ ( $-0.53$ , $-0.23$ ) P= less than 0.001 Yes (173) $-0.21$ ( $-0.52$ to 0.11) p=0.21 Triglycerides (mmol/l) No (190) $-0.21$ ( $-0.42$ to $-0.01$ ) p= 0.049	

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					Yes $(384) - 0.31 (-0.56 to - 0.05) p= 0.02$ Total cholesterol (mmol/l) No $(190) - 0.14 (-0.33 to 0.06) P= 0.16$ Yes $(384) - 0.20 (-0.37 to - 0.02) p=0.03$ LDL cholesterol (mmol/l) No $(190) - 0.09 (-0.25, 0.07) P=0.25$ Yes $(384) -0.10 (-0.25, 0.05) P= 0.20$ HDL cholesterol (mmol/l) No $(190) 0.04 (-0.02 to 0.09) p=0.17$ Yes $(384) 0.03 (-0.03 to 0.08) P=0.35$	
Delahanty	Cohort	n=532 <b>Sex</b>	To determine whether diet	Interview (Burke- type	HbA1c inversely associated with carbohydrate intake	Moderate risk of bias
2009	Type 1 diabetes	52% women Age mean (SD):	composition	diet history) by dietician	(p=0.01)	Not adjusted for

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[8] USA	DCCT, Observational Study within an RCT 5 years follow- up	27.3 (7) years BMI mean (SD): 23.2 (2.7) kg/m2 Insulin use Insulin dose at basline not given All patients from the RCT that were followed for 5 years were at study end were included	was associated with subsequent glycated Hb A1c concentrations Diet compositions include carbohydrate, saturated, monounsatura ted, total fat	<ul> <li>+ food preparation questionnaires at entry, 2 and 5</li> <li>years. Validation at average total</li> <li>calories at 2 and 5</li> <li>years were used to</li> <li>calculate dietary</li> <li>composition.</li> <li>Data adjusted for</li> <li>Potential</li> <li>confounders.</li> </ul> Age and sex. Exercise level, serumtriglyceride concentration, and BMI, concurrent insulin dose as a measure <ul> <li>of adequate insulin</li> <li>and baseline Hb</li> <li>A1c concentrations.</li> </ul>	NS (p=0.2) if baseline HbA1c and concurrent insulin dose was corrected for Intake of saturated, monounsaturated, total fat directly associated with HbA1c (p=0.002, 0.02, 0.004)	socioeconomic factors

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Lamb	Cohort study	n=401 <b>Sex</b>	I: High fruit, high	Self-reported F&V intake was assessed	F&V intake increased in year 1 but decreased by	Moderate risk of bias
2017 [9]	Type 2 diabetes screen-detected	Women: 43,4%	vegetables, high plasma	using a validated 130-item food	year 5, whereas variety remained unchanged.	
United Kingdom	diabetes from the ADDITION- Cambridge study (an RCT	<b>Age</b> mean (SD) 61.4 (6.6) years <b>BMI</b>	vitamin C /based on SD increase	frequency questionnaire	Plasma vitamin C increased at 1 year and at 5 years. Each s.d. increase (250g between baseline and 1	
	study). Individuals were	not stated (mean weight 93.1 (17.4) kg		Model 1: adjusted for age and sex.	year and 270g between 1 and 5 years) in F&V intake was associated with	
	from the general practice clinics in the East of England, UK. Diabetes diagnosed	Insulin use Not stated (Glucose- lowering drugs (n %) 0,2 %)		<b>Model 2</b> : model 1+intervention group, occupational socio-economic status, baseline and	lower waist circumference (-0.92 (95% Cl: - 1.57, - 0.27) cm), HbA1c (-0.11 (-0.20, - 0.03) %) and CCMR (-0.04 (-0.08, - 0.01)) at 1	
	according to WHO criteria. Follow up at 1 and 5 years			follow-up smoking status, physical activity, alcohol intake, total energy intake (except	year and higher high- density lipoprotein (HDL)- cholesterol (0.04 (0.01, 0.06) mmol/l) at 5 years. Increased plasma vitamin C	

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				plasma vitamin C), blood pressure- lowering (for SBP and CCMR), glucose lowering medication (for HbA1c and CCMR) and lipid-lowering medication (for TG, HDL-c and CCMR) and change in variety of intake (except plasma vitamin C).	(per s.d., 22.5 μmol/l) was associated with higher HDL- cholesterol (0.04 (0.01, 0.06) mmol/l) and lower CCMR (-0.07 (-0.12, - 0.03)) between 1 and 5 years CVD Waist circumference Systolic blood pressure HbA1c Triglycerides HDL-cholesterol	
Sala-Vila et al.	Prospective	n=3,482	Consuming at	Dietary intake	Number of events	Moderate risk
2016	observational	Sex	least 500 mg/d of fish-derived	assessed at baseline and at	New cases of sight- threatening diabetic	of bias (prel)
	study within the PREDIMED trial	Women, 52%	LCw3PUFA	yearly follow-ups	retinopathy (DR): n=69	No data on
[10]	(Prevención con		(the ISSFAL	using a 137-item		prevalent DR
	Dieta	Age (mean)	recommendati	(eight of which	HR (95% CI) for incidence of	were available
	Mediterránea)	67.5 years	on for primary	focused on seafood	<b>DR</b> when consuming at	at baseline, but

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Spain	Middle-aged and older individuals with type 2 diabetes and without CVD at baseline Median follow- up time 6 years	BMI, kg/m2 (mean) 29.8 Insulin use 14%	cardiovascular prevention) Yes: n=2611 (75%) No: n=871 (25%)	products) FFQ at face-to-face interviews Controlling for age, sex, BMI, intervention group, duration of diabetes, use of insulin, use of oral hypoglycemic agents, smoking, blood pressure, history of hypertension, use of angiotensin- converting-enzyme inhibitor and/or angiotensin-II receptor blockers, physical activity, and diet adherence	least 500 mg/d of LCω3PUFA at baseline (multivariate-adjusted model): 0,52 (0,31 to 0,88) P=0.001 <b>Drop-outs, %</b> Not stated <b>Side effects</b> Not stated	results after excluding early events (first 2 years) were similar

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Savory LA et al.	Pooled analysis	n=736	Change of	Dietary behaviour	Unstandardized b-	Moderate risk
2014	of the two trial arms of a	Sex	intake of fruit, vegetables,	self-reported at baseline and at 1	coefficients (95% CI) of associations between diet	of bias
2021	cluster RCT	Women, 37%	fibre, fat, and	year using a	change 1 year after screen-	
[11]		,	sodium	validated FFQ	detected diabetes and CVD	
England	People with type 2 diabetes, screen-detected and recruited at 49 primary care units Secondary pooled analysis within the ADDITION- Cambridge study, a cluster RCT comparing multifactorial	Age (mean, range) 61.1 (7.1) years BMI, kg/m <sup>2</sup> (mean, SD) 33.4 (5.6) HbA1c (mmol/mol) 56 Insulin use, % Not stated Lipid-lowering		measuring usual average intake during the past year of specific foods Adjusted for baseline dietary behaviour, age, sex, randomization group, socio- economic status, change in smoking status, change in self-reported total physical activity	risk factors: <b>BMI (kg</b> /m <sup>2)</sup> <i>Fruit (80 g/day):</i> -0.132 (-0.302 to 0.037) <i>Vegetable (80 g/day):</i> 0.620 (0.323 to 0.918) <i>Fat (% of total energy):</i> 0.005 (-0.067 to 0.077) <i>Englyst fibre (g/day):</i> 0.005 (-0.060 to 0.070) <i>Sodium (g/day):</i> 0.307 (-0.140 to 0.754)	
	treatment with	medication		levels, change in	Waist circumference (cm) Fruit (80 g/day):	

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	routine care in screen-detected diabetes 1 year follow-up of completers	23.4% Anti- hypertensive medication 55.4% Glucose-lowering medication 2%		alcohol intake, and change in medication, where relevant (eg. lipid- lowering-, anti- hypertensive-, or glucose-lowering medication)	-0.414 (-0.816 to -0.012) Vegetable (80 g/day): 1.180 (0.456 to 1.905) Fat (% of total energy): 0.039 (-0.131 to 0.209) Englyst fibre (g/day): -0.044 (-0.198 to 0.110) Sodium (g/day): 0.689 (-0.364 to 1.743) Systolic blood pressure (mmHg) Fruit (80 g/day): 0.309 (-0.260 to 0.878) Vegetable (80 g/day): -0.470 (-1.547 to 0.608) Fat (% of total energy): 0.004 (-0.245 to 0.253)	
					Englyst fibre (g/day): -0.059 (-0.277 to 0.160) Sodium (g/day): 0.190 (-1.318 to 1.700)	

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					HbA1c (mmol/mol) Fruit (80 g/day): -0.040 ( $-0.066$ to $-0.013$ ) Vegetable (80 g/day): 0.000 ( $-0.050$ to $0.048$ ) Fat (% of total energy): 0.012 ( $0.001$ to $0.023$ ) Englyst fibre (g/day): -0.005 ( $-0.014$ to $0.006$ ) Sodium (g/day): 0.046 ( $-0.025$ to $0.117$ ) Total cholesterol (mmol/mol) Fruit (80 g/day): -0.036 ( $-0.065$ to $-0.006$ ) Vegetable (80 g/day): 0.035 ( $-0.020$ to $0.091$ ) Fat (% of total energy): 0.013 ( $-0.001$ to $0.026$ ) Englyst fibre (g/day):	

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					-0.002 (-0.014 to 0.010) Sodium (g/day): 0.087 (0.008 to 0.166) HDL-C (mmol/L) Fruit (80 g/day): -0.011 (-0.022 to 0.001) Vegetable (80 g/day): -0.014 (-0.035 to 0.007) Fat (% of total energy): -0.001 (-0.006 to 0.004) Englyst fibre (g/day): -0.002 (-0.007 to 0.003) Sodium (g/day): -0.013 (-0.044 to 0.017) Side-effects Not reported Drop-outs (%) Completers analysis, not including the 15% lost to follow-up	

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	Duration of follow-up			measurements Confounders adjusted for		

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