PICO 3: Hvad er effekten af et diætbehandlingsforløb (kostanamnese, analyse, vejledning i kostprincipper/kostplan) sammenlignet med kostråd ved type 2 diabetes?

Methods

Criteria for considering studies for this review

Types of outcome measures

Primary outcomes

BMI < 1 år - kritisk
HbA1c >= 1 år - kritisk

Secondary outcomes

Følgende outcomes er vurderet vigtige:

Vægt =< 1 år
HbA1c< 1 år
LDL =< 1 år
Kostvaner - længste follow-up
QoL – længste follow-up

Characteristics of studies

Characteristics of included studies

Andrews 2011

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was done according to computergenerated allocation
Allocation concealment (selection bias)	Low risk	Allocations remained concealed by the trial coordinator until patients attended visit 4, when they saw a dietitian who telephoned to get the next code.
Blinding of participants and personnel (performance bias)	High risk	Dietitians, nurses, and patients were aware of allocation, but doctors were not. All assessments were done by nurses.
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Franz 1995

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Control (BC group) ● *Age (years)*: 55.9 (8.0) ● *Males (%)*: 44 ● *BMI*: 33 (6.9) ● *Weight (kg)*: 93.7 (22.2) ● *HbA1c (%)*: 8.3 (1.9) ● *LDL cholesterol (mmol/l)*: 3.5 (1.0) Intervention (BGC group) ● *Age (years)*: 56.9 (7.6) ● *Males (%)*: 45 ● *BMI*: 32.9 (6.3) ● *Weight (kg)*: 93.8 (19.9) ● *HbA1c (%)*: 8.3 (1.8) ● *LDL cholesterol (mmol/l)*: 3.34 (1.0) **Included criteria:** Newly diagnosed persons with Non insulin dependent diabetes melitus (NIDDM), free of diabetes complications, recent heart attacks or other serious acute illness (cancer or surgery) in the previous 4 weks; or an illness requiring corticosteroid therapy **Excluded criteria:** Diabetes complications (gastroparesis, renal disease), recent heart attacks or stroke, other serious, acute illnesses (cancer, or surgery within the previous four weeks), or an illness requiring corticosteroid therapy.
Interventions	**Intervention Characteristics** Control (BC group) Intervention (BGC group)

Outcomes	*Continuous*: ● Body Mass Index (BMI) ● Weight (kg) ● HbA1c (%) ● LDL Cholesterol
Identification	**Sponsorship source:** This research was funded by The American Dietetic Association **Country:** US **Setting:** Outpatient diabetes centers in three states (Minnesota, Florida and Colorado) **Comments:** **Authors name:** Marion J Franz **Institution:** International Diabetes Center **Email:** not stated **Address:** Park Nicollet Medical Foundation, 3800 Park Nicollet Bvld, Minneapolis, MN 55416
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Henning Keinke Andersen* Outcome measures were performed after 6 weeks and 6 months. The outcome table (<12 months) represents values for 6 months **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to make a judgement
Allocation concealment (selection bias)	Unclear risk	Insufficient information to make a judgement
Blinding of participants and personnel (performance bias)	Unclear risk	Neither patient nor personnel were blinded, but unclear whether this will have an impact on the objective reported outcomes.
Blinding of outcome assessment (detection bias)	Low risk	Insufficient information to make a judgement
Incomplete outcome data (attrition bias)	Unclear risk	Drop out rate 18%, but thoroughly expl. Attention to the number of participants monitored for LDL outcome, both at baseline and after 6 mths! However this outcome is not critical.
Selective reporting (reporting bias)	High risk	all outcome reported, but for unknown reasons two of the key outcomes (BMI and Weight) at different times??
Other bias	Unclear risk	Insufficient information to make a judgement

Huang 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Routine care control group ● *Age (SD)*: 56.9 (7.5) ● *Males (%)*: 48.1 ● *Diabetes Duration (years)*: 4.8 (4.5) ● *BMI*: 27.0 (4.7) ● *HbA1c (%)*: 8.4 (1.8) ● *LDL Cholesterol (mmol/l)*: 3.05 (0.84) Intervention Group (On-site diabetic self-management education)

	● *Age (SD)*: 56.6 (8.0) ● *Males (%)*: 38.7 ● *Diabetes Duration (years)*: 4.8 (4.4) ● *BMI*: 25.7 (3.2) ● *HbA1c (%)*: 8.0 (1.5) ● *LDL Cholesterol (mmol/l)*: 3.04 (0.86) **Included criteria:** Patients with newly diagnosed Type 2 Diabetes (by a physician and based upon ADA criteria. **Excluded criteria:** Pregnancy, undergoing dialysis, received an amputation, comorbid blindness, systemic illness such as cancer or cadiovascular disease (MRI or stroke)
Interventions	**Intervention Characteristics** Routine care control group ● *Description*: Patients in the control group received the routine care practiced at their primary care, which may have also included asummary of basic dietary principles by nurses- ● *Duration in weeks*: 52 ● *Lenght of follow-up*: Intervention Group (On-site diabetic self-management education) ● *Description*: Patients in the intervention group, in addition to receiving usual care, received ongoing instruction on the selfmonitoringof glucose, medications, exercise, hygiene (foot care), and complication management from two registered dietitians. ● *Duration in weeks*: 52 ● *Lenght of follow-up*:
Outcomes	*Continuous*: ● Body Mass Index (BMI) ● HbA1c (%) ● LDL Cholesterol
Identification	**Sponsorship source:** This project was supported by grants funded by the NationalHealth Research Institute (96A1-HDPP08-017) of Taiwan) **Country:** Taiwan **Setting:** Diabetes patients from Public Health bureau of Kaohsiung, a city in southern Taiwan **Comments:** Corresponding author: Shyi-Jang Shin

	Authors name: Meng-Chuan Huang **Institution:** Division of Endocrinology and Metabolism, Department of Internal Medicine, Kaohsiung Medical University Hospital, Kaohsiung, Taiwan. **Email:** sjshin@kmu.edu.tw **Address:** Department of Public Health, Faculty of Medicine, Kaohsiung Medical University, Kaohsiung,Taiwan
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Henning Keinke Andersen* LDL cholesterol measured as mg/dl, coverted to mmol/l by dividing the figures by 38.78 - change values after 12 months for control group was 0.0026 +/- 0.94, and for the intervention group -0.15 +/- 0.93 **Dichotomous outcomes:** *Henning Keinke Andersen* Dropouts reported pre-intervention: 21 from the control group and 18 from the intervention group. However, the baseline characteristics did not include these, so the reported figures represent the actual numbers finalising the 12 months (as an ITT analysis) **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Unclear risk	Not sufficient information to permit judgement
Blinding of participants and personnel (performance bias)	Unclear risk	Neither patient nor personnel were blinded, but unclear whether this will have an impact on the objective reported outcomes.
Blinding of outcome assessment (detection bias)	Low risk	Not sufficient information to permit judgement

Incomplete outcome data (attrition bias)	Low risk	drop outs reported pre-treatment. All data from participants at baseline also reported after 12 months
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	None known

Footnotes

Characteristics of excluded studies

Baradaran 2006

Reason for exclusion	Wrong intervention

Battista 2012

Reason for exclusion	Wrong study design

DalmauLlorca 2003

Reason for exclusion	in spanish

Guldbrand 2014

Reason for exclusion	QoL results from primary study from 2012, included in PICO 4

Hiss 2001

Reason for exclusion	Wrong intervention

Lozano 1999

Reason for exclusion	in spanish

Nield 2007

Reason for exclusion	Wrong intervention

Rickheim 2002

Reason for exclusion	unbalanced study

Sturt 2008

Reason for exclusion	waiting list control

Toobert 2007

Reason for exclusion	Wrong outcomes

Trento 2008

Reason for exclusion	Wrong intervention

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Andrews 2011

Andrews RC, Cooper AR, Montgomery AA, Norcross AJ, Peters TJ, Sharp DJ, et al. Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial. Lancet 2011;378(9786):129-39. [PubMed: 21705068]

Franz 1995

Franz MJ, Monk A, Barry B, McClain K, Weaver T, Cooper N, et al. Effectiveness of medical nutrition therapy provided by dietitians in the management of non-insulin-dependent diabetes mellitus: a randomized, controlled clinical trial. Journal of the American Dietetic Association 1995;95(9):1009-17. [DOI: S0002-8223(95)00276-6 [pii]]

Huang 2010

Huang MC, Hsu CC, Wang HS, Shin SJ. Prospective randomized controlled trial to evaluate effectiveness of registered dietitian-led diabetes management on glycemic and diet control in a primary care setting in Taiwan.. Diabetes care 2010;33(2):233-239. [DOI: http://dx.doi.org/10.2337/dc09-1092]

Excluded studies

Baradaran 2006

Baradaran,H. R.; Knill-Jones,R. P.; Wallia,S.; Rodgers,A.. A controlled trial of the effectiveness of a diabetes education programme in a multi-ethnic community in Glasgow [ISRCT28317455].. BMC Public Health 2006;6(Journal Article). [DOI: http://dx.doi.org/10.1186/1471-2458-6-134]

Battista 2012

Battista,M. C.; Labonte,M.; Menard,J.; Jean-Denis,F.; Houde,G.; Ardilouze,J. L.; Perron,P.. Dietitian-coached management in combination with annual endocrinologist follow up improves global metabolic and cardiovascular health in diabetic participants after 24 months.. Applied Physiology, Nutrition, & Metabolism = Physiologie Appliquee, Nutrition et Metabolisme 2012;37(4):610-620. [DOI: http://dx.doi.org/10.1139/h2012-025]

DalmauLlorca 2003

Dalmau Llorca,M. R.; Garcia Bernal,G.; Aguilar Martin,C.; Palau Galindo,A.. [Group versus individual education for type-2 diabetes patients]. Atencion Primaria 2003;32(1):36-41. [DOI:]

Guldbrand 2014

Guldbrand,H.; Lindstrom,T.; Dizdar,B.; Bunjaku,B.; Ostgren,C. J.; Nystrom,F. H.; Bachrach-Lindstrom,M.. Randomization to a low-carbohydrate diet advice improves health related quality of life compared with a low-fat diet at similar weight-loss in Type 2 diabetes mellitus. Diabetes research and clinical practice 2014;(Journal Article). [DOI: S0168-8227(14)00398-2 [pii]]

Hiss 2001

Hiss,R. G.; Gillard,M. L.; Armbruster,B. A.; McClure,L. A.. Comprehensive evaluation of community-based diabetic patients: effect of feedback to patients and their physicians: a randomized controlled trial. Diabetes care 2001;24(4):690-694. [DOI:]

Lozano 1999

Lozano,M. L.; Armale,M. J.; Tena Domingo,I.; Sanchez Nebra,C.. The education of type-2 diabetics: why not in groups?.. Atencion Primaria / Sociedad Espanola de Medicina de Familia y Comunitaria 1999;23(8):485-492. [DOI:]

Nield 2007

Nield,L.; Moore,H. J.; Hooper,L.; Cruickshank,J. K.; Vyas,A.; Whittaker,V.; Summerbell,C. D.. Dietary advice for treatment of type 2 diabetes mellitus in adults. Cochrane Database of Systematic Reviews 2007;(3):004097. [DOI:]

Rickheim 2002

Rickheim,P. L.; Weaver,T. W.; Flader,J. L.; Kendall,D. M.. Assessment of group versus individual diabetes education: a randomized study.. Diabetes care 2002;25(2):269-274. [DOI: http://dx.doi.org/10.2337/diacare.25.2.269]

Sturt 2008

Sturt,J. A.; Whitlock,S.; Fox,C.; Hearnshaw,H.; Farmer,A. J.; Wakelin,M.; Eldridge,S.; Griffiths,F.; Dale,J.. Effects of the Diabetes Manual 1:1 structured education in primary care.. Diabetic Medicine 2008;25(6):722-731. [DOI: http://dx.doi.org/10.1111/j.1464-5491.2008.02451.x]

Toobert 2007

Toobert, D. J.; Glasgow, R. E.; Strycker, L. A.; Barrera Jr, M.; Ritzwoller, D. P.; Weidner, G.. Long-term effects of the Mediterranean lifestyle program: A randomized clinical trial for postmenopausal women with type 2 diabetes. International journal of behavioral nutrition and physical activity 2007;4:1. [DOI: 10.1186/1479-5868-4-1]

Trento 2008

Trento,M.; Basile,M.; Borgo,E.; Grassi,G.; Scuntero,P.; Trinetta,A.; Cavallo,F.; Porta,M.. A randomised controlled clinical trial of nurse-, dietitian- and pedagogist-led Group Care for the management of Type 2 diabetes.. Journal of endocrinological investigation 2008;31(11):1038-1042. [DOI:]

Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

Data and analyses

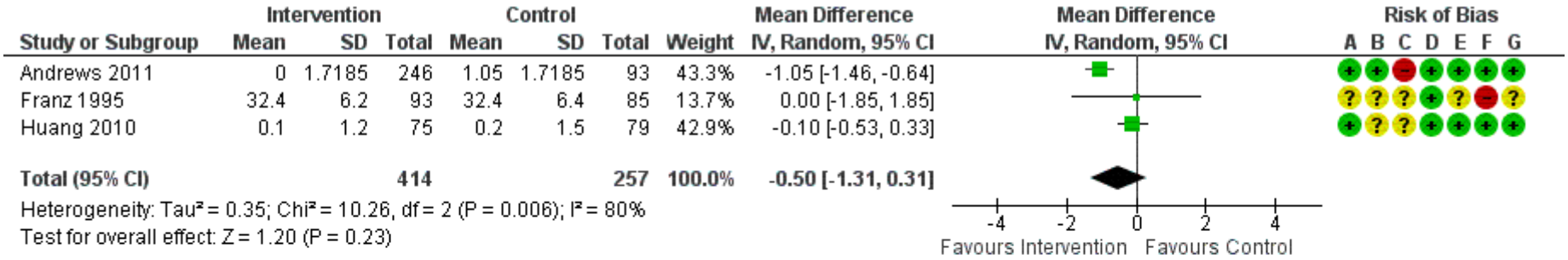
1 Control vs Intervention

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 BMI =< 12 months	3	671	Mean Difference (IV, Random, 95% CI)	-0.50 [-1.31, 0.31]
1.2 Vægt =<12 months	2	518	Mean Difference (IV, Random, 95% CI)	-2.32 [-3.38, -1.26]
1.3 HbA1c (%) =<12 months	3	672	Mean Difference (IV, Random, 95% CI)	-0.30 [-0.45, -0.14]

1.4 LDL =<12 months	3	657	Mean Difference (IV, Random, 95% CI)	-0.11 [-0.24, 0.02]

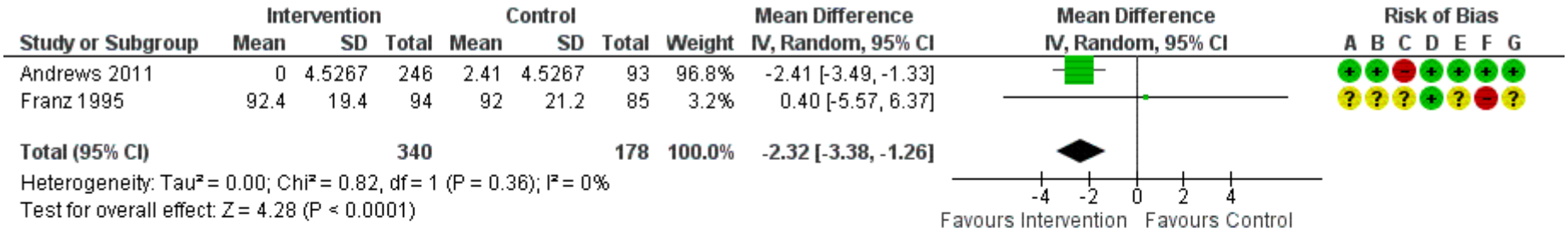
Figures

Figure 1 (Analysis 1.1)



Forest plot of comparison: 1 Control vs Intervention, outcome: 1.1 BMI =< 12 months.

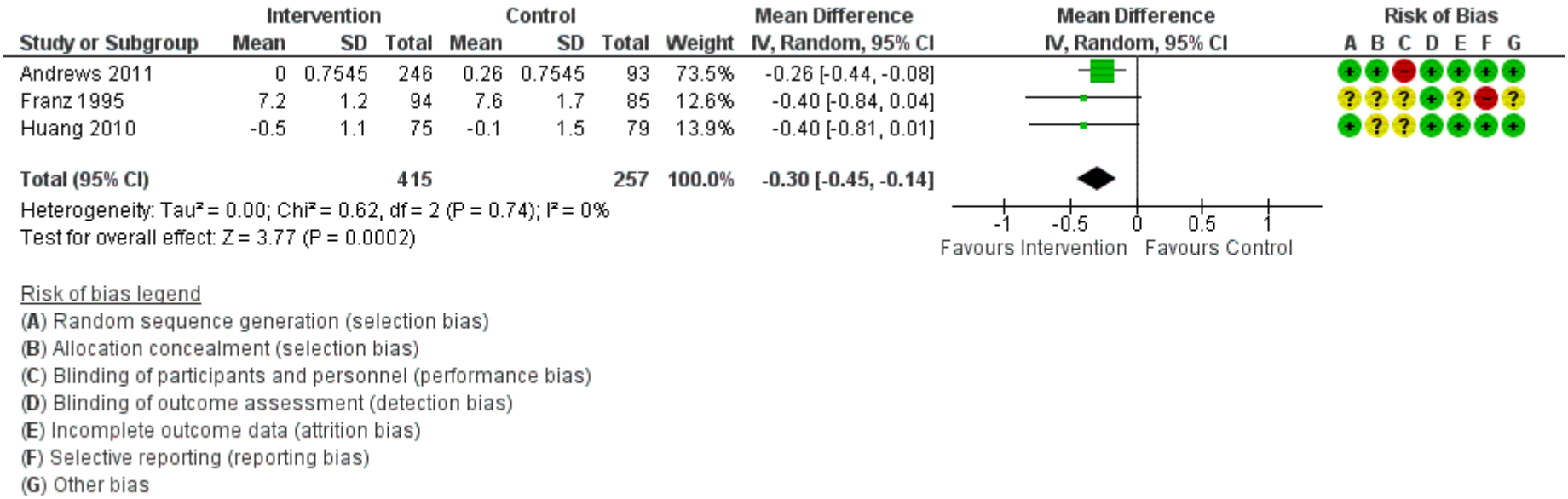
Figure 2 (Analysis 1.2)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Forest plot of comparison: 1 Control vs Intervention, outcome: 1.2 Vægt =<12 months.

Figure 3 (Analysis 1.3)

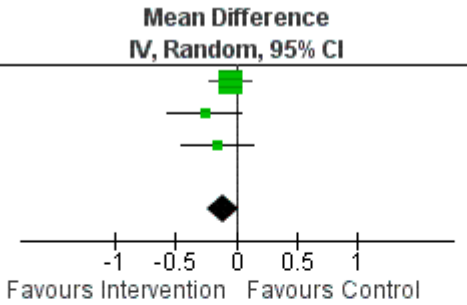


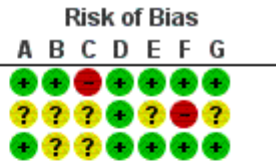
Forest plot of comparison: 1 Control vs Intervention, outcome: 1.3 HbA1c (%) =<12 months.

Figure 4 (Analysis 1.4)

Study or Subgroup	Intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Andrews 2011	0	0.7125	246	0.05	0.7125	93	61.0%	-0.05 [-0.22, 0.12]
Franz 1995	3.25	0.78	89	3.51	1.15	75	18.8%	-0.26 [-0.57, 0.05]
Huang 2010	-0.15	0.93	75	0.003	0.94	79	20.2%	-0.15 [-0.45, 0.14]
Total (95% CI)			**410**			**247**	**100.0%**	**-0.11 [-0.24, 0.02]**

Heterogeneity: Tau² = 0.00; Chi² = 1.48, df = 2 (P = 0.48); I² = 0%
Test for overall effect: Z = 1.63 (P = 0.10)





Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Forest plot of comparison: 1 Control vs Intervention, outcome: 1.4 LDL =<12 months.