PICO1: Bør patienter med type 2 diabetes tilbydes en sammenhængende rehabilitering bestående af sygdomsspecifik patientuddannelse og diætbehandling, med eller uden træningsprogram?

Methods

Criteria for considering studies for this review

Types of outcome measures

Primary outcomes

HbA1c >= 1 år - kritisk
Livskvalitet (QoL) – længste follow-up - kritisk (NB! SF-36 scores for fysisk score og mental score)

Secondary outcomes

Følgende secondære outcomes er vurderet vigtige

BMI >= 1 år
Vægt >= 1 år
HbA1c< 1 år
LDL =< 1 år
Antidiabetisk medicin (tabletbehandling (antal); Insulin (antal))
Antidiabetisk medicin < 1 år (antal præparater, dosis)
komplikationer >= 1 år
Hjertekarsygdom >= 1 år
Frafaldsrate - efter endt forløb

Characteristics of studies

Characteristics of included studies

Adolfsson 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 62.4 (8.9) ● *females (%)*: 43 ● *BMI*: 30.4 (4.3) ● *HbA1c (%)*: 7.4 (1.0) ● *duration of DM*: 6.5 (3.9) usual care ● *age*: 63.7 (9.0) ● *females (%)*: 39 ● *BMI*: 29.6 (3.3) ● *HbA1c (%)*: 7.1 (0.8) ● *duration of DM*: 6.7 (4.2) **Included criteria:** receiving dietary or oral anti-diabetes treatment; <=75 years of age; HbA1c value ranging from 6.5 to 10%; diabetes duration of at least 1 year;considered by the physician and the diabetes specialist nursesat each primary care centre to be able to participate in aneducation group together with other people with diabetes; andable to understand the Swedish language. **Excluded criteria:** known alcohol abuse; known mental disability; presenceof serious disease (stroke, late stage of cancer); patientswho had previously participated in group education

Interventions	**Intervention Characteristics** intervention ● *program*: Each group consisted of at least five patients and at mosteight patients (mean value: 5.6) at the seven primary carecentres. The minimum number of empowerment group educationsessions was four and the maximum was five (meanvalue: 4.7), including one follow-up session given within 7months. The sessions lasted 2.5 h at each centre. usual care ● *program*: All patients, irrespective of participation in the interventionor control group, underwent the same routine diabetescare at their primary care centre. This meant that the patientsusually visited the primary care centres in charge of theirdiabetes twice a year. At these visits, they met their physicianonce and their diabetes specialist nurse once. Biochemicaltests and examinations were performed during thevisits in accordance with regional diabetes guidelines basedon the Swedish National Guidelines. The patients receivedindividual counselling and recommendations based on theresults of the examinations, biochemical tests and their selfmonitoringof blood glucose. They also received renewal ofprescribed medication and test strips for blood glucosemonitoring.
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas

	● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** This study was supported by grants from the SwedishDiabetes Association. **Country:** Sweden **Setting:** **Comments:** **Authors name:** Eva Thors Adolfsson **Institution:** Department of Medical Sciences, Faculty of Medicine, Uppsala University, Uppsala, Sweden **Email:** eva.thors-adolfsson@ltv.se **Address:** Herrgärdets Vårrdcentral, Karlsgatan 17A, SE-722 14 Västerås, Sweden
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Tina Povlsen* QOL (Satisfaction with daily life, difference). This is measured in inter quartile range: Intervention group (n = 42): 2.5 (3.9, 7.5)Control group (n = 46): 0.0 (6.0, 7.5) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A research assistant at the Centre for Clinical Research performed the randomization in blocks of 4 (two assignments to intervention and control groups, respectively) at each of the 7 centres. Only the research assistant was aware of the blocks," Comment: Unclear if randomisation was done randomly

Allocation concealment (selection bias)	Low risk	Quote: "Only the research assistant was aware of the blocks, which were contained in a set of sequentially numbered opaque sealed envelopes. These"
Blinding of participants and personnel (performance bias)	Low risk	Comment: Not described. probably not done but for objective outcomes this is probably not important
Blinding of outcome assessment (detection bias)	Low risk	Comment: Not described. probably not done but for objective outcomes this is probably not important
Incomplete outcome data (attrition bias)	Low risk	Comment: Intention to treat and per protocol analyses have beenperformed. Data are presented per protocol. When the resultsof intention to treat analyses differed from those of the perprotocol analyses it is presented in the text. (And relatively small dropout)
Selective reporting (reporting bias)	Unclear risk	Comment: No trial protocol. Relevant outcome seems assessed.
Other bias	Low risk	Comment: The study appears to be free of other sources of bias.

Cooper 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 59 ● *females (%)*: 44 ● *BMI*: ● *HbA1c (%)*: 8.4 (2.3) ● *duration of DM*: 6 usual care ● *age*: 59 ● *females (%)*: 44 ● *BMI*: ● *HbA1c (%)*: 7.9 (2.2)

	● *duration of DM*: 6 **Included criteria:** All patients had type 2 diabetesdiagnosed for at least 1 year. Theywere undergoing at least annual medical checks related totheir diabetes. **Excluded criteria:** Persistent defaulters, or those with significantalcohol or drug addiction problems were excluded, as werethose with significant disability which would interfere withthe educational process (e.g. blindness or deafness).
Interventions	**Intervention Characteristics** intervention ● *program*: The system of education is known as the ‘‘LAY’’ (Look AfterYourself) programme, and has been described in detailpreviously [9]. It is theoretically constructed on the premisethat knowledge acquisition alone does not necessarilypromote self-directed action. Rather, systems of motivationand the teaching of skills (practical, physical, conceptual,emotional, social and personal) are stressed. A variety ofteaching methods are used, including group discussion, roleplaying,goal-setting, relaxation and skills practice [11]. Theessential components of the programme are shown in Table 1,and the course was delivered by trained leaders, in 2-hoursessions weekly for 8 weeks. The course leaders wereexperienced and qualified diabetes specialist nurses, trainedin the LAY programme by one of the authors (HC). A uniquefeature of the LAY programme was the use of ‘‘DiabetesBoxes’’, designed by one of us (HC) in conjunction with anartist [12,13]. These were 3-dimensional cubes with specificthemes—living with diabetes, changing behaviour, and preventingcomplications. They included specific illustrationsaimed to visually challenge and to stimulate debate, e.g. ahealthy and unhealthy artery, depicted as a waterfall and astagnant pool respectively. They were used to stimulate groupdiscussion, help understanding of the biological and psychologicalconcepts relating to diabetes, and to aid articulation ofemotional responses to diabetes. usual care ● *program*: usual medical care
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%)

	● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** We are grateful to Diabetes UK who funded this research **Country:** UK **Setting:** **Comments:** **Authors name:** Helen Cooper **Institution:** Faculty of Health & Social Care, Department of Community & Child Health, University of Chester,Chester United Kingdom **Email:** g.gill@liv.ac.uk **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* Der er opgivet BMI i studiet men den eneste usikkerhed i forbindelse med værdien er et "NS" **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Not described
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably not blinded but outcome objective
Blinding of outcome assessment (detection bias)	Low risk	Comment: Not describedProbably not blinded but outcome objective
Incomplete outcome data (attrition bias)	Low risk	Quote: "A total of 11 failed to complete the programme (12%). This included 5 deaths, and the remaining 6 were not able to complete because of time constraints. Of the remaining, 76% attended at least 7 of the 8 educational sessions, with the commonest reason for non-attendance being illness." Comment: Relatively small equal dropout
Selective reporting (reporting bias)	High risk	
Other bias	Low risk	

Davies 2008

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Deakin 2006

Methods	**Study design:** **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: ● *females (%)*: ● *BMI*: ● *HbA1c (%)*: ● *duration of DM*: usual care ● *age*: ● *females (%)*: ● *BMI*: ● *HbA1c (%)*: ● *duration of DM*:

	Included criteria: **Excluded criteria:**
Interventions	**Intervention Characteristics** intervention ● *program*: usual care ● *program*:
Outcomes	*Continuous*: ● BMI ● vægt (kg) ● HbA1c (%) ● LDL ● QoL VAS ● QoL PCS (SF-36) ● QoL MCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health *Dichotomous*: ● antal i po behandling ● antal i insulin ● frafald antal *Adverse Events*: ● Death from CVD ● death from any cause ● myocardial infarction ● any new or worse microvas ● stroke ● other adverse event

Identification	**Sponsorship source:** **Country:** UK **Setting:** **Comments:** **Authors name:** **Institution:** **Email:** trudi.deakin@nhs.net **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Mette Sonne* QoL data from study noted as QoL VAS in table **Dichotomous outcomes:** *Ole Snorgaard* 16% of patient in intervention reduced medication compared to 1% in controls. 21% increased medication in intervention against 46 in control *Mette Sonne* Only medicine increase/decrease or if unchanged is mentioned. No information regarding what type of medicaion. **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and personnel (performance bias)		
Blinding of outcome assessment (detection bias)		

Incomplete outcome data (attrition bias)		
Selective reporting (reporting bias)		
Other bias		

Gabbay 2006

Methods	**Study design:** **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 65 (12) ● *females (%)*: 43 ● *BMI*: 33 (8) ● *HbA1c (%)*: 7.4 (1.4) ● *duration of DM*: 10 (9) usual care ● *age*: 64 (20) ● *females (%)*: 48 ● *BMI*: 34 (8) ● *HbA1c (%)*: 7.36 (1.5) ● *duration of DM*: 9 (8) **Included criteria:** patients with diabetes, age18 or over, were identified by ICD 9 encounter codes(two or more visits for diabetes within the last year). **Excluded criteria:** Patients unable to speak English and residents ofnursing homes were not eligible for participation inthe study
Interventions	**Intervention Characteristics** intervention ● *program*: The nurse case manager was a registered nurse,associate of applied sciences (AAS) who was trainedat

	the Penn State Diabetes Center through a series ofseminars with a dietitian, a certified diabetes nurseeducator and an endocrinologist. The nurse implementedspecific diabetes management algorithmsunder the supervision of the patient's primary carephysician (PCP) (a family physician or an internist).Goals were based on the ADA recommendations [7]:BP < 130/80 mmHg, LDL < 100, A1C < 7.0, quarterlyA1C measurement, biannual lipid measurement,yearly opthalmological and monofilament exam,microalbumin/creatinine ratio, flu vaccine, appropriatePnemovax immunization, certified diabetes nurseeducator and dietician visits.The nurse case manager used behavioral goalsetting, established individualized care plan, providedpatient self-management education and surveillanceof patients, including phone calls to patients, referredpatients to a certified diabetes nurse educator or adietitian where appropriate, ordered protocol-drivenlaboratory tests, tracked the outcomes using thecomputerized data registry and made therapeuticrecommendations based on ADA diabetes guidelines with approval of PCP. usual care ● *program*: The control group receivedongoing usual care by their PCP, and had nointeraction with the nurse case manager.
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction

	● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** Not described **Country:** US **Setting:** **Comments:** **Authors name:** Robert A. Gabbay **Institution:** The Penn State College of Medicine, Penn State Diabetes Center, Department of Endocrinology, Diabetes and Metabolism, 500 University Drive, HO44, Hershey, PA 17033, USA **Email:** rgabbay@psu.edu **Address:** Endocrinology Department, Reading Hospital, Reading, 19601, PA, USA
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Tina Povlsen* Weigt is measured in pund:Intervention:6 mounth: 205 (47) 12 mount 207 (47)Control: 6 mounth: 201 (46) 12 mount 202 (47) *Elisabeth Ginnerup-Nielsen* Vægt (LBS) changed to kg LDL mg/dl changed to mmol/l via http://www.endmemo.com/medical/unitconvert/Low-density_lipoprotein_cholesterol.php **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A total of 332 patients were randomized (by method of odd and even numbers)"
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably not blinded but outcomes are objective
Blinding of outcome assessment (detection bias)	Low risk	Comment: Not described. probably not done but for objective outcomes this is probably not important
Incomplete outcome data (attrition bias)	Unclear risk	Comment: Dropout not described no intention to treat.
Selective reporting (reporting bias)	High risk	Comment: No trial protocol. Strange that QOL scores are only for the interevtnion group. Also unclearly reported!
Other bias	Low risk	

Goudswaard 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 62.6 (9.0) ● *females (%)*: 48 ● *BMI*: 30.2 (4.4) ● *HbA1c (%)*: 8.2 (1.1) ● *duration of DM*: 7.3 (5.0) usual care ● *age*: 58.7 (11.4) ● *females (%)*: 56

	● *BMI*: 29.8 (5.5) ● *HbA1c (%)*: 8.8 (1.5) ● *duration of DM*: 7.6 (3.8) **Included criteria:** patients under age 76 years and with HbA1c≥ 7.0%, oral medication was optimized [8]. After this optimization,76 patients had HbA1c≥ 7.0% while taking the maximumfeasible dosages of two different oral hypoglycaemic agents,mostly sulphonylurea and metformin. These patients were eligiblefor the present study. **Excluded criteria:** severecomorbidity (defined as having an illness that surpasses the impactof diabetes); insufficient understanding of spoken Dutch tofollow instructions; or requirement for insulin therapy in theshort term on account of severe hyperglycaemic symptoms.
Interventions	**Intervention Characteristics** intervention ● *program*: a collaborative, 'mixed' educational intervention [5],and was provided by two skilled diabetes nurses in one-to-one sessions. It focused on: general information on diabetes; reinforcingcompliance with actual medication; importance ofphysical exercise and losing body weight; and nutritionaladvice. All patients were also taught how to control their bloodglucose at home on a regular basis, for which they were given ablood glucose meter (Glucotouch; Lifescan Benelux, Beerse,Belgium) and necessary materials (reagent strips, lancets).During the 6-month period, six sessions were given, at intervalsof 3–6 weeks. The sessions were intended to take between15 and 45 min, resulting in a total contact time of approximately2.5 h. usual care ● *program*: remained under the care of their GP,and were managed according the current Dutch guideline onType 2 diabetes [9]. This guideline recommends 3-monthly reviews,focusing on diabetic symptoms and measurement of fastingblood glucose, with education being given during normalmedical appointments. During the 6-month intervention periodthe GP was asked not to refer the patient to a diabetes nurse.Furthermore, the GP was instructed not to alter the medication,unless a patient developed severe hyperglycaemic symptoms.
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI

	● vægt (kg) ● HbA1c (%) ● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** This study was supportedby an unrestricted research grant from Novo NordiskPharma. **Country:** The Netherlands **Setting:** **Comments:** **Authors name:** Alex N. Goudswaard **Institution:** Julius Centre for Health Sciences and Primary Care **Email:** lex@goudswaard.cx **Address:** Julius Centre for Health Sciences andPrimary Care, PO Box 80560, 3508 AB Utrecht, the Netherlands.
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* > 1 år svarer her til 18 mdr. **Dichotomous outcomes:**

	Elisabeth Ginnerup-Nielsen **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was done by a telephone call to an independent trial centre, which used a computer-generated random assignment with blocks of eight at a time."
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was done by a telephone call to an independent trial centre,"
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "Moreover, since this was an unblinded study and randomization was done on a patient level, in the control group patients as well as doctors have become increasingly aware of the issue of tighter control and started acting upon it. This may have diminished the effect of the intervention." Comment: It is noteworthy that glycaemic control in the control groupgradually improved during the study (Fig. 2). This might be aregression-to-the-mean effect [15]. Moreover, since this wasan unblinded study and randomization was done on a patientlevel, in the control group patients as well as doctors havebecome increasingly aware of the issue of tighter control andstarted acting upon it. (Interessant-normalt ville jeg sige at det ingen betydning havde for resultatet når outcomes er objektive)
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "Moreover, since this was an unblinded study and randomization was done on a patient level, in the control group patients as well as doctors have become increasingly aware of the issue of tighter control and started acting upon it. This may have diminished the effect of the intervention. Further"
Incomplete outcome data (attrition bias)	Low risk	Quote: "Analyses were based on intention to treat, with the last value carried forward for missing data. Ineligible patients mistakenly randomized, and patients who withdrew before the start of the intervention, were excluded from analysis [10]."
Selective reporting (reporting bias)	Unclear risk	Comment: No trial protocol
Other bias	Low risk	

Heller 1988

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** YES **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 56.5 (55.0--58.0) ● *females (%)*: 44 ● *BMI*: 31.2 (30.2-32.2) ● *HbA1c (%)*: 12.3 (11.4-13.2) ● *duration of DM*: usual care ● *age*: 56.4 (53.0-59.9) ● *females (%)*: 59 ● *BMI*: 32.0 (30.8-33.2) ● *HbA1c (%)*: 12.7 (11.9-13.5) ● *duration of DM*: **Included criteria:** BMI >27 kg m-2) 30-75 years old. Random blood glucose over 11 mmol 1 -1 in symptomatic patients or a blood glucose over 11mmol 1-1 2 h after a 75 g oral glucose load in those who were asymptomatic. **Excluded criteria:** Ketonuria, Diabetes diagnosis made as an inpatient.Use of any type of glucose lowering drug
Interventions	**Intervention Characteristics** intervention ● *program*: Patients were advised to exclude sugar from their diet.Group of 4 to 6 patients, each with a spouse or friend, attended 3 90-mi n sessions, weekly interval, follow up visits (90 min) at 3 and 6 months. Sessions were run by diabetes nurse and one dietitian. After 6 months no visits scheduled, but the nurses could be contacted at any time. usual care ● *program*: First visit by a doctor, then referred to a dietitian who saw them individually as often as nessecary. Visits at 3, 6 and 12 rnonths were rnandatory for study outcomes.

Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** Boehringer Corporation, Lewes, UK and British Diabetic Association **Country:** UK **Setting:** Hospital, out patient clinic **Comments:** **Authors name:** S. R. Heller, P. Clarke, H. and Daly, I. et. al. **Institution:** Diabeles Unit, Depart menl ol Medicine, Universily Hospilal, Nollingham, UK **Email:** **Address:** Heller, Diabetes Unit, Department of Medicine, C Floor, South Block, University Hospital, Queen's Medical Centre,Nottingham, NG7 2UH, UK.

Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Tina Povlsen* HbA1 was rapported in median and inter quartile range.Intervention:6 mounth: 7.5 (7.0-8.1) 12 mounth: 9.0(8.2-9.8)n: 36Control:6 mounth: 9.5 (8.7-10.4) 12 mounth: 9.9(8.9-10.9)n: 39 **Dichotomous outcomes:** *Mette Sonne* The groups studied were on diet alone, no glucose lowering drugs allowed **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Eligible patients were randomized to receive usual clinic care or to attend group education classes"
Allocation concealment (selection bias)	Unclear risk	Comment: no mention in text
Blinding of participants and personnel (performance bias)	High risk	Comment: no mention i the text but the subjects could possibly not be blinded.
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Not described, problably no blinding, however problably no influences in outcome
Incomplete outcome data (attrition bias)	High risk	Comment: drop outs and reason for drop out mentioned. Only completers included in the analysis. No intention to treat.
Selective reporting (reporting bias)	Unclear risk	Comment: No available study protocol, however all outcomes are rapported
Other bias	Unclear risk	

Hornsten 2005

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:** YES
Participants	**Baseline Characteristics** intervention ● *age*: 63.6 (9.3) ● *females (%)*: 48 ● *BMI*: 29.4 (4.7) ● *HbA1c (%)*: 5.7 (0.8) ● *duration of DM*: usual care ● *age*: 63.4 (9.1) ● *females (%)*: 45 ● *BMI*: 29.9 (4.1) ● *HbA1c (%)*: 5.8 (0.7) ● *duration of DM*: **Included criteria:** All of their patients (aged 40–80 years) who, according to computerized patientrecords, had been diagnosed with type 2 diabetesduring the previous 2 years were identified (n = 257). **Excluded criteria:** a psychiatric diagnosis, dementia, alcoholism or otherdrug addiction; a severe somatic or disabling diagnosis(e.g. final-stage cancer, reduced perception such asdeafness or blindness); and inability to speak Swedish.
Interventions	**Intervention Characteristics** intervention ● *program*: Ten group sessions of 2 hours each over 9 mounths addressing themes related to the patients' personal understanding their illness usual care ● *program*: The patients in the control groupbelonging to other health care centres continuedreceiving their regular 1–2 visits/year with theirrespective diabetes nurses.

Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL ● Longest follow-up (final value) *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** This study was funded by the Swedish DiabetesAssociation, the County Council of Va¨sterbotten, andthe Medical Faculty of Umea° University, Umea°,Sweden. **Country:** Sweden **Setting:** **Comments:** **Authors name:** Åsa Hörrnsten **Institution:** Department of Nursing, Umeå University, Umeå 90187, Sweden **Email:** asa.hornsten@nurs.umu.se **Address:**

Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Elisabeth Ginnerup-Nielsen* longst f.u. 5 years *Tina Povlsen* Longest follow-up is 5 years **Dichotomous outcomes:** *Elisabeth Ginnerup-Nielsen* Frafald er frafald ved længste follow - up (5 years) **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: unclear how random
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably not blinded but outcome is objective
Blinding of outcome assessment (detection bias)	Low risk	Comment: Not descibed. Outcome objective
Incomplete outcome data (attrition bias)	Unclear risk	Comment: 4/44 dropouts in intervention and 1/60 in the control group. 5 years f.u. 5 and 10 respectively. Ikke så stort dropout, men de burde have lavet intention to treat
Selective reporting (reporting bias)		Comment: No trial protocol
Other bias	Low risk	

Jansink 2013

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Ko 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**

Participants	**Baseline Characteristics** Structured health education programme by a trained diabetic education nurse. The nurse concentrated on the major CVD risk factors ● *age*: 55.0 ± 9.0 ● *females (%)*: 51.1 ● *BMI*: 25.4 ± 3.9 ● *HbA1c (%)*: 8.6 ± 1.6 ● *duration of DM*: Usual medical care ● *age*: 56.0 ± 10.2 ● *females (%)*: 61.4 ● *BMI*: 25.7 ± 3.9 ● *HbA1c (%)*: 8.4 ± 1.2 ● *duration of DM*: **Included criteria:** The inclusion criterion included poor glycaemic control[glycated haemoglobin (HbA1c)≥ 8–11%] and age range 35 to70 years. Patients were recruited irrespective of their anti-diabetic,anti-hypertensive or lipid-lowering medication regimens. **Excluded criteria:** Not described
Interventions	**Intervention Characteristics** Structured health education programme by a trained diabetic education nurse. The nurse concentrated on the major CVD risk factors ● *program*: The Group were seen by their physicians an briefly told of the importance of CVD risk factors. They were then seen by the education nurse for further explanation. After every follow-up by the physicians, participants visited the education nurse for reinforcement. Each education session lasted for about 30 min. With five visits for each subject within the study period, the average education time was 2.5 hours. The education intervention was conducted by the same nurse throughout the Whole study in all the three centres. The pronciples of the education process included: a structured curriculum, regular reminders of important messages, a one-to-one session imediately after each physician consultation, motivation enhancement by good documentation of Progress (clinical and biochemical data) and feedback, use of educational aterials including pamphlets, stories book, accesories (e.g. anti-smoking stickers etc)) Usual medical care

	● *program*: Same Medical care as intervention Group, except no nursing reinforcement.
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** Not described **Country:** Kina **Setting:** **Comments:** **Authors name:** G. T. C. Ko **Institution:** Department of Medicine, AH Nethersole Hospital, Hong KOng **Email:** gtc_ko@hotmail.com **Address:** Gary T. C. Ko, Department of Medicine, AH Nethersole Hospital, 11, Chuen On Road, Tai Po, NT, Hong Kong

Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Randomization was done by coin-tossing s. 1275. Should be fine but The greater number of men and smokers in the intervention Group may be due to `suboptimal` randomization s. 1278
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably No blinding of participants or personnel not but outcomes are objective
Blinding of outcome assessment (detection bias)	Low risk	Comment: Some blindingand outcomes are objective Quote: "Each participant's cardiovascular status and any CVD risk factors were recorded by the educator (at the end of the study in the controls). The physicians were blind to which group the patients belonged to." Comment: Some blinding
Incomplete outcome data (attrition bias)	Unclear risk	Comment: No intention to treat - apparantly no dropout but even in China this seems strange!
Selective reporting (reporting bias)	Unclear risk	
Other bias	Low risk	

Piatt 2006

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:** YES
Participants	**Baseline Characteristics** intervention ● *age*: 69.7 (10.7) ● *females (%)*: 50 ● *BMI*: ● *HbA1c (%)*: 7.6 ● *duration of DM*: 10.3(8.4) usual care ● *age*: 68.6(8.6)50 ● *females (%)*: 41.2 ● *BMI*: ● *HbA1c (%)*: 6.9 ● *duration of DM*: 13.1(10.9) **Included criteria:** Diabetes conformend by lab data (high fasting glucose, high random glucose, HbA1c > 7%) or the use of diabetes medications **Excluded criteria:** Not mentioned
Interventions	**Intervention Characteristics** intervention ● *program*: six diabetes self-management training sessions and monthly support groups held until the time of their 1-year follow-up usual care ● *program*:

Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL ● WHO-QWB10 *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** **Country:** US **Setting:** general, family, and internal medicine practices **Comments:** **Authors name:** Piatt, Trevor and Emerson et.al. **Institution:** Department of Epidemiology and Diabetes Center and Medical Center,University of Pittsburgh, Pittsburg, **Email:** piattg@upmc.edu **Address:** Kaufmann Building, Suite 601, 3471 Fifth Ave., Pittsburgh, PA 15213.

Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Mette Sonne* Diabetes empowerment scale score noted as SF-36 mental health **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "prac- tices were randomized into one of three study groups (Fig. 1). An initial block ran- domization procedure was undertaken, with practice size"
Allocation concealment (selection bias)	Unclear risk	Comment: no mention of concealment of sequence
Blinding of participants and personnel (performance bias)	High risk	Comment: not blinded
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: Not described, problably not done, however will problably not influence outcome.
Incomplete outcome data (attrition bias)	High risk	Comment: Numbers in each group mentioned compared with total number of randomized. Reasons for drop out mentioned. No mention of how/ or if drop outs were included in the analysis eg. intention to treat. Attrition is mentioned with a greater than 75 % attending more than 75% of the sessions.
Selective reporting (reporting bias)	Unclear risk	Comment: No study proctocol available, however all outcome are presented.
Other bias	Unclear risk	

Sarkadi 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention ● *age*: 66.4 (7.9) ● *females (%)*: ● *BMI*: 27.2 (3.6) ● *HbA1c (%)*: 6.4 ● *duration of DM*: 5.9 5.8 usual care ● *age*: 66.5 (10.7) ● *females (%)*: ● *BMI*: 28.6 (5.8) ● *HbA1c (%)*: 6.5 ● *duration of DM*: 2.6 2.2 **Included criteria:** Two inclusion criteria for registeringpersons applying for participation were used: participantshad to be diagnosed with Type 2 diabetes and, if treatedwith insulin, only for 2 years or less. **Excluded criteria:** The exclusion of persons with long-term insulin treatmentwas determined based on reports from the study circleleaders who felt that dietary and exercise interventions didnot lead to immediately demonstrable effects for this groupof participants.
Interventions	**Intervention Characteristics** intervention ● *program*: The intervention was a 12-month long group educationalprogram led by specially trained pharmacists, assisted bya diabetes nurse specialist on the first two occasions.Throughoutthe course the pharmacists monitored their blood-glucoselevels, did the shopping for lunch and snacks, preparedmeals, and went on walks after meals to test the effects Throughoutthe course the pharmacists monitored their blood-glucoselevels, did the shopping for lunch and snacks, preparedmeals, and went on walks after meals to test the effects. The educational materialsused

	were identical to what the pharmacists wereto use with program participants: a video on how to “livewell” with diabetes, exemplifying lifestyle changes madeby those interviewed; a dice game where questions had tobe answered, but where no set answers were available, buthad to be negotiated by players; and a booklet or guideon “how to manage your diabetes”, using the metaphor ofa rowboat, which is first difficult and scary to control, butwith time possible to master. The booklet also containedlogs of imaginary people who had some typical faults intheir diet or treatment and were used to stimulate discussionof more appropriate routines. The book further includedinformation about diabetes complications (including bothfemale and male sexual dysfunction) and a personal planfor follow-up visits. The pharmacists were instructed notto intervene with participants’ medical regimens, but referthem to their medical team when glucose control seemedunsatisfactory despite adequate diet and exercise. Continuousback-up and support was provided to the pharmacistswith regular follow-up group meetings every 6 months. Thepharmacists also kept a diary for each participant to recordtheir learning experience throughout the program.The goal of the educational program was to reinforcethe participants’ experiences and use these experiences asa basis for the acquisition of practical skills needed forself-management of diabetes. usual care ● *program*: The control group was assigned to a waiting list of 2 years. Then they were invited to participate in the educationalprogram.
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL ● HbAc1 (%) *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin

	Adverse Events: ● Death from CVD ● any new or worse microvas ● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** This study was supported by the Swedish Foundationfor Health-care Sciences and Allergy Research Grant No.V2000 225, the National Corporation of Swedish Pharmacies,and Uppsala University. Funding for the first author,Anna Sarkadi, have been thankfully received from the Knutand Alice Wallenberg Foundation in Stockholm, Sweden,grant nr. KAW 2001.0303. **Country:** Sweden **Setting:** **Comments:** **Authors name:** Anna Sarkadi **Institution:** Department of Public Health and Caring Sciences, Uppsala University, Uppsala Science Park, Uppsala SE-751 85, Sweden **Email:** Anna.Sarkadi@pubcare.uu.se **Address:**
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "For those participants eligible for randomisation, the in- formed consent sheet and the questionnaire were put into an unmarked envelope, one for each participant. The identical envelopes were then put into a box. Each time 20 complete sets of participant items were collected, randomisation was performed. An assistant mixed the envelopes in the box, took them out one at a time, and randomly placed them into two piles. A"
Allocation concealment (selection bias)	Low risk	Quote: "third person, acting as a witness, pointed out which pile should be allocated to the intervention group and which" Quote: "pile to the control group. Each participant was then assigned a code, beginning with a different letter for the intervention (I) and control (C) groups."
Blinding of participants and personnel (performance bias)	Low risk	Comment: Not described, problably not done, however outcome is not likely to be influenced by this
Blinding of outcome assessment (detection bias)	Low risk	Comment: Not described, problably not done, however outcome is not likely to be influenced by this
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	High risk	Comment: No study protocol. Very hard to read the numbers in the graph. There is uncertainty in reading the. numbers
Other bias	Low risk	Quote: "This selection procedure introduced a systematic bias in the sample, pre- sumably resulting in persons motivated to improve diabetes self-management. This observation also provides a probable explanation for the rather low mean initial HbA 1c of partic- ipants, with 52% under the WHO target value of 6.5% [20], which can be compared with a proportion of ~ 40% in a national sample of 10,000 persons [21]. On the other hand, randomisation occurred after the recruitment of participants so the bias, if any, was equally present for both intervention and control groups."

Scain 2009

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Shibayama 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**

Participants	**Baseline Characteristics** intervention ● *age*: 61(8) ● *females (%)*: 34.8 ● *BMI*: 25(6) ● *HbA1c (%)*: 7.3 (0.8) ● *duration of DM*: 10 usual care ● *age*: 62(7) ● *females (%)*: 34.8 ● *BMI*: 26(5) ● *HbA1c (%)*: 7.4 (0.7) ● *duration of DM*: 13 **Included criteria:** We enrolled adults between ages 20 and 75 years who wereoutpatients seen atDepartment of Diabetes and Metabolism, theUniversity of Tokyo Hospital, and who were diagnosed withtype 2 diabetes, and who had HbA1C values between 6.5% and8.5% on an average in three tests assessed within recent 3months, and who could not use insulin. **Excluded criteria:** Subjects were requiredto have neither serious ongoing illness nor cognitive disorder
Interventions	**Intervention Characteristics** intervention ● *program*: received both habitual medical consultation and one-to-onecounseling with a Certified Expert Nurse (CEN) in diabetesnursing (Author, AT) at monthly hospital visit for 1 year. Theymet the CEN in the exclusive compartment during waitingtime at hospital. The key features of the CEN counseling areassessment, patient participation in goal setting, selectingpersonalized strategies to overcome barriers and follow-upincluding evaluation and problem solving. During the counseling,the CEN assessed the patient's eating patterns, level ofphysical activity, adherence to medication, level of self-carefor diabetic complications, and management of daily stress.Based on this information, she established the patient currentlifestyle, identified the most problematic areas, and identifiedthe patient's barriers to making lifestyle changes. Using thetechniques of attentive listening and empathy, a personalizedprogramme was formulated in which realistic manageablegoals for lifestyle change are negotiated, and specific interventionstrategies to decrease barriers to change and empowerthe patient to change are developed. If necessary, relevanteducational materials of the CEN's own making and printedlaboratory results were also provided. This counseling took8–76 min (median, 25 min).

	usual care ● *program*: Control patients continued to receive usual care. They wereseen by the same physicians in charge of patients in theintervention group. Physicians did not know which patientsserved as control subjects for this study. Main outcome measures were changes
Outcomes	*Continuous*: ● QoL MCS (SF-36) ● QoL VAS ● QoL PCS (SF-36) ● SF-36 Physical function ● SF-36 Mental health ● BMI ● vægt (kg) ● HbA1c (%) ● LDL ● BMI ● HbA1c ● Physical function (SF-36) ● Role-physical (SF-36) ● Bodily pain (SF-36) ● General health (SF-36) ● Vitality (SF-36) ● Social function (SF-36) ● Role-emotional (SF-36) ● Mental health (SF-36) *Dichotomous*: ● frafald antal ● antal i po behandling ● antal i insulin *Adverse Events*: ● Death from CVD ● any new or worse microvas

	● myocardial infarction ● other adverse event ● death from any cause ● stroke
Identification	**Sponsorship source:** This study was supported by theMinistry of Health, Labour, and Welfare ScientificResearch Grants in FY2003, and by Japanese NursingAssociation in FY2004. **Country:** Japan **Setting:** **Comments:** **Authors name:** Taiga Shibayama **Institution:** Institute of Nursing Science, Graduate School of Comprehensive Human Sciences, University of Tsukuba **Email:** taiga@md.tsukuba.ac.jp **Address:** Institute of Nursing Science, Graduate School of Comprehensive Human Sciences, University of Tsukuba,1-1-1 Tennoudai, Tsukuba-shi, Ibaraki 305-8575, Japan
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Tina Povlsen* *Elisabeth Ginnerup-Nielsen* 95% CI i Role Physical er ændret. I teksten står den som - 6 (13;1) den er ændret til -6 (-13; 1) **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Not described
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	High risk	Comment: probably none - QOL scores subjective
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Physicians did not know which patients served as control subjects for this study." Comment: QOL scores selfreported and other outcomes objective
Incomplete outcome data (attrition bias)	Unclear risk	Comment: No intention to treat analysisRelatively small dropout but itt should have been done
Selective reporting (reporting bias)	Unclear risk	Comment: No trial protocol
Other bias	Low risk	

Sperl Hillen 2011

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Wing 2013

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	
Allocation concealment (selection bias)	Unclear risk	
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	

Selective reporting (reporting bias)	Unclear risk	
Other bias	Unclear risk	

Footnotes

Characteristics of excluded studies

Hiss 2001

Reason for exclusion	Wrong intervention

Hornsten 2008

Reason for exclusion	followup study

Trento 2001

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

Adolfsson 2007

Adolfsson ET, Walker-Engstrom ML, Smide B, Wikblad K.. Patient education in type 2 diabetes: a randomized controlled 1-year follow-up study.. Diabetes Research & Clinical Practice 2007;76(3):341-50. [DOI: S0168-8227(06)00424-4 [pii]]

Cooper 2008

Cooper H, Booth K, Gill G. A trial of empowerment-based education in type 2 diabetes-Global rather than glycaemic benefits.. Diabetes research and clinical practice 2008;82(2):165-71. [DOI: http://dx.doi.org/10.1016/j.diabres.2008.07.013]

Davies 2008

Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Cradock S, et al. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. BMJ 2008;336(7642):491-5.

Deakin 2006

Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the diabetes X-PERT Programme makes a difference.. Diabetic Medicine 2006;23(9):944-54. [DOI: http://dx.doi.org/10.1111/j.1464-5491.2006.01906.x]

Gabbay 2006

Gabbay RA, Lendel I, Saleem TM, Shaeffer G, Adelman AM, Mauger DT, et al.. Nurse case management improves blood pressure, emotional distress and diabetes complication screening.. Diabetes research and clinical practice 2006;71(1):28-35. [DOI: http://dx.doi.org/10.1016/j.diabres.2005.05.002]

Goudswaard 2004

Goudswaard AN, Stolk RP, Zuithoff NPA, De Valk HW, Rutten GEHM. Long-term effects of self-management education for patients with Type 2 diabetes taking maximal oral hypoglycaemic therapy: A randomized trial in primary care.. Diabetic Medicine 2004;21(5):491-6. [DOI: http://dx.doi.org/10.1111/j.1464-5491.2004.01153.x]

Heller 1988

Heller SR, Clarke P, Daly H, Davis I, McCulloch DK, Allison SP, et al.. Group education for obese patients with Type 2 diabetes: Greater success at less cost.. Diabetic Medicine 1988;5(6):552-6. [DOI:]

Hornsten 2005

Hornsten A, Lundman B, Stenlund H, Sandstrom H. Metabolic improvement after intervention focusing on personal understanding in type 2 diabetes. Diabetes research and clinical practice 2005;68(1):65-74. [DOI: S0168-8227(04)00262-1 [pii]]

Jansink 2013

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Sarkadi A, Rosenqvist U. Experience-based group education in Type 2 diabetes: a randomised controlled trial. Patient Education and Counseling 2004;53(3):291-8. [DOI: 10.1016/j.pec.2003.10.009 [doi]]

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Scain SF, Friedman R, Gross JL. A structured educational program improves metabolic control in patients with type 2 diabetes: a randomized controlled trial. Diabetes Education 2009;35(4):603-11.

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Shibayama T, Kobayashi K, Takano A, Kadowaki T, Kazuma K. Effectiveness of lifestyle counseling by certified expert nurse of Japan for non-insulin-treated diabetic outpatients: a 1-year randomized controlled trial.. Diabetes Research & Clinical Practice 2007;76(2):265-8. [DOI:

http://dx.doi.org/10.1016/j.diabres.2006.09.017]

Sperl Hillen 2011

Sperl-Hillen J, Beaton S, Fernandes O, Von Worley A, Vazquez-Benitez G, Parker E, et al.. Comparative effectiveness of patient education methods for type 2 diabetes: a randomized controlled trial. Archives of Internal Medicine 2011;171(22):2001-10.

Wing 2013

Wing RR, Bolin P, Brancati FL, Bray GA, Clark JM, Coday M, et al.. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. New England Journal of Medicine 2013;369(2145-54).

Excluded studies

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:]

Hornsten 2008

Hornsten,A.; Stenlund,H.; Lundman,B.; Sandstrom,H.. Improvements in HbA1c remain after 5 years--a follow up of an educational intervention focusing on patients' personal understandings of type 2 diabetes. Diabetes research and clinical practice 2008;81(1):50-55. [DOI: 10.1016/j.diabres.2008.02.005 [doi]]

Trento 2001

Trento,M.; Passera,P.; Tomalino,M.; Bajardi,M.; Pomero,F.; Allione,A.; Vaccari,P.; Molinatti,G. M.; Porta,M.. Group visits improve metabolic control in type 2 diabetes: a 2-year follow-up.. Diabetes care 2001;24(6):995-1000. [DOI:]

Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

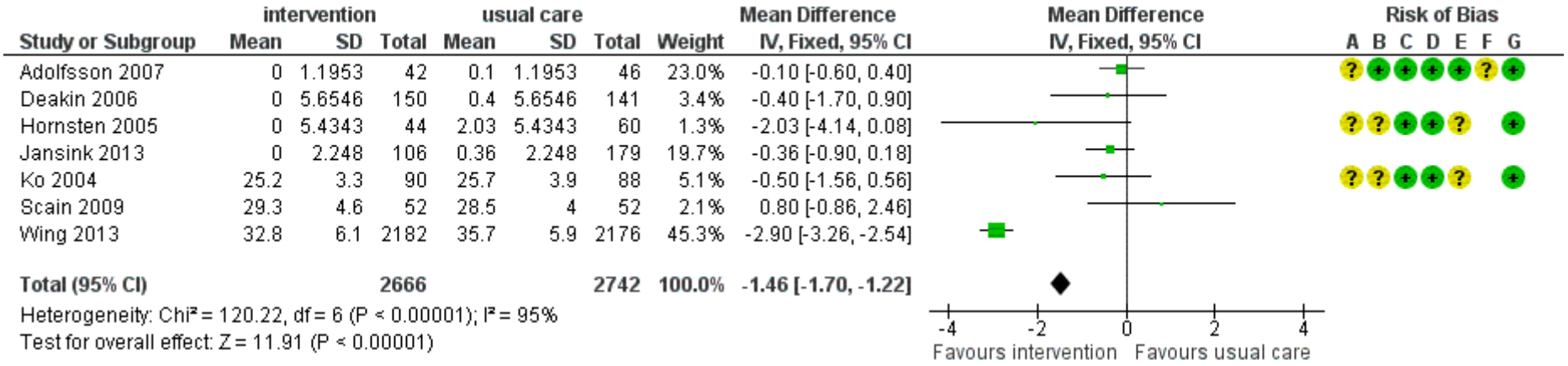
Data and analyses

2 intervention vs usual care

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 BMI =>1år	7	5408	Mean Difference (IV, Fixed, 95% CI)	-1.46 [-1.70, -1.22]
2.2 vægt (kg) =>1år	3	1779	Mean Difference (IV, Random, 95% CI)	-0.59 [-1.63, 0.45]
2.3 HbAc1 (%) <1år	5	1632	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.37, 0.09]
2.4 HbAc1 (%) =>1år	13	7498	Mean Difference (IV, Fixed, 95% CI)	-0.38 [-0.43, -0.33]
2.5 LDL <1år	5	5983	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.03, 0.06]
2.6 QoL	3	546	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.05, 0.29]
2.7 QoL PCS (SF-36)	3	5902	Std. Mean Difference (IV, Fixed, 95% CI)	-0.28 [-0.34, -0.23]
2.8 QoL MCS score	3	5902	Std. Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.08, 0.02]
2.9 antal i po behandling	3	5894	Risk Ratio (IV, Fixed, 95% CI)	0.90 [0.88, 0.92]
2.10 antal i insulin	6	6223	Risk Ratio (IV, Fixed, 95% CI)	0.79 [0.70, 0.89]
2.11 frafald antal	15	8454	Risk Ratio (IV, Fixed, 95% CI)	0.85 [0.70, 1.02]

Figures

Figure 1 (Analysis 2.1)



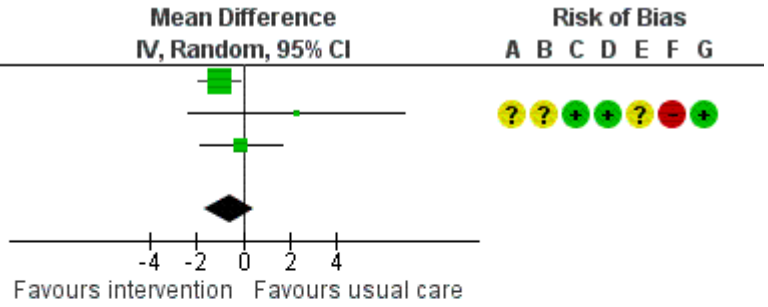
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

2 intervention vs usual care, outcome: 2.1 BMI =>1år.

Figure 2 (Analysis 2.2)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Davies 2008	0	6.5785	437	1.01	6.5785	387	66.8%	-1.01 [-1.91, -0.11]
Gabbay 2006	93.89	21.32	150	91.63	21.32	182	4.9%	2.26 [-2.35, 6.87]
Sperl Hillen 2011	0.5439	9.0134	489	0.65	9.1038	134	28.3%	-0.11 [-1.84, 1.63]
Total (95% CI)			**1076**			**703**	**100.0%**	**-0.59 [-1.63, 0.45]**

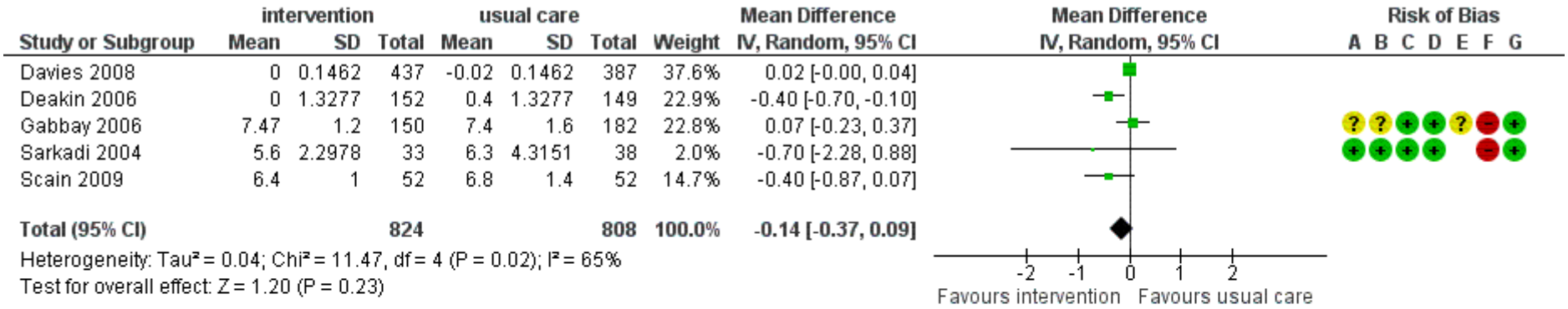
Heterogeneity: Tau² = 0.21; Chi² = 2.49, df = 2 (P = 0.29); I² = 20%
Test for overall effect: Z = 1.12 (P = 0.26)



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

2 intervention vs usual care, outcome: 2.2 vægt (kg) =>1år.

Figure 3 (Analysis 2.3)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
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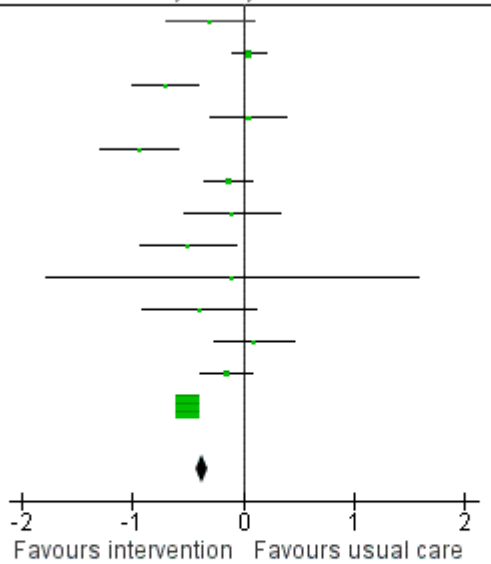
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

2 intervention vs usual care, outcome: 2.3 HbAc1 (%) <1år.

Figure 4 (Analysis 2.4)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Adolfsson 2007	0	0.9563	42	0.3	0.9563	46	1.7%	-0.30 [-0.70, 0.10]
Davies 2008	0	1.0964	437	-0.05	1.0964	387	12.0%	0.05 [-0.10, 0.20]
Deakin 2006	0	1.3049	150	0.7	1.3049	141	3.0%	-0.70 [-1.00, -0.40]
Gabbay 2006	7.45	1.4	150	7.4	1.8	182	2.3%	0.05 [-0.29, 0.39]
Hornsten 2005	0	0.8997	44	0.94	0.8997	60	2.2%	-0.94 [-1.29, -0.59]
Jansink 2013	0	0.991	129	0.13	0.991	197	5.6%	-0.13 [-0.35, 0.09]
Ko 2004	8.1	1.5	90	8.2	1.4	88	1.5%	-0.10 [-0.53, 0.33]
Piatt 2006	-0.6	1.0853	27	-0.1	0.4631	46	1.4%	-0.50 [-0.93, -0.07]
Sarkadi 2004	6.3	2.8723	33	6.4	3.8974	31	0.1%	-0.10 [-1.79, 1.59]
Scain 2009	6.5	1.3	52	6.9	1.4	52	1.0%	-0.40 [-0.92, 0.12]
Shibayama 2007	0.1	1.2299	67	0	0.8199	67	2.1%	0.10 [-0.25, 0.45]
Sperl Hillen 2011	-0.391	1.925	488	-0.24	0.9948	134	4.7%	-0.15 [-0.39, 0.09]
Wing 2013	6.6	1	2182	7.1	1.2	2176	62.5%	-0.50 [-0.57, -0.43]
Total (95% CI)			**3891**			**3607**	**100.0%**	**-0.38 [-0.43, -0.33]**

Heterogeneity: Chi² = 82.36, df = 12 (P < 0.00001); I² = 85%
Test for overall effect: Z = 14.25 (P < 0.00001)



Risk of bias legend
(**A**) Random sequence generation (selection bias)
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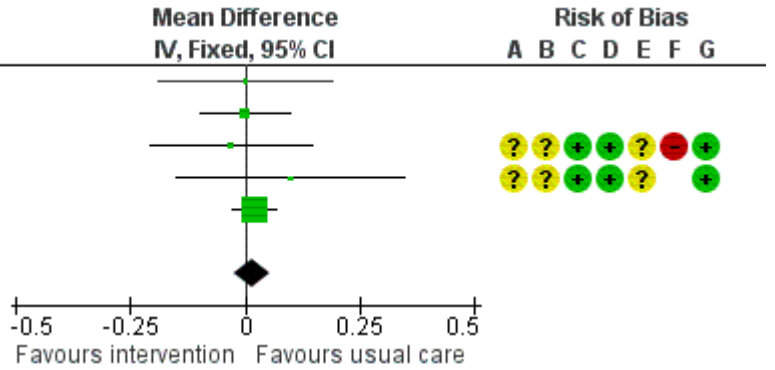
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

2 intervention vs usual care, outcome: 2.4 HbAc1 (%) =>1år.

Figure 5 (Analysis 2.5)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Davies 2008	0	1.3961	437	-0.001	1.3961	387	4.7%	0.00 [-0.19, 0.19]
Deakin 2006	0	0.435	150	0	0.435	141	17.0%	0.00 [-0.10, 0.10]
Gabbay 2006	2.53	0.83	150	2.56	0.82	182	5.4%	-0.03 [-0.21, 0.15]
Ko 2004	3.05	0.86	90	2.95	0.84	88	2.7%	0.10 [-0.15, 0.35]
Wing 2013	2.77	0.83	2182	2.75	0.83	2176	70.2%	0.02 [-0.03, 0.07]
Total (95% CI)			**3009**			**2974**	**100.0%**	**0.02 [-0.03, 0.06]**

Heterogeneity: Chi² = 0.84, df = 4 (P = 0.93); I² = 0%
Test for overall effect: Z = 0.72 (P = 0.47)



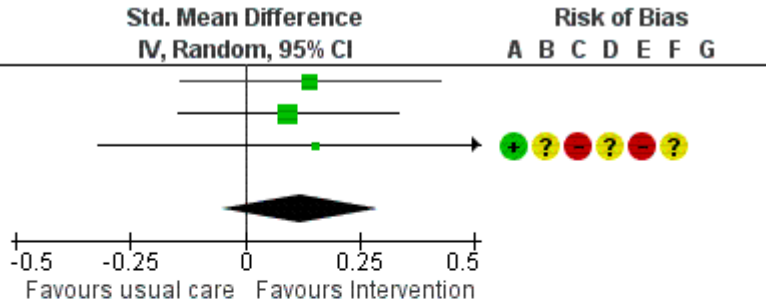
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

2 intervention vs usual care, outcome: 2.6 LDL <1år.

Figure 6 (Analysis 2.6)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Deakin 2006	0	2.113	100	-0.3	2.113	91	36.1%	0.14 [-0.14, 0.43]
Jansink 2013	0	13.5623	111	-1.27	13.5623	171	51.0%	0.09 [-0.15, 0.33]
Piatt 2006	1.3	6.8046	27	0.5	3.7449	46	12.9%	0.16 [-0.32, 0.63]
Total (95% CI)			**238**			**308**	**100.0%**	**0.12 [-0.05, 0.29]**

Heterogeneity: Tau² = 0.00; Chi² = 0.09, df = 2 (P = 0.96); I² = 0%
Test for overall effect: Z = 1.36 (P = 0.17)



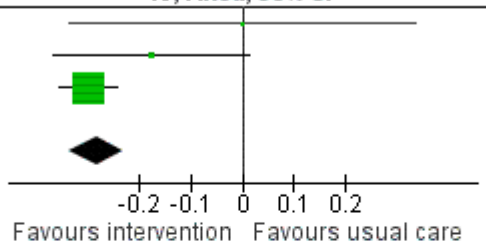
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

2 intervention vs usual care, outcome: 2.6 QoL.

Figure 7 (Analysis 2.7)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Shibayama 2007	-1	12.52860118	67	-1	10.44050098	67	2.4%	0.00 [-0.34, 0.34]
Sperl Hillen 2011	-1.2223	8.6298	489	0.28	8.1087	134	7.4%	-0.18 [-0.37, 0.02]
Wing 2013	0	9.6982	2570	2.91	9.6982	2575	90.2%	-0.30 [-0.35, -0.25]
Total (95% CI)			**3126**			**2776**	**100.0%**	**-0.28 [-0.34, -0.23]**

Heterogeneity: Chi² = 4.25, df = 2 (P = 0.12); I² = 53%
Test for overall effect: Z = 10.65 (P < 0.00001)



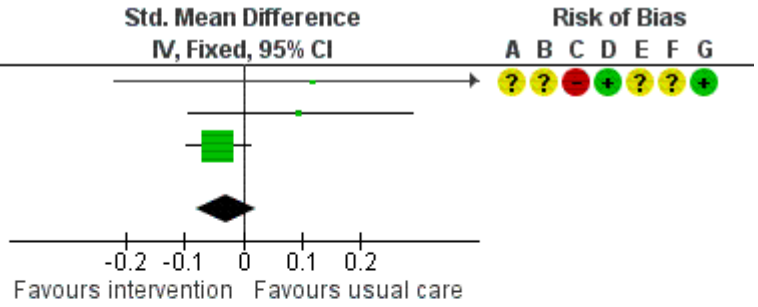
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

2 intervention vs usual care, outcome: 2.7 QoL PCS (SF-36).

Figure 8 (Analysis 2.8)

Study or Subgroup	intervention Mean	SD	Total	usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Shibayama 2007	1	18.79290177	67	-1	14.61670138	67	2.3%	0.12 [-0.22, 0.46]
Sperl Hillen 2011	0.7813	10.2729	489	-0.19	9.6467	134	7.4%	0.10 [-0.10, 0.29]
Wing 2013	0	10.6131	2570	0.46	10.6131	2575	90.3%	-0.04 [-0.10, 0.01]
Total (95% CI)			**3126**			**2776**	**100.0%**	**-0.03 [-0.08, 0.02]**

Heterogeneity: Chi² = 2.62, df = 2 (P = 0.27); I² = 24%
Test for overall effect: Z = 1.11 (P = 0.27)



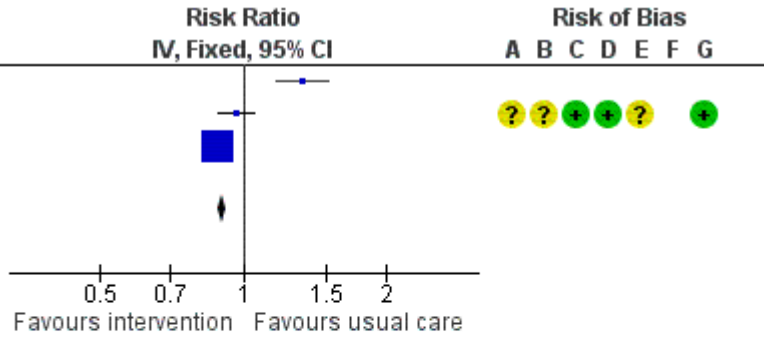
Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective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

2 intervention vs usual care, outcome: 2.8 QoL MCS score.

Figure 9 (Analysis 2.9)

Study or Subgroup	intervention Events	Total	usual care Events	Total	Weight	Risk Ratio IV, Fixed, 95% CI
Davies 2008	247	332	152	272	3.6%	1.33 [1.18, 1.51]
Ko 2004	81	90	82	88	6.8%	0.97 [0.88, 1.06]
Wing 2013	2006	2556	2268	2556	89.6%	0.88 [0.86, 0.91]
Total (95% CI)		**2978**		**2916**	**100.0%**	**0.90 [0.88, 0.92]**
Total events	2334		2502			

Heterogeneity: Chi² = 43.19, df = 2 (P < 0.00001); I² = 95%
Test for overall effect: Z = 8.61 (P < 0.00001)



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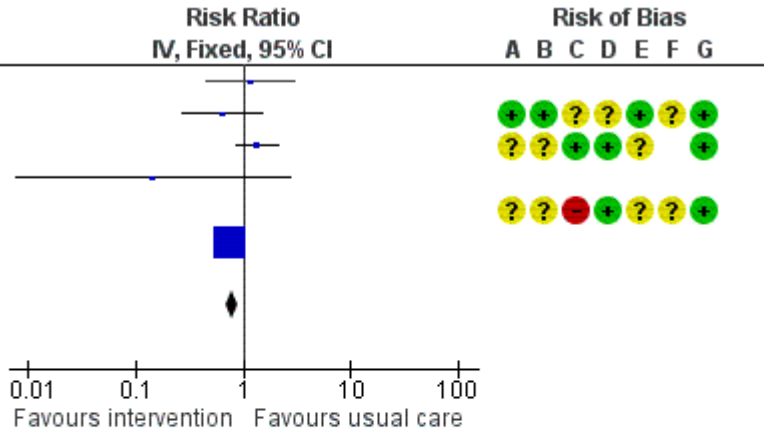
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

2 intervention vs usual care, outcome: 2.9 antal i per oral behandling.

Figure 10 (Analysis 2.10)

Study or Subgroup	intervention Events	Total	usual care Events	Total	Weight	Risk Ratio IV, Fixed, 95% CI
Davies 2008	10	332	7	272	1.6%	1.17 [0.45, 3.03]
Goudswaard 2004	6	28	10	30	1.9%	0.64 [0.27, 1.54]
Ko 2004	33	90	24	88	7.8%	1.34 [0.87, 2.08]
Scain 2009	0	52	3	52	0.2%	0.14 [0.01, 2.70]
Shibayama 2007	0	67	0	67		Not estimable
Wing 2013	343	2570	454	2575	88.5%	0.76 [0.67, 0.86]
Total (95% CI)		**3139**		**3084**	**100.0%**	**0.79 [0.70, 0.89]**
Total events	392		498			

Heterogeneity: Chi² = 8.30, df = 4 (P = 0.08); I² = 52%
Test for overall effect: Z = 3.76 (P = 0.0002)



Risk of bias legend
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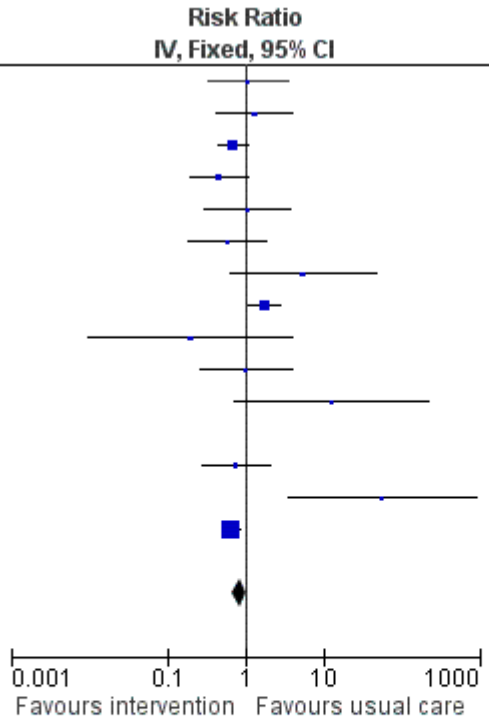
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

2 intervention vs usual care, outcome: 2.10 antal i insulin.

Figure 11 (Analysis 2.11)

Study or Subgroup	intervention Events	Total	usual care Events	Total	Weight	Risk Ratio IV, Fixed, 95% CI
Adolfsson 2007	5	47	5	51	2.6%	1.09 [0.34, 3.51]
Cooper 2008	6	53	5	59	2.8%	1.34 [0.43, 4.12]
Davies 2008	33	437	42	387	18.8%	0.70 [0.45, 1.07]
Deakin 2006	7	149	16	157	4.8%	0.46 [0.20, 1.09]
Goudswaard 2004	4	28	4	30	2.1%	1.07 [0.30, 3.88]
Heller 1988	4	40	8	47	2.8%	0.59 [0.19, 1.81]
Hornsten 2005	4	44	1	60	0.8%	5.45 [0.63, 47.13]
Jansink 2013	36	229	26	292	15.8%	1.77 [1.10, 2.84]
Ko 2004	0	90	2	90	0.4%	0.20 [0.01, 4.11]
Piatt 2006	3	30	5	51	1.9%	1.02 [0.26, 3.97]
Sarkadi 2004	6	39	0	38	0.4%	12.68 [0.74, 217.47]
Scain 2009	0	52	0	52		Not estimable
Shibayama 2007	6	67	8	67	3.5%	0.75 [0.28, 2.04]
Sperl Hillen 2011	103	489	0	134	0.5%	57.03 [3.57, 911.91]
Wing 2013	74	2570	112	2575	42.7%	0.66 [0.50, 0.88]
Total (95% CI)		**4364**		**4090**	**100.0%**	**0.85 [0.70, 1.02]**
Total events	291		234			

Heterogeneity: Chi² = 32.29, df = 13 (P = 0.002); I² = 60%
Test for overall effect: Z = 1.75 (P = 0.08)



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(**G**) Other bias

2 intervention vs usual care, outcome: 2.11 frafald antal.