

## **PICO 9: Er der effekt af 'Self-management' tilgange som integreret del af (eller supplement til) den sygdomsspecifikke patientuddannelse af type 2 diabetes?**

### **Methods**

#### **Criteria for considering studies for this review**

##### ***Types of outcome measures***

##### **Primary outcomes**

HbA1c  $\geq$  1 år - kritisk

QoL - længste follow-up

##### **Secondary outcomes**

##### **Følgende outcomes er vurderet vigtige:**

HbA1c  $<$  1 år

Komplikationer  $\geq$  1 år

Hjertekarsygdom  $\geq$  1 år

Selvrapporteret helbred - længste follow-up

Self-efficacy - længste follow-up

Depression - længste follow-up

Frafaldsrate - efter endt forløb

### **Characteristics of studies**

#### **Characteristics of included studies**

**Chen 2012**

<p><b>Methods</b></p>	<p><b>Study design:</b> Randomized controlled trial  <b>Study grouping:</b> Parallel group  <b>Open Label:</b>  <b>Cluster RCT:</b> YES</p>
<p><b>Participants</b></p>	<p><b>Baseline Characteristics</b>  intervention</p> <ul style="list-style-type: none"> <li>● age: 59.19 (10.24)</li> <li>● gender (% females): 58 (55.8)</li> <li>● diabetes duration (yrs): 7.98 (7.57)</li> <li>● HbA1c (%): 8.92 (2.17)</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● age: 58.67 (10.23)</li> <li>● gender (% females): 50 (45.0)</li> <li>● diabetes duration (yrs): 7.91 (6.95)</li> <li>● HbA1c (%): 8.52 (1.82)</li> </ul> <p><b>Included criteria:</b> The inclusion criteria for study subjects were: enrolled in the diabetes clinic and have a diagnosis for more than 3 months with type 2 diabetes; more than 18 years of age; able to consent to participate on their own behalf; have no obvious confusion or psychiatric illness; and able to speak, read and write Chinese.  <b>Excluded criteria:</b> Individuals were excluded from participating if they demonstrated: difficulty communicating in Chinese or were too ill to participate because of a terminal illness or hemodialysis.</p>
<p><b>Interventions</b></p>	<p><b>Intervention Characteristics</b>  intervention</p> <ul style="list-style-type: none"> <li>● <i>education and intervention:</i> Participants allocated to the intervention group received the motivational interview intervention comprising a 45–60 min interview. The researcher who conducted the motivational interviews has a nursing background and has had extensive experience conducting motivational interviews with diabetic people. The researcher introduced the motivational interview to participants as an opportunity to talk about their thoughts and feelings about diabetes, emphasizing that it was up to the participants themselves to make decisions about diabetes self-management.</li> </ul> <p>control</p>

	<p>● <i>education and intervention</i>: Control participants were invited to attend hospitalbased educational sessions (including individual education during clinic visiting) and the 'Diabetics Club'. The diabeteseducational sessions and Diabetics Club are conducted by diabetes team of experienced allied health care professionals in the hospital. The educational material and sessions provided to participants are endorsed by the Taiwan Diabetes Association. The material addresses diet, exercise, medication and self-monitoring blood glucose, and gives a clear rationale for adopting a self-management approach to diabetes. The education sessions are conducted for 1 h/week and provided by nurse, diabetes educator, physician, dietician, pharmacist, social worker in hospital.</p>
<p><b>Outcomes</b></p>	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> <li>● QoL (VAS)</li> <li>● self rated Health</li> <li>● HbA1c (%)</li> <li>● QoL (EuroQoL)</li> <li>● self efficacy (diet)</li> <li>● Self efficacy (physical)</li> <li>● Depression score</li> </ul> <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> <li>● komplikation</li> <li>● CVD</li> <li>● irafald</li> </ul> <p><i>Adverse Events:</i></p> <ul style="list-style-type: none"> <li>● admitted to hospital (SAE) and terminal disease</li> </ul>
<p><b>Identification</b></p>	<p><b>Sponsorship source:</b> This research was supported by grants from the Pingtung Christian Hospital (PS-97002).</p> <p><b>Country:</b> Taiwan</p> <p><b>Setting:</b></p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Shu Ming Chen</p> <p><b>Institution:</b> School of Nursing, Fooyin University, Kaohsiung, Taiwan</p> <p><b>Email:</b> ff036@mail.fy.edu.tw</p> <p><b>Address:</b> Faculty of nursing, Fooyin University, 151 Chin-Hsueh Rd., Ta-Liao, Hsiang, Kaohsiung, Hsion 83102, Taiwan, ROC.</p>

<b>Notes</b>	<p><b>Identification:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b></p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b>  <i>Solveig Jansen</i> The participants in both group had the same chronic oral prescriptions during this 3 month period</p> <p><b>Continuous outcomes:</b>  <i>Solveig Jansen</i> There were no significant differences between the withdrawal participants and those who continued with respect to baseline characteristics, HbA1c, self-management, and psychological outcomes. total randomized 250, 125 intervention and 125 control group. 214 people completed the outcome data collection. 104 (83%) intervention and 110 (85%) control group.</p> <p><i>Elisabeth Ginnerup-Nielsen</i> Euroqol er i dette tilfælde "WHOQOL" Citat: Quality of life increased steadily in the experimental group (t = -4.49, p &lt; 0.01) but not in control group (t = -0.93, p = 0.35) from baseline to 3 month follow-up. Because the interaction of group and baseline quality of life was significant (F = 6.49, p = 0.012), The diabetes management self-efficacy increased steadily in the experimental group (t = -6.40, p &lt; 0.01) but not in control group (t = -1.94, p = 0.054) from baseline to 3 month follow-up. Because the interaction of group and baseline self-efficacy was significant (F = 6.76, p = 0.010), Johnson-Neyman methods rather than ANCOVA was used to explore the intervention effect on diabetes management self-efficacy. The result showed the motivational intervention did improve participants significantly in diabetes management self-efficacy among diabetes people with baseline value less than 174.57 (possible score range: 0-200)</p> <p><b>Dichotomous outcomes:</b></p> <p><b>Adverse outcomes:</b></p>
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Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "125 were randomly assigned to the experimental group, and 125 were randomized to the control group." Comment: unclear how random
Allocation concealment (selection bias)	Unclear risk	Comment: Not described

Blinding of participants and personnel (performance bias)	High risk	Comment: neither the nurses, researcher nor the patients could be blinded, due to intervention assignment No blinding and self-reported outcome
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The research assistant involved in the recruitment, baseline and outcomes measures data collection was not informed of a participant's group allocation. To ensure that the research protocol was followed precisely a research assistant with a clinical background was employed for baseline and post intervention data collection. Neither the research assistant nor the clinical diabetes educators knew the group allocations of participants." Comment: Self-reported and objective outcome not likely to be changed by blinding
Incomplete outcome data (attrition bias)	Low risk	Quote: "The participants in both group had the same chronic oral prescriptions during this 3 month period. There were no significant differences between the withdrawal participants and those who continued with respect to baseline characteristics, HbA1c, self-management, and psychological outcomes."
Selective reporting (reporting bias)	Unclear risk	Comment: No trial protocol. Outcomes are unclearly reported.
Other bias	Low risk	

**D'Eramo Melkus 1992**

<b>Methods</b>	
<b>Participants</b>	
<b>Interventions</b>	
<b>Outcomes</b>	
<b>Identification</b>	
<b>Notes</b>	

Risk of bias table

	<b>Authors' judgement</b>	<b>Support for judgement</b>
<b>Bias</b>		
Random sequence generation (selection bias)	Low risk	Quote: "Subjects were computer randomized IO one of three intervention groups."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: Objective outcomes not indicated, probably not blinded
Blinding of outcome assessment (detection bias)	Low risk	Not so relevant for outcome
Incomplete outcome data (attrition bias)	High risk	Comment: 8/26 og 11/28 dropped out. No intention to treat
Selective reporting (reporting bias)	Unclear risk	Comment: outcome probably assessed but no trial protocol
Other bias	Low risk	

### Goderis 2010

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial  <b>Study grouping:</b> Parallel group  <b>Open Label:</b>  <b>Cluster RCT:</b> YES</p>
<b>Participants</b>	<p><b>Baseline Characteristics</b>  intervention  <ul style="list-style-type: none"> <li>● age: 68 (12)</li> <li>● gender (% females): 51</li> <li>● diabetes duration (yrs): 7.2 (6.9)</li> <li>● HbA1c (%): 7.1 (1.3)</li> </ul> control  <ul style="list-style-type: none"> <li>● age: 68 (12)</li> <li>● gender (% females): 53</li> <li>● diabetes duration (yrs): 7.2 (7.3)</li> <li>● HbA1c (%): 7.2 (1.3)</li> </ul> </p>

	<p><b>Included criteria:</b> Not described. Randomization at GP level  <b>Excluded criteria:</b> Not described. Randomization at GP level</p> <p><b>Interventions</b></p> <p><b>Intervention Characteristics</b>  intervention</p> <ul style="list-style-type: none"> <li>● <i>education and intervention:</i> GPs of both arms received the same basic support program of interventions (UQIP) that was based on the chronic care model and theoretical frameworks for change management [24–26]. These interventions represent standard requirements for what is considered quality diabetes care [1]. The aim of UQIP was to implement the evidence-based guidelines recommending a global, target-driven and intensified treatment of type 2 diabetes. For patients of the AQIP arm, the IDCT was reinforced with a health psychologist and a diabetes educator who delivered diabetes education at the patient's home. Referral to the health psychologist was recommended for all patients with difficulties in maintaining healthy lifestyle habits. The counselling techniques included extended motivational interviewing based on the transtheoretical model of change with difficulties in maintaining healthy lifestyle habits. The counselling techniques included extended motivational interviewing based on the transtheoretical model of change</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● <i>education and intervention:</i> The intervention period was January 2005 to November 2006. As explained in the study protocol, GPs of both arms received the same basic support program of interventions (UQIP) that was based on the chronic care model and theoretical frameworks for change management [24–26]. These interventions represent standard requirements for what is considered quality diabetes care [1]. The aim of UQIP was to implement the evidence-based guidelines recommending a global, target-driven and intensified treatment of type 2 diabetes. The interventions of UQIP were available for all participating GPs and patients.</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> <li>● HbA1c (%)</li> <li>● QoL (EuroQoL)</li> <li>● QoL (VAS)</li> <li>● self-rated Health</li> <li>● self-efficacy (diet)</li> <li>● Self-efficacy (physical)</li> <li>● Depression score</li> <li>● HbA1c</li> </ul> <p><i>Dichotomous:</i></p>

	<ul style="list-style-type: none"> <li>● frafald</li> <li>● komplikation</li> <li>● CVD</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> The Belgian National Institute for Health and Disability Insurance (NIHDI)</p> <p><b>Country:</b> Belgium</p> <p><b>Setting:</b></p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Geert Goderis</p> <p><b>Institution:</b> Department of General Practice, Katholieke Universiteit Leuven, Belgium</p> <p><b>Email:</b> geert.goderis@skynet.be, geert.goderis@med.kuleuven.be</p> <p><b>Address:</b> Katholieke Universiteit Leuven, Department of General Practice (Academisch Centrum voor Huisartsgeneeskunde), Kapucijnenvoer 33/J Bus 7001, 3000 Leuven, Belgium</p>
<b>Notes</b>	<p><b>Identification:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b></p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b></p> <p><b>Dichotomous outcomes:</b></p> <p><b>Adverse outcomes:</b></p> <p><i>Solveig Jansen</i> Number of events are not directly mention. Reason for patient lost to follow up are for example: died, moving to a nursing home.</p>

**Risk of bias table**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "After the initial recruitment phase, a researcher blinded to the study design used computer-generated numbers to randomly assign practices."
Allocation concealment (selection bias)	Unclear risk	Comment: Not described



Blinding of participants and personnel (performance bias)	Low risk	<p>Comment: HbA1c not likely to be changed by this</p> <p>Quote: "All patients were blinded to the study design, but physicians were not, as they were involved in the execution of the programs."</p>
Blinding of outcome assessment (detection bias)	Low risk	<p>Comment: objective outcomes.</p> <p>Quote: "All patients were blinded to the study design, but physicians were not, as they were involved in the execution of the programs."</p>
Incomplete outcome data (attrition bias)	Low risk	<p>Comment: A little skewed dropout, but not too large.. intention to treat analysis has been done</p>
Selective reporting (reporting bias)	Low risk	<p>Quote: "registered as # NTR1369,"</p> <p>Comment: Outcomes from protocol reported</p>
Other bias	High risk	<p>Quote: "A total of 142 physicians from 90 practices agreed to participate and were randomized (Fig. 1). Within the first 30 days, 22 physicians dropped out (UQIP = 18, AQIP = 4, p &amp;lt; 0.001). Thus, only 120 physicians (36% of those available, 67 AQIP vs. 53 UQIP) registered baseline data. During the study"</p> <p>Quote: "There were several weaknesses of the present study. First, considerable effort was required to motivate GPs for the project, resulting in a global enhancement of diabetes awareness throughout the region. Secondly, despite the motivation of the GPs, we observed a significant difference in initial drop-out rate between the UQIP and AQIP-assigned GPs, which may indicate that being assigned to AQIP motivated more physicians to pay closer attention to T2DM care. However, probably the most motivated GPs remained in the UQIP arm, with possible effects on the final outcomes. Thirdly, some of the additional interventions of the AQIP arm were only used by a small number of participants. This is particularly true for the health psychologist counseling, which was only used by 18 patients. Finally, the follow-up period may have been too short to find a significant difference between AQIP and UQIP. Therefore, it will be interesting to organize a post-intervention follow-up of the included patients."</p>

**Gregg 2007**

<b>Methods</b>	
<b>Participants</b>	
<b>Interventions</b>	
<b>Outcomes</b>	
<b>Identification</b>	
<b>Notes</b>	

**Risk of bias table**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "participants were then randomly assigned (using a random numbers table)"
Allocation concealment (selection bias)	Unclear risk	Quote: "assessment, participants were then randomly assigned (using a random numbers table) to one" Comment: difficult to conceal allocation with a table. Might have been done though
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably not but for subjective outcome not relevant
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Psychosocial assessments and a blood draw for HbA 1 c were administered during the 1st hr (and again at 3-month follow-up) by clinic and research personnel blind to group assignment."
Incomplete outcome data (attrition bias)	Low risk	Complete blood data were therefore available for 73 of the participants (90%). The main outcome analysis was done on an intent-to-treat basis, and missing follow-up values were assumed not to have changed."
Selective reporting (reporting bias)	Unclear risk	No trial protocol
Other bias	Low risk	

**Naik 2011**

<p><b>Methods</b></p>	<p><b>Study design:</b> Randomized controlled trial  <b>Study grouping:</b> Parallel group  <b>Open Label:</b>  <b>Cluster RCT:</b></p>
<p><b>Participants</b></p>	<p><b>Baseline Characteristics</b>  intervention</p> <ul style="list-style-type: none"> <li>● age: 63.82 (7.9)</li> <li>● gender (% females): 0</li> <li>● diabetes duration (yrs): 4.98(3.1)</li> <li>● HbA1c (%): 8.86(1.3)</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● age: 63.45 (7.8)</li> <li>● gender (% females): 0</li> <li>● diabetes duration (yrs): 5.04(3)</li> <li>● HbA1c (%): 8.74(1.2)</li> </ul> <p><b>Included criteria:</b> type 2 diabetes 50-90 yrs, HbA1c &gt;= 7.5% prior to study  <b>Excluded criteria:</b> dementia, creatinin above 200 micromol/l</p>
<p><b>Interventions</b></p>	<p><b>Intervention Characteristics</b>  intervention</p> <ul style="list-style-type: none"> <li>● education and intervention: 4 Group sessions every 3 weeks over 3 Moths. Each session were followed by the Diabetes ABC session, goal setting, proactive patient behavior and physician-patient communication and finally performance feed-back</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● education and intervention: traditional Group education, 2 sessions by educator and dietician</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> <li>● HbA1c (%)</li> <li>● QoL (EuroQoL)</li> <li>● QoL (VAS)</li> </ul>

	<ul style="list-style-type: none"> <li>● self rated Health</li> <li>● self efficacy (diet)</li> <li>● Self efficacy (physical)</li> <li>● Depression score</li> <li>● Diabetes self-efficacy score</li> </ul> <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> <li>● ifrafald</li> <li>● komplikation</li> <li>● CVD</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> EPIC study sponsors: Agency for Healthcare and quality, Centres for research and education on therapeutics, Clinical Scientist Development Award from the Doris Duke Charitable Foundation, National Institute of Aging and the Houston Health Service Research and DEvelopment Center of Excellence</p> <p><b>Country:</b> USA</p> <p><b>Setting:</b> Medical Center</p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Naik</p> <p><b>Institution:</b> Houston Health and Development Center of Excellence</p> <p><b>Email:</b> anaik@bcm.edu</p> <p><b>Address:</b> 2002 Holcombe, Houston, TX 77030, USA</p>
<b>Notes</b>	<p><b>Identification:</b></p> <p><b>Participants:</b></p> <p><b>Study design:</b></p> <p><b>Baseline characteristics:</b></p> <p><b>Intervention characteristics:</b></p> <p><b>Pretreatment:</b></p> <p><b>Continuous outcomes:</b></p> <p><b>Dichotomous outcomes:</b></p> <p><b>Adverse outcomes:</b></p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: block randomization of 10
Allocation concealment (selection bias)	Low risk	Comment: assignment was blinded using sequentially numbered and Sealed envelopes
Blinding of participants and personnel (performance bias)	High risk	Comment: Selfreported outcome - no blinding. Only affects the important outcome though
Blinding of outcome assessment (detection bias)	Low risk	Comment: outcome either selfreported or objective
Incomplete outcome data (attrition bias)	Low risk	Comment: attrition was described, equal drop-out rates was seen
Selective reporting (reporting bias)	Low risk	Comment: this is discussed
Other bias	Low risk	Comment: older male veterans. No oother sources of bias

**Smith 1997**

Methods
Participants
Interventions
Outcomes
Identification
Notes

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomized, method not indicated
Allocation concealment (selection bias)	Unclear risk	Comment: Not described
Blinding of participants and personnel (performance bias)	Low risk	Comment: unblinded but objective outcomes
Blinding of outcome assessment (detection bias)	Low risk	Comment: assessment were conducted by trained technicians blind to Group assignment
Incomplete outcome data (attrition bias)	High risk	Comment: Relatively large dropout and unclear why only 16 and not 22 were used. Originally 22 randomized..
Selective reporting (reporting bias)	Low risk	Comment: no trial protocol but also only a protocol study. No reason to be selective in reporting.
Other bias	Unclear risk	Comment: different rate of exercise, recorded calories and glucose monitoring

### Welch 2011

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>intervention</p> <ul style="list-style-type: none"> <li>● age: 54.9(9.3)</li> <li>● gender (% females): 57.9</li> <li>● diabetes duration (yrs): 9.0(7.3)</li> <li>● HbA1c (%): 9.1(1.5)</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● age: 54.4(10.3)</li> <li>● gender (% females): 62.1</li> </ul>

	<ul style="list-style-type: none"> <li>● <i>diabetes duration (yrs)</i>: 7.1(5.8)</li> <li>● <i>HbA1c (%)</i>: 8.8(1.3)</li> </ul> <p><b>Included criteria:</b> type 2 diabetes, age 30-70, HbA1c &gt;= 7.5%</p> <p><b>Excluded criteria:</b> major complications, pregnancy, psychiatric disorders, mental retardation or other problem affecting the completion of questionnaires</p>
<p><b>Interventions</b></p>	<p><b>Intervention Characteristics</b> intervention</p> <ul style="list-style-type: none"> <li>● <i>education and intervention:</i> Diabetes self-management education and support in 4 sessions,3 of these were followed by 30 min motivational interviewing</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● <i>education and intervention:</i> Diabetes self-management education and support in 4 sessions,</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> <li>● HbA1c (%)</li> <li>● QoL (EuroQoL)</li> <li>● QoL (VAS)</li> <li>● self rated Health</li> <li>● self efficacy (diet)</li> <li>● Self efficacy (physical)</li> <li>● Depression score</li> </ul> <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> <li>● frafald</li> <li>● komplikation</li> <li>● CVD</li> </ul>
<p><b>Identification</b></p>	<p><b>Sponsorship source:</b> none indicated</p> <p><b>Country:</b> USA</p> <p><b>Setting:</b> Baystate Medical Center</p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Garry Welch</p> <p><b>Institution:</b> Department of Behavioraol Medicine Research, Baystate Medical Center.</p>

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<b>Notes</b>	<p><b>Identification:</b>  <b>Participants:</b>  <b>Study design:</b>  <b>Baseline characteristics:</b>  <b>Intervention characteristics:</b>  <b>Pretreatment:</b>  <b>Continuous outcomes:</b>  <b>Dichotomous outcomes:</b>  <b>Adverse outcomes:</b></p>

Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Comment: method not indicated
Allocation concealment (selection bias)	Unclear risk	Comment: not indicated
Blinding of participants and personnel (performance bias)	High risk	Comment: Neither physicians nor patient could be blinded to the intervention assignment
Blinding of outcome assessment (detection bias)	Low risk	Comment: biochemical parametres was measured in random samples, mediators of possible change in HbA1c were self-reported
Incomplete outcome data (attrition bias)	Low risk	Comment: large but equal drop-out rate (32.8-43.1%). Mean change in HbA1c was not significantly different comparing completers and drop-outs
Selective reporting (reporting bias)	Low risk	Comment: few studies in the litteratur show different results, selective outcome reporting therefore nor likely
Other bias	Low risk	Comment: Different educational status at baseline was discussed as possible bias



**West 2007**

<b>Methods</b>	
<b>Participants</b>	
<b>Interventions</b>	
<b>Outcomes</b>	
<b>Identification</b>	
<b>Notes</b>	

**Risk of bias table**

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Comment: randomization done within races, method not indicated
Allocation concealment (selection bias)	Low risk	Quote: "using a sequentially num-bered, closed-envelope procedure."
Blinding of participants and personnel (performance bias)	Low risk	Comment: Probably not but outcome is objective
Blinding of outcome assessment (detection bias)	Low risk	Comment: Outcome assessors not involved in patients care
Incomplete outcome data (attrition bias)	High risk	Comment: intervention group was significantly more compliant to group sessions 16/108 and 6/109. A little skewed dropout. Intention to treat should have been done!
Selective reporting (reporting bias)	Unclear risk	Quote: "NCT00007800, clinicaltrials.gov." Comment: No outcomes provided in protocol?
Other bias	Low risk	Comment: Selected group (overweight women), but this will affect indirectness.

*Footnotes*

**Characteristics of excluded studies**

***Barcelo 2010***

Reason for exclusion	Wrong patient population
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***Browning 2011***

Reason for exclusion	method paper
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***Cooper 2009***

Reason for exclusion	Wrong comparator
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***Heinrich 2010***

Reason for exclusion	Wrong comparator
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***Hill Briggs 2011***

Reason for exclusion	Wrong comparator
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***Jansink 2013***

Reason for exclusion	Wrong comparator
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***McGowan 2011***

Reason for exclusion	
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***Naik 2011a***

Reason for exclusion	Wrong comparator
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### ***RosenbekMinet 2011***

Reason for exclusion	Wrong patient population
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### ***Surwit 2002***

Reason for exclusion	
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### ***Weinger 2011***

Reason for exclusion	Wrong patient population
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### ***Welschen 2013***

Reason for exclusion	
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*Footnotes*

## **Characteristics of studies awaiting classification**

*Footnotes*

## **Characteristics of ongoing studies**

*Footnotes*

## **Summary of findings tables**

## **Additional tables**

## References to studies

### Included studies

#### **Chen 2012**

Chen SM, Creedy D, Lin HS, Wollin J. Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: a randomized controlled trial.. *International journal of nursing studies* 2012;49(6):637-44. [DOI: <http://dx.doi.org/10.1016/j.ijnurstu.2011.11.011>]

#### **D'Eramo Melkus 1992**

D'Eramo-Melkus GA, Wylie-Rosett J, Hagan JA. Metabolic impact of education in NIDDM. *Diabetes Care* 1992;15(7):864-9.

#### **Goderis 2010**

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[Empty]

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## **Studies awaiting classification**

### **Ongoing studies**

## **Other references**

### **Additional references**

**Other published versions of this review**

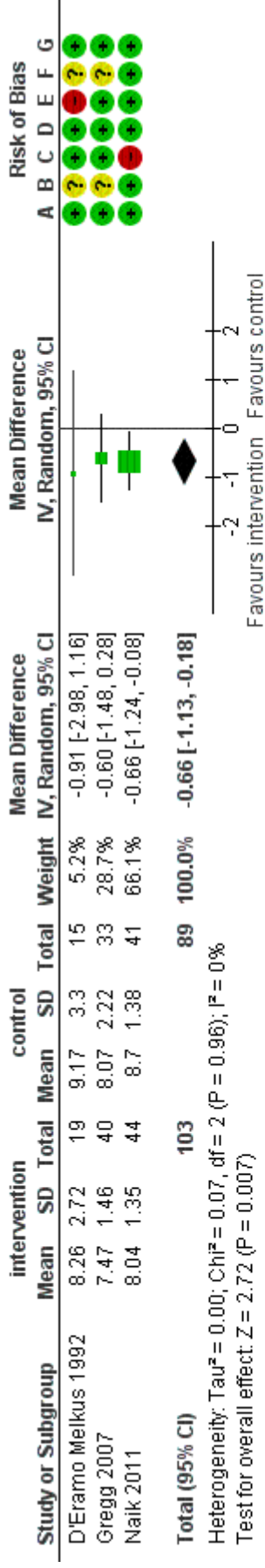
**Data and analyses**

**1 intervention vs control**

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 HbA1c (%) < 1 year	3	192	Mean Difference (IV, Random, 95% CI)	-0.66 [-1.13, -0.18]
1.2 HbA1c (%) >= 1 year	2	2580	Mean Difference (IV, Random, 95% CI)	-0.22 [-0.78, 0.34]
1.3 Self-efficacy, 3 months	2	157	Std. Mean Difference (IV, Random, 95% CI)	0.58 [0.26, 0.90]
1.4 dropout end of study	4	2717	Risk Ratio (IV, Random, 95% CI)	0.69 [0.56, 0.87]

**Figures**

**Figure 1 (Analysis 1.1)**



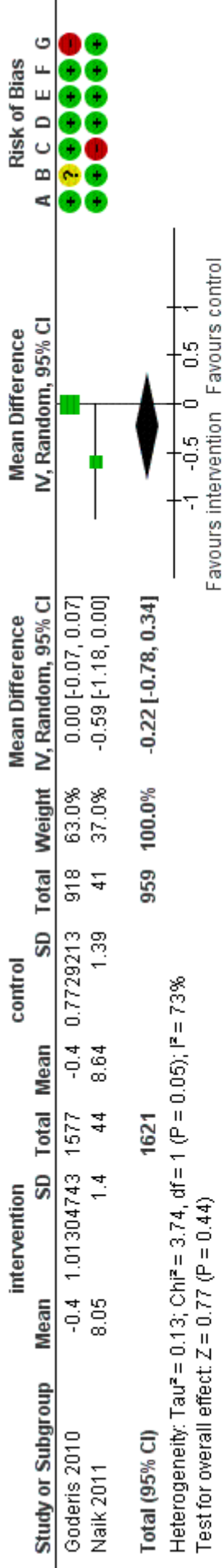
Risk of bias legend

- (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

1 intervention vs control, outcome: 1.1 HbA1c (%) < 1 year.

**Figure 2 (Analysis 1.2)**



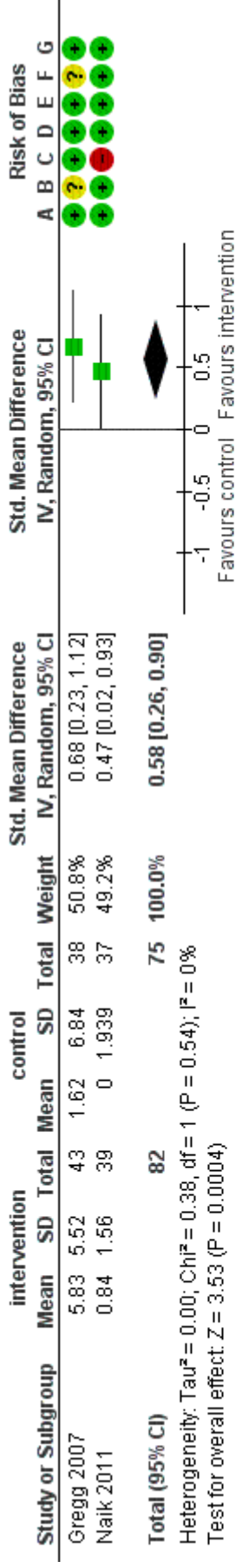


Risk of bias legend

- (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

1 intervention vs control, outcome: 1.2 HbA1c (%) >= 1 year.

**Figure 3 (Analysis 1.3)**

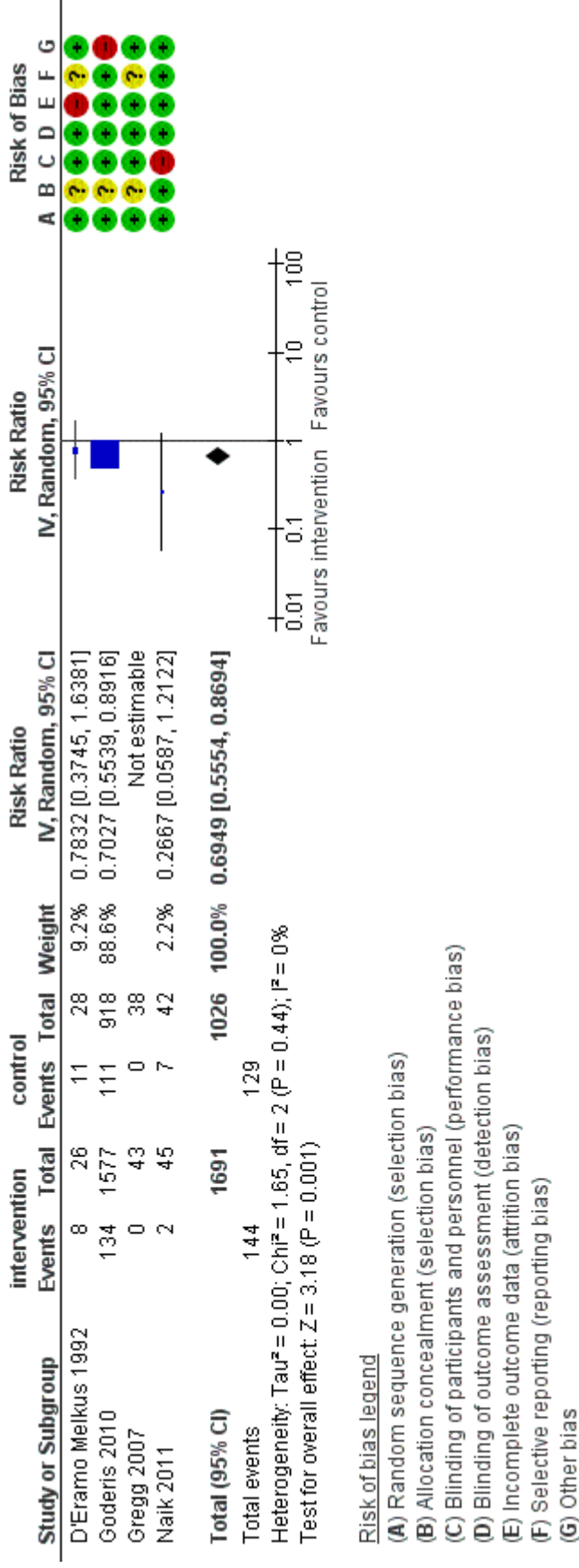


Risk of bias legend

- (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

1 intervention vs control, outcome: 1.7 Self-efficacy, 3 months.

**Figure 4 (Analysis 1.4)**



Forest plot of comparison: 1 intervention vs control, outcome: 1.4 dropout end of study.