Supplementary Material A

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Shaw, 2006 **Country:** Australia **Study type:** Systematic review **Evidence level:** I	**Aims:** Examine the effectiveness of chronic disease self management for people with asthma, diabetes and coronary heart disease. **Participants:** Adults > 18 years with diabetes, asthma, coronary heart disease and then generic intervention **Search period:** 1994 - 2006 **Search method:** Limited to English language AustHealth Medline, PsycINFO, CINAHL, EMBASE, CENTRAL, Cochrane library, Expert centres, reference lists Search string provided	**Inclusion:** Type of study not specified but included adults, published after 1994, With a control group, in English language, meeting pre-determined quality criteria **Exclusion:** Not relevant to question Not a primary study Univariate analysis only Insufficient data reported to asses quality Quality was weak in four or more pre-determined criteria Absence of specified outcomes	**Exposure:** Intervention had to contain a minimum of two of the following: Problem solving Behavioural support Managing emotions Self monitoring/treatment action plans **Comparison:** Control group **Outcome measures:** Quality of life Self efficacy Health service use Physical activity Clinical measures Cost effectiveness **Follow-up time:** unclear	**Results:** 11 papers from 10 studies. Six were group based. Duration ranged from 6 weeks to 12 months, 54% were female and the mean age was 60 years. The comparison was usual care in 8 of the studies. Physical activity: 5 studies, 2 showed benefit over control. 3 found no difference between groups. 2 reported a higher level of participation in the intervention compared with the control group up to six months. Quality of Life: 4 studies. 3 showed improvement compared with controls. 1 reported no between group differences. Studies did not indicate the magnitude of the change for a clinical benefit nor the long term impact as the follow-up did not extend beyond 6 months. Self Efficacy: 4 studies. 3 studies demonstrated a benefit of the intervention.	**Author's conclusions:** Diabetes self management programme was not significantly better than usual care for improving glycaemic control, weight loss or physical activity. **Reviewer's conclusions:** Self efficacy and quality of life were improved but not other outcomes. Main methodological issues were to do with recruitment bias, short duration of studies and follow up and high attrition rates. Well conducted review but not clear if applicable due to variations in interventions and populations included **Source of funding:** International Diabetes Institute, **Additional comments:**

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				Health Service use: 1 study. Intervention group more likely to visit podiatrist at 3-6 months (P=0.05) but his did not persist at 1 year. No difference between groups for visits to the hospital or doctor over 12 months A1c: 10 studies. 3 studies demonstrated a benefit in favour of the intervention, although one of these was due to a deterioration in the control group but no change in the intervention. Improvement s were not sustained beyond 12 months and were not assessed in the long term	
Internal validity:	+				
Study results – precision:	Na				
Applicability (external validity):	?				
Overall score:	?				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Deakin 2005 **Country:** **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the effects of group-based patient centred diabetes training on clinical, lifestyle and psychosocial outcomes both in the short (four to six months) and longer-term (more than 12 months) compared with routine care delivered on a one-to-one basis, or a combination of the two. To observe whether the setting the educator (, the type of educational model or the duration/ intensity of the group-based education programme affects the outcomes. **Participants:** Adults with diagnosed type 2 diabetes regardless of gender or ethnicity. Diagnosed using standardised criteria. The review excluded interventions that were specific for maturity	**Inclusion:** RCTs or CCTs using interventions involving a single or series of group sessions. Only studies that assessed outcome measures six months or more from baseline were included in this study. **Exclusion:** -	**Exposure:** Group-based educational programmes which met the following criteria: • specific for people with type 2 diabetes; • delivered in primary or secondary care; • based on learner/patient-centred education; • included or excluded family and friends; • had a minimum of six participants in each group; • was a minimum of one session lasting for one hour. **Comparison:** The intervention group was compared with those participants either: • undergoing routine treatment (receiving the standard of care recommended in that country e.g. regular follow-up with the required health professionals and a full diabetes annual review); • remaining on a waiting list; • experiencing no intervention i.e. the present healthcare was continued. In three of the four included RCTs	**Results:** Duration of the interventions ranged from 3 hours per year for two years to 52 hours in one year. The majority of the interventions were conducted in primary care. All of the educators were health professionals apart from one study which was lay led. Five studies reported on theoretical framework, 3 of which had adapted the Diabetes Treatment and Teaching Programme which was originally developed in Germany for Type I diabetes, one study used empowerment and one used multiple theories including Adult Learning, Public Health Model, Health Belief Model and Trans Theoretical Model. Thirteen publications from 11 studies were therefore analysed (Brown 2002; Deakin 2003; Domenech 1995; Heller 1988;Holtrop 2002;Kronsbein 1988; Lozano 1999; Pieber 1995b; Rickheim 2002; Trento 1998; Trento 2001; Trento 2002; Zapotoczky 2001). Three of these were CCTs. Only four of the remaining RCTs were conducted in primary care.	**Author's conclusions:** Group-based training for self-management strategies in people with type 2 diabetes is effective by improving fasting blood glucose levels, glycated haemoglobin and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication. **Reviewer's conclusions:** Group intervention reasonable effective **Source of funding:** N/A **Additional comments:** Variations in studies as to duration of input from 3 hours per year for two years to 52 hours over one year. Educators were health professionals and in the Holtrop trial they were lay-health advisors. The theoretical model was not described in any of the RCTs in primary care settings

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
	onset diabetes of the young (MODY) or for pregnant women. Mean age of participants was between 51 and 65 years Mean duration of disease ranged from newly diagnosed to nine years **Search period:** Inception to 2003 **Search method:** *The Cochrane Library*;MEDLINE; CINAHL; ERIC; ASSIA; AMED; PsycINFO; EMBASE; LILACS; NHS Economic Evaluation Database (NHS EED); British Education Index (BEI); British Nursing Index (BNI);Web of Science (WOS); Index of Scientific &Technical Proceedings;National Research Register;DigitalDissert		the comparison was routine care and the fourth trial placed patients on a wait list to receive the intervention at the end of the study. **Outcome measures:** **Primary outcomes** Clinical: • Metabolic control: Glycated haemoglobin (%) and fasting blood glucose (mmol/L). Lifestyle: • Diabetes knowledge*. Psychosocial: • Quality of life*; • Empowerment/self-efficacy*. **Secondary outcomes** Clinical: • Body weight (Kg)/body mass index (BMI)(Kg/m2); • Blood pressure (systolic/diastolic) (mmHg); • Lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) (mmol/L); • Diabetes complications (myocardial infarction, angina, heart failure, stroke, renal failure, neuropathy, retinopathy, peripheral vascular disease); • Diabetes-related mortality (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyper- or hypoglycaemia or sudden	Overall quality not very high. The results of the meta-analyses in favour of group-based diabetes education programmes were reduced glycated haemoglobin at four to six months (1.4%; 95% confidence interval (CI) 0.8 to 1.9; P < 0.00001), at 12-14 months (0.8%; 95% CI 0.7 to 1.0; P < 0.00001) and two years (1.0%; 95% CI 0.5 to 1.4; P< 0.00001); reduced body weight at 12-14 months (1.6 Kg; 95% CI 0.3 to 3.0; P = 0.02); and reduced systolic blood pressure at four to six months (5 mmHg: 95% CI 1 to 10; P = 0.01). 1 study reported on self efficacy for which there was significant improvement in self efficacy and empowerment in favour of the intervention which was sustained up to 14 months (P<0.001) Quality of life was reported by two studies. One study found no overall improvement in QoL. The other trial found improvement in both groups in mental health subscales but no between group differences.	

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	ation Abstracts. Conference proceedings and reference lists of articles were also searched and contact was bemade with experts in the field. Examining references of included studies, contacting authors and experts.		death; • Adverse effects e.g. increased hypoglycaemia. Lifestyle: • Self-management skills (including dietary habits and physical activity levels)*. Psychosocial: • Patient treatment satisfaction*. **Follow-up time:** Minimum of 6 months	There were no differences in the physical health subscales.	
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	+				
Overall score:	+				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Murray 2009 **Country:** UK **Study type:** Systematic review **Evidence level:** I	**Aims:** Systematic review of Interactive Health Communication Applications **Participants:** Any age with a chronic condition in primary or secondary care. Some interventions could be directed at carers **Search period:** 1990 to 2003 **Search method:** Cochrane Issue 2 2003 Medline Embase PsycINFO CINAHL CENTRAL DARE HTA ASLIB Dissertation Abstracts SIGLE Index to Scientific and	**Inclusion:** RCTs of Interactive Health Communication Applications **Exclusion:** Decision aids, computerised cognitive behavioural therapy, decision support for professionals only	**Exposure:** Interactive Health Communication Applications – Use of computer health information and either peer support, decision support or behaviour change support **Comparison:** Normal care, non-interactive or interactive education **Outcome measures:** Knowledge, social support, self efficacy, emotions, health behaviours, health outcomes, health care utilisation **Follow-up time:** Up to 10 months for relevant studies	**Results:** 24 RCTs including adults and children. All 6 of the asthma trials were paediatric. Diseases included eating disorder, asthma, alzheimers, AIDS, diabetes, cancer, incontinence, obesity. There were 4 trials of diabetes in adults (Glasgow, 2003; Lehman, 2001; Smith 2000; Turnin, 1992) of which three reported data on relevant target outcomes. Glasgow 2003 reported that the control group showed an increase in the average minutes of physical activity per day compared with the intervention group SMD -0.09 (no p value) and A1c was also lower in the control group -0.23. Lehman (2001) reported a decrease in A1c in favour of the intervention group SMD 0.77 (no p value) Turnin (1992) reported a reduction in the percentage fat of calorific intake in the intervention group (SMD 0.44;	**Author's conclusions:** IHCAs appear to be effective in general in improving self efficacy, behavioural and clinical outcomes **Reviewer's conclusions:** Good Cochrane methodology but population too indirect to be of much value **Source of funding:** None **Additional comments:**

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
	Technical Proceedings Database National and international research registers Contacting authors No language restriction			no P value)	
Internal validity:	?				
Study results – precision:	Na				
Applicability (external validity):	X				
Overall score:	?				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Boren 2008 **Country:** USA **Study type:** Systematic review **Evidence level:** I	**Aims:** Evaluate computerised learning technology interventions that can empower patients in the self management of diabetes and support diabetes education over a distance **Participants:** Mean age and gender of those trials reporting this outcome were tabulated **Search period:** Inception to 2006 and 1st quarter 2007 for CENTRAL **Search method:** MEDLINE CINAHL CENTRAL	**Inclusion:** RCT evaluating computerised diabetes learning technology, **Exclusion:** Not RCT, no control, planned studies not in english	**Exposure:** Computerised diabetes learning technology **Comparison:** Usual care in all but one trial **Outcome measures:** Learning Behavioural change Clinical improvement Health Status **Follow-up time:** Range 1-24 months	**Results:** 21 RCTs included (3561 participants of which 3329 were adults). Average trial duration was 7.7 months and the number of sessions ranged from 1 to 19 and the duration of sessions from 10 minutes to 3.5 hours. Three types of interventions computerised touch screen assessment and instruction; computerised assessment with individualised counselling or feedback; games or simulation. The common content in the interventions was: understanding diabetes, self care, prevention and management of complications, foot and skin hygiene, eye examinations, smoking cessation, SMBG, insulin adjustment and administration, medication, diet and nutrition, food purchase and meal planning, exercise and physical activity, goal setting, problem solving, social support. 18/21 trials claimed the intervention to be successful in improving at lest one outcome. Three trials showed no benefit	**Author's conclusions:** Evidence suggests that computerised learning technology can play a role in self management behaviours in chronic disease management **Reviewer's conclusions:** Indirect population included children and type I diabetes Heterogeneity prevented meta-analysis Lack of detail provided in included studies for what constituted 'usual care' Lack of detail around methodology and no appraisal of study quality. **Source of funding:** Department of Veterans Affairs, University of Missouri **Additional comments:** No details on theoretical frameworks

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
				(computerised assessment with individual counselling or feedback). 12 of 17 dietary behavioural change outcomes reported significant benefits in favour of the intervention although these were primarily self reported. 1 trial reported no differences in levels of physical activity between groups. 3 trials reported no differences between groups for self efficacy. 3 trials reported no differences between groups for depression. Improvements in A1c were reported in only 3 of 13 trials. Blood pressure was recorded in three trials using multiple measure but only one reported a significant difference. 8 trials assessed a health status measure using multiple tools. 7 of 25 outcomes were reported as successful.	

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Internal validity:	X				
Study results – precision:	NA				
Applicability (external validity):	X				
Overall score:	X				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Chodosh 2005 **Country:** USA **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the effectiveness and essential components of self management programmes for hypertension, osteoarthritis and diabetes **Participants:** Patients with diabetes, hypertension or osteoarthritis Classified as older but no definition of what 'older' was. **Search period:** Up to Sept. 2004 **Search method:** Cochrane Library MEDLINE PsycINFO Nursing and Allied Health Indexed Bibliographies Health Care Quality Improvement Projects database Contact with experts	**Inclusion:** Randomised controlled trials **Exclusion:** No details	**Exposure:** Self management interventions **Comparison:** Usual care or control **Outcome measures:** A1c Fasting blood glucose Blood pressure Pain Function **Follow-up time:** For hypertension- 6 weeks to 9 months For diabetes - 3 months to 32 weeks	**Results:** 53/780 potential studies included. 26 diabetes, 13 hypertension, 14 osteoarthritis. Diabetes Analysis of 20 Self management interventions led to a statistically and clinically significant pooled effect size of -0.36 (95%CI -0.52 - -0.21; P value not given), this is equivalent to a decrease of 0.81% in A1c levels. 17 comparisons from 14 studies indicated no significant difference in weight in the intervention or control groups (ES -0.04, 95%CI -0.16 – 0.07). Hypertension 17 comparisons from 13 studies - Self management interventions decreased systolic blood pressure by 5mmHg (ES -0.39; 95%CI -0.51 - -0.28) and decreased diastolic blood pressure by 4.3mmHg (ES -0.51, 95%CI -0.73 - -0.30). P values were not given.	**Author's conclusions:** Self management programmes for diabetes and hypertension probably produce clinically important benefits Heterogeneity and the potential of publication bias means that the findings should be interpreted with caution. The important components for these programmes could not be isolated **Reviewer's conclusions:** Indirect population as included osteoarthritis, also included education only and self monitoring only interventions and not sub-grouped in analysis. Not detailed the theoretical basis of any of the interventions. 'older' people not defined. There was an observed benefit in A1c and blood pressure. There was significant heterogeneity and potential publication bias. **Source of funding:** Centers for Medicare & Medicaid Services **Additional comments:**

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	X				
Overall score:	?				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Huisman 2009 **Country:** Netherlands **Study type:** Systematic review **Evidence level:** I	**Aims:** Evaluate self regulation interventions for weight reduction in patients with type II diabetes **Participants:** Type II diabetes **Search period:** 1990-2005 **Search method:** Web of Science PubMEd WebSPIRS Reference lists, experts contacted and restricted to english language only. No search strategy only keywords	**Inclusion:** Limited to RCTs and English language A non-surgical or non-pharmacological intervention conducted in an out-patient setting Adults Type II diabetes Sample size >10 Reporting weight loss and A1c **Exclusion:** -	**Exposure:** Self management interventions using self regulation such as anticipatory coping, goal setting efficacy, self reinforcement and emotion control. Duration of interventions 6 to 208 weeks (mean 43.8 weeks). Nearly all face to face and mixture of group and individualised **Comparison:** Not clear **Outcome measures:** A1c Weight BMI **Follow-up time:** 12 weeks to 4 years (mean 58.5 weeks)	**Results:** 34 included studies Weight decreased significantly in the intervention group ES 0.08 (95%CI 0.03 – 0.14; P<0.01). The inclusion of a partner had a moderating effect and increased the effect of weight loss. A1c was significantly lowered in the intervention group ES 0.35 (95%CI 0.21 – 0.49; P<0.001).	**Author's conclusions:** Effective in weight loss and A1c reduction **Reviewer's conclusions:** Systematic review not well reported. Population unclear. Appeared to be heterogeneity that was not discussed and small effect size may not be clinically significant **Source of funding:** Netherlands Organization for Scientific Research **Additional comments:** Self Regulation theory
Internal validity:	X				
Study results – precision:	+				
Applicability (external validity):	X				
Overall score:	X				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Minet 2010 **Country:** Denmark **Study type:** Systematic review **Evidence level:** I	**Aims:** Assessment of self care management in improving glycaemic control in type II diabetes **Participants:** Mean age 60.7 years in behavioural studies and 59.3 in education studies **Search period:** Inception to 2007 **Search method:** MEDLINE, EMBASE, CINAHL, PsycINFO, Cochrane library, SveMed+, Bibliotek.dk, Web of Sciences. Search terms provided only. No attempt to find unpublished studies, reference lists searched.	**Inclusion:** Adults > 18 years Published in English only or Nordic RCTs Diagnosed with type II diabetes **Exclusion:** Abstracts	**Exposure:** Self care management intervention using educational or behavioural strategies **Comparison:** No intervention **Outcome measures:** Behavioural change in A1c **Follow-up time:** 3 months to 8 years. Many studies not stated	**Results:** 47 RCTs A1c - There was a 0.36% (95%CI 0.21 – 0.51) improvement in glycaemic control in the intervention group. This was significant although no P values are provided. Those studies with a shorter follow-up period < 12 months showed greater decrease in A1c than those > 12 months (P=0.017) When the results were adjusted for the effect of education technique versus behavioural psychosocial technique there was an increase in the reduction in A1c in favour of education techniques. Eighteen studies were classified as behavioural, psychosocial techniques and 29 as educational.	**Author's conclusions:** Self care management interventions have an effect, especially those that are compact with sessions tightly grouped together. However the effect may not last over time. There may be an advantage of education techniques over psychosocial, behavioural techniques. **Reviewer's conclusions:** Theoretical framework not discussed only as behavioural psycho-social or motivational or education. Indirect data from educational interventions There was also significant heterogeneity which makes the whole meta-analysis questionable **Source of funding:** Danish Association of Diabetes **Additional comments:**
Internal validity:	?				
Study results – precision:	+				
Applicability	?				
Overall score:	?				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Cochran 2008 **Country: USA** **Study type:** Systematic review **Evidence level:** I	**Aims:** Conduct a meta-analysis to look at the effect of self management interventions on quality of life **Search period:** 1970 - 2005 **Search method:** Good coverage of unpublished literature and 11 electronic databases including CINAHL, CENTRAL, MEDLINE, PsycINFO, EMBASE… And conference abstracts from specified journals and attempt to contact authors	**Inclusion:** Adults (21 years or over) with diabetes undergoing a diabetes self management training programme with quality of life as an outcome. **Exclusion:** - Mean age 59.1 years, baseline A1c 8.38%, 55% females.	**Exposure:** Self management intervention including a recommendation to increase physical activity **Comparison:** Not specified **Outcome measures:** Quality of life **Follow-up time:** Not reported	**Results:** Twenty comparison studies identified There was a lot of heterogeneity in study design. On average there were 7.67 (range 2 - 24) sessions of 117.69 (range 15 – 300) minutes duration and spread over a mean of 27.56 (range 1 – 208) weeks. Only 3 trials reported theoretical frameworks (studies not identified) : transtheoretical model, cognitive behavioural model, behaviour modification theory QoL – There was no between group effect on quality of life. However the intervention group showed significant improvement in QoL over time (P<0.001). There was no effect observed in the control group.	**Author's conclusions:** Results indicated that self management interventions did improve quality of life whilst there was no improvement in quality of life in control subjects. **Reviewer's conclusions:** Less than half of the studies were RCTs. Included indirect population of type I and II diabetes. Only 3 studies included theoretical frameworks. There was heterogeneity between single and multiple intervention comparison studies. Intervention effective but no differences between groups observed. **Source of funding:** National Institutes of Health **Additional comments:** Metholodology not clear
Internal validity:	X				
Study results – precision:	?				
Applicability (external validity):	X				
Overall score:	X				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Heinrich 2010 **Country:** Netherlands **Study type:** Systematic review **Evidence level:** I	**Aims:** To determine the methods and effectiveness of multiple component interventions aimed at self management in type II diabetes **Search period:** 2000 – 2010 **Search method:** Pubmed PsycINFO Web of Science Key word clusters given but no search strategy	**Inclusion:** RCTs of self management in adults (≥18 years) with type II diabetes with a pre-test, post-test design **Exclusion:** Study only focused on one self management component, clinical parameters were the only outcome, not describing specific results for type II diabetes, the control group received a different intervention	**Exposure:** Multiple component self management interventions **Comparison:** Usual care with no intervention **Outcome measures:** Behaviour, clinical outcomes, process outcomes **Follow-up time:** Not reported	**Results:** 19 papers of 14 studies. Seven of the studies included learning and planning and three studies used learning, planning and practice. Seven studies reported the theoretical background of the intervention. Four described some theoretical concepts such as self efficacy (Anderson, 2005; Christian, 2008; Adolfsson, 2007; Gaede 2001) The remaining had no theoretical foundation (Skelly, 2005; Kim, 2003; Hornsten, 2005) A significant effect size was observed for diet in favour of the intervention groups (range ES 0.29 to 1.0) and positive effects were seen in different intervention types. 5/10 trials reported positive effects for physical activity with medium to large effects. The remainder reported a lack of effectiveness. 4/5 studies reporting frequency of SMBG found positive effects	**Author's conclusions:** Self management interventions had positive effect on diet, SMBG, and quality of life. There were mixed results for exercise. Group interventions with a practice component seemed most effective in glycaemic control. Multi component interventions potentially lead to clinically relevant changes in behaviour and some clinical parameters. **Reviewer's conclusions:** Included pilot studies and studies with indirect populations and lifestyle interventions as well as multiple and single self management interventions No appraisal of quality, no meta-analysis, no P values given. Some interventions appear to have been effective but it is not clear of the effectiveness over time. **Source of funding:** Dr Paul Janssen Foundation **Additional comments:** Overall, not a good quality systematic review

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				with large effect sizes regardless of intervention type. 5/13 studies reported decreased A1c levels at follow up in favour of the intervention group and four of these studies used a group intervention (ES ranged from 0.26 to 1.25). No overall effect on decreased BMI appears to have been reported in the summary.(No ES given) No effects were reported on blood pressure changes between intervention and control.(No ES given) Beneficial effects of the intervention on quality of life were reported in four studies that reported this outcome. The interventions varied in type and method.(no ES given). Positive benefits on self efficacy were also reported in 3/5 studies reporting this outcome (no ES given)	
Internal validity:	X				
Study results – precision:	Na				
Applicability	+				
Overall score:	X				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Fan 2009 **Country:** Canada **Study type:** Systematic review **Evidence level:** I	**Aims:** To examine differences in knowledge, self management behaviours and metabolic control with various diabetes self management intervention elements **Participants:** > 18 years, . Type II diabetes, undergoing a self management intervention which was education, psychological, behavioural or mixed, delivered in primary or acute settings, outcomes to include knowledge, self management behaviours, A1c, fasting glucose, blood pressure, lipid profile or BMI Mean age of participants 56.4 years, females ≤40%, years of formal education 9.7 years, mean duration of disease 7.9 years,	**Inclusion:** RCTs Published in english Employing diabetes self management interventions which could be educational, psychological, behavioural or a combination **Exclusion:** -	**Exposure:** Employing diabetes self management interventions which could be educational, psychological, behavioural or a combination **Comparison:** No intervention **Outcome measures:** Knowledge, self management behaviours, A1c, fasting glucose, blood pressure, lipid profile or BMI **Follow-up time:** Not specified	**Results:** 50 studies identified (not detailed in paper) The interventions were typically mixed types offering a mixture of didactic and interactive elements in individualised and group formats. They usually covered more than one topic and were delivered in a mean of 10 sessions (range 1-28) for a mean of 17 contact `hours (range 1 to 52) over a mean of 22 weeks (range 1 to 48). 68% did not provide any booster sessions. The effects sizes reported were: Diet (n=18 studies) 0.26 (SE 0.04) P = 0.00 Exercise (n = 16 studies) 0.40 (SE 0.09) P = 0.00 SMBG (n=9 studies) 0.70 P = 0.00 Systolic blood pressure (n=12 studies) 0.57 (SE 0.14) P = 0.00	**Author's conclusions:** The findings will help in the design of diabetes self management programmes **Reviewer's conclusions:** Some indirectness in the populations as there were a few education only interventions, could be delivered in primary or acute settings. Poorly conducted systematic review. Lacked forest plots, assessment of heterogeneity and summary of individual trials. **Source of funding:** Canadian Diabetes Association **Additional comments:** The included studies were not identified anywhere in the paper. The quality of included studies was not discussed in the paper There was no discussion of any theoretical framework related to any of the papers

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
	the majority of the studies were conducted in outpatient or primary care settings. **Search period:** 1990 - 2006 **Search method:** Medline, CINAHL, Health STAR, EMBASE, key words provided in paper. Additional journals also searched manually, no evidence of grey literature searching or contacting authors			Diastolic blood pressure (n=10 studies) 0.66 (SE 0.20) P =0.00 BMI (n= 34 studies) 0.28 (SE 0.08) P = 0.00 Larger effect sizes were seen in behavioural studies than for other types of interventions for self care outcomes (Effect size 0.92, SE 0.24, P ≤ 0.05) and metabolic outcomes (effect size 0.63, SE 0.24, P ≤ 0.05) The effect size was greatest for self care behaviour for interactive teaching methods (effect size 0.54, SE 0.11, P≤ 0.05) There was a general trend do increased effect sizes with increased number of sessions offered. Those interventions offering multiple topics had consistently larger effect sizes compared to those offering one topic Interventions of longer duration	

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				≥ 24 weeks produced larger effect sizes in metabolic and self management outcomes.(P≤ 0.05)	
Internal validity:	X				
Study results – precision:	X				
Applicability (external validity):	+				
Overall score:	X				

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Adolfsson 2006 **Country:** Sweden **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate the impact of an empowerment programme on type 2 diabetes patients' confidence in diabetes knowledge, self efficacy, satisfaction with daily life, BMI and glycaemic control compared with the impact of routine diabetes care on the same factors at a 1-year follow-up.	**Study setting:** Primary care settings in central Sweden **Participant characteristics:** Identified from practice registers 61% female, mean duration of disease 6.6 years **Inclusion:** Receiving dietary or oral anti-diabetes treatment; ≤75 years of age; ranging from 6.5 to 10%; diabetes duration of at least 1 year; considered by the physician and the diabetes specialist nurses at each primary care centre to be able to participate in an education group; and able to understand the Swedish language. **Exclusion:** Known alcohol abuse; known mental disability; presence of serious disease (stroke, late stage of cancer); patients who had previously participated	**Exposure: n=50** 'Empowerment' 4-5 sessions (timeframe not clear) 2.5hrs each Content: Identifying problem areas, diet, physical activity, general diabetes facts, medication, complications, SMBG, goal setting Plus usual care biannual physician visits **Comparison: n=51** Usual care including biannual physician visits **Outcome measures:** Confidence in diabetes knowledge, self efficacy and satisfaction with daily life A1c BMI **Follow-up time:** 1 year	**Results:** There were no differences in self efficacy, satisfaction with daily life, BMI or A1c between the intervention and control groups	**Author's conclusions:** No differences between groups for self efficacy, satisfaction with daily life, BMI or A1c **Reviewer's conclusions:** Intervention and control patients came from different primary care centres. **Source of funding:** Swedish Diabetes Association **Additional comments:** 'Empowerment' Group intervention – 5- 8 per group Led by physicians and diabetes nurse specialists trained in empowerment

		in group education.			

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer randomised
Allocation concealment	Low risk	Sequential sealed opaque envelopes
Blinding	High risk	No blinding
Incomplete outcome data	Unclear risk	Minimal losses over time, ITT analysis but per protocol data presented
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Anderson 2005 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the impact of a problem based empowerment programme for African Americans with diabetes	**Study setting:** Convenient community based setting in Detroit **Participant characteristics:** Recruited through community, churches and media advertising 82% female, Mean age 61 years, 96% African American, mean duration of disease 8.5 years, 73% completed high school. Baseline A1c 8.6% **Inclusion:** No details **Exclusion:** No details	**Exposure: n=125** Empowerment programme 6 weeks- 2 hour sessions, group intervention Content include review of blood work. Identifying goals and action plans, emotions of living with diabetes, problem solving, diabetes facts, culturally relevant materials such as recipes **Comparison: n=114** Wait list control who then were offered the intervention at the end of 6 weeks **Outcome measures:** A1c Lipid profile Blood pressure Diabetes Care Profile (DCP) Diabetes Empowerment Scale – short form (DES) **Follow-up time:** 6 weeks	**Results:** There were no significant differences between intervention and control group at six weeks follow up in A1c, weight change, blood pressure, Diabetes Empowerment. Both group showed significant improvements in glycaemic control through reduced A1c over time. Both groups showed significant improvements in Diabetes Empowerment Scale	**Author's conclusions:** There was no benefit to participation in a 6 week intervention programme. **Reviewer's conclusions:** Self selected Over-represented by females Study lacked clear inclusion and exclusion criteria No differences were identified in target behaviours between groups although there were improvements over time within the groups. **Source of funding:** NIH and Michigan Diabetes Research and Training Center **Additional comments:** Empowerment theory Group intervention led by certified diabetes educators At the end of 6 weeks the control group were offered the intervention and then all participants followed up for 1 year. As there is no control after 6 weeks we are only reporting on follow up data to this point.

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	No reasons for attrition , not clear if ITT
Selective reporting	High risk	Reported weight change which was not listed a priori

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Anderson 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate a telephone self management intervention in an underserved population with type II diabetes	**Study setting:** Underserved population in Connecticut, USA **Participant characteristics:** 58% female, 64.1% Hispanic, 49% educated for 9-12 years, Recruited from clinic registers Baseline A1c 8.0% **Inclusion:** Type II diabetes, aged 18 or over **Exclusion:** Unwilling or unable to consent, not able to speak English/Spanish, no telephone, active substance abusers, mental or physical impairment preventing engagement	**Exposure: n=146** Telephone intervention, unstructured, lasting for 1 year. Calls could be weekly, bi-weekly or monthly based on risk stratification for A1c and/or hypertension and/or complications. Also received mail educational material. Contents of telephone calls included diet, stress reduction, exercise, smoking cessation, readiness to change, goal setting, self monitoring, problem solving and medication adherence **Comparison: n=149** Usual care **Outcome measures:** A1c Height Weight BMI Rapid Assessment of Physical Activity Patient Health Questionnaire – for depression Overall health Brief Dietary Assessment Lipid profile	**Results:** A1c levels adjusted for baseline showed no differences between groups. Nor was there any effect based on baseline A1c <7% or >9%. There were no differences between groups at 12 months for perceived health status, self reported physical activity, intake of fruit and vegetables, BMI or Blood pressure. There was no influence of language, education or baseline depression	**Author's conclusions:** The intervention was not effective with this population **Reviewer's conclusions:** Significant differences in baseline A1c between groups. Only 297 of 1754 eligibles enrolled in study. Non- Compliance in both groups >20% Although the intervention took place over a year it did not appear to be any more effective than usual care Usual care may have included some education and self management components thus negating effect **Source of funding:** Connecticut Health Foundation **Additional comments:** Chronic Disease Self Management Programme (Stanford Model) Individualised Delivered by 'trained' nurses

			Follow-up time: 1 year		

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Block randomised
Allocation concealment	Low risk	Centralised by research assistant
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Main reason for losses was loss to follow-up, ITT conducted but quite high attrition and lack of compliance
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Bond 2007 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the effectiveness of a web based intervention on diabetes management in those aged 60 years or older	**Study setting:** Own home **Participant characteristics:** Enrolled through diabetes centre and through community advertising and flyers Mean age 67.2, years of education 15.85, years of diabetes 16.95, 45% female, 86.5% white. Baseline A1c 7.1% **Inclusion:** Diagnosed with type II diabetes for 1 year or more, aged 60 years or older, living independently in the community and able to speak english **Exclusion:** Moderate to severe cognitive impairment, physical or visual impairment. Presence of severe comorbid disease.	**Exposure: n=** Web based intervention Content included access to articles, online advice, counselling and encouragement, tailored self management instruction for developing personal action plan, weekly online chat/forum, education/discussion session, internet bulletin board, problem solving, psychosocial support, daily logging of blood glucose, physical activity, blood pressure and medication and diet. **Comparison: n=** Usual care **Outcome measures:** A1c Weight Blood pressure Lipids Comorbidity Questionnaire **Follow-up time:** 6 months	**Results:** There was a significant decrease in A1c levels in the intervention group compared with the controls (P<0.01) Those with a higher baseline A1c in the intervention group saw the greatest decrease in levels at follow-up. Diastolic blood pressure was significantly lowered in the intervention group (P<0.01) by a mean of 6.8mmHg compared with 5.2mmHg in the control group which did not differ significantly between baseline and follow-up. The authors did not report between group differences. Weight decreased significantly in the intervention group over time (P<0.001) but not in the control group. No between group differences were reported.	**Author's conclusions:** Intervention appears to be effective in reducing target behaviours using a web based intervention **Reviewer's conclusions:** Some indirectness as only 81% had type II diabetes Appears to be effective but authors only report within group differences and not between group differences **Source of funding:** National Institute of Nursing Research **Additional comments:** Self efficacy Individualised and group facilitated by a nurse
Bias	**Judgement**			**Support for judgement**	

Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	Low risk	Research staff blinded
Incomplete outcome data	Low risk	All subjects appear to be accounted for in analysis
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Cade 2009 **Country:** UK **Study type:** RCT **Evidence level:** II	**Aims:** To assess whether the Expert Patient Programme, adapted for patients with Type II diabetes can be used to promote healthy eating and glycaemic control	**Study setting:** GP practices in Lancashire **Participant characteristics:** Mean age 65.8 years, 42% were female, 95% were White European, 20.5% had degree level education. **Inclusion:** Type II diabetes, over 30 years, not on insulin within first year, registered with GP practices selected from socially deprived areas **Exclusion:-**	**Exposure: n= 162** Expert Patient Programme First six sessions included coping with a long term problem, improved eating, relaxation and exercise patterns. One session specifically about diabetes which focused on self monitoring, food intake, physical activity, blood glucose, blood pressure, goal setting **Comparison: n=155** Standard care, including appointment with dietician (15-30 minutes) given standard dietary advice **Outcome measures:** A1c BMI Waist circumference, lipid profile, blood pressure Dietary change Diabetes Empowerment Scale (DES) Audit of Diabetes Dependant Quality of lIfe Scale (ADDQoL) **Follow-up time:** 6 months and 1 year	**Results:** There was no significant differences in any of the outcome measures between groups including A1c and no differences in any of the lifestyle outcomes, BMI, Blood pressure	**Author's conclusions:** The EPP approach was not effective in changing glycaemic control or dietary behaviour **Reviewer's conclusions:** Compliance was poor, only 22 patients attended all 7 sessions. The paper did not report any data on psychological outcomes. High levels of attrition may have compromised results **Source of funding:** Food Standards Agency **Additional comments:** Peer led intervention Expert Patient Programme
Bias	**Judgement**		**Support for judgement**		

Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Patients were lost between randomisation and baseline no details of attrition, no ITT
Selective reporting	High risk	There were no details on the psychological measures

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Christian 2008 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To test the effect of physicians providing lifestyle counselling with patients with type II diabetes during usual care	**Study setting:** 2 Outpatient clinic settings. Potential participants identified from registries **Participant characteristics:** Over 65% Hispanic 66.5% female Mean age 53.2 years Mean A1c 8.17% **Inclusion:** Latino/Hispanic, aged 18 – 75 years, diagnosis of type II diabetes, BMI >25, uninsured, Medicaid eligible or beneficiaries **Exclusion:** Substance use or abuse, severe arthritis, or other medical conditions limiting physical activity, recent MI or stroke, peripheral vascular disease or scheduled or undergone or gastric bypass surgery.	**Exposure: n=155** Lifestyle counseling using motivational interviewing during a usual care follow up meeting Computer baseline assessment of motivational readiness which resulted in an individualized report looking at goals, barriers, suggestions on motivation, self efficacy and decision making. Participants identified 2-3 goals based on this report for dietary and physical activity changes. Also received a 30 page guide on diabetes and achieving lifestyle changes. Summary of report also provided for physician and provided them with patient specific counseling recommendations **Comparison: n=155** Received health education materials on diabetes at baseline visit, attended usual physician follow-up but no motivational interviewing **Outcome measures:** BMI 7 day physical activity recall instrument	**Results:** The number of intervention patients achieving 150 MET-min or more minutes of physical activity per week at moderate intensity increased from 16% to 53% (P<0.001) compared with the controls (30% to 37%) (P=0.27) No differences in weight loss between groups. However, 21% of the intervention group had sustained weight loss of 5% or more at 12 months compared with 10.6% of controls (P<0.01). The intervention group decreased self reported caloric intake by a mean of 8.3% per patients versus 4.4% in the controls (P=0.06) There was no difference between groups in A1c level at follow up	**Author's conclusions:** A brief intervention between patients and health provider about behavioural goals can lead to increased physical activity and weight loss **Reviewer's conclusions:** Patients selected their goals in advance of meeting the doctor and appeared effective in brief encounters with the primary care physician sustained to 12 months **Source of funding:** US National Institute of Diabetes and Digestive Kidney Diseases **Additional comments:** Motivational interviewing Individualised intervention Led by primary care physicians who had undergone 3 hr training session using motivational interviewing

			Food frequency instrument Weight loss A1c **Follow-up time:** 3, 6, 9 months		

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated
Allocation concealment	Low risk	assignment concealed to the researcher
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Lacked reasons for all attrition but did conduct ITT analysis
Selective reporting	High risk	Some outcome measures like BP not listed a priori

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Cooper 2008 **Country:** UK **Study type:** RCT **Evidence level:** II		**Study setting:** 3 centres (inner city, suburban and urban) 89 participants **Participant characteristics:** Recruited from diabetic clinics or GP clinics Mean age 59 (range 35 – 73) years, duration of disease 6 years (1 – 30), 44% female, A1c at baseline 7.5% (4.6 – 11%) **Inclusion:** Type II diabetes, diagnosed for at least a year, aged 21-75 years, undergoing annual check-ups **Exclusion:** Persistent defaulters, significant drug or alcohol problem or other disability preventing participation	**Exposure: n=53** LAY (Look After Yourself) 8 weeks 2 hr duration each Uses group discussion, role playing goal setting, relaxation, skills practice, physical activity and exercise, diet, smoking cessation, diabetes facts **Comparison: n=59** Wait list **Outcome measures:** A1c BMI Medication Diabetes Integration Questionnaire Personal Models of Diabetes Questionnaire Summary of Diabetes Self-Care Activities Qualitative focus group **Follow-up time:** 6 and 12 months	**Results:** No changes in BMI at 6 or 12 months A1c levels were significantly lower in the intervention group at 6 months but this did not persist to 12 months (change -0.1% versus +1.0%, P =0.0005) Regression analysis indicated that the higher the baseline A1c level the more likely it was for the level to fall and higher attendance at the intervention also predicted greater falls in A1c levels. There was no significant difference between groups for level of perceived control although the intervention group did show a positive increase at 6 and 12 months. There were no significant differences in diet or exercise patterns at 6 or 12 months Self monitoring practice did show a highly significant increase (change +25% versus +16%, P=0.002) in the intervention group at 12 months (but not 6 months)	**Author's conclusions:** Associated with only limited benefits in glycaemic control, Positive effects on educational and psychological outcomes **Reviewer's conclusions:** Compliance with intervention okay. The subjects represented less than half of those approached and generalisability may be compromised Benefit observed in A1c did not perist **Source of funding:** Diabetes UK **Additional comments:** Based on empowerment stressing motivation and skill teaching Group programme Led by health professionals – diabetes nurse specialists
Bias	**Judgement**			**Support for judgement**	

Random sequence generation	Unclear risk	Non details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	No subjects in intervention group lost to short term follow up . Reasons given for long term losses and ITT analysis conducted
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: D'Eramo Melkus 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate a culturally appropriate diabetes self management programme	**Study setting:** Primary care **Participant characteristics:** N= 109 Mean age 46 years, 46 % had a education at high school level or higher **Inclusion:** Black women, aged 21-65 years, confirmed diagnosis of type II diabetes, not requiring insulin therapy, BMI < 37, receiving treatment from a primary care provider, not pregnant or lactating, able to read English. **Exclusion:** Serious psychological or medical illness or diabetes related complication	Both groups received nurse practitioner delivered diabetes care visits in the primary care setting and were encouraged to self monitor blood glucose (SMBG) **Exposure: n= 57** 11 weekly group sessions. Sessions 1-6 (2 hrs each) Culturally appropriate, cognitive-behavioural diabetes self management based on AADE standards. Used transtheoretical model to move subjects from preparation to action stage. Content included what is diabetes and health related risks for Black Americans, especially women; social networks, and healthy food. Intervention supported by video and cookbook. Weeks 7- 11 (1 hr each) was coping skills training led by a clinical psychologist or psychiatric mental health nurse practitioner. Content included understanding stress, problem identification, problem solving strategies, stress management and communication **Comparison: n=52** Conventional diabetes education followed by group question and answer sessions for 10 weeks in groups of 8-10. Weeks 1-5 were (1.5hr duration) and involved diabetes education and sessions 6-	**Results:** Both groups showed significant decreases in A1c and systolic blood pressure compared with baseline. However at 24 months follow there were no significant differences between groups Diabetes related emotional distress was lower in the intervention group at 24 months than the control group (P=0.01) Diabetes knowledge increased in both groups (P<0.001). No between group effects were reported. Between group differences were not reported for self efficacy which fell below baseline in both groups at 24 months follow-up Quality of life. In the physical function domain . This was significantly higher in the intervention compared to the control group at 24 months (P=0.03) Non compliers were more likely to have lower education, income and be unemployed.	**Author's conclusions:** There was a marked improvement in glycaemic control in both groups. Education alone play ed a role in its reduction. Some psychological factors were reduced and sustained in the diabetes self management group suggesting that a combination of interventions is required for physiological and psychological benefit. **Reviewer's conclusions:** Different duration of interventions. Mixed methods used for selection, 70% referrals and 30 self selected. Somatic anxiety higher at baseline in intervention group. Attrition levels high **Source of funding:** National Institutes of Health **Additional comments:** *Combined social learning theory and transtheoretical model of behavioural change.* Nurse led programme Group programme

			10 (1 hr) and were for diabetes discussion. **Outcome measures:** BMI, Serum screening tests A1c, Fasting glucose BP, Lipids Anxiety (Crown-Crispin Index) Emotional distress – Problem Areas in Diabetes Survey Social support – Diabetes Care Profile Diabetes Self Efficacy Outcomes Expectancies Questionnaire Diabetes Knowledge Test QoL – SF36 Health Provider Support – Modified Health Care Climate Questionnaire **Follow-up time:** 12 month and 24 month follow-up		

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Randomised
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Attrition high but authors looked at differences between completers and non completers
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Davies 2008 **Country:** UK **Study type:** RCT- cluster randomised **Evidence level:** II	**Aims:** To evaluate the effectiveness of a structured group education programme on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed type 2 diabetes.	**Study setting:** Primary care sites **Participant characteristics:** 45% female, mean age 59.5 years, 94% White, Basleine A1c 8.1% **Inclusion:** Newly diagnosed with type 2 diabetes, within 4 weeks of diagnosis **Exclusion:** Aged less than 18 years, had severe and enduring mental health problems, were not primarily responsible for their own care, were unable to participate in a group programme (for example, housebound or unable to communicate in English), or were participating in another research study.	**Exposure: n= 437 education and self management programme** Group (mean 5, range 3-11) Intervention to commence within 12 weeks of diagnosis and provided by trained health care professionals,. Programme was 6 hours long and facilitated by two educators. Learning was elicited rather than taught. Content: lifestyle factors (food, physical activity, cardiovascular risk factors), medication, identification of personal risk factors and setting of achievable goals of behaviour change. Included access to usual education programme. In addition the practices were also provided with examples of resources, guidelines, treatment algorithms and guidance notes on 'breaking bad news' **Comparison: n=387 Usual Care** Usual education provided by health care provider, dietician or nurse and support group **Outcome measures:** A1C BP Body weight, waist circumference	**Results:** After adjustment for baseline and cluster effect there was no significant difference between groups for A1C at 12 months follow-up (P=0.52). Weight loss – Intervention mean -2.98kg (95%CI-3.54 - -2.41), control -1.86kg (95%CI -2.44 - -1.28). After adjustment for baseline and cluster effect there was a significant difference at 4 months (P=0.024) and 12 months (P=0.027). Those who reported a greater increase in their perceived responsibility for the course of their diabetes lost more weight (P<0.002 at 4 months and P<0.008 at 12 months) Participants in the intervention group showed a greater increase in physical activity at all time points, and this was significant at four months (P=0.046). Significant differences in the illness belief scores (P<0.01) in favour of the intervention group	**Author's conclusions:** A group structured education programme focused on behaviour change can successfully engage those with newly diagnosed type 2 diabetes in starting additional effective lifestyle changes sustainable over 12 months from diagnosis. There was an improvement in health beliefs in the intervention group. **Reviewer's conclusions:** Baseline characteristics not well matched at baseline for A1C, medication and females. The representativeness of the eligible population is not clear Changes sustained over 12 months. The weight loss reported is very modest and may not be clinically significant for health improvement. Intervention can be used for groups of up to ten at a time allowing delivery to a large number of people **Source of funding:** Diabetes UK, Novo Nordisk **Additional comments:** Newly diagnosed (within 4 weeks) Group education, community based.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			Diabetes self care activities questionnaire International physical activities questionnaire WHOQOL-BREF Illness perceptions questionnaire – revised Diabetes illness representations questionnaire Problem areas in diabetes scale Hospital Anxiety and Depression scale (HAD) **Follow-up time:** 12 months	indicated that they had greater understanding of their illness and its seriousness. Depression scores were lower in the intervention group compared with the control group at all time points and this was significant at 12 months (P=0.032). There were no differences in measures of quality of life	Based on Leventhals common sense theory, the dual process theory and social learning theory Primarily self efficacy). The philosophical background was patient empowerment. The authors reported on the UK prospective diabetes study risk engine although this was not pre-specified.

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details but stratified
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No details
Incomplete outcome data	Unclear risk	ITT paper details how missing data was dealt with statistically
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Deakin 2006 **Country:** UK **Study type:** RCT **Evidence level:** II	**Aims:** To develop a patient centred, group based self management programme	**Study setting:** Primary care in Lancashire, UK. 16 GP practices. **Participant characteristics:** N= 314 Average age 61.5 years, duration of disease 6.7 years, educated up to age of 15.8 years of age, ethnicity not reported 48% women. **Inclusion:** Type II diabetes **Exclusion:** Housebound or those with reduced cognitive ability	**Exposure: n=157** X-PERT programme. Six weekly sessions lasting 2 hrs with an average of 16 participants plus carers. Content: Diet, self monitoring, emotions, exercise, complications, board game, goal setting, psychosocial aspects of diabetes. All patients received a diabetes resource manual **Comparison: n=157** Routine care plus diabetes education and review with dietician (30 minutes), practice nurse (15 minutes) and GP (10 minutes) **Outcome measures:** A1c Lipid profile Blood pressure BMI Body fat Waist circumference Medication prescribed Diabetes knowledge Nutritional intake Diabetes Self Care Activities Satisfaction	**Results:** Significant decreases in A1c in intervention group compared to control group (-0.6% versus +0.1%, P<0.001) at 14 months Body weight decreased in intervention group (-0.5kg versus +1.1kg, P<0.001) compared with control Reduced BMI in intervention group (-0.2kg/m2 versus+0.4kg/m2, P<0.001) There was no statistical significant difference between groups in blood pressure. At 4 months the intervention group were exercising significantly more often than the control group (difference 0.9 days/week, 95%CI 0.3 – 1.6) similarly at 14 months (difference 0.9 days/week, 95%CI 0.3 – 1.6) (P values not given) At 4 months SMBG was significantly increased in the intervention group (no p value given) but the number of days per week undertaking SMBG was not sustained at 14 months.	**Author's conclusions:** Participation in the programme resulted in increased glycaemic control, reduced body weight, BMI, increased dietary changes, self empowerment and self management skills. **Reviewer's conclusions:** High levels of attendance. Subjects identified from practice registers. Attempt made to maximise attendance through having translators available. Changes in A1c, body weight and BMI were sustained at 14 months. Changed in the frequency of monitoring that had been reported at 4 months were not sustained at 14 months. May be due to increased confidence an less need to self monitor **Source of funding:** NHS Executive North-West, Burnley Health Care Trust, Pendle Primary Care Group British Dietetic Association **Additional comments:** Based on theories of 'empowerment' and 'discovery learning' Led by research dietician

			Quality of Life (ADDQoL) Diabetes Empowerment Score (DES) **Follow-up time:** 4 and 14 months	The intervention group significantly increased their daily consumption of fruit and vegetables more than the control group (+2.4 portions versus +0.2 portions P=0.008) There were significant differences in favour of the intervention group for empowerment (P=0.04) and in subscales for psychosocial adjustment (P=0.03), readiness to change (P=0.01) and goal setting (P=0.003).	

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Permuted block randomisation
Allocation concealment	Low risk	Opaque envelopes
Blinding	Low risk	Attempt for patients and outcome assessors were blinded
Incomplete outcome data	Low risk	Flow chart, minimal losses and ITT conducted
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Glasgow 2006 Glasgow 2006a (This describes the same trial as Glasgow 2006) Williams 2007 - secondary analysis **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate a computer assisted self management intervention for diabetes	**Study setting:** Identified from GP registers in Denver, Colorado **Participant characteristics:** Mean age 61.5 years, 30% had achieved high school education , 75% were White Baseline A1c7.4% **Inclusion:** Adults diagnosed with Type II diabetes for at least 6 months, residing in Denver, Colorado, 25 years or older, able to read and write english **Exclusion:** Physicians opinion on suitability of patient	**Exposure: n=174** Tailored Self Management Delivered in a central clinic or medical office close to patients home. Used a CD-ROM programme based on assessment of current health behaviour, feedback, identification of barriers and benefits to change, tailored goal setting, action planning. Focus on healthy eating and physical activity Included reinforcement with tailored follow up letters Supported by individuals with experience in motivational interviewing Print out used as tool to facilitate dialogue with health coach After 1 week and 1 month follow up calls received from health coach to review goals and revise plan if required. A tailored newsletter also received approx. 6 weeks after first visit.	**Results:** There was a significant and clinically meaningful reduction in dietary fat intake in the intervention group (P=0.006). No difference in fruit and vegetable intake. There was significantly greater weight loss (-0.68kg versus 0kg) in the intervention group compared with the control (P=0.0007) No differences in A1c between groups No differences in psychosocial or quality of life scales	**Author's conclusions:** Intervention appealed to participants and improved target behaviours **Reviewer's conclusions:** Only 41% of eligible patients participated Attrition only 10% at 2 month follow-up Very short term follow up . Unclear if sustained at 6 months **Source of funding:** National Institute of Diabetes and Digestive and Kidney Diseases **Additional comments:** Chronic Care Model, health coaching and motivational interviewing Individualised Supported by individuals experienced but not trained in motivational interviewing

			Summary also sent to primary care physician **Comparison: n=161** Usual care **Outcome measures:** Dietary change All Day NCI Fruit and Vegetable Screener Diabetes Distress Scale/Problem Areas in Diabetes Scale Patient Health Questionnaire A1c Lipid profile **Follow-up time:** 2 months		

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Although attrition low and ITT analysis conducted authors reported per protocol data, no reasons given
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Gregg, 2007 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To apply an acceptance approach to coping with diabetes	**Study setting:** Low income community health centre **Participant characteristics:** Mean age 50.9 years, 46.9% female, 28.4% Hispanic and 23.5% White, 24.1% attended high school, diabetes duration 6.0 years. Baseline A1c 8.19% **Inclusion:** English speaking, type II diabetes, receiving medical care in a low income community, referred by primary care provider. **Exclusion:** -	**Exposure: n=43** Acceptance and Commitment Therapy Attended workshop based on an ACT manual that covered the educational material in an abbreviated form (4hr) and in addition participants received mindfulness and acceptance training, exploring personal values. **Comparison: n=38** Attended a workshop following an education manual that lasted 7 hours and was run by the manuals author. Contents: disease process, nutrition, physical activity, medication, SMBG, use of glucose results, complications. **Outcome measures:** A1c Exercise Diet SMBG Diabetes Care Profile Acceptance and Action Diabetes Questionnaire (AADQ) **Follow-up time:** 3 months	**Results:** There was a significant effect in favour of the intervention group on A1c <7% (P=0.009) indicating good diabetic control. There was no significant difference between groups for A1c levels although the intervention group showed a significant decrease in A1c between baseline and follow-up (P<0.05).	**Author's conclusions:** A one day workshop including mindfulness and values-based action improved glycaemic control compared with traditional education **Reviewer's conclusions:** Likely to be low literacy population. One day workshop appeared to be effective in this group after 3 months but no longer term follow up reported to see if this was sustained **Source of funding:** No details **Additional comments:** Acceptance and commitment therapy (ACT) 10-24 participants Led by authors of manuals

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Random number tables
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Attrition low and reasons given, ITT analysis
Selective reporting	Low risk	A priori outcomes reported

ACT teaches individuals to accept their feelings and 'diffuse' or disengage from the content by focusing more mindfully on the process of thinking itself and to link this to goal based action. Individuals are asked to work towards those goals and values they hold while experiencing their thoughts and feelings.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: King 2006 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the effectiveness of a multifaceted physical activity intervention for people with type II diabetes	**Study setting:** External to the primary care setting but not clear where **Participant characteristics:** Recruited from lists of participating physicians Mean age 61.5 years, 50.2% female, 15.2% had graduate degree, 76.5% White and 17.8% Hispanic **Inclusion:** At least 25 years, diagnosed type II diabetes for 6 months or more, able to read and write English, able to participate in physical activity at a moderate level. **Exclusion:** -	**Exposure: n=174** Tailored self management intervention that combined an interactive CDROM (developed for the Diabetes Health Conection Study) with one on one health counselling and telephone follow-up support between visits. The CDROM examined problem solving, goal setting and participant choice. For physical activity part of the plan participants were asked to select 2 specific activities from a list of common physical activities. Participants identified barriers to achieving the goal and selected strategies to overcome these. The computer printed a tailored diet/physical activity action plan that was then further tailored by the participant and the coach. Also asked to set a goal for resistance training using Therabands and this formed part of the printed tailored action plan. Visits at baseline and 2 months lasted 3 hrs and included 30 minutes assessment, 45 minutes CDROM use, 60 minutes coaching and 30 minutes to review the	**Results:** The intervention significantly increased 'moderate' physical activity compared with controls (P=0.001). Intervention group also showed significant increase in strength training compared with the control group (P<0.001). The gains in the intervention group were due to a decrease in lifestyle physical activity such as taking the stairs and walking or biking for transport and an increase in rote activity such as jogging, stretching and resistance training. Participation in sporting physical activity was very low in both groups and remained virtually unchanged. Those who favoured a mix of rote and lifestyle activities expended the greatest amount of weekly calories in moderate physical activity	**Author's conclusions:** Adults with type II diabetes who used a combination of computer assisted self management and health coaching were able to develop a tailored plan to increase their moderate physical activity. **Reviewer's conclusions:** <10% attrition High compliance with computer activity Only 2 months follow-up so not clear if effects persist over time Did not look at non-participants to see if they differed Relied on self report for physical activity Intervention appears effective but is limited due to the short follow-up . Unclear if the difference is sustained **Source of funding:** National Institutes of diabetes and digestive and kidney disease **Additional comments:** Based on goal systems theory, social cognitive theory (self efficacy) and social ecological theories.

			Theraband exercises. Also received phone call follow-up at 1 week and 1 month after first visit and a newsletter 6 weeks after first visit. **Comparison: n=161** Completed an interactive health risk computerised appraisal and received brief generic health counselling but no follow-up. Session was 90 minutes (30 mins assessment, 20-30 mins computer interaction 20-30 mins review of printout). **Outcome measures:** CHAMPS Questionnaire for physical activity self reported **Follow-up time:** 2 months		Used motivational interviewing Individualised intervention, facilitated by a trained health professional.

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Reasons for attrition not given, <10% and used last observation carried forward
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Kulzer 2007 **Country:** Germany **Study type:** RCT **Evidence level:** II	**Aims:** Comparison of three education programmes for type II diabetes on efficacy outcomes	**Study setting:** Community settings **Participant characteristics:** 181 participants Mean age 55.6 ± 6.3 years, duration of disease 6.6 ±6.2 years, 49.7% female Groups similar at baseline Patients referred by general practitioners and self selected through media advertising and radio **Inclusion:** Type II diabetes, 40-65 years, not requiring insulin, stimulated C peptide >0.8nmol/l, BMI >26.7, no acute psychiatric illness, able to speak german **Exclusion:** -	**Exposure: n=63** Self management/empowerment focused on emotional, cognitive, and motivational processes of behavioural change particularly in the domains of eating and physical exercise. Group programme, 12 sessions of 90 minutes duration each **n=66** Self management/empowerment focused on emotional, cognitive, and motivational processes of behavioural change particularly in the domains of eating and physical exercise. 12 sessions of 90 minutes each. Six were group and six individualized. **Comparison: n=64** Didactic-oriented intervention focusing on acquisition of knowledge, skills and information about the correct treatment for diabetes. 4 sessions of 90 minutes each **Outcome measures:** A1c Weight Diabetes knowledge Three Factor Eating Questionnaire	**Results:** A1c was significantly reduced in the Group self management intervention compared with the control (P=0.017) the individualised/group self management group also had decreased A1c compared with the control at 3 months (no value given) but this was not sustained to 15 months. The decreased BMI observed in the self management groups was sustained over time Anxiety was significantly reduced in the group self management programme compared with control and there were no differences between self management programmes and the effect was sustained over time There was no difference between groups in negative well being although this was reduced in all three groups. Regular exercise was significantly more stimulated in the self management programmes compared with control and the group programme was superior to the	**Author's conclusions:** Self management had a significantly higher medium term effect than didactic diabetes education. The group sessions were more effective than individual ones **Reviewer's conclusions:** Attrition levels low and reasons provided. Mixture of self selection and referral . The group self management programme showed sustained effects for A1c, reduced anxiety, eating and BMI over time. Attendance rates for all groups was very high. What was termed individualised was half group sessions. Difference number of sessions in intervention and control groups **Source of funding:** German Federal Bureau for Research and Technology **Additional comments:** Used a self regulation model (Kanfer, 1987) which allowed patients to negotiate treatment goals, monitor self eating and exercise behaviour, support self analysis of emotional, cognitive and motivational barriers to behaviour change. Programme conducted by four health

			State-Trait Anxiety Inventory Psychological Strain Questionnaire Self care measures **Follow-up time:** 3 months and 15 months	mixed intervention group. There were significant improvements in the variables of the Three factor eating questionnaire (cognitive restraint of eating, inhibition, hunger) in favour of the intervention groups and there was no superiority of individualised over group self management.	psychologists

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Block randomisation
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Attrition rates were low across the groups (6.6%) and reasons were provided
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Look Ahead 2010 Wadden 2009 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Examine effects of a lifestyle intervention on changes in weight, fitness and CVD risk in patients with type II diabetes	**Study setting:** Multicentre (n=16) **Participant characteristics:** 5145 participants, 59.5% women, 36.9% from racial or ethnic minorities, mean age 58.7 years, average BMI 36.0, average duration of disease 6.8 years **Inclusion:** 45- 76 years old, increased to 55 to 76 years; confirmed self reported diagnosis of type II diabetes,BMI > 25, A1c < 11%, systolic blood pressure <160mmHg, diastolic blood pressure < 100 mmHg, triglycerides <600mg/dl **Exclusion:** -	**Exposure: n=2570** Intensive lifestyle intervention Diet modification and physical activity aimed to reduce and sustain 7% weight loss after 1 year. Group size 10-20 Assigned a calorie goal, a portion control diet was used, exercise goal of 175 minutes physical activity per week. Behavioural strategies included self monitoring, goal setting and problem solving. Seen weekly for six months and 3 times per month for next six months. In years 2-4 seen monthly, contacted by other means monthly and offered ancillary group classes **Comparison: n=2575** Diabetes support and education 3 group sessions per annum (1 hr). Focused on diet, physical activity or social support. No information on behavioural strategies provided. **Outcome measures:** Weight and height Blood pressure Tryglycerides Fitness A1c	**Results:** Averaged over four years the intervention group had a greater percentage weight loss (-6.15% vs -0.88%, P < 0.001), and greater improvement in treadmill fitness (12.74% vs 1.96%, P <0.001), H1Ac levels (-0.36% vs -0.09%, P <0.001), systolic blood pressure (-5.33 vs -2.97mm Hg, P < 0.001) and diastolic blood pressure (-2.92 vs -2.48 mm Hg, P =0.01)	**Author's conclusions:** Intensive lifestyle interventions can produce sustained weight loss and improvements in fitness, glycaemic control and CVD risk factors in those with type II diabetes **Reviewer's conclusions:** Change in protocol to try to increase capture of CVD events in long term follow up. Attrition rate satisfactory at 4 year follow-up . No details on recruitment method in paper. **Source of funding:** Department of Health and Human Services and numerous other federal agencies **Additional comments:** Group and individual sessions Led by lifestyle counsellors (trained dieticians, behavioural counsellors or exercise specialists) No details of theoretical underpinning behind intervention

			Follow-up time: 4 years		

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Unclear risk	Randomly assigned, no details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Flow chart , no reasons given after randomisation. Attrition at follow up was low
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Lorig 2008 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To demonstrate if patients with type II diabetes receiving the Spanish DSMP had improvements in glycaemic control, health status , health behaviour and self efficacy	**Study setting:** Community settings in San Fransisco Bay area **Participant characteristics:** Recruited in the community by word of mouth and community and media messaging Mean age 52.9 years, mean years of education 7.5, 62% female **Inclusion:** > 18 years, not pregnant, not diagnosed with cancer, having type II diabetes **Exclusion:** -	**Exposure: n=219** Spanish Diabetes Self Management Programme (SDSMP) 6 weeks 2.5hr sessions Content: Exercise, diet, relaxation, foot care, communication **Comparison: n=198** Wait list control offered the intervention after 6 months **Outcome measures:** A1c Activity Limitation Scale Fatigue Health Distress Scale Self rated health Total minutes aerobic and nonaerobic exercise Frequency of glucose monitoring per week Communication Spanish self efficacy scale Health care utilisation **Follow-up time:** 6 months	**Results:** A1c significantly reduced compared to control group - 0.41% versus -0.05%, P=0.04. For those with baseline A1c ≥7% (n=101) 30% of intervention group were below 7% at 6 months compared to 22% of control group. Health distress was significantly lower in the intervention than the control group at 6 months (change -0.59 versus -0.09, p=0.009) Symptoms of hypo (change -0.45 versus +0.03, P=0.04) and hyper glycaemia (change -0.83 versus +0.03, P<0.001) were both decreased in favour of the intervention group at 6 months. Self efficacy was significantly improved in the intervention group compared with control (P<0.001) There were no significant differences between groups in health behaviours (aerobic and non-aerobic exercise), BMI or	**Author's conclusions:** The intervention appeared to benefit glycaemic control, self efficacy health distress and the ability to self monitor hypo and hyper glycaemia **Reviewer's conclusions:** Self selected population , not balanced by gender at baseline. Authors found that non-completers (n=65) did differ from completers at baseline Benefit in glycaemic control and self efficacy at 6 months **Source of funding:** NIH grants, Michigan Diabetes Research and Training Centre **Additional comments:** Based on social learning theory (self efficacy) – probable Stanford Model but not explicit Led by two trained peer leaders Group intervention (size 10-15) Due to the study protocol only follow up at 6 months was appropriate for this systematic review

				health care utilisation	

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Lacked details on attrition at 6 months
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Lorig 2009 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To determine the effectiveness of a community based diabetes self management programme at 6 months	**Study setting:** Community based in churches and senior centres in San Francisco Bay Area **Participant characteristics:** Recruited through word of mouth, community notices, media and through clinics. Mean age 66.7, 66% female, mean years of education 15.9. Baseline A1c 6.72% **Inclusion:** 18 years or older, not pregnant or in care for cancer, diagnosed with type II diabetes **Exclusion:** -	**Exposure: n=186** DSMP 6 weeks for 2.5 hr per session. Content: Overview of self management and diabetes, action plans, nutrition and healthy eating, problem solving, hypoglycaemia, prevention of complications, fitness/exercise, stress management and relaxation, managing emotions, SMBG, depression, positive thinking, communication, mediations, communication with health professional, skin and foot care. Also received a book 'Living a Healthy Life With Chronic Conditions' **Comparison: n=159** Usual care, after 6 months offered the intervention **Outcome measures:** A1c Symptoms of hyper- and hypoglycaemia PHQ-9 for depression Fatigue Health Distress Scale Self rated health	**Results:** At 6 months the DSMP did not demonstrate improvements in A1c compared with controls. The intervention group had statistically lower symptoms of hypoglycaemia (P=0.002) and less depression (P<0.001) than the usual care group. Healthy eating was significantly improved for the intervention group (P<0.01) After taking multiple comparisons into account aerobic exercise (p=0.049) and frequency of glucose testing (P=0.024) were also improved in the intervention group. Participants in the intervention group did demonstrate improvements in patient activation (P=0.017) and self efficacy (P=0.001) There were no differences between groups in health care utilisation	**Author's conclusions:** People with diabetes without an elevated A1c can benefit from a community based, peer led diabetes programme. **Reviewer's conclusions:** Self selected participants. Attendance at sessions high (mean 4.9/6 sessions) Attrition at 6 months less than 20%. Evaluated differences between completers and non-completers at 6 months. Completers were more likely to be non-Hispanic White and older, also trend towards having higher health distress and more activity limitation. But they did not differ from usual care non-completers significantly. Lack of change in A1c is probably due to the fact that baseline levels were well controlled. **Source of funding:** California Health Care Foundation **Additional comments:** Diabetes Self Management Programme (English translation of SDSMP) Led by 2 trained peer leaders

			Physical activity Weekly frequency of glucose monitoring Communication with physician Healthy eating Patient Activation Measure Diabetes Self Efficacy Scale Health care utilisation over 6 months **Follow-up time:** 6 months intervention, follow up at 1 year		Group intervention (n=10-15) Intervention group was followed up again at 12 months but as the control group had been offered the programme there was no control and as such data is not discussed here.

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Random number tables
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	ITT , attrition less than 20%, evaluated differences between completers and non-completers
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Lorig 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate an online diabetes self management programme for patients with type 2 diabetes compared with usual-care.	**Study setting:** Own homes recruited via internet and media **Participant characteristics:** N = 761 including subgroup of American Indians and Alaskan natives 76% non-hispanic White, 73% female, 66% married. Mean age 54.3 years. Well educated, mean 15.7 years. **Inclusion:** ≥ 18 years, not pregnant or under care for cancer, medial diagnosis of type II diabetes, access to the internet. **Exclusion:** No details	**Exposure: n=259** IDSMP Online diabetes self management programme based over 6 weekly sessions (english/Spanish). Content includes: design of individualised exercise programme, use of cognitive symptom management, methods of managing negative emotions such as anger, fear and depression, overview of medications, aspects of physician-patient communication, healthy eating, fatigue management, action planning, feedback, methods for problem solving. Participants asked to identify a problem related to their diabetes and develop an action plan which are posted on a bulletin board in a Discussion Centre for all participants to see. A number of tools are available that include exercise and medication logs, audio relaxation exercises, meal planning and SMBG tools as well as access to other diabetes websites. Help is available via moderators who can be contacted by e-mail or telephone. Also provided with a book titled Living a Healthy Life with Chronic Conditions. Each programme is facilitated by	**Results:** In the intervention group there was no benefit of the reinforcement addition. The self management group had significantly lower A1C (P<0.039), improved patient activation (P< 0.021) and improved self efficacy (P<0.001). No differences for health distress, activity limitation, depression and health care utilisation (number of physician visits). No differences in the duration of aerobic exercise undertaken per week. For those eligible for follow-up at 18 months, self efficacy (P<0016) and patient activation (P<0.007) were significantly improved in the intervention compared to the control group.	**Author's conclusions:** In general patients A1C was well controlled at baseline, the programme may be better targeted as those with a higher baseline A1C. Intervention does show some benefits to those with diabetes. **Reviewer's conclusions:** Not all participants followed for same length of time and they were self selected and represented a mainly white, well educated profile. Data for ethnic minority was not sufficiently powered and the findings taken with extreme caution. They are therefore not presented here. **Source of funding:** National Institutes of health grant, Robert Wood Johnson Foundation grant **Additional comments:** *Based on self efficacy theory and is a modification of the Chronic Disease Self Management Programme – Stanford Model. Also referred to as the Expert Patients Programme (EPP)*

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			two peers who encourage participants to log in and post information but do not provide content. **Intervention group + reinforcement through listserve membership N=232** **Comparison: n=270** Usual care – no programme or other treatment offered apart from previously received clinic or specialist care. They were not prevented from seeking other care or programmes. After 6 months the AI/NA subgroup were all offered the intervention. **Outcome measures:** A1c at 6 and 18 months Symptoms Level of exercise Limitations of activity Self efficacy Patient activation (knowledge, skill, confidence) Health care utilisation Health related distress Depression (patient health questionnaire)		

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			Follow-up time: 6 month intervention with 18 month follow-up		

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Random number tables 2:1
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No details
Incomplete outcome data	High risk	29 /761 no details given apart from 2 who died but they did look at characteristics of responders and non-responders at 6 months which was 85% and 81% of those still eligible at 18 mths. ITT analysis
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Piatt 2010 Piatt 2006 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To determine if improvements in clinical behavioural and psychosocial outcomes measured at 1 year were sustained at 3 years	**Study setting:** Suburb of Pittsburg, Pennsylvania, USA 24 general , family and internal medicine practices **Participant characteristics:** Mean age at study entry 66.5 years, 90.7% female, 98.4% white, duration of disease 11.6 years **Inclusion:** Clinical diagnosis of type II diabetes **Exclusion:** -	**Exposure: n=30** Chronic care model 6 weekly diabetes self management education sessions facilitated by the certified diabetes educator. Followed by monthly support groups held until 1 yr follow-up visit. A diabetes educator nurse was available in all practices on specified days for 6 months **Comparison: n=38** Provider education only. In this group the provider had a single education session and received their patients chart audit results. The certified diabetes educator was not placed in these practices but was available for consultation **n=51** Usual care Providers were mailed their practices audit report and decision support items. The decision support items were received by all practices and included American Diabetic Association guidelines, flow sheets, posters and information	**Results:** Improvements that had been observed at 1 year follow up in glycaemic and blood pressure control, and the proportion who self monitored blood glucose in the intervention group receiving CCM were sustained at 3 years follow up. At follow-up at 3 years the usual care group were more likely to have had treatment intensification than the other two groups (P=0.04) Mean improvement in A1c at 12 months (-0.5%) in the CCM intervention group were sustained in 8 of 12 subjects at 3 years as were the levels of the provider education only and usual care groups which had not seen any improvements at 1 year. There were also sustained improvements in systolic blood pressure over time in all groups although differences were not significant. Diastolic blood pressure decreased significantly in the CCM group (P=0.04) although the authors do not report on a between group effect.	**Author's conclusions:** Improvements in outcomes could be sustained over and extended period of time up to 3 years **Reviewer's conclusions:** Patients identified from chart review. Over-represented by female and White participants and low socioeconomic position. Very high attrition rates at long term follow up and low participants makes inference of findings difficult. Those who returned at 3 years differed significantly from those who did not return in that they were significantly less likely to require insulin, have a higher socio-economic profile and experienced greater improvements in A1c. May not be representative. The authors failed to report on differences between groups but only on differences over time Although the levels attained at 1 year were sustained there were no additional improvements in A1c or blood pressure. **Source of funding:** United States Airforce **Additional comments:** Based on Chronic Care Model using

			Outcome measures: A1c Non HDLc Blood pressure Self monitoring blood glucose World Health Organization Quality of Wellbeing Index Modified Diabetes Care Profile **Follow-up time:** 3 years	Quality of wellbeing was sustained or improved in all groups but did not reach statistical significance. The authors did not report on differences between groups	clinical , behavioural and psychosocial processes to improve outcomes. Patient and provider education as well as elements of service redesign in the community and organizational support. Providers were given a single problem based learning education session. Programme based on 'empowerment' approach

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Block randomisation of practices
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Very high attrition at 4 year follow up almost 50% in each group. Reasons given
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Rugerrio 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate an intervention with medical assistant coaches in an underserved population with type II diabetes	**Study setting:** Primary care **Participant characteristics:** None provided **Inclusion:** Latino or African American, ≥50 years, two A1c readings ≥7%, diagnosed a min of 1 year, prescribed diabetes medication **Exclusion:** -	**Exposure: n=25** Medical Assistant Coaching Certified Medical Assistant Coach trained in diabetes self care and behavioural coaching. 2 face to face sessions quarterly (<30m mins each) and 4 monthly telephone calls (<15 mins each). Coach was able to make appropriate referrals. Content: Healthy eating, SMBG, physical activity, foot care, smoking cessation, medication adherence. Setting and achieving personal goals. Education material provided was from the National Diabetes Education Programme **Comparison: n=25** Usual care received education material available through the National Diabetes Education Programme **Outcome measures:** A1c Problem Areas in Diabetes Scale (PAID) Diabetes Empowerment Scale (DES) **Follow-up time:**	**Results:** The intervention group showed improvements in A1c over time but these did not differ significantly from the usual care group. There were no differences between groups for the PAID and DES scales. ANCOVA controlling for baseline DES scores indicated significant increase in DES scores in the intervention group compared with usual care (P<0.01)	**Author's conclusions:** MAC group showed improvements in A1c and empowerment **Reviewer's conclusions:** Small number make generalisation difficult. All eligible patients approached. High compliance No data on population baseline demographics Improvements shown in medical coaching group but not differences overall **Source of funding:** National Institutes of Health **Additional comments:** A third no intervention group was used but these were not randomised and are not included here. *Behavioural coaching, and 5A's of counselling*

			6 months		
Bias	**Judgement**			**Support for judgement**	
Random sequence generation	Low risk			Randomised	
Allocation concealment	Unclear risk			No details	
Blinding	High risk			No blinding	
Incomplete outcome data	High risk			No details provided	
Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Samuel-Hodge 2009 Samuel Hodge 2006 **Country: USA** **Study type:** RCT **Evidence level:** II	**Aims:** Develop and test a church based intervention to improve diabetes self management	**Study setting:** 24 African American churches in North Carolina **Participant characteristics:** Mean age 59.2 years; 63.5% female; mean of 9 years diagnosed with disease, 12.4 years of education **Inclusion:** 20+ years, diagnosed with type II diabetes, clinical care provided by primary care physician, planning to live within 50 mile radius of church for next year, home phone or access to phone **Exclusion:** Other forms of diabetes, lactation, unable to speak english	**Exposure: n= 13 churches 117 participants** 60 minute counselling session with dietician including goal setting. 12 biweekly group sessions held at the church lasting 90-120 minutes. Included 15 minute physical activity session and tasting 1-2 recipes. Content : dietary information and options, self monitoring blood glucose, Blood pressure, diabetic medications, personal health habits, stress management Contacted monthly by peer counsellor who offered support for behaviour change around the goals set with dietician. 3 postcard messages of encouragement sent on behalf of primary care physician tailored to goals set by participant and related to diet, physical activity HbA1c and blood pressure control **Comparison: n= 111 churches, 84 participants – Minimal intervention** Direct mailing of 'healthy Eating' and 'Staying Active' (ADA publications) and 3 bimonthly newsletters providing general	**Results:** A1C Difference between groups was 0.4% (95%CI 0.1 – 0.6; adj P <0.001). Stratified by those with A1C≥7% at baseline (P=0.04). However at 12 months there were no differences between groups for all participants or for those with higher baseline A1C levels. Dietary outcomes The only differences between groups in the types of food intake was in the percentage of calories from trans fats (P=0.05) which was lower in the intervention group. Physical activity No difference in the hours of physical activity undertaken per day, but moderate activity was significantly higher in the intervention group (8.1 minutes vs 5.4 minutes; P = 0.02). Blood pressure At 8 months DBP was significantly lower in the control group mean difference -3.3mmHg (95%CI -5.2 - -1.4; P < 0.001)	**Author's conclusions:** Intervention improved short term metabolic control, diabetes knowledge, and diabetes quality of life compared with the control. Differences in diet and physical activity were not statistically or clinically significant. Intervention acceptable within the church community. **Reviewer's conclusions:** Participants self selected through the church, over 60% female, not newly diagnosed, most had completed a high school education. Only 51% overall compliance to group sessions and similarly with telephone follow-up Benefits observed up to 12 months for some outcome but changes in A1C not sustained. **Source of funding:** Centers for Disease Control and Prevention **Additional comments:** Community based Provided by church diabetes advisor (a peer counsellor) trained in motivational interviewing, listening skills, diabetes self management and

			health information and study updates. **Outcome measures:** A1C Weight Blood pressure Physical activity Food Frequency Questionnaire Diabetes Knowledge Scale SF36 **Follow-up time:** 12 months	Diabetes knowledge Diabetes knowledge increased in both groups but was significantly higher in the intervention group at 8 months follow-up (P= 0.03). Quality of life No difference between groups in general health status but diabetes related mental well being improved in the intervention group and worsened in the control group with significant differences between groups at 8 months (-2.3; 95%CI -3.6 - -0.7; P=0.004) and 12 months (-2.3; 95%CI -4.2 - -0.05, P= 0.15).	telephone counselling. *Individual counselling* included dietary habits, stress management, social support and problem solving, eating patterns and barriers to behaviour change. *Small Group sessions based on Chronic Care Model (Wagner); social cognitive theory , stages of change model, and adult learning theory*.

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Randomised and stratified by church
Allocation concealment	Low risk	Sequential sealed envelopes
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Graphical representation of losses but no ITT
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: **Schillinger 2009** **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Effectiveness of two self management models compared with usual care	**Study setting:** Primary care **Participant characteristics:** Mean age of participants (n=339) 56.1±12 years; 59% were women; 46.9% were white/non-Latino; 45.4% spoke English; 58.8% had limited health literacy, duration of diabetes was 9.5±7.4 years; A1C 9.5±2.0; BMI 31.5±10 **Inclusion:** Adults with Type II diabetes, spoke Spanish, English or Cantonese, made ≥1 primary care visit in previous year, most recent A1C > 8% **Exclusion:** Moved away or deceased, moderate to severe dementia,not expected to survive the year, anticipated travel > 3 months in upcoming year, too ill/ unable to travel to GMV, no phone access, self reported hearing impairment, visual acuity ≥	**Exposure: n= 112** **The Automated Telephone Self Management Support System.** Provides surveillance, education and patient activation. ATSM provides weekly calls with rotating queries, in patients' native language, regarding self-care (e.g. symptoms, medication adherence, diet, physical activity, self-monitoring of blood glucose, smoking); psychosocial issues (e.g. coping, depressive symptoms, etc.); referrals for preventive services (e.g. ophthalmologist, etc.). Patients respond via touch-tone commands. Depending on the response to an individual item, patients also receive automated health education messages in the form of narratives. Patients answering 'out of range' on ≥1 item, based on predetermined clinical thresholds, receive a call back from a language concordant care manager within 48 hours. The care manager helps patients problem-solve around the issue identified in the report, with a focus on collaborative goal-setting with action plans. N = 113 **Group Medical Visit Model.**	**Results:** Diabetes self efficacy improved for ATSM and GMV compared with usual care (P<0.01). There was no difference between ATSM and GMV. Interpersonal processes of care were significantly improved in the ATSM group compared with both GMV (P=0.03) and the usual care groups (P<0.001). Compared with usual care there were improvements in explanations of processes of care, self care and empowerment and significant improvements in elicitation of problems and decision making compared with both usual care and GMV. Both ATSM (P =< 0.0001) and GMV (P = 0.04) showed increased evidence of self management behaviours compared to usual care. This was also the case for ATSM compared with GMV (P = 0.02). Only ATSM participants reported increased physical activity with 2 or more hours per week compared with usual care	**Author's conclusions:** Self management strategies improves some aspects of diabetes care. ATSM seemed to be more effective in improving self management behaviours and increasing physical activity than GMV **Reviewer's conclusions:** Although the RCT appeared to be well conducted there was a lack of evidence regarding concealment and blinding. There was a lack of precision in some of the summary effects which was not discussed by the authors **Source of funding:** The Commonwealth fund, AHRQ, The California Endowment, San Francisco Dept. Public Health, California Health Foundation. **Additional comments:** Based on the Chronic Care Model. Both self management interventions based in self efficacy theory and promote collaborative goal setting and action plans. Both interventions provided skill enhancement, health education follow-up and support, access to community resources and continuity of clinical care. Both used motivational interviewing

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		20/100 or unable to follow instructions on a telephone keypad.	Provides support, education and patient activation. GMV involves language-specific monthly group medical visits for 9 months. GMVs involve 6-10 patients, are co-facilitated by a language concordant primary care physician and health educator, last 90 minutes and share the same basic structure: 1) group check-in, in which participants report any problems or progress with action plans and the group facilitates problem-solving, adjustment and/or re-commitment to action plans, 2) discussion of common concerns, or modeling of self-management practices, 3) social break with healthy snacks, 4) short planning session to select subsequent topics, and 5) brief, individualized care to patients with unmet medical needs. **Comparison: n= 114** **Usual care** All patients encouraged to see their regular doctor as usual **Outcome measures:** A1C BP BMI Changes in self management behaviours over previous week for	(P=0.03) There were no between group differences for quality of life as measured by SF12. Glycaemic control improved in all three groups but no differences between groups. Neither were there statistically significant differences between groups for blood pressure or BMI	Delivered in Spanish, English and Cantonese Not a population of newly diagnosed diabetics

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			eating healthy foods, following diabetic diet, exercising, self monitoring blood glucose, caring for feet. Self reported moderate/vigorous physical activity in previous week Functional status SF12 for quality of life Patient Assessment of Chronic Illness Care instrument Diabetes Quality Improvement Programme self efficacy measure Interpersonal Processes of Care for Diverse Populations instrument **Follow-up time:** 1 year		

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Block randomised
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No blinding
Incomplete outcome data	High risk	ITT, flow chart with reasons in text, no analysis to see if they differed
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Shibayama 2007 **Country:** Japan **Study type:** RCT **Evidence level:** II	**Aims:** Effect of lifestyle counselling on outcomes in diabetes	**Study setting:** Out patient department of Tokyo hospital **Participant characteristics:** Female 35.8%, age 61.5 years, duration of disease 12 years, baseline A1c 7.35% **Inclusion:** Adults aged 20-75 , seen as outpatients in Tokyo hospital, diagnosed with type II diabetes, A1c values between 6.5 to 8.5% on average of three tests within 3 months, not able to use insulin **Exclusion:** Serious ongoing illness or cognitive disorder	**Exposure: n=67** One to one counseling provided monthly for one year (Median duration 25 minutes). Assessment, participation in goal setting, selecting personal strategies to overcome barriers, problem solving. Content: Diet, physical activity, medication, complications, stress management. Personalised plan and additional educational material provided if needed **Comparison: n=67** Usual care by physician **Outcome measures:** A1c SF36 Problem Areas in Diabetes Scale Cognitive modification Behavioural modification Overall satisfaction in counselling **Follow-up time:** 1 year	**Results:** No significant changes in A1c over the year within each group nor any differences between groups. The intervention group visited the hospital more times in the one year follow up than the controls (12±2 versus 11±3, P = 0.03) No change in blood pressure No change in BMI No change in quality of life	**Author's conclusions:** No evidence of an effect of the intervention on glycaemic control **Reviewer's conclusions:** 10% attrition at 1 year, groups not matched on some baseline measures in the SF36 Intervention does not appear to be effective Additional outcomes reported that were not described a priori **Source of funding:** Ministry of Health, Labour, and Welfare **Additional comments:** Led by Certified Expert Diabetes Nurse Techniques of attentive listening and empathy Individualised intervention

Bias	Judgement	Support for judgement

Random sequence generation	Unclear risk	Randomly – no details
Allocation concealment	Unclear risk	No details
Blinding	Low risk	Physicians blinded
Incomplete outcome data	High risk	No details for attrition, no clear if ITT analysis or not
Selective reporting	High risk	Some outcomes reported on were not listed clearly a priori

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Sixta 2008 **Country:** Mexico **Study type:** RCT **Evidence level:** II	**Aims:** 3 objectives to test. Objective 3 To establish if community worker led self management improved diabetic control	**Study setting:** Community centre in a remote county on Texas Mexico border **Participant characteristics:** Recruitment through provider referral, and research assistant invitation from a diabetic clinic 71% female Mean age 56.3 years Mean duration of disease 6.8 years **Inclusion:** Mexican American Type II diabetes >18 years Seen in the clinic within previous year **Exclusion:** -	**Exposure: n=63** Self management programme 10 weeks – 1.5 hrs each Contents: diabetes facts, emotions, complications self monitoring,, exercise, nutrition, communication, coping strategies, goal setting, problem solving **Comparison: n=68** Usual care **Outcome measures:** A1c Diabetes Knowledge Questionnaire Health Belief Questionnaire Acculturation Scale **Follow-up time:** 3 and 6 months follow up	**Results:** There was no difference in A1c level over the length of the study within or between groups Subgroup analysis indicated that duration of disease had an significant effect on A1c implying that those with the disease for longer were more likely to have better control (P=0.0021). Age also had a significant effect with older individuals having poorer control (P<0.0001)	**Author's conclusions:** The community worker led self management course did not have a significant effect on A1c in either group **Reviewer's conclusions:** Over represented by females, compliance 65%. Mean baseline data for A1c was 7.49 and therefore quite well controlled already. No effect on A1c High attrition at 20% **Source of funding:** Local scholarship **Additional comments:** Community worker delivered supported by nurse if required

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details

Blinding	High risk	No blinding
Incomplete outcome data	High risk	High attrition at 20%, ITT conducted, no reasons given
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Song 2009 **Country:** South Korea **Study type:** RCT **Evidence level:** II	**Aims:** To assess the effects of a diabetes out-patient intensive management programme on glycaemic control and adherence	**Study setting:** A university affiliated diabetes centre **Participant characteristics:** Mean age 50.3 years, 57% female, duration of disease 4.95 years, 63.1% attended high school, A1c at baseline 9.2% **Inclusion:** Able to perform SMBG, taking oral hypoglycaemics **Exclusion:** Currently experiencing angina or heart failure, had more than one vascular event, had retinopathy requiring laser treatment, had malignant hypertension, had an uncorrected endocrine disorder, had severe concurrent illness or unwilling to participate	**Exposure: n=25** Diabetes Outpatient Intensive Management Programme Education, counseling and monitoring. 12 weeks- 2 day programme Day 1 one-on-one sessions with physician and diabetes education nurse Education sessions included overview of diabetes, self care management, obesity, foot care, skin care, psychological support, stress management, medical nutrition therapy. Supported by audiovisual material. Individual sessions to support self monitoring, exercise and diet. Complication monitoring Followed up with weekly calls to promote adherence and telephone counselling provided if needed **Comparison: n=24** Control received brief description of diabetes and instructed to learn about medical nutrition therapy by a diabetes education nurse . Regular exercise recommended Follow-up as per usual care at 1-2month intervals **Outcome measures:** A1c	**Results:** There was no difference between groups in A1c level. However there was a significant percentage change in A1c levels for the intervention group ($P<0.05$) over time (9.4% pre test to 7.1% post test). Both groups increased adherence to diet over time. This was significant for the intervention group ($P<0.05$) There were no significant differences between groups at follow-up. There was no significant difference between groups for adherence to exercise There was no significant difference between groups for adherence to medication	**Author's conclusions:** A1c levels were significantly decreased in the intervention group **Reviewer's conclusions:** Over represented by females and not matched at baseline by gender. Although A1c was significantly lowered in the intervention group over time there was no difference between groups at follow-up Short follow-up, only 12 weeks **Source of funding:** No details **Additional comments:** Mixed individual and Group intervention n=10 per group Led by mixture of health professionals including endocrinologist, nurse educator, family physician, dermatologist, dietician, pharmacist, ophthalmologist and physiotherapist

			Adherence **Follow-up time:** 12 weeks		

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Coin toss randomisation
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Only reported per protocol data
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Sturt 2008 **Country:** UK **Study type:** RCT **Evidence level:** II	**Aims:** To determine the effects of the Diabetes Manual on glycaemic control, diabetes related distress and confidence in self care in patients with type II diabetes	**Study setting:** Primary care settings in 48 GP practices in the West Midlands, UK in areas of high deprivation and ethnic diversity. 2257 eligible patients. **Participant characteristics:** N = 245 Mean age 62 years, 39.5% female, 78% had had diabetes for 1-15 years.80% were White **Inclusion:** Type II diabetes, not taking insulin, able to read and write english, most recent A1c >8% (lowered to >7% after 1 year of trial due to poor recruitment) **Exclusion:** -	**Exposure: n=114** Diabetes Manual 15 minute face to face consultation to introduce the 12 week Diabetes Manual programme. Patients worked independently through the work book. Nurse telephone support at weeks 1, 5, and 11 **Comparison: n=131** Wait list Continued with usual care and received intervention after 26 weeks. **Outcome measures:** A1c Blood pressure Lipid profiles Problem Areas in Diabetes (PAID) Scale Diabetes Management Self Efficacy Scale (DMSES) **Follow-up time:** 6 months	**Results:** No effect on glycaemic control (A1c) (P=0.33, ITT). No statistical difference between groups in blood pressure Diabetes related distress was lower in the intervention group compared to control (difference -4.5, 95%CI -8.1 - -1.0; P=0.044 ITT). Confidence to self care were 11.2 points higher (95%CI 4.4 – 18.0; P=0.013 ITT) in the intervention group.	**Author's conclusions:** The Diabetes Manual achieved a small improvement in diabetes related distress and confidence to self care in the short term. No effect on glycaemic control **Reviewer's conclusions:** Subjects did not have good control of A1c. Change in protocol to increase recruitment by lowering inclusion criteria for A1c. Patients identified from practice registers and invited to participated only 245 out of original 2257 eligible were randomised. No differences between eligible participants and non-participants. If high deprivation and presumably low literacy a self completed workbook probably not ideal intervention although written at level of British 'tabloid papers' . Study is limited by lack of completers of outcome measures. Over-represented by males and White ethnicity **Source of funding:** Diabetes UK and Department of Health, UK. **Additional comments:** Based on social learning theory (self

					efficacy) Two day training for practice nurses Individualised intervention 230 page workbook – recommended 0.5hr day over 12 weeks. Topics included: diabetes facts, metabolism, goal setting and evaluation, exercise, nutrition, SMBG, weight loss, smoking cessation, tests, complications, medication, stress, anxiety and depression. Self assessment to encourage evaluation of current behaviours and setting new goals. Relaxation audiotape, Question and answer audiotape Nurse telephone support x3 to assess goal progress, promote self evaluation and re-negotiation, offer support and problem solve.

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Used permuted blocks
Allocation concealment	Low risk	Statistician blinded to allocation
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Attrition >20% overall. Did do ITT analysis
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Thoolan 2009 Thoolan 2007 **Country:** Netherlands **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate effectiveness of a proactive coping intervention in newly diagnosed type II diabetes	**Study setting:** Run in community settings **Participant characteristics:** Participants were recruited from the Dutch arm of the Addition study. Mean age 61.95 years, 40.5% female, mean education level 3.25 on a scale of 1- lowest and 5 – highest), mean duration of disease in months 17.7 **Inclusion:** Newly diagnosed type II diabetes **Exclusion:** Not suffering from serious physical or mental comorbidities	**Exposure: n=89** Proactive coping 12 week intervention (Beyond Good Intentions) for newly diagnosed type II diabetes. Two individual and four group sessions (2 hrs duration). Content: experiences of diabetes (individual session); work on relevant goals in physical activity, diet, medication (group sessions). Plus patient workbook **Comparison: n=108** Brochure on diabetes self management **Outcome measures:** Intentions Self efficacy The Proactive Competence Inventory Proactive Diabetes Management Inventory Diabetes Self Care Activities Measure Physical Activity Scale for the Elderly Kristal Food Habits Questionnaire Dutch Fat Consumption Questionnaire Medication Adherence Report	**Results:** The intervention group showed significant improvements over the control group for Diet intention P<0.05 Intervention group improved dietary habits (P<0.001) Fat consumption was lower in the intervention group compared with controls (P<0.01) BMI was significantly lowered in the intervention compared with control group (P<0.001) Exercise intention P<0.0001 Participation in exercise over previous 7 days was higher in the intervention group (P<0.0001) General self efficacy P<0.0001 The self management intervention had no effects on mean levels or changes in A1c. Between group comparisons were not made. Medication intention and medication adherence- NS	**Author's conclusions:** A proactive coping intervention was effective in altering self care behaviours and sustaining changes over time **Reviewer's conclusions:** 227/509 potential participants were randomised, participants were more educated than non-participants but no other socio-demographic differences. 30 patients found the distance to travel to group sessions too far and were subsequently excluded from the study. Post hoc analyses were not pre-specified The differences observed in physical activity and diet, although small were deemed to be clinically significant implying an extra day of physical activity per week. As medication adherence was high at baseline it was unlikely to observe significant differences over time or between groups. **Source of funding:** No details **Additional comments:** Proactive coping – a self regulatory model

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			Scale BMI **Follow-up time:** 12 months	The changes observed in the intervention group were sustained at 1 year.	Led by nurse Group and individual – group size = 6

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated number tables
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	30 patients found the distance to travel to group sessions too far and were subsequently excluded from the study
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Toobert 2011 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To test a cultural adaptation of a behaviour change programme	**Study setting:** Nine Kaiser Permanente clinics in Denver and one large community health centre **Participant characteristics:** Identified through clinic coding. 61% of those eligible agreed to participate and 68% of these were randomised. 61% female, mean age 57.11, mean duration of disease 9.4 years, 29.95% were high school graduates, baseline A1c was 8.3%. All were Latino **Inclusion:** Self identified Latina ethnicity, 30- 75 years old, diagnosis of type II diab4etes for at least 6 months, living independently, having a telephone, able to read English or Spanish, not developmentally disabled, living close enough to intervention site to attend sessions. **Exclusion:** Being on an insulin pump,	**Exposure: n=142** Viva Bien – 12 month intervention 2.5 day retreat followed by weekly meetings (4 hours) for 6 months then bimonthly for 6 months Content: Following Mediterranean diet adapted for Latinos, stress management, physical activity, smoking cessation, problem solving, social support, managing emotions. **Comparison: n=138** Usual care **Outcome measures:** Diabetes Problem Solving Interview Confidence in Overcoming Challenges to Self Care Instrument UCLA Social Support Inventory Food frequency questionnaire Self reported stress management Modified International Physical Activity Questionnaire Brief Chronic Illness Resources Survey Height and weight A1c Health related quality of life (CDC Healthy Days measure) Ten year heart disease risk	**Results:** The intervention improved self efficacy at 6 months compared to usual care (ES 0.4, P<0.001) and this was maintained at 12 months. % of calories from fat was improved in the intervention group at 6 months compared with usual care (ES 0.6, 7P<0.001) but not sustained at 12 months. Days per week exercised was improved in the intervention group at 6 months compared with usual care but not sustained at 12 months and not significant between groups Control of A1c was improved in the intervention group compared with control (ES 0.4, P<0.05). not sustained at 12 months where it had returned to baseline levels. No differences in physical and mental health between groups, not sustained at 12 months.	**Author's conclusions:** A multiple factor behaviour change intervention is effective **Reviewer's conclusions:** Query representativeness of participants Baseline differences between groups for age, BMI an d duration of disease. High attrition (22%) at 6 months for completion of outcomes. Although authors claim effective intervention this is not demonstrated by sustained benefit over 12 months even though the intervention was continued over that period. **Source of funding:** National Heart, Lung and Blood Institute **Additional comments:** Based on self regulation and social cognitive theory – self efficacy Group intervention led by facilitators (no details) No blinding Computer randomisation

		end stage chronic renal disease.	**Follow-up time:** 12 months		ITT

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Low risk	Computer generated
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Reasons for losses not reported
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Watanabe 2007 **Country:** Japan **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the short term effectiveness of an individually based counselling programme in mild type II diabetes	**Study setting:** Not clear but likely to be community based **Participant characteristics:** 223/255 randomised. 28.7% female, age 50.9 years, baseline A1c 5.55% **Inclusion:** Adults aged 30 to 69 years, elevated fasting blood glucose, post prandial glucose or A1c following work based health check in the previous two years, **Exclusion:** Being treated for diabetes, history of hormonal diseases, renal function failure, hepatic disease, pancreatic disease, anaemia, angina, myocardial infarction, stroke or post-gastrectomy. Fasting plasma glucose >200mg/dL.	**Exposure: n=119** 4 months duration 4 sessions and one reminder on lifestyle modification. Content: Diet, physical activity (provided with pedometer), weight loss, motivation, goal setting. Additional information and quizzes, diagrams and summary sheets. **Comparison: n=114** Usual care + information about diabetes and blood results. Were able to participate in programme after 4 months if they desired. **Outcome measures:** Serum glucose investigations A1c Lipid profiles Food Frequency Questionnaire **Follow-up time:** 4 months	**Results:** Total energy intake (kcal/day) was significantly lower in the intervention group (-191±460 versus -34±434; P =0.008). Weight loss of ≥4kg was achieved by 13% of the intervention group and 4% of the controls (P=0.025) Leisure time activity ≥12 times per month was achieved by 20% of the intervention group and 6% of the controls (P=0.022), walking ≥1time/month was achieved by 24% of the intervention group and 9% of controls (P=0.0006) A1c reduction of ≥0.3% was achieved by 14% of intervention group and 4% of controls (P=0.01)	**Author's conclusions:** The intervention improved glycaemic control at four months **Reviewer's conclusions:** Aimed to recruit all population with mild diabetes. Improved glycaemic control and physical activity participation in the short term Short term follow up **Source of funding:** Not reported **Additional comments:** No theoretical framework Individualised
Bias	**Judgement**			**Support for judgement**	

Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Very low attrition, reasons given and per protocol and ITT analysis conducted
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Wattana 2007 **Country:** Thailand **Study type:** RCT **Evidence level:** II	**Aims:** To compare A1c, cardiovascular risk factors and quality of life between diabetic patients receiving a self management programme and those receiving usual nursing care	**Study setting:** Two diabetic clinics in two community hospitals in Eastern Thailand **Participant characteristics:** N= 157 recruited. 76.2% female, mean age 56.8 years, 92.5% had some level of primary education, duration of disease 6.18 years. Baseline A1c 8.09% **Inclusion:** Aged ≥35 years, type II diabetes for at least 6 months, fasting plasma glucose levels >140mg for at least two visits, able to speak and read in Thai. **Exclusion:** Severe complications restricting ability to participate, using insulin, changing therapy during intervention, not completing all sessions.	**Exposure: n=75** Self management intervention Small group education class (120 minutes), four small group discussions (90 mins) two individual home visits (45 minutes) and a patient education manual. Content: Meal planning, physical activity, foot care, proper use of medication, monitoring for signs and symptoms of complications, meditation for stress relief. Also received an education manual "Living Well With Diabetes" **Comparison: n=72** Education and wait list for intervention at end of study **Outcome measures:** A1c Lipid profiles Quality of Life (SF36) Framingham Heart Study Coronary Heart Disease Risk Profile **Follow-up time:** 6 months	**Results:** Intervention group had a significantly lower A1c compared to the controls at follow-up at 24 weeks (7.4% versus 8.02%, P =0.014). 12% of participants in the intervention group reached target A1c levels of <7% compared with1.39% of control participants. Quality of life was significantly increased in the intervention group compared to the control group at 24 weeks follow-up (P<0.0001)	**Author's conclusions:** A self management programme using group and individual components to increase self efficacy appeared to be effective for glycaemic control and quality of life **Reviewer's conclusions:** Likely to include participants with low literacy. Attrition less than 10%. Age differed at baseline (used as a covariate in the analysis). Over represented by females. No details on recruitment methods **Source of funding:** Graduate school, Chiang Mai University **Additional comments:** Theoretical framework was self efficacy (Bandura, 1977) and self management (Creer, 2000) Mixed group and individual Led by nurse researcher
Bias	**Judgement**		**Support for judgement**		

Random sequence generation	Unclear risk	No details
Allocation concealment	High risk	Not adequate allocation concealment
Blinding	High risk	No blinding
Incomplete outcome data	High risk	Only per protocol data reported, no details of losses before analysis
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Wolever 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the effectiveness of integrative health coaching on psychosocial factors, behavioural change, and glycaemic control in patients with type II diabetes	**Study setting:** Own home **Participant characteristics:** 56 patients recruited through community notices and media advertisements of 114 screened Mean age 53 years, 77% female, 39% White, 57% Black, duration of disease 11.2 years. Baseline A1c 8% **Inclusion:** English speaking, at least 18 years or over, diagnosis of diabetes for at least 1 year, taking oral medication for at least 1 year **Exclusion:** Dementia, Alzheimers disease, schizophrenia or other cognitive impairment that would preclude informed consent	**Exposure: n=30** Integrative health coaching for 6 months Initial telephone sessions within 2 weeks of baseline followed by 30 minute coaching sessions by telephone (8 weekly calls, 4 biweekly calls and a final call 1 month later) for a total of 14 sessions. Asked about how they were managing their health. Guided to create a vision of health and long term goals using 'A Wheel of Health'. Encouraged to set realistic goals for medication adherence, diet , exercise, SMBG or any other topic they wanted to. Sessions lasted 29.9 minutes on average. Also received educational material GlaxoSmithKline's Adherence Starts With Knowledge (ASK-20) and Essential Connections, information from Duke Integrative Medicine. **Comparison: n=28** Usual care, received no materials or correspondence during the 6 month trial period **Outcome measures:**	**Results:** Participants in the intervention group had a significant reduction in perceived barriers to medication adherence (P=0.001) and differed significantly from the control group (P=0.036). Medication adherence increased significantly in the intervention group (P=0.004) However there were no differences between groups at the end of the study. Intervention group reported a significant increase in exercise frequency per week (P=0.026), no such change was observed in the control group. No statistical comparison between groups was conducted. Although the intervention group showed a significant improvement in quality of life at the end of the trial (P=0.027) and no effect was observed in the control group there was still no between group differences. There were no significant differences between groups in A1c at the end of the trial.	**Author's conclusions:** A coaching intervention may provide additional benefit to a traditional education programme to improve self efficacy, accountability and medication adherence **Reviewer's conclusions:** Self selected Short duration of follow up Higher baseline A1c appeared to be influenced more by the intervention Trial effective in some target behaviours but not A1c **Source of funding:** GlaxoSmithKline **Additional comments:** Integrative health coaching Led by two experienced health coaches

			Ask20, Morisky Adherence Scale Patient Activation Measure (PAM-13) Appraisal of Diabetes Scale Interpresonal Support Evaluation List Perceived Stress Scale SF-12 Quality of life Benefit Finding Scale Exercise frequency – self reported A1c **Follow-up time:** 6 months	Those in the intervention group with an A1c ≥7% at baseline significantly reduced their A1c by 0.64% over 6 months (=0.030). Overall there was no improvement in A1c over time for either group.	

Bias	**Judgement**	**Support for judgement**
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	Low risk	Researcher blinded
Incomplete outcome data	Low risk	Low attrition and reasons given
Selective reporting	Low risk	A priori outcomes reported