Structured diabetes education outcomes: looking beyond HbA₁c. A systematic review

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Abstract

Diabetes education aims to equip people with diabetes with positive self-care behaviours and management strategies to improve glycaemic control. The preferred outcome measure of education effectiveness is often HbA₁c reduction. However, the move towards person-centred education has led to renewed calls to capture associated behavioural and psychosocial change. The aim of this study was to review indicators of diabetes education efficacy in light of the growing emphasis on person-centric care.

A systematic search of MEDLINE, EMBASE, PsycINFO, CINAHL and Scopus databases, from January 2006 to December 2016, was conducted. Studies meeting the inclusion criteria, focusing on diabetes education effectiveness primarily measured using HbA₁c, were selected.

Twenty-three studies were included, comprising 6747 participants. They yielded mixed results, with 13 studies reporting significant reductions in HbA₁c following intervention. Thirteen studies assessed multiple behavioural and psychosocial measures as secondary outcomes with significant, positive changes in these outcomes following intervention. Studies utilising diabetes-specific measures yielded positive results.

It was concluded successful diabetes education involves changing participant cognitions and behaviours. Changes in behavioural and psychosocial aspects should inform education effectiveness. Development of effective diabetes education programmes requires better understanding of how they affect behavioural and psychosocial change, facilitating glycaemic control.

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Key words
diabetes education; efficacy; HbA₁c; behavioural; psychosocial; systematic review

Introduction

Structured diabetes education (SDE) aims to equip people with improved self-care behaviours and self-management strategies, assisting them to improve wellbeing and achieve glycaemic control.¹–³ The impact of SDE is more potent when tailored to individual needs.⁴–⁶ Studies assessing evidence of SDE effectiveness report improved knowledge, clinical and psychosocial outcomes.⁷–¹³ The complex nature of SDE interventions makes it difficult to isolate, define or standardise outcome measures of effectiveness.⁷ In the absence of clarity the preferred outcome measure of effectiveness is HbA₁c reduction, indicative of improved glycaemic control.² Person-reported outcomes of SDE receive less attention as ‘there are still no explicitly defined and widely agreed… indicators to parallel clinical indicators’.¹⁴ The use of a standardised outcome measure, in HbA₁c, allows evidencing of SDE effectiveness against diabetes diagnostic criteria and treatment targets.¹⁵ It is argued that treatment targets are more objective than person-reported outcomes.⁴,¹⁶ However, the move towards person-centred provision recognises the role of the patient in SDE.¹⁴ Accordingly, the literature suggests person-reported outcomes should be considered on a par with glycaemic and physiological outcomes when evaluating SDE.¹⁷

More than HbA₁c needed?

Studies reflect that HbA₁c may be impacted by behaviours learned in SDE.⁵,⁶,¹⁸ In essence, SDE programmes work as interventions to shape behaviours which in turn impact on treatment targets. This creates uncertainty in the assessment of SDE interventions: are we measuring what we should?¹⁴ To date the results for the SDE effectiveness, assessed using HbA₁c, have lacked consensus around the need to include behavioural and psychosocial measures. This article aims to review indicators of SDE efficacy in light of the growing emphasis on patient-centric care. Due to the dominance of HbA₁c in the literature, the review focuses on randomised
controlled trials (RCTs) that include HbA1c as a primary outcome indicator of SDE effectiveness.

Methods
A systematic review of the literature was undertaken using Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.19

Search strategy
Five electronic databases (MEDLINE, EMBASE, PsycINFO, CINAHL and Scopus) were searched for studies published between January 2006 and December 2016. The timeframe reflects the period following the introduction of benchmarking for SDE outcomes and effectiveness.20,21 The search criteria used the following keywords in isolation or combination: diabetes mellitus; type 2 diabetes; diabetes patient; patient education; diabetes education; structured diabetes education; education programme; educational programme; education intervention; educational programmes; HbA1c; haemoglobin A; glycosylated; blood glucose; glycated haemoglobin; haemoglobin A1c; glycaemic control; blood glucose level; glycosylated haemoglobin; glycaemic control.

Study selection
Records were selected based on study eligibility criteria, i.e. must be/have: (1) Randomised control trial; (2) Original research; (3) HbA1c explicitly stated as a primary outcome; (4) Education intervention carried out with patients with type 2 diabetes only; (5) Publication between 2006–2016; (6) Publication in the English language only; (7) Full text.

Data extraction
A total of 23 studies (in 25 publications) met the eligibility criteria (see Figure 1).

Participant and study characteristics
The studies (RCTs) comprised 6747 participants. Studies were conducted across four different continents: Europe, n=8; Asia, n=6; North America, n=7; and South America, n=2. Both sexes were included in all studies. Mean participant age ranged from 47 to 67 years. Study duration ranged from ≤6 months (n=17) through to ≥1 year (n=6). Twelve studies included participant follow up, with five reporting follow-up data at one point in time; the others collected follow-up data across time.

Intervention characteristics
Patient education was delivered in a variety of settings: 11 in primary care clinics,22,23,28,30,32–34,39,40,42,45 four in hospital,25,46,41,43 three in community venues,27,37,44 two at home,29,38 and one in a research centre.43

Programmes were delivered by: health care professionals,22–36,41–45,46 community-health workers,38,40 or peers,37,39,44

The education was delivered either on an individual basis (n=10),22,24,25,28,29,31,36,40,42,45 or on a group basis (n=13),25,30,32,36,37,39,41,3,4,14

Content spanned topics including: diet (n=20),22–24,26–28,30–34,36–41,43–45 physical activity (n=19),22–24,26–28,30–34,36–41,43–45 preventing complications (n=16),22,24,26,30–32,33,36–41,43–45 self-monitoring of glucose (n=15),23,27,28,30–33,36–40,43–45 treatments (n=12),25,24,27,31–33,37,40,44,45 mental health/coping (n=7),22,26–28,30–34,44,45 foot care (n=6),25,30,33,36,37,43 sick-day management (n=5),30,32,36,37,40 smoking status (n=2),26,40 management of weight (n=2),27,30 injection technique used (n=2),31,36 cardiovascular risk (n=1),34 health education (n=1),25 and lifestyle modification (n=1).29

In all but two studies the control group received ‘usual care’.

In nine studies usual care was supplemented with additional education provision.22,25,27,31,33,34,36,40,42

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Figure 1. Summary of identification, screening, eligibility and selection of evidence to inform the study.

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Records identified through database search (n=3929)
Records after duplicates removed (n=2173)
Records screened (n=2173)
Records excluded based on abstract (n=2031)
Full text articles assessed for eligibility (n=142)
Full text articles excluded (n=117)
Reasons:
• Systematic review (n=18, 15.4%)
• Review papers (n=10, 8.6%)
• Not RCT (n=48, 41.0%)
• Criteria not met (n=24, 20.5%)
• HbA1c not primary outcome (n=15, 12.9%)
• Other (n=2, 1.7%)
Articles included in systematic review (n=23 – reported in 25 publications)
**Glycaemic and physiological outcomes**

In line with the eligibility criteria, all studies reported HbA1c as a primary outcome. In 13 studies, significantly greater reductions in HbA1c were reported in the intervention compared to the control group.22,27,29,31,33,36,38–40,42–45 Some of these studies measured HbA1c (following baseline) at more than one point in time, showing significant reductions generally sustained over time.24,33,36,38,39,45 Among inpatients who underwent an intensive five-day education programme, significant differences in HbA1c were reported between the intervention and control groups at follow up.56 In a further study, with culturally tailored education on self-management delivered by community health workers, HbA1c decreased by 0.9 percentage points at three months, a reduction sustained across time.58 One study reported a 0.3 percentage point decrease in HbA1c after four weeks of education that was maintained up to 12 months; this difference between groups was sustained at follow up.43 In three of the studies with significant improvement in control group HbA1c, some form of education was administered for these groups.29,32,34 A variety of anthropometric measurements were used in the studies. The most common were: body mass index (BMI), used in three studies as a primary outcome,25,42,43 and in 12 studies as a secondary outcome measure;22,23,26–31,37,39–41 and body weight used as a secondary outcome in 11 studies.25,27,28,31–34,37,40,41,45

**Behavioural and psychosocial outcomes**

Nineteen of the studies included in this review incorporated behavioural or psychosocial outcomes as measures of education effectiveness.22,23,25–37,41,43–46 Only one of these studies included behavioural and psychosocial measures as primary outcomes.41 In the other 18 studies, behavioural and psychosocial measures were included as secondary outcomes.22,23,26–37,43–46 The most commonly reported measures were: diabetes knowledge, understanding and condition management (n=10),23,27,29,30,32,34,41,43–45 and quality of life (n=8),23,27,32–34,37,41,45 Diabetes-related beliefs and/or attitudes were also widely assessed (n=8).23,26,27,31,34,37,41,45 Significant, positive changes in behavioural and psychosocial outcomes, following intervention, were reported in 13 studies,22,23,26,27,29,31,32,34,36,37,41,44,45 with significant differences between the intervention and control groups reported in nine of these studies.22,23,26,27,32,37,41,44,45

One study reported significantly higher quality of life scores at six months in the intervention group compared to the control.33 Of the 10 studies exploring diabetes knowledge and condition management, seven reported significantly higher levels of knowledge of diabetes and self-management in the intervention group.25,27,34,41,43–45 A number of studies reported knowledge remained significantly higher in the intervention group at follow up.27,34,41,45,46 One study reported better understanding of the seriousness of diabetes and patients’ role in the development of their condition, in the intervention group, sustained at 4, 8, 12 and 36 months’ follow up.34,35 Some studies reported greater empowerment towards self-care behaviour in the intervention compared to the control group.27,31,37,45,46 Lower levels of diabetes-related stress were reported in the intervention group in two studies.32,46 Three studies reported significant improvement in self-care behaviour in the intervention group compared to the control.31,35,34 Three studies reported significant improvement in dietary habits in the intervention compared to the control group.22,27,36 In one study this behaviour was sustained at 14 months,27 while in another the difference was significant at all four follow-ups between one to four years.36 In all three studies a dietitian delivered the programme. Four studies reported significant improvements in physical activity in the intervention compared to the control group.27,34,36,41 Three studies reported a significant improvement in glucose self-monitoring behaviours in the intervention compared to the control group.26,27,37 One study reported higher medication compliance among the intervention group.31

**Discussion**

This article aimed to review indicators of SDE efficacy in light of the growing emphasis on patient-centric care. It is perhaps timely, given the recent focus on the Core Outcome Measures in Effectiveness Trials initiative (COMET), that consideration be given to behavioural and psychosocial measures to inform a core outcome set exploring SDE efficacy.47 Indeed, the literature calls for these outcomes to be afforded the same consideration as glycaemic measures in the assessment of SDE effectiveness.2,48 The inclusion criteria for this review reflect the current reliance on treatment targets; however, growing awareness of the importance of behavioural and psychosocial aspects is evidenced by the number of trials (n=19) including these types of outcome measures.22,23,26–37,41,43–46 Thirteen studies assessed multiple behavioural or psychosocial outcomes.22,23,26,27,29,31,32,34,36,37,41,44,45 These studies report significant positive changes as a result of the intervention, with significant differences in outcomes noted between intervention and control groups in the majority (n=9) of cases.22,23,26,27,32,37,41,44,45 Six of the RCTs tracked behavioural and psychosocial outcomes across time, with sustained change noted in many cases.26,34,35,37,41,46 In these studies there was also a general significant improvement in HbA1c across time.

Nevertheless, discrepancies exist with some studies indicating a lack of significant change in behavioural or psychosocial change at follow up. However, these studies differ in the measures used to capture these outcomes, reflecting the argument that general assessment tools are not suited to assessment of diabetes-specific outcomes.7 There is a move towards the use of diabetes-specific measures in the assessment of SDE effectiveness.3,41,45 Significant changes resulting from SDE have been noted in studies using diabetes-specific measures.32,45,46

The results show improved non-physiological outcomes with health care professional (HCP) led interventions, but also report significant changes in patient knowledge
Structured diabetes education outcomes: looking beyond HbA1c


Bezazit E, Mollioglu M. Investigation of effect on self-care in peer-led programmes. Therefore, SDE may be most effective when directed and delivered by HCPs, with peer-led aspects. Group education appears to be most effective in the development of desired behavioural and psychosocial outcomes. Diabetes can be a restrictive and isolating condition, and group interventions that allow for shared experiences and peer support may serve to address patient-reported social stigma and distress.

Study limitations
This review has some limitations that should be noted. The lack of inclusion criteria around the control group in the articles has affected clarity in relation to the success of interventions. Broadening of the eligibility criteria to include trials that provided no additional diabetes-related information or support materials to control group participants would have allowed the unique effects of the intervention to emerge. The lack of consensus in relation to appropriate behavioural and psychosocial measures of SDE is reflected in the literature. Different studies have selected and assessed similar outcomes using a variety of patient-reported outcome measures. This has resulted in varied findings on the effectiveness of SDE in shaping self-management behaviours. The lack of longitudinal studies in this review has also made it difficult to assess the impact of non-physiological outcomes over time. This ultimately has impacted on the ability to generalise findings, and has indicated that further work is needed to ensure a consensus on appropriate behavioural and psychosocial outcomes and on the measurement scales by which these are assessed.

Conclusions
Eliciting changes in HbA1C is a simple, uni-dimensional measure that does not adequately assess or reflect SDE effectiveness. Diabetes education is primarily focused on changing patient thoughts and behaviours. Therefore, it follows that behavioural and psychosocial outcomes should be assessed to determine SDE effectiveness. The development of effective SDE programmes will rely on the ability to understand how programmes affect behavioural and psychosocial change, as these facilitate glycaemic control.

Future research should focus on understanding more about the impact of SDE on behavioural and psychosocial outcomes; it should inform changes to existing SDE provision, and improve facilitation and transfer of learning to effective self-care practice.

Declaration of interests
There are no conflicts of interest declared.

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References
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<th>Intervention; Content</th>
<th>Format; Delivery method (Educator)</th>
<th>Main outcomes; Glycaemic/other physiological (behavioural/psychosocial); Time of measures</th>
<th>Main results</th>
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<tr>
<td>Adachi 2010, Japan 22</td>
<td>Intervention group (IG): N=100; 60.4 years; F: 55% Control group (CG): N=93; 62.3 years; F: 58%</td>
<td>Primary care clinics (6 months); 3–4 sessions</td>
<td>IG: SILE (structured individual-based lifestyle education). Self-management (exercise, stress management, dietary modification) CG: Usual care – supplemented by single session of glycaemic control and dietary intake advice</td>
<td>Individual – Interactive Face-to-face and/or by telephone (Dietitians)</td>
<td>1°: HbA1c change 2°: FPG, BMI, BP (SBP, DBP) and lipids (LDL, HDL, TG) change 1°: HbA1c change 2°: BMI (2°: Change in energy and vegetable intake, dietary fibre intake &amp; proportions of carbohydrate, protein &amp; fat to total energy intake) Baseline (BL) &amp; 6 months</td>
<td>IG had greater decrease in HbA1c than CG: -0.7 vs -0.2; p=0.004. IG had greater decrease in energy intake than CG: -23 vs -4 kcal; p=0.031. IG had greater increase in vegetable intake (whole day) than CG: 35.1 vs -0.2g; p=0.000</td>
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<td>Adolffsson 2007, Sweden 23</td>
<td>IG: N=42; 62.4 years; F: 43% (6.5 years) CG: N=46; 63.7 years; F: 39% (6.7 years)</td>
<td>Primary care clinics (12 months); 4–5 x 2.5 hour sessions. Additional follow-up session</td>
<td>IG: Empowerment group education Self-care: (general issues, treatment, complications, SMBG, diet, exercise, foot care) CG: Usual care – supplemented by 2 meetings/year with physician &amp; diabetes nurse</td>
<td>Group (5–8 per group) – Interactive Face-to-face, presentation (Physicians and diabetes specialist nurses [DSNs])</td>
<td>1°: HbA1c change 2°: BMI &amp; confidence in daily life, self-efficacy &amp; confidence in diabetes knowledge BL &amp; 1 year</td>
<td>IG had higher levels of confidence in diabetes knowledge than CG: 14.8 vs 5.1; p=0.012. NS difference in HbA1c between groups</td>
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<td>Beyazit 2011, Turkey 24</td>
<td>IG: N=25; 53.2 years; F: 64%; (11.1 years) CG: N=25; 51.8 years; F: 52%; (12.1 years)</td>
<td>Hospital &amp; home (8 weeks); 3 sessions: 1 in hospital (40 minutes) and 2 &amp; 3 at home (30 minutes)</td>
<td>IG: DIEP (diabetes intensive education programme) Structured self-care focus (general info, medical, complications, diet &amp; exercise) CG: Usual care</td>
<td>Individual (relatives invited) – Interactive Face-to-face: Education brochure &amp; visual aids (Nurse)</td>
<td>1°: HbA1c, BP (SBP, DBP) and BMI change BL &amp; 8 weeks</td>
<td>HbA1c decrease (-2.0%) in IG (p&lt;0.001) – no change in CG. BP 13mmHg decrease in SBP (p&lt;0.05) and 7mmHg decrease in DBP (p&lt;0.05) in the IG – no change in CG. BMI: no change in IG/CG</td>
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<td>Chen 2008, Taiwan 25</td>
<td>IG: N=52; 62.0 years; F: 59%; (10.4 years) CG: N=50; 63.6 years; F: 50%; (10.0 years)</td>
<td>Hospital (12 months); 1 session every 3–4 months</td>
<td>IG: Usual care with regular diabetes health education Structured: General information and diet CG: Usual care – supplemented by an 8-page holiday pamphlet with specific diet, exercise &amp; travel info</td>
<td>Individual Face-to-face (Diabetic and diabetes educator)</td>
<td>1°: HbA1c, FBG &amp; fructosamine change 2°: BP (SBP, DBP) &amp; bodyweight change BL &amp; every 4–6 weeks (for 3 months) HbA1c at BL, post-holiday, 9 &amp; 12 months</td>
<td>The change in HbA1c from baseline was greater in IG than CG (0.34 vs 0.09%; p=0.03) post-holiday only. FBG higher in IG than CG pre-holiday (187.1 vs 163.1mg/dL; p=0.02) and post-holiday (199.9 vs 171.2mg/dL; p=0.01). Fructosamine higher in IG than the CG pre-holiday (350.6 vs 331.7µmol/L; p=0.03) and post-holiday (354.0 vs 331.2µmol/L; p=0.01). SBP lower in IG than CG (136.8 vs 149.4mmHg; p=0.009) post-holiday</td>
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Abbreviations: RCT, randomised controlled trial; HbA1c, glycosylated haemoglobin; IG, Intervention group; CG, Control group; SMBG, self-monitoring blood glucose; DSN, diabetes specialist nurse; FPG/FBS, fasting plasma/blood glucose/sugar; BMI, body mass index; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; tchol, total cholesterol; LDL, low-density lipoprotein cholesterol; HDL, high-density lipoprotein cholesterol; TG, triglycerides; NS, non-significant; f, female; M, male; DSMP, Diabetes self-management programme; CDMP, Chronic disease self-management programme

Appendix 1. Summary of characteristics and major study findings in randomised controlled trials focused on educational interventions in patients with type 2 diabetes. (Continued on the next 7 pages)
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<th>First author, year, location</th>
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<th>Setting (duration); No./length of sessions</th>
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<td>Cooper 2008, UK&lt;sup&gt;12&lt;/sup&gt;</td>
<td>IG: N=157; 61.3 years, (6.7 years) CG: N=157; 61.8 years, (6.7 years)</td>
<td>Community venues (6 weeks); 2 hours/ week</td>
<td>IG: X-PERT programme – Patient-centred self-management education Structured: General, weight, complications, self-care, lifestyle, diet, exercise, SMBG &amp; medication CG: Usual care – supplemented by diabetes education and review via individual appointments with a dietitian, practice nurse &amp; GP</td>
<td>IG: Group – Interactive Face-to-face: visual aids, patient manual, supermarket tour, board game (Diabetes research dietitian)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt; change 2&lt;sup&gt;nd&lt;/sup&gt;: BMI and medication use change (2&lt;sup&gt;nd&lt;/sup&gt;: Self-care behaviour [exercise, diet and self-monitoring], attitudes to diabetes, beliefs about treatment effectiveness, seriousness &amp; control)</td>
<td>Change in HbA&lt;sub&gt;1c&lt;/sub&gt; lower in the IG than the CG at 6 months (0.1 vs 1.0%; p=0.005), NS at 12 months. % with medication changes was higher in IG than CG but NS, IG had more positive attitudes than CG at 6 (2.1 vs -3.3; p=0.04) &amp; 12 months (2.1 vs -4.1; p=0.01). Treatment effectiveness perceptions were better at 6 months only in IG than CG (0.3 vs 0.0; p=0.03). Perceptions of personal control were better in IG than CG (NS). Perceptions of seriousness did not change in either group. Self-monitoring was generally higher in IG than CG but only significant at 12 months (25 vs 16% increase; p=0.002). IG reported greater change in diet &amp; exercise than CG (NS)</td>
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<tr>
<td>Deakin 2006, UK&lt;sup&gt;22&lt;/sup&gt;</td>
<td>IG: 6-month study: N=23; 12-month study: N=30 CG: N=36</td>
<td>Hospitals and community health centre (8 weeks); 2 hours/ week</td>
<td>IG: LAY (Look After Yourself) Empowerment-based education Structured: Lifestyle, stress management, complications CG: Usual care – wait-list</td>
<td>Group – Interactive Face-to-face: role-playing, visual aids, skills practice (DSN)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt; change 2&lt;sup&gt;nd&lt;/sup&gt;: BMI and medication use change</td>
<td>IG had greater reduction in HbA&lt;sub&gt;1c&lt;/sub&gt; than CG (-0.6 vs 0.1%; p&lt;0.001). IG had greater reduction in tchol than CG (-0.3 vs -0.2mmol/L; p=0.01). IG had greater reduction in weight than CG (-0.5 vs 1.1kg; p&lt;0.001). IG had greater reduction in BMI than CG (-0.2 vs 0.4kg/m&lt;sup&gt;2&lt;/sup&gt;; p&lt;0.001). IG had greater reduction in waist circumference than CG (-4 vs -1cm; M: -2 vs 0cm; p&lt;0.001). Knowledge scores improved more in IG than CG (1.8 vs 0.8; p&lt;0.001). Fruit and veg intake increased more in IG than CG (2.4 vs 0.2 portions/d; p=0.008). IG did significantly more exercise at 4 &amp; 14 months than CG. IG performed significantly more foot care at 4 &amp; 14 months only. Satisfaction with diabetes treatment was higher in IG than CG (p=0.04). Frequency of hyperglycaemia improved in both groups. Quality of life was NS between groups. Total empowerment score was higher in IG than CG (p=0.04) and in the subscales, psychosocial adjustment (p=0.03), readiness to change (p=0.01) &amp; goal-setting (p=0.003)</td>
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| Franciosi 2011, Italy²⁸     | IG: N=46; 48.9 years, F:30.4%, (3.4 years)  
CG: N=16; 48.7 years, F: 12.5%, (3.2 years) | Outpatient clinics (6 months); session every 3 months, with monthly phone contact | IG: Structured self-monitoring of blood glucose & intensive educational intervention SMBG, lifestyle modification (diet and exercise)  
CG: Usual care | Individual Face-to-face, telephone support, food & exercise diaries (DSN) | 1°: HbA¹c change  
2°: % patients reaching target HbA¹c of <7.0; % requiring medication change, changes in lipids (chol, HDL, TG), BP (SBP, DBP), body weight, BMI & waist circumference  
BL & 6 months | HbA₁c improved in both groups but change was greater in IG than CG (-1.2 vs -0.7; p=0.04). % reaching target HbA₁c <7.0% higher in IG than CG (61.9 vs 20.0%; p=0.005). Body weight reduced in both groups; change was greater in IG than CG (-4.49 vs -0.50kg; p=0.02). BMI reduced more in IG than CG (>1.6 vs -0.1kg/m²; p=0.03). Waist circumference reduced more in IG than CG (-4.4 vs -0.9cm; p=0.01); Lipids & BP improved in both groups (NS) |
| Frosch 2011, US²⁹         | IG: N=100; 56.7 years, F:54%, (10.4 years)  
CG: N=101; 54.3 years, F: 43%, (9.5 years) | Home (max 2.5 hours); 24-minute DVD, up to 5 sessions of phone coaching | IG: Behaviour support intervention & phone coaching  
Self-management: lifestyle focus  
CG: 20-page brochure on controlling diabetes for life | Individual Telephone, DVD & workbook (DSN) | 1°: HbA¹c change  
2°: BP (SBP, DBP), LDL and BMI  
BL, 1 & 6 months | HbA₁c decreased in both groups. Knowledge increased in both groups.  
Self-care behaviours improved in both groups with significant improvements from baseline for: general diet (p<0.001), BG testing (p=0.03), foot care (p<0.001), taking most prescribed medications (p=0.01) and taking all prescribed medications (p=0.001). Change in other outcomes was NS in both groups |
| Gagliardino 2013, Argentina³⁰ | IG: Patient educ group: N=117; 62.2 years, F:33.3%  
Duration: 8 years  
IG2: Patient/physician educ group: N=117; 62.2 years, F: 37.6%, (8 years)  
CG: N=117; 6.2 years, F: 32.5%, (9 years) | Primary care clinics (6 months); 2-hour session/week for 4 weeks. Re-inforcement session at 6 months | IGs: Structured General info, SMBG, self-care, diet, exercise, weight reduction, foot care, sick day management & comprehensive care  
CG: Usual care | Group (≤10/  
group) – Interactive Face-to-face, educational materials & programme book (Diabetes educators) | 1°: HbA¹c change  
2°: BP, TG and BMI  
(2°: Well-being and diabetes knowledge)  
BL & every 6 months, up to 42 months | HbA₁c decreased in all groups by 42 months (p<0.05), largest decrease in IG2. SBP decreased in all groups by 42 months (p<0.05), largest decrease in IG2. Triglycerides decreased in IG1 & 2 (p<0.05).  
Well-being improved in all groups (p<0.05) |

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<tr>
<td>Guo 2014, China²¹</td>
<td>IG: N=646; 57 years, F: 51%, (7.5 years) CG: N=643; 57.4 years, F: 50%, (7.8 years)</td>
<td>Research centres (16 weeks); both groups visited centre at baseline, 2, 4, 8, 12, 16 weeks IG: 3 telephone follow-ups at weeks 1, 3 &amp; 6</td>
<td>OPENING (Organisation Programme of Diabetes insulin management) IG: Structured diabetes education plus insulin therapy Medication, injection technique, SMBG, diet, exercise, hypoglycaemia &amp; complications CG: Usual care — supplemented by insulin therapy education</td>
<td>Individual – Interactive Face-to-face and telephone, diabetes knowledge manual (Nurse)</td>
<td>1°: HbA₁c change 2°: proportion with HbA₁c &lt;7% and ≤6.5%; FBG, SMBG, body weight &amp; BMI change (2°: Self-care activities, medication adherence and self-efficacy changes)</td>
<td>BL &amp; 16 weeks</td>
</tr>
<tr>
<td>Hermanns 2012, Germany²²</td>
<td>IG: N=94; 62.6 years, F: 52.1%, (13.8 years) CG: N=92; 63.9 years, F: 37.0%, (13.6 years)</td>
<td>Outpatient clinics (6 months); 10 x 90-minute sessions</td>
<td>MEDIAS 2 ICT (More diabetes self-management for type 2 diabetes – Intensive conventional insulin therapy) IG: Structured self-management/empowerment approach Insulin treatment, monitoring, lifestyle, diet, exercise, complications, sick day rules, attitudes and personal perceptions CG: Established education programme Didactic-oriented education: Treatment of diabetes &amp; hypertension</td>
<td>Group (family/ friend invited to lesson 7) – Interactive Face-to-face, printed materials, games, practice sessions (Diabetes educators)</td>
<td>1°: HbA₁c change 2°: number of insulin injections/day, insulin dose, SMBG 2°: Lipids (cholesterol, HDL, LDL, TG), blood pressure (SBP, DBP) and body weight change (2°: Self-care behaviour, diabetes-related distress, knowledge &amp; quality of life changes)</td>
<td>BL &amp; 6 months</td>
</tr>
<tr>
<td>Jaipakdee 2015, Thailand²³</td>
<td>IG: N=203; 61.4 years, F: 76.4%, (7 years) CG: N=200; 61.5 years, F: 77%, (8 years)</td>
<td>Primary care clinic (6 months); 3-hour session every 6 months</td>
<td>IG:DSMS (Diabetes self-management support) programme incorporating computer-assisted technology Structured: General info, behaviour change (diet, exercise), foot care, medication, complications, stress management, self-monitoring CG: Usual care</td>
<td>Group – Interactive Face-to-face, computer assisted instruction (Nurses)</td>
<td>1°: HbA₁c change 2°: FPG and body weight change (2°: health behaviour, depression &amp; quality of life changes)</td>
<td>BL, 3 &amp; 6 months</td>
</tr>
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Appendix 1. Summary of characteristics and major study findings in randomised controlled trials focused on educational interventions in patients with type 2 diabetes. (Continued from previous page and continued on next 4 pages)
Structured diabetes education outcomes: looking beyond HbA1c

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<tr>
<td>Davies 2008, UK14</td>
<td>IG: N=437; 59 years, F: 47%; CG: N=387; 60 years, F: 43%</td>
<td>Community primary care (1–2 days); 1 x 6-hour session or 2 x 3-hour sessions</td>
<td>DESMOND (Diabetes education and self-management for ongoing and newly diagnosed programme</td>
<td>IG: Diabetes education and self-management programme Structured: Curriculum focus on lifestyle (food choices, activity, &amp; cardiovascular risk) CG: Enhanced usual care</td>
<td>Group – guests invited to attend; 4–16 patients/guests per group Interactive Face-to-face (2 health care professionals)</td>
<td>1ª: HbA1c change 2ª: BP (SBP, DBP), lipids (cholesterol, LDL, HDL, Triglycerides) body weight and waist circumference change (2ª: Smoking, physical activity, beliefs about illness seriousness and impact, emotional distress, depression and quality of life) BL, 4, 8 &amp; 12 months</td>
</tr>
<tr>
<td>Khunti 2012, UK15</td>
<td>As above IG: N=332; 59.4 years, F: 45.6% CG: N=272; 61.0 years, F: 44.1%</td>
<td>As above 3 year follow-up of above RCT</td>
<td>As above</td>
<td>As above</td>
<td>1ª: As above 2ª: As above (2ª: As above) 3 year follow-up</td>
<td>Beliefs about illness was the only outcome where the higher scores at 12 months were maintained at 3 years (p&lt;0.01). All clinical, lifestyle &amp; other psychosocial outcomes did not differ between groups at 3 years</td>
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<tr>
<td>Ko 2007, South Korea16</td>
<td>IG: N=219; 53.3 years, F: 56%, (6.0 years) CG: N=218; 54.1 years, F: 54%; (6.2 years)</td>
<td>Hospital (12 months); 6 hours/day for 5 days. 1 x 3-hour session annually</td>
<td>IG: SIDEP (Structured intensive diabetes education programme) Self-management, general info, SMBG, injection technique, sick day care, meal planning, physical activity, foot care, hypoglycaemia &amp; stress CG: Usual care – supplemented by education, pamphlets/ handouts on nutrition therapy, diabetes, exercise, injecting &amp; SMBG</td>
<td>Group – 5–10 patients/group; family invited – Interactive Face-to-face, audio-visual (Team of 8 diabetes health professionals)</td>
<td>1ª: Mean value &amp; HbA1c change 2ª: Adherence to lifestyle modification and maintenance of self-care behaviour) BL, 6, 12, 24, 36 &amp; 48 months</td>
<td>IG had significantly lower HbA1c than CG at 6, 36 and 48 months – mean difference at 6 months: 0.87 (0.58 to 1.16), p&lt;0.0001; mean difference at 36 months: 0.51 (0.17 to 0.85), p=0.004; mean difference at 48 months: 0.80 (0.49 to 1.12); p&lt;0.0001. IG had higher self-care behaviour scores at all time-points for diet (p&lt;0.001), physical activity (p=0.004) and SMBG (p&lt;0.001)</td>
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Appendix 1. Summary of characteristics and major study findings in randomised controlled trials focused on educational interventions in patients with type 2 diabetes. (Continued from previous page and continued on next 3 pages)
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<td>McGowan 2015, Canada&lt;sup&gt;37&lt;/sup&gt;</td>
<td>IG: DSMP N=86; 64.6 years, F: 36%; (8.8 years) IG2: CDMP N=63; 63.8 years, F: 46%; (8.9 years) CG: N=89; 63.8 years, F: 40%; (9.5 years)</td>
<td>Community venues (6 weeks); CDMP 2.5 hours/week</td>
<td>IG: DSMP (Diabetes self-management programme) General info, SMBG, preventing hypoglycaemia, complications, diet, medication, sick days, foot care &amp; dealing with stress IG2: CDMP (Chronic disease self-management programme) Skills to manage/cope with chronic disease CG: Usual care</td>
<td>CDMP Group of 10–16. Families/friends/carers invited Face-to-face (Peers)</td>
<td>1st: HbA1c change 2nd: BP, body weight, BMI, waist circumference and cholesterol change (2): Self-care behaviours (communication with physician, exercise and relaxation frequency), attitudes, quality of life, health status and self-efficacy change</td>
<td>BL, 6 &amp; 12 months</td>
</tr>
<tr>
<td>Perez-Escamilla 2015, US&lt;sup&gt;38&lt;/sup&gt;</td>
<td>IG: N=105; 55.4 years, F: 72.4%; CG: N=106; 57.3 years, F: 74.5%</td>
<td>Home (12 months); weekly visits during month 1; biweekly in months 2 &amp; 3, then monthly</td>
<td>DIALBEST (Diabetes Among Latinos Best Practice Trial) IG: Usual care plus structured culturally tailored diabetes education and counselling General info, behaviour change, SMBG, medication, compliance, complication &amp; mental health CG: Usual care</td>
<td>Individual (family can attend) – Interactive Face-to-face, visual aids, supermarket tour &amp; activities (Community health worker)</td>
<td>1st: HbA1c change 2nd: FPBG, SBP, lipids (tcho, HDL, LDL, TG) and body weight change</td>
<td>BL, 3, 6, 12 &amp; 18 months</td>
</tr>
<tr>
<td>Philis-Tsimikas 2011, US&lt;sup&gt;39&lt;/sup&gt;</td>
<td>IG: N=104; 52.2 years, F: 66.3%; CG: N=103; 49.2 years, F: 74.8%</td>
<td>Health centre (4 months); 2 hours/week for 8 weeks, then monthly 2-hour group sessions</td>
<td>Project Dulce model IG: Culturally sensitive structured self-management peer education programme General info, complications, diet, exercise, medication, SMBG, cultural beliefs CG: Usual care</td>
<td>Group – Interactive Face-to-face (Peer educator &amp; guest speakers)</td>
<td>1st: HbA1c change 2nd: BP (SBP, DBP), lipids (tcho, HDL, LDL, TG) and BMI change</td>
<td>BL, 4 &amp; 10 months</td>
</tr>
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**Appendix 1.** Summary of characteristics and major study findings in randomised controlled trials focused on educational interventions in patients with type 2 diabetes. *(Continued from previous page and continued on next 2 pages)*
## Structured diabetes education outcomes: looking beyond HbA1c

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| **Prezio 2014, US**<sup>10</sup> | IG: N=90; 47.9 years, F: 66.7%, (4.80 years)  
CG: N=90; 45.7 years, F: 54.4%, (4.54 years) | Primary care clinic  
12 sessions; 1 hour in each quarter | CODE (Community Diabetes Education) programme  
IG: Usual care & culturally tailored education & self-management  
SMBG, diet, medication, sick days, smoking, exercise & complications  
CG: Usual care – wait-list  
Educational materials | Individual – face-to-face & printed educational materials  
(Community health worker) | 1º: HbA1c change  
IG & CG: (difference -0.18%; p=0.01)  
2º: BMI, BP (SBP, DBP) and lipids (LDL, HDL, TG) change  
BL & 12 months | HbA1c decreased in both the IG and CG  
(change of -1.6 and -0.9% respectively; p<0.001)  
Change from baseline in BP, BMI and lipids was NS in both groups  
IG had greater mean change in HbA1c than CG (difference -0.7%; p=0.02) |
| **Rygg 2012, Norway**<sup>45</sup> | IG: N=73  
CG: N=73 | Hospitals  
IG: Hospital 1: 15 hours over 3 sessions; 1 week between sessions  
IG: Hospital 2: 15 hours over 3 sessions; 2 weeks between sessions  
CG: 3 x 1-hour sessions in first 8 weeks, then 1 hour in each quarter  
| IG: Locally developed Structured DSME  
(diabetes self-management education)  
General info, complications, diet, exercise, improving metabolic control  
with hospital 2 also including session on solution focused brief therapy  
CG: Usual care – wait-list | Group – 8–10/  
Inter-active Face-to-face, lectures  
(Diabetes nurse with physician, physio and lay person input.  
Diet session by nutritionist [hospital 1] or by diabetes nurse [hospital 2]) | 1º: HbA1c change  
IG: (difference -0.7%; p=0.02)  
2º: BMI, BP (SBP, DBP), lipids (tchol, HDL, TG)  
and complications  
CG: Treatment satisfaction, diabetes distress, global health and quality of life – physical/mental health change  
BL & 12 months | Treatment satisfaction was higher in IG than CG at 6 months (difference 2.4; p=0.019); NS at 12 months; Diabetes knowledge test improved more in IG than CG at 6 months (difference 1.2; p=0.000) and at 12 months (difference 0.9; p=0.004); Foot care was higher in IG than CG (difference -18%; p=0.002) at 12 months; NS at 6 months  
NS difference between groups at 6/12 months for HbA1c, BP, weight, BMI, lipids, complications, PAM, diabetes distress, global health, physical and mental health, avoidance of fatty foods, high vegetable intake and SMBG |
| **Salinero-Fort 2011, Spain**<sup>32</sup> | IG: N=304; 66.1 years, F: 53.8%, (8.8 years)  
CG: N=304; 67.3 years, F: 49.3%, (9.5 years) | Primary care clinics  
(2 years); 2 baseline visits then visits every 3 months, both IG and CG (total of 10 visits).  
For IG, 4 visits were education sessions lasting 40 minutes/session | IG: Usual care and individual counselling based on the Precede model for Health Promotion Education (PHPE)  
Structured: Behaviour change (2 behaviours selected per patient)  
CG: Usual care, individual counselling based on the model for Health Promotion Education (CHPE)  
Self-monitoring, exercise, diet, medication, smoking | Individual – face-to-face (Researchers/ nurses) | 1º: HbA1c, BP (SBP, DBP), lipids (tchol, LDL, HDL, TG), BMI and control criteria  
(i.e. aligned to CV risk factors) change  
BL & 24 months | HbA1c decreased in IG (-0.03%; p<0.01)  
but increased in CG (0.04%; p<0.01)  
SBP decreased in IG (-4.22mmHg; p=0.05) but no change in CG; DBP decreased in IG (-2.76mmHg; p<0.01) but no change in the CG  
Change in HbA1c was greater in IG than CG but only significant in the adjusted analysis (difference -0.18%; p=0.01)  
Change in SBP was greater in IG than CG in unadjusted/adjusted analysis (p<0.01); NS improvement for BMI, DBP, tchol and LDL in both IG and CG  
% on target for CV risk factors was higher in IG than CG for: HbA1c <7%; p=0.01; HbA1c <7% and LDL <100mg/dL: p=0.02; SBP <130mmHg: p=0.02; DBP <80mmHg: p=0.01; SBP <130 and DBP <80mmHg: p<0.01; HbA1c <7%, LDL <100mg/dL, SBP <130 and DBP <80mmHg: p=0.02 |

### Appendix 1. Summary of characteristics and major study findings in randomised controlled trials focused on educational interventions in patients with type 2 diabetes. (Continued from previous page and continued on next page)
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<td>Scain 2009, Brazil&lt;sup&gt;43&lt;/sup&gt;</td>
<td>IG: N=52; 59.3 years, F: 55.8%; CG: N=52; 59.5 years, F: 50.0%</td>
<td>Health care centre (4 weeks); 2 hours/week</td>
<td>IG: Structured self-management education programme &lt;br&gt;Self-care (diet, exercise, self-monitoring, foot care), complications &amp; general info&lt;br&gt;CG: Usual care</td>
<td>Group – 8–10/12 sessions &lt;br&gt;Interactive&lt;br&gt;Face-to-face, visual resources (Nurse)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt;, FBG, BMI, waist-hip ratio, BP (SBP, DBP) &amp; lipids (tchol, HDL, TG) change &lt;br&gt;2&lt;sup&gt;nd&lt;/sup&gt;: Diabetes knowledge&lt;br&gt;BL, 1, 4, 8 &amp; 12 months</td>
<td>BMI, SBP, DBP, tchol &amp; HDL improved significantly in both IG &amp; CG (p&lt;0.01). IG had lower HbA&lt;sub&gt;1c&lt;/sub&gt; at 4 (p=0.007), 8 (p=0.009) and 12 months (p=0.04) compared to CG. Knowledge improved more in IG than CG at 1 month (p&lt;0.01)</td>
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<tr>
<td>Sinclair 2013, US&lt;sup&gt;44&lt;/sup&gt;</td>
<td>IG: N=48; 53 years, F: 63% (mean age first diagnosed: 38 years) CG: N=34; 55 years, F: 62% (mean age first diagnosed: 39 years)</td>
<td>Community venues (3 months); 12 x 1-hour sessions</td>
<td>Partners in Care study&lt;br&gt;IG: Culturally adapted self-management educational intervention SMBG, complications, diet, exercise, medication &amp; stress reduction&lt;br&gt;CG: Usual care – wait-list</td>
<td>Group – Interactive&lt;br&gt;Face-to-face, written materials, visual aids, skill-building&lt;br&gt;(Peer educator)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt; change &lt;br&gt;2&lt;sup&gt;nd&lt;/sup&gt;: Self-management understanding and performance of self-care activities and diabetes-related distress&lt;br&gt;BL &amp; 3 months</td>
<td>IG had greater change in HbA&lt;sub&gt;1c&lt;/sub&gt; than CG (-1.1 vs -0.3%; p=0.001). IG had greater change in understanding than CG (13.1 vs 1.8; p&lt;0.0001). IG had greater change in self-care score than CG (4.9 vs 1.4; p&lt;0.0001)</td>
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<td>Sperl-Hillen 2013, US&lt;sup&gt;45&lt;/sup&gt;</td>
<td>IG: N=246; 61.6 years, F: 49.6% (11.9 years) CG: N=134; 63.3 years, F: 46.3% (13 years)</td>
<td>Clinics (3 months); 3 x 1-hour sessions, approx. every month</td>
<td>IDEA (Journey for control of diabetes Interactive Dialogue to Educate and Activate) study&lt;br&gt;IG: Individual structured education for behavioural change&lt;br&gt;Self-management: diet, exercise, monitoring, medication problem solving, risk reduction, &amp; coping&lt;br&gt;CG: Usual care</td>
<td>Individual – Interactive&lt;br&gt;Face-to-face (Diabetes educator)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt; change &lt;br&gt;2&lt;sup&gt;nd&lt;/sup&gt;: BP (SBP, DBP) &amp; body weight change&lt;br&gt;(2&lt;sup&gt;nd&lt;/sup&gt;): nutrition, exercise, physical health, mental health, diabetes care profile, diabetes-related distress and empowerment change&lt;br&gt;BL &amp; 6 months</td>
<td>Change in HbA&lt;sub&gt;1c&lt;/sub&gt; was greater in IG than CG (-0.27%; p=0.01). Understanding was higher in IG (0.28; p&lt;0.001) than in CG. Nutrition improved more in IG than CG (0.63; p=0.05). Physical activity increased more in IG than CG (42.95min/week; p=0.03). Physical health score was higher in IG than CG (1.88; p=0.04)</td>
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<tr>
<td>Sperl-Hillen 2013, US&lt;sup&gt;46&lt;/sup&gt;</td>
<td>As above</td>
<td>As above; 1-year follow-up</td>
<td>As above</td>
<td>As above</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: HbA&lt;sub&gt;1c&lt;/sub&gt; change &lt;br&gt;(2&lt;sup&gt;nd&lt;/sup&gt;): Nutrition, exercise, understanding, diabetes-related distress and empowerment change&lt;br&gt;BL &amp; 12 months</td>
<td>Understanding was higher in IG (0.25; p&lt;0.001) than in CG. Diabetes distress score was lower in IG than CG (-2.94; p=0.04). Empowerment score was higher in than CG (0.11; p=0.03)</td>
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