Can Structured Education Improve Metabolic Outcome and Quality of Life in Diabetes? A Systematic Review of Randomised Controlled Trials

Osama Moheb Ibrahim Mohamed (1)
Mohamed Hassanein (2)

(1) Osama Moheb Ibrahim Mohamed, MBBCh, MSc , MD Family medicine, MSc Diabetes Cardiff, UK , Consultant Family Medicine, Ambulatory Health Services, SEHA corporate, Abu Dhabi, UAE
(2) Mohamed Hassanein, FRCP-Lon, FRCP-Edin, MPhil. Consultant Endocrinology, Dubai Hospital, Dubai Health Authority, Dubai, UAE

Correspondence:
Dr. Osama Moheb Ibrahim Mohamed
Ambulatory Health Services, SEHA corporate, Abu Dhabi, UAE
Email: osamamohebibrahim@gmail.com

Abstract

Background: Diabetes people who want to live a good quality of life will need to be educated about management of their illness. Although structured education is essential to provide diabetic patients with the necessary self-management knowledge and skills to achieve accepted glycaemic control still there is a controversy on the effectiveness of the current structured diabetes education Programs (SDEP).

Objective: To evaluate the effectiveness of SDEP on metabolic outcomes and quality of life among diabetic patients.

Methods: A systematic review of randomized controlled trials (RCT) published between 2002 and 2013 on SDEP.

Results: This study identified 19 trials (9378 participants); 12 of them had low risk of bias, 3 had unclear risk of bias and 4 had high risk of bias. The number of participant per study ranged from 84 to 1054 participants. All included studies used HbA1c as a primary outcome measure and most of studies measured psychosocial outcomes e.g. quality of life and depression. Thirteen out of 19 trials demonstrated a significant glycated haemoglobin (HbA1c) reduction in intervention group compared to control group at the end of the intervention while 6 trials did not demonstrate a significant change. Seven trials out of 16 demonstrated statistically significant reduction in Body Mass Index(BMI) or weight in intervention group. Nine trials evaluated the effect of structured diabetes education on quality of life, 3 of them reported significant improvement in the intervention group compared to the control group at the end of intervention.

Conclusion: The results of this systematic review showed that structured diabetes education has a positive impact on biomedical and quality of life on diabetic patients especially with some degree of reinforcement at additional points of contacts. Further research is needed to evaluate the effect of education on longer duration.

Key words: Structured education, metabolic outcome, diabetes, quality of life

Introduction

The Global prevalence and burden of diabetes has reached epidemic proportions in most populations. It was estimated that 366 million of the world population were diabetics in 2011; by 2030 this number will be increased to 552 million. Diabetes is a major leading cause of death; 4.6 million died due to diabetes complications in 2011. The cost of treatment of diabetes and its complications was 11% of total world healthcare expenditures in 2011. (1)

The importance of patient education is evident from studies reporting that patients who never attended structured diabetes education showed four-fold increased risk of diabetes complications. (2)

Many studies showed that only 26 - 36 % of diabetic patients had attended a course to help them manage their diabetes since diagnosis(3, 4). The average duration of a diabetic patient visit with a primary care provider was 16.1 minutes; of all primary care office consultations 14.3% received diet or nutrition counselling, 10% received exercise counselling, and 3.6% received weight-management counselling. (5) Studies have shown that there is 50-80% shortage of knowledge and skills in patients with diabetes and the recommended glycaemic control is achieved in less than 60% of diabetic patients (6)

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Globally, structured education is considered an important tool for Diabetes management; in the UK, the national institute for health and clinical excellence (NICE), Clinical Excellence guidelines for diabetes (7) and National Service Framework for Diabetes (8) adopted providing a structured diabetes education from the time of diagnosis. Similarly the American Diabetes Association (ADA) recommended that diabetes education should be started from the time of diagnosis as well. (9)

Health education of diabetic patients is a therapeutic action that helps patients to acquire the necessary knowledge and to develop abilities and skills to improve self-management (10). Although it is well known that lifestyle modification and good compliance to management are important, adults with chronic diseases are often having difficulties to achieve these changes.(11)

Many factors of the educational process might be related to this difficulty. Adults have different abilities from school-age children in their accumulated experience, maturity, independence, and self-determination. They need to know the reasons for learning something new, and they only acquire new knowledge and skills if the topic being addressed is related to their daily life routine(12). Learning process can occur with continuous motivation and stimulation throughout the treatment so a specific structured education is important to promote, update, and maintain proper health related knowledge, attitudes and skills. (13)

Studies of diabetes education programmes have reported conflicting results on the outcomes; some studies of structured diabetes education reported improvement of self-efficacy, biomedical outcomes and quality of life (14).

On one hand some trials conducted with Type 2 diabetes demonstrated better dietary and medication adherence, more frequent self-monitoring blood glucose (SMBG), physical activity (15), enhancement of self-efficacy(16) and is likely to be cost effective compared to usual diabetes care (17). Another study to evaluate the impact of SDEP on type 1 diabetic patients (18) on biomedical and quality of life parameters showed a significant reduction in HbA1c at 6 months in intervention group, sustained at around 0.5% at 1 year after the course (19). The cost-benefit analysis demonstrated that it is better than current standard practice and has modest effects on survival, and yields significant improvements in quality of life.(20)

On the other hand in a study (21) of adults with newly diagnosed type 2 diabetes, SDEP demonstrated benefits in weight control, quitting smoking and health beliefs about diabetes but no difference in A1c at 12 months after diagnosis. The follow up study(22) of the same patients demonstrated a favourable effect on body mass index, risk factors, beliefs and health practices, but no effect on the level of HbA1c in the intervention group at one and three years compared to control group.

Because of controversy on the effectiveness of SDEP, this study was aiming to review the impact of latest evidence and recommendation regarding diabetes education and to discuss the differences in studies design which could have had an impact on outcome.

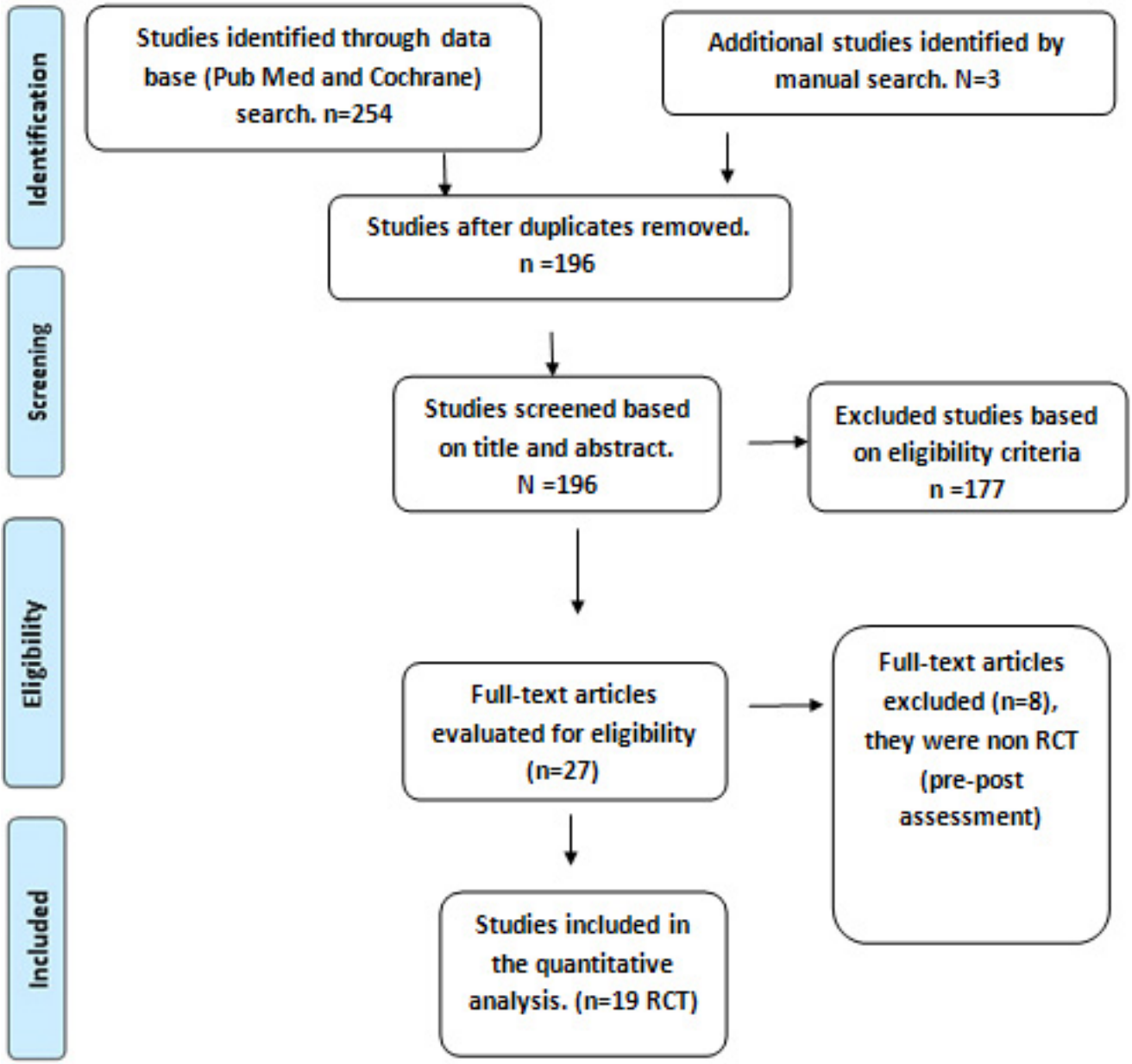
Methods

1) Study design: this was a systematic review to study the impact of SDEP on self-management of patients with diabetes.

2) Eligibility criteria: randomized controlled trials studying the impact of SDEP on promoting diabetes self-management and met the following criteria were included: randomized controlled trials, studies published in the English language, studies identified from an electronic database, studies meeting the definition of SDEP by NICE(7), documented specific learning objectives and delivered by a trained diabetes educator. Articles published between years 2002 and 2013 for type 1 and type 2 diabetes regardless of the age of participants and considered HbA1c as a primary outcome measure, were included. Articles and reviews which present the author's opinion rather than evidence, and education programmes published before year 2002, were excluded

3) Information sources: the PubMed and Cochrane databases were searched for relevant RCT in structured diabetes education between January 2002 and August 2013. Key word searches were based on the search terms and included RCT, controlled clinical trials, random allocation, diabetes, SDEP.

4) Selection of included trials: titles, abstracts and key words of every study were screened for selection of eligible articles. Full articles were reviewed for more assessment



if there were indications based on titles and abstracts suggesting that the study met the eligibility criteria study selection were performed by the researchers to identify the included studies according to the inclusion and exclusion criteria, with disagreement resolved by discussion between researchers. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (23) chart was used to present the flow of information through different phases of study selection. (Figure 1)

5) Data items: information was extracted from individual studies regarding:

1) Participant characteristics including age, number of participants.

2) Type of intervention including number of teaching sessions, duration of intervention.

3) Type of outcome measures including HbA1c, cholesterol and triglycerides, blood pressure, BMI, knowledge, quality of life and hypoglycemic episodes.

6) Data collection process: data extraction forms were developed by the researchers to present the extracted data. Data extraction forms included the following: general characteristics of included studies, risk of bias assessment of every included RCT, systolic and diastolic blood pressure, BMI, lipids, quality of life and episodes of hypoglycaemia.

7) Risk of bias in included studies: The validity of eligible RCT was determined by the following parameters according to Cochrane's tool for assigning risk of bias(24); the adequacy of sequence generation, randomization and concealment of allocation, data collectors and, outcome assessors, blindness and completing primary outcome. Trials were classified as (low risk i.e. low risk of bias), (high risk i.e. high risk of bias), and (unclear risk of bias i.e. lack of information regarding the research methods used).

8) Summary measures: Mean and standard deviation was used to assess the difference between continuous data, significant change was considered if p - value > 0.05%.Knowledge and quality of life data were extracted

only if validated questionnaire score was used. Hypoglycemia is evaluated by the number of hypoglycemic episodes per person per year; symptomatic hypoglycemia is evaluated by patient self-report and medical records using number of episodes/person/year; severe hypoglycemia is defined as an event requiring assistance of another person. (25)

9) Outcome measurements: HbA1c is an indicator that reflects glucose levels in the blood over a three month period, Blood pressure (BP) and blood lipids (cholesterol and triglycerides), BMI and weight, Episodes of acute complications; hypo glycaemia, Quality of life indicators, Patient's knowledge

Results

1. Study Selection: The search strategy of two electronic databases Pub Med-NCBI -National library of Medicine identified 125 studies and Cochrane library identified 129 studies; another 3 studies were identified by manual search, giving a total number of 257. After excluding the duplicates the remaining studies were 196; of these 177 studies were excluded based on abstract screening for eligibility as they were irrelevant to the current study. Twenty seven full articles were evaluated for eligibility based on inclusion and exclusion criteria resulting in exclusion of another 8 articles that were irrelevant. Nineteen studies(18, 21, 22, 26-41) were assessed and met the eligibility criteria. The processes of filtering the searched studies was presented in Figure 1 according to PRISMA flow chart.(23)

2. Study Characteristics: A total of 19 studies (18, 21, 22, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41) were included. They have a combined population size of 9387 patients. The included studies were generally focused on evaluations of metabolic control, quality of life and self-management in both type 1 and type 2 diabetes. Topics that were covered in the intervention groups were nutrition, weight, HbA1c level, blood lipids, blood pressure, quality of life and psychosocial aspects. The interventions were derived by trained certified health care personnel in 15 trials (18, 22, 28-30, 32-41) while educator qualifications were mentioned in the remaining 4 trials (26,27,31,37). All the studies used group approach to their intervention except one study which used group training followed by one to one education during the follow up visits(35). The control group in all the included studies received the usual care without any specific intervention. The number of participants per study ranged from 84 to 1054 participants and assessment of outcomes were at baseline in all studies and extended up to 3/6/12/18 months and 2 / 5 years in 2 RCTs (36, 42). Inclusion criteria were mentioned in all included studies. The age of participants ranged from 18 to 75 years in type 1 and T2DM. All included studies used HbA1c as a primary outcome measure. The studies were ordered by type date and size (most recent and largest first). Table 1 shows more details about characteristics of included studies.

3. **Risk of bias assessment in included RCT**

The quality of studies and risk of bias were assessed according to Cochrane's tool for assessing risk of bias (35). The quality of included studies was generally satisfactory; there were 3 studies (28,29,38) classified as unclear risk of bias because it was not clear in these studies whether the data collectors and outcome assessors were blind or not. Four (31,35,39,41) out of 19 studies were classified as high risk of bias because the methods used to generate the allocation sequences and conceal the allocation were not clear. The rest of studies (12 out of 19 studies) (18, 21, 22, 26,27, 30, 32, 33, 34, 36, 37, 40) were classified as low risk of bias because the methods used to generate and conceal the allocation and to describe the blinding methods of data collection and outcome assessment were clear. Table 2 demonstrated Risk of bias assessment of included RCT according to Cochrane's tool for assigning risk of bias.

4. Primary outcomes

All included studies 18, 21, 22, 26-41 measured HbA1c at baseline and at the end of the intervention Table 3. There were no significant differences between intervention and control groups before the intervention in all included trials. After intervention and follow up period 13 studies (18,26,27,28,29,31,32,33,34,35,36,37,41) out of 19 demonstrated significant reductions in A1c in the intervention group compared to control group where A1c levels were shown to have decreased in intervention groups, the remaining 6 studies 21, 22,30,38,39,40 did not demonstrate a significant change in A1c after the intervention. Three studies (21, 22, 46) followed the patients for a long period: two of them (46, 47) demonstrated a significant impact of structured diabetes education in 2 and 5 years consecutively, on the other hand one study 22 did not demonstrate significant difference after 3 years follow up. All studies (21,26,27, 28,29,33,,34,37,38,39) that assessed A1c after one year or less demonstrated significant change except one study 21 that reported insignificant reduction in A1c level in both intervention group and control group after one year of follow up in a relatively large number of participants (824 adults) compared to the other included trials.

5. Secondary outcomes

5.1 Blood Pressure: Blood Pressure measurement was a secondary outcome in a few structured diabetes studies. Only 7 studies (22,26,27,29,36,38,40) evaluated BP in a follow period ranging from 6 months to 3 years. 6 of them demonstrated no significant difference between intervention group and control group or pre and post structured diabetes education. Only one study (35) demonstrated significant BP reduction.

5.2 Body mass index and weight : Sixteen studies (26, 27,28,29,30,22,31,32,33,34,35,36,21,40,41,18) evaluated the impact of structured diabetes education in BMI or wt.; duration of follow up ranged from 6 months to 3 years. Only 7 trials (21,22,27,33,34,35,40) out of the 16 studies demonstrated statistically significant reductions in BMI or weight in intervention group compared to control group at the end of the studies, whereas BMI and weight in the

Table 1: Characteristics of studies included in the systematic review of randomized controlled trials assessing the effect of structured diabetes education programmes on metabolic outcomes and quality of life in Diabetes (also continued next page)

Author / study Duration	Intervention	Inclusion criteria	Participant numbers study/control	Educators Training	Assessment / follow up	Age	Outcome measures
Bosi et al., 2013[26] /12-month	DM specific modules include charts and other materials to facilitate patient SMBG and improve quality of life.	Adults with T2DM not on insulin HbA1c (7–9 %.)	501 / 553	Not mentioned	At baseline, months 3, 6, 9, and 12	Aged 35–75 years	BGI, SMBG, HbA1c , QoL
Mohamed et al., 2013[27] /12-month	SDEP, four educational sessions (10-20 patients per session), lasting for 3-4h.to discuss LSM , KAP ,PE, DSMT	Adults with type 2	215 / 215	Not mentioned	At baseline and one-year	Above 18 years	HbA1C, lipid, ACR, BMI, BP, SMBG and KAP
Beverly et al., 2013[28] / 12-month	SDEP specific cognitive behavioural strategies and techniques for implementing self-care behaviours five sessions over 6 weeks	Adults: 18–75 years with T 1 or 2 DM for one year (A1C ≥7.5%)	149 / 69	Qualified Diabetes educator	At baseline and 3, 6, and 12 months	Aged 18-75 years	HbA1C, QoL, BMI, BP, SMBG
Adachi et al.,2013[29] 6 months	A structured individual-based lifestyle education program to reduce the HbA1c level in type 2 diabetes 3 or 4 sessions	Adults with type 2 diabetes	113 / 102	Trained , registered dietitians	At base line / 6 months	Mean age 61.3	HbA1c, BMI, BP, FPG, lipid profiles, QoL
Coates et al., 2013[30] /24 months	SDEP that focused on insulin adjustment to elaborate diet and life style, delivered on 4 consecutive weekly sessions, for 3 hours	Adolescents aged 13- 19 years	70 / 65	Trained diabetes nurse	At baseline, months 3, 6, 12 and 24	Mean age 15+.13	HbA1c, weight, hypoglycaemia , BMI, FBG, QOL
Khunti et al.,2012[22] /3 years	SDEP for six hours to support the diabetic to increase knowledge and understanding of what having diabetes means, empower patient to make their own decisions	Adults T 2 DM	437 / 387	Trained healthcare professionals	At base line / 4/8/12 months and 3 years	Above 18 years	HbA1c, BP, QOL weight, lipids, smoking status, PE,
Tan et al.,2012[31] /3 months	SDEP consisted of monthly sessions - two were face-to-face and one was a telephone follow-up to support healthy life style and hypoglycaemia awareness.	Adults >18 years HbA1c >7%.	82 / 82	Not mentioned	At base line / 3 months	Mean age 54 ±10.74 years	HbA1c, Medication adherence, Dietary intake, PE, SMBG
Sperl-Hillen, et al., 2011[32] /3 months	DEP consistent with the AADE7 Self-Care behaviours. The AADE7 content areas were healthy eating, monitoring, taking medications, problem solving, risk reduction, healthy coping, and being active.	Adults with type 2 DM	489 / 134 3 arms trial 246 = GE 243 = IE	Trained diabetes educators	Baseline 3/6/12 months	Mean age; 61 ±8 years	HbA1c, weight, blood pressure and QOL
Weinger et al., 2011[33] /12-month	A structured behavioural intervention consisted of five 2-hour sessions, for 6 weeks that included behavioural support for implementing self-care behaviours and cognitive behavioural strategies	Adults with type 1 or 2 DM, HbA1c > 7.5%.	149 / 75 3 arms trial 74 = GE 73 = IE	Diabetes educators	Baseline 3/ 6/ 12 months	Range; 18-70 years	HbA1c, MBI, Lipid Profiles, SMBG and QOL

Abbreviations: SMBG; self-monitoring blood glucose, **LSM;** Life Style Modification, **SDEP;** Structured Diabetes Education Program**, PE;** Physical Activity, **BGI;** blood glucose index**, QoL;** Quality of Life, **KAP;** Knowledge, Attitude and Practices**, ACR;** Albumin Creatinine Ratio, **BMI;** Body mass Index**, BP ;**Blood Pressure, **FBG ;**Fasting Blood Glucose**, AADE7;** American Association of Diabetes Educators Seven;**, IE ;** Individual education, **GE ;** Group education**, DSMT;** Diabetes self-management training**, T2DM;**Type 2 Diabetes Mellitus**, BP:** Blood Pressure

Table 1: (continued) Characteristics of studies included in the systematic review of randomized controlled trials assessing the effect of structured diabetes education programmes on metabolic outcomes and quality of life in Diabetes

Author / study Duration	Intervention	Inclusion criteria	Participant numbers study/control	Educators Training	Assessment / follow up	Age	Outcome measures
McGowan et al 2011[34] / 12 months	Programme topics : self-management behaviours, self-efficacy and coping with emotional distress, LSM and glycaemic target , a 4-day training workshop	Adults with type 2 diabetes	169 / 152	Trained educators	At baseline / 6 months	Mean age; 55±59 years	A1c, lipids
Trento et al ., 2010 5 years[35] (ROMEO)	SDEP, 50 minutes diabetes education every 3 months in small groups followed by one to one physician education to plan meals, increase PE, improve metabolic control and smoking cessation.	Adults Patients with T2DM	421 / 394	Trained Physicians, Nurses and Dieticians	Baseline /1/2/3/4 years	Mean Age; 69.3 ± 8 year	HbA1c, FBG, BMI, BP, lipid Profiles , QoL, Knowledge and health behaviours
Melkus et al., 2010[36] / 24 months	SEDP consisted of a series of 11 weekly group sessions. The first 6 sessions (each 2 hr. in duration) provided DSMT based on AADE standards.	Above 18 with T2DM	57 / 52	Trained educators	Baseline 3, 6, 9, 12 and 24 months	Mean Age; 57.3 ± 14.4 year	HbA1c, BP, FBG, Lipid Profiles , PE,BMI, QOL, SMBG
Braun et al., 2009[37] 12 months	A brief structured education programme consisted of 7 educational classes of 45 minutes about diabetes self-management	T2DM on insulin therapy age >65	83 / 72	Not clearly mentioned	At base line / 6 months	Mean Age; 76.2±6.3	HbA1c, , SMBG, knowledge , QOL, hypoglycaemia
Davies, et al.,2008[21] /12-month	SDEP to raise the importance of LSM, PE ,DM follow up, glycaemic targets and food intake	Adults with T2DM	437 / 387	Trained educators	At baseline, 8 and 12 months	Mean Age 59.5 years	HbA1c , BP, weight, lipids, smoking status, PE, QOL
Sturt et al ., 2008[38] / 6 months	SDEP to improve patient self confidence in managing their diabetes and reduced diabetes anxiety levels. one to one education with a 12 week diabetes manual	Adults with T2DM	245 / 245	Trained Practice nurses	Baseline / 6 /12 months	Mean Age; 62 years	A1c, BP, TC, BMI, Confidence to self-care, diabetes related stress
Cooper et al., 2008[39] /12-month	Physical activity, LSM target A1c in a SDEP consists of 2-hour sessions weekly for 8 weeks	Adults with T2DM	53 / 59	Trained diabetes specialised nurses	At baseline /6 and 12 months	Ages range; 21–75 years	HbA1c, BMI, BP, lipids and QOL
Deakin et al., 2006[40] 14 months.	SDEP to improve knowledge and diabetes self-care. 2 hours per week for 6weeks (12 hours)	Adults with type 2 diabetes	314 / 291	Diabetes research Dietician	Baseline / 14 months	Mean age 61.3± 9.7	HbA1C, BMI, blood pressure, and QOL
Trento et al., 2004[41] / 5 years	Group sessions every 3 months to plan meals, increase PE, improve A1c, smoking cessation.	Adults with T2DM	42 / 42	Physicians and diabetes educator	Baseline /4/8/12 months	-	HbA1c , blood lipids pressure, weight, PE, smoking status, QOL
DAFNE Study Group., 2002[18] 6 months	SDEP over five consecutive days (38 h), to groups of 6-8 people to adjust insulin dose and improve self-care	Age > 18 T1DM 2 A1c 7.5-12%	68 / 72	Trained diabetes educators	At baseline / 6 months	Mean age; 40±9 years	HbA1c, severe hypoglycaemia, impact of diabetes QOL

Abbreviations: SMBG; self-monitoring blood glucose, **LSM;** Life Style Modification, **SDEP;** Structured Diabetes Education Program**, PE;** Physical Activity, **BGI;** blood glucose index**, QoL;** Quality of Life, **KAP;** Knowledge, Attitude and Practices**, ACR;** Albumin Creatinine Ratio, **BMI;** Body mass Index**, BP ;**Blood Pressure, **FBG ;**Fasting Blood Glucose**, AADE7;** American Association of Diabetes Educators Seven;**, IE ;** Individual education, **GE ;** Group education**, DSMT;** Diabetes self-management training**, T2DM;**Type 2 Diabetes Mellitus**, BP:** Blood Pressure

Table 2: Risk of bias assessment of included RCT according to Cochrane's tool for assigning risk of bias

References	Sequence generation	Allocation concealment	Data Collectors Blinded	Outcome Assessors Blinded	Completed Primary outcome	Risk of bias
Bosi et al ,2013[26]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Mohamed et al , 2013[27]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
BEVERLY et al ,2013[28]	adequate	adequate	adequate	adequate	Completed	Unclear risk of bias
Adachi et al .2012[29]	adequate	adequate	adequate	adequate	Completed	Unclear risk of bias
Coates et al ,2013[30]	adequate	adequate	adequate	unknown	Completed	Low risk of bias
Khunti et al,2012[22]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Tan et al.2012[31].	unknown	unknown	Single blind	Single blind	Completed	High risk of bias
Sperl-Hillen, et al, 2011[32].	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Weinger et al 2011[33]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
McGowan et al, 2011[34]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Trento et al ., 2010[35]	adequate	unknown	unknown	unknown	completed	High risk of bias
Melkus et al, 2010[36]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
BRAUN et al 2009[37].	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Davies, et al,2008[21]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Sturt et al ., 2008[38]	adequate	adequate	unknown	unknown	completed	Unclear risk of bias
Cooper et al, 2008[39]	adequate	adequate	unknown	unknown	Completed	High risk of bias
Deakin et al,2006[40]	adequate	adequate	adequate	adequate	Completed	Low risk of bias
Trento et al 2004[41]	adequate	unknown	unknown	unknown	Completed	High risk of bias
DAFNE Study Group, 2002[18]	adequate	adequate	adequate	adequate	Completed	Low risk of bias

remaining 9 trials (18, 26, 28, 29, 30, 31, 32, 36, 41) were shown to have no significant difference in intervention group compared to control group.

5.3 Cholesterol and triglycerides: Ten trials (18, 21, 26, 27,29,33,35,36,38,40) reported lipid profile as an outcome in included structured diabetes education trials. Only 2 trials (27, 21) demonstrated significant reductions in cholesterol in intervention group compared to control group at the end of follow up period of one year and 2 years respectively.

5.4 Quality of life: Only 9 trials (18, 21, 26, 33, 35, 36, 38, 40, 41) evaluated quality of life in structured diabetes education as a primary or secondary outcome in included studies. 3 studies (18, 36, 41) reported significant improvement in the intervention group compared to the control group at the end of intervention. All the include trials used validated questionnaires with specific scores for assessment of quality of life. One study (36) reported significant improvement only in bodily pain and vitality scales of quality of life at the end of 3 years follow up. One study (35) reported significant improvement in quality of life in intervention group at the end of 5 years follow up, and one study (18) reported a significant improvement in all domains of quality of life in intervention group compared to control group at the end of the study at the end of 6 months follow up in type 1 DM.

5.5 Diabetes patients' Knowledge: Six trials (27, 31, 35, 37, 40, 41) reported the results of knowledge assessments in structured diabetes education. All of them demonstrated that there is statistically significant improvement in intervention group compared to study group at the end of intervention.

5.6 Hypoglycaemic episodes reported in structured diabetes education: Four trials (18, 30, 37, 40) only evaluated the effect of structured diabetes education in frequency of hypoglycaemia. One study (37) demonstrated statistically significant decrease in hypoglycaemia episodes in intervention group compared to control group at the end of follow up. One study (30) used mean days per month in which hypoglycaemia was experienced at baseline 1, 3, 6, 12 and 24 months. There was no significant difference between study and control groups during the study period. One study(37) assessed symptomatic hypoglycaemia by patient self-report and medical records using number of episodes/person/year and reported statistically significant reduction in mean episodes of hypoglycaemia in

Table 3: Effect of structured diabetes education programmes from included studies on HbA1c in diabetic patients

Reference and Study duration	Mean ±SD Baseline HbA1c		P- Value	Mean ±SD follow up HbA1c		P- Value
	Intervention	Control		Intervention	Control	
Bosi et al 2013[26] /12-month	7.4	7.3	> 0.05	6.01	6.03	0.013
Mohamed et al,2013[27] / 12 months	8.67±1.2	8.5± 0.5	> 5	7.87±1.38	8.42±199	0.012
BEVERLY et al ., 2013[28] 12-month	9.2 ± 1.0	8.5 ± 0.5	> 0.05	8.48±1.4	7.85± 0.9	0.03
Adachi et al .2013[29] 6 months	7.6±1.4	7.3±1.1	> 0.05	6.7±1.2	7.0±7.0	0.004
Coates et al , 2013[30] 24 months	8.73±1.54	9.04±1.42	> 0.05	8.99	9.53	> 0.05
Khunti et al, 2012[22] 3 years	8.3±2.2	7.7±1.9	0.27	6.73	6.89	0.81
Tan et al.2012[31] 3 months	9.8	9.6	> 0.05	8.75 ± 1.75	9.67 ± 2.01	0.03
Sperl-Hillen, et al , 2011[32] 12-months	8.1	8.0	0.06	8.66	7.63	0.01
Weinger et al 2011[33] 12-months	9.12±1.1	8.8	> 0.05	8.45± 1.3	8.69± 1.3	0.04
McGowan et al, 2011[34]	6.8±1.2	7.1± 1.5	> 0.05	6.4± (0.6)	6.7± 1.0	0.02
Trento et al ., 2010[35] 5 years /ROMEO	7.75 ± 1.57	7.81 ± 1.43	> 0.05	7.30 ± 0.9	8.80±1.2	<0.001
Melkus et al , 2010[36]	8.02 + 2.09	8.28 + 2.25	> 0.05	8.0% + 2.41	7.2+ 2.15	0.0001
BRAUN et al 2009[37] 12.months	8.3±1.5	7.7±1.3	0.85	7.7±1.5	7.6±1.5	0.02
Davies, et al,2008[21] 12-months	8.3±2.2	7.9 ± 2.0	> 0.5	6.81	6.69	0.52
Sturt et al ., 2008[38] 6 months	8.92 ±1.44	8.69±1. 42	> 0.5	8.35± 1.41	8.37±1.40	> 0.5
Cooper et al, 2008[39] 12-months	8.5 ±2.3	7.8 ±2.2	> 0.5	8.5±2.3	8.5±2.3	> 0.5
Deakin et al,2006[40] 14 months	7.7 ±1.6	7.7±1.6	> 0.5	7.1 ± 1.1	7.8 ± 1.6	> 0.5
Trento et al,2004[41] 5 years	7.4 ± 1.4	7.4 ± 1.4	> 0.5	7.3 ± 1.0	9.0 ± 1.6	0.001
DAFNE Study Group, 2002[18] 6 months	9.4 ± 1.2	9.3 ± 1.1	> 0.5	8.4± 1.2	9.4 ± 1.3	<0.0001

intervention group compared to control group. One study (40) used a validated questionnaire to assess perceived frequency of hypoglycaemia (scored 0-6) baseline, (scored -3 to +3) 2 months post intervention; higher scores indicate greater perceived frequency of hypoglycaemia.

One study (18) assessed symptomatic and severe hypoglycaemia. Patients recorded severe hypoglycaemic episodes (episodes causing coma or requiring the assistance of another person) in diaries. They measured satisfaction with perceived frequency of hypoglycaemia by The diabetes treatment satisfaction questionnaire. There was no significant difference in severe hypoglycaemia in intervention group compared to control group after 6 months, with regard to perceived frequency of hypoglycaemia there was significant decrease in intervention group compared to control group at six months duration.

Discussion

Statement of principal findings: The present study looked at the impact of structured diabetes education in biomedical and psychosocial aspects in people with diabetes. Health care providers usually prescribe medication and life style modifications but only patients implement these important recommendations so this study tried to investigate the effectiveness and obstacles of current diabetes education programmes in improving diabetes self-care.

This study identified 19 trials (18, 21, 22, 26-41) that evaluated the effectiveness of SDEP. 12 studies (18, 21, 22, 26, 27, 30, 32, 33, 34, 36, 37, 40) had low risk of bias, 3 trials (28,29,38) had unclear risk of bias and 4 trials (31,35,39,41) had high risk of bias. Thirteen (18, 26, 27, 28, 29, 31,32, 33, 34, 35, 36, 37, 41) out of 19 trials (18, 21, 22, 26-41) demonstrated a significant HBA1c reduction in intervention group compared to control group at the end of the intervention while 3 trials did not demonstrate a significant change. A systematic review of 71 trials (42) showed reductions in A1C and systolic blood pressure in patients who received structured diabetes education. Four trials (18, 30, 37, 40) only evaluated the effect of structured diabetes education in frequency of hypoglycaemia; one study (37) demonstrated statistically significant decrease in hypoglycaemia episodes in intervention group compared to control group at the end of follow up.

Only 7 studies (22, 26, 27, 29, 36, 38, 40) evaluated BP in a follow period ranging from 6 months to 3 years without demonstrating any significant change. Seven trials (26, 27, 28, 29, 30, 22, 31, 32, 33, 34, 35, 36, 21, 40, 41, 18) out of 16 trials (26, 27, 28, 29, 30, 22, 31, 32, 33, 34, 35, 36, 21, 40, 41, 18) demonstrated statistically significant reductions in BMI or weight in intervention group compared to control group at the end of the studies. Ten trials (18, 21, 26, 27 29, 33, 35, 36, 38, 40) reported lipid profile as an outcome in included structured diabetes education; only 2 trials (27, 21) demonstrated significant reductions in cholesterol in intervention group compared to control group. Nine trials (18, 21, 26, 33, 35, 36, 38, 40, 41) evaluated quality of life in structured diabetes education as a primary or secondary outcome in included studies; 3 of them (18, 36, 41) reported significant improvement in the intervention group compared to the control group at the end of intervention. Six trials (27, 31, 35, 37, 40, 41) reported the results of knowledge assessments in structured diabetes education all of them demonstrated significant improvement in the intervention group.

Interventions with longer duration of education and more frequent reinforcement showed more significant and sustainable changes where the educational programme was delivered at the base line in groups then followed by contentious reinforcement education during routine care by their physicians using tailored diabetes education according to the patients' needs as reported in the trial (35). On the other hand SDEP that was not followed by reinforcement educational messages failed to demonstrate significant improvement in HbA1c as reported in 2 trials (21, 40).

Quality of study design: Although the SDEP were delivered by trained certified health care personnel in 16, (18, 21, 22, 28, 29, 30, 31, 32, 33, 34, 35, 63, 38, 39, 40, 41) out of 19 (18, 21, 22, 26-41) trials, (only 3 trials (26,27,37) did not mention educator qualifications) the exact training details were not mentioned in any of the included trials. As mentioned in patient education working group report 32 (7), the diabetes education program should have four criteria to be effective: structured written curriculum conducted by trained educators and be audited and quality assured. In this systematic review all the included studies have not mentioned any information regarding auditing and quality assurance of the educational programs. All trials mentioned a structured written diabetes education.

The quality of included studies was generally satisfactory; about one third of included trials were considered to have either high (31,35,39,41) or unclear risk (28,29,38) of bias because the data collectors or assessors were not blind, The good thing is the method of randomization and allocation concealment were mentioned in 16 trials (18, 21, 22, 26, 27, 28, 29, 30, 32, 33, 34, 36, 37, 38, 39, 40). Randomization produces similar groups in known and unknown variable and validity to statistical tests used in the trial because the deference between intervention and control groups should have the same difference between the two groups if selected from the general population. (43) Allocation concealment prevents over or underestimation of the intervention. It was estimated that the effect of intervention is 40% larger in trials without adequate allocation concealment. (44)

Most, (12 out of 19) of included trials (18, 27, 28, 29, 30, 31, 33, 34, 36, 37, 39, 41) had small sample sizes ranging from 89 to 314 patients which are likely to have been under powered; moreover very few studies mentioned power calculation and sample size justification to estimate the proper sample size.

The importance of sample size calculation in RCT has been addressed in many studies, and according to the Consolidated Standards of Reporting Trials (CONSORT) 45 statement these calculations must be reported and justified in published articles. Four factors affected sample size and should be considered in all trials: type I error (α), power, event rate in the control group, and a treatment effect of interest (46).

Attrition: Three included studies (26,35,40) had fairly high levels of drop-out between initial recruitment and reporting of results; the remaining 16 trials (18, 21, 22, 27, 28, 29, 30, 31, 32, 33, 34, 36, 37, 38, 39, 41) had not mentioned whether there were drop out or not. The 3 trials (26, 35, 40) that had mentioned drop out did not report that intention to treat analysis had been carried out. Misleading results can be produced by attrition if the motivated patients remained in the study while the other patients discontinued. (47)

Simplicity of educational message: It was observed that whenever the education message is simple, and followed by reinforcement, the education outcomes were significantly better as shown in most of included studies. On the other hand if the message was too long and not patient- centred, the outcomes were not significantly improved. This observation was clear in one included study (38), where the education programme manual included 320 papers i.e. too complicated programme. An RCT (48) showed that brief educational messages attached to laboratory test results represent a simple and sustainable way to bring about improvements in diabetes care.

Follow up and duration of intervention: Most of included trials (18,26,27,28,29,31,32,33,34,35,36,37,41) reported improvement in HbA1c level 6-12 months after the intervention then most of patient could not retain the same HbA1c control after a further 6-12 months of the intervention. These findings were consistent with another study which demonstrated that self-management education improves glycated haemoglobin levels at immediate follow up; the benefit declines 1-3 months after the intervention ceases, however, suggesting that learned behaviours' change over time. (49)

Group versus one to one intervention: One study 38 used one to one education, which did not demonstrate a significant change in outcome parameters especially HbA1c. These findings were consistent with a study 50 of a systematic review found that individual education did not appear to be significantly different compared to usual care.

Education Approach: All the included studies used the didactic method as a teaching approach which is consistent with a study (51) which included such intervention. Diabetes intervention education should shift from didactic teaching approaches towards more patient-centred or 'empowerment' approaches. Diabetes education should consider more emphasis on the impact of diabetes on the quality of life of the individuals and their families. Teaching coping Strategies and behaviour change strategies such as self-directed goal setting are now recognized as essential components of diabetes self-management to be consistent with the most recent recommendations of Diabetes Attitudes Wishes and Needs 2 study. (52)

Quality of life: Only 9 trials (18,21,26,33,35,36,38,40,41) evaluated quality of life in structured diabetes education as a primary or secondary outcome in the included studies. Three of these studies (18, 36, 41) reported significant improvement in the intervention group compared to the control group at the end of intervention. All the included trials used validated questionnaires with specific scores for assessment of quality of life. One study (36) reported significant improvement only in bodily pain and vitality scales of quality of life at the end of 3 years follow up. Another study (35) reported significant improvement in quality of life in intervention group at the end of 5 years follow up, and only one study (18) reported a significant improvement in all domains of quality of life in intervention group compared to control group at the end of the study at the end of 6 months follow up in type 1 DM.

The improvement of QOL in the included studies is in line with the results of a meta-analysis study (53) which showed that people with diabetes experience improvement in QOL from participation in diabetes self-management training programs. The lack of QOL improvement in 6 trials (21, 26, 33,35,38,40,) out of 9 could be due to short follow up period as observed in one study. (54) It showed that self-management education has little effects on the quality of life in a relatively short term follow up (less than 2 years) and it showed also that the improvement of quality of life occurs in long term interventions (more than 2 years).

Strengths: This systematic review collected the impact of structured diabetes education in a standard method of critical appraisal. The work was proceeded by a detailed protocol including all the study details which was approved by the supervisor.

Limitations: Synthesis of results was conducted by a narrative review not a meta- analysis. Included studies were limited to English language only.

Conclusion: Overall the results of this systematic review showed that structured diabetes education programmes have a significant positive impact on biomedical parameters especially HbA1c in most of the included studies. Quality of life improvement was reported only on long term interventions on diabetic patients. These findings support an ongoing model of education for the sustainability of outcomes; the optimum interval and contact time needs further assessment.

Recommendations: Based on the findings of this systematic review, it is clear that structured diabetes education has a short and long term positive effect especially on HbA1c and quality of life. It is recommended that all people with diabetes should be engaged in a structured diabetes education programme which is consistent with NICE55, ADA56, IDF57 and many other organizations' recommendation.

Long term research to evaluate the effectiveness of structured diabetes education on the diabetes complications and mortality rate is recommended because of the natural progressing history of diabetes and the educational message may decline over time and may need reinforcement.

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