





BMJ Open Effect of educational interventions on knowledge of the disease and glycaemic control in patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomised controlled trials

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ABSTRACT

Background Globally, type 2 diabetes has continued to increase, now accounting for over 90% of all diabetes cases. Though the magnitude of uncontrolled glycaemic levels in patients with type 2 diabetes is steadily rising, evidence showed that effectively controlled glycaemic levels can prevent complications and improve the quality of life of these patients. As little is known about the effect of educational interventions on this population, this systematic review and meta-analysis evaluated the effectiveness of educational interventions versus standard care on glycaemic control and disease knowledge among patients with type 2 diabetes.

Methods PubMed, Google Scholar, Cochrane Library, Scopus, African Journals Online and Wiley Online Library were searched. Two authors independently assessed within-trial risk of bias in each included study using revised Cochrane risk-of-bias tool for randomised trials. A random-effects model was employed to estimate combined effect sizes. Subgroup analyses were employed to investigate possible sources of heterogeneity between studies. The overall certainty of the evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation approach.

Results A total of 19 trials with 2708 study participants were included in the review. Primary outcomes (glycaemic control) were reported in 18 trials. The pooled estimated impact of educational intervention on glycaemic levels using the random-effects model was -0.83 (95% CI: -1.17 to -0.49 , $p < 0.001$). Subgroup analyses revealed greater A1c reductions in those studies with intervention duration of up to 3 months and with empirical intervention designs. Educational interventions led to significant increases in participants' knowledge of type 2 diabetes (standardised mean difference: 1.16; 95% CI: 0.71 to 1.60; $I^2=93%$).

Conclusion In the current review overall, educational interventions can potentially lead to improved glycaemic control levels in patients with type 2 diabetes despite heterogeneity across the studies. Besides, the findings showed that educational interventions could increase disease knowledge among patients with type 2 diabetes.

Strengths and limitations of this study

- This systematic review will provide a comprehensive search of the literature, the effect of educational intervention on glycaemic control and knowledge of type 2 diabetes.
- An extensive search of multiple databases and search engines (ie, PubMed, African Journals Online, Web of Science, Scopus and Google Scholar) was performed to ensure a comprehensive review; nevertheless, potentially relevant articles from other/additional databases may be missed.
- We only used English-language articles, although our target was global, which could be in several other languages such as Spanish, French or Portuguese.

PROSPERO registration number CRD42020205838.

BACKGROUND

Diabetes mellitus (DM) is increasingly becoming an extensive non-communicable health problem, leading to significant morbidity and mortality.¹ Globally, a recent estimate showed that approximately 422 million adults are living with DM.² According to the International Diabetes Federation projection, approximately 629 million people will be affected by 2045.³ Of these, approximately 80% of affected individuals live in low-income countries.⁴ In particular, type 2 DM (T2DM) is responsible for more than 90% of all diabetes cases.⁵ The increasing burden is due to several risk factors such as sedentary behaviours, obesity, unhealthy diet, lack of exercise, family history and age.^{6–8}

Maintaining optimal glycaemic levels is vital to diabetes control.⁹ However, evidence showed that poor glycaemic control

(glycosylated haemoglobin (HbA1c) $\geq 7\%$) contributes to kidney failure, myocardial infarction, stroke, retinopathy, hypertension, increasing costs for patient care and reduced quality of life.^{10–14} The aims of T2DM management are to attain glycaemic targets, minimise adverse events and prevent complications.^{15–16} Therefore, lifestyle modifications, such as diet and exercise, have been reported to reduce the complications of uncontrolled glycaemic levels in patients with T2DM.¹⁷

Evidence has revealed that self-management education can reduce the glycaemic level by 30%–80%.¹⁸ Besides, diabetes education can improve glycaemic control, change people's behaviours, promote self-care, and reduce complications and progression of the disease.^{19–21} Moreover, numerous studies suggest that diabetes educational interventions can increase knowledge of diabetes^{22–23} and medication compliance,²⁴ decrease readmissions,^{25–26} reduce length of stay and mortality rate,²⁵ and improve glycaemic control.^{27–28} In addition, the American Diabetes Association (ADA) position statement provides the evidence and strategies for the provision of education and support services to all adults living with T2DM.²⁹ Moreover, the consensus report showed that there are four critical times to provide diabetes self-management education and support: (1) at diagnosis, (2) annually and/or when not meeting treatment targets, (3) when complicating factors develop, and (4) when transitions in life and care occur.³⁰

Though knowledge about diabetes has paramount benefit to patients' self-care management, insufficient diabetes knowledge is unfavourable to the patients' health due to most of the complications that arise can be prevented through self-care practice.^{31–32} However, numerous studies have shown that improving patient knowledge about T2DM and its complications has substantial benefits to maintain optimal glycaemic levels, enhance treatment adherence, reduce treatment cost and decrease the progression of disease.^{33–35} Previously, several reviews on the effect of self-management interventions for patients with T2DM exist.^{36–38} However, most reviews included inadequate number of articles, did not address the effects of education on knowledge of diabetes and included interventions which were poorly described. Thus, research is required to estimate the effects of educational interventions on sufficient methodological quality and substantive statistical analysis. Hence, the present review and meta-analysis aimed to evaluate the effect of educational interventions on glycaemic control and disease knowledge in patients with T2DM.

Review questions

- ▶ Does a structured educational intervention increase diabetes knowledge in patients with T2DM?
- ▶ Does a structured diabetes educational intervention reduce HbA1c levels among patients with T2DM?

METHODS

Protocol and registration

Initially, PROSPERO was searched to confirm for other reviews on the effect of educational interventions on glycaemic control and disease knowledge among patients with T2DM. But no such reviews were identified. Thus, the protocol was registered on PROSPERO (www.crd.york.ac.uk/PROSPERO/) as recommended by the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.³⁹

Search strategy and data sources

We did a comprehensive systematic search to collect all relevant articles using the Peer Review of Electronic Search Strategies for systematic reviews.⁴⁰ The search was limited to studies published in peer-reviewed journals from January 2000 to August 2021 (as authors were interested in up-to-date data). The PRISMA guidelines were used to conduct and report the present review.³⁹ The literature was searched in PubMed, Scopus, Google Scholar, African Journals Online, Cochrane Library and Wiley Online Library. The keywords used for the review included “educational”, “behavioral”, “knowledge”, “glycemic control”, “glycosylated hemoglobin”, “HbA1c”, “Type 2 diabetes mellitus”, “Type 2 diabetes” and “T2DM”. Boolean operators like ‘AND’ and ‘OR’ were used to combine search terms. The Medical Subject Headings (MeSH) terms employed in the PubMed search engine in various combinations are shown in [table 1](#). To access all articles on this topic, we manually review all references to reduce publication bias. Searches were performed on 20 August 2020. The search was restricted to full texts, human studies and English-language publications. In the present review, the Patient/Population (P); Intervention (I); Comparison (C) and Outcomes (O) question was as follows: is educational intervention (I) in people with T2DM (P), when compared with people who had not taken part in the educational intervention or had standard care (C), associated with improved glycaemic control and disease knowledge (O)?

Eligibility criteria

Types of participants

This review takes into consideration studies that included adult patients (≥ 18 years old) with T2DM in outpatient health settings, primary care settings, diabetes clinics and hospitals within the catchment. Those articles focusing on or including children or those with T1DM were excluded from the review.

Types of interventions

The review considered any educational intervention provided to adult patients with T2DM in diabetes care settings receiving standard or routine care. Intervention could be provided by any healthcare provider, involved any medium (written, oral, video and computer), delivered at the individual or group level, focused on theory-based or empirical content, and of varying duration.

Table 1 PubMed search history

Search	Search terms	Hits
#1	Type 2 diabetes[tw] OR Type 2 diabetes mellitus[tw] OR T2DM[tw] OR insulin non dependent diabetes [tw]	199276
#2	Education [tw] OR intervention [tw] OR behavioral intervention[tw] OR self-management [tw]	1587693
#3	Glycemic control [tw] OR glycosylated hemoglobin[tw] OR HbA1c[tw]	65114
#4	Knowledge [tw] OR behavioral outcomes [tw]	851164
#5	#1 AND #2 AND #3 AND #4	5428
#6	#5; limits: studies done with humans, English language, full text, RCT and publication year (2000–2020)	496

RCT, randomised controlled trial.

Studies lacking an education intervention, unclear information respecting the intervention and insufficient data on the main outcome variable were considered criteria for exclusion.

The comparator in this study was the delivery of the usual care/routine care for T2DM. Routine care refers to diabetes care that healthcare staff usually and normally provides in their daily care. Articles were excluded if they did not implement a comparison with routine care.

Types of studies

In the present review, studies were included if they were randomised controlled trials. Full-text articles were included, whereas studies published with only abstract or unpublished data were excluded. Of note, non-randomised controlled trials, quasi-experimental, before and after, cohort, case-control and cross-sectional studies were excluded because uncontrolled trials and observational studies lead to greater risk of biased estimates of effect size.⁴¹

Type of outcome

This review included the following outcome measures: glycaemic control as the primary outcome of the meta-analysis, and knowledge of diabetes considered as the secondary outcome. A study was excluded if outcomes were not measured or data could not be extracted.

Study selection

After database exploration, all recognised studies were uploaded into EndNote V.8, and duplicate articles were removed. Predefined selection criteria were used to select relevant full-text articles during the screening process. Three authors (WSS, PMP and YAA) independently screened the title, abstract and keywords of the studies identified for possible eligibility in the review. Afterward, all full-text articles were evaluated carefully for inclusion and data extraction. Further screening of full text was done by two (TY and YAA) independent authors to select the studies which satisfied the eligibility standards. The possible justification for the exclusion of full-text studies was documented and reported in the systematic review. Any uncertainties about study eligibility were discussed between authors.

Data extraction

After identifying studies for eligibility, data abstraction was conducted by two (AMK and WSS) independent authors using Microsoft Excel (version 10) for Windows. The first author undertook the data abstraction, whereas the second author assumed control for the quality of extracted and entered data. The data extracted from each study included first/corresponding author, year of publication, study setting, education provider, duration of intervention, intensity of intervention, components of the intervention, number of participants in each arm (intervention and standard care group), intervention design, outcome measures, before and after intervention HbA1c levels, and knowledge scores. The outcome measures in this review were reported as the variation from starting point to closing date of follow-up in the intervention and standard care groups. If the SD of mean difference (MD) was not reported in an included study, the values were recalculated according to the guideline in the Cochrane Handbook.⁴²

Assessment of risk of bias in included studies

Two (MD and PMP) independent authors assessed within-trial risk of bias in each included study using revised Cochrane risk-of-bias tool for randomised trials (RoB 2).⁴³ The Cochrane's RoB 2 tool evaluation domains used to evaluate validity and bias in studies of clinical trials were applied regarding randomisation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other biases. For this review, the overall risk of bias was rated as high/low/some concerns, in agreement with the RoB 2 tool. Any disagreement was resolved through discussion and consensus.

Assessment of certainty of the evidence

To evaluate the quality of the evidence, the authors used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.⁴⁴ GRADE pro-GDT was employed to summarise the quality of evidence.⁴⁵ The certainty of the evidence encompasses consideration of the within-study risk of bias which comprises methodological worth, indirectness of evidence, unexplained

heterogeneity, imprecision and probability of publication bias. The GRADE approach has four levels of quality such as high-quality evidence that recommends that additional study is very unlikely to change our confidence in the estimate of effect size; moderate quality reflects further research as likely to have a vital impact on the estimate of effect size and may alter the estimate; low quality reveals that further research is very unlikely to have a significant influence on the current estimate of effect size and is likely to change the estimate; and very low quality suggests one is precise indeterminate about the estimate.

Data synthesis and analysis

The primary and secondary outcomes were reported as MD and standardised MD (SMD) with a 95% CI, using a random-effects model,⁴⁶ respectively. Degree of heterogeneity was examined with the I^2 statistic, which expresses the amount of heterogeneity between studies.⁴⁷ To interpret the effect sizes, authors followed Cohen's guidelines where $d \leq 0.2$ was small, $d = 0.5$ was medium and $d > 0.8$ were large variation among intervention and control groups.⁴⁸ We performed subgroup analyses to reduce the level of heterogeneity for the primary outcomes using duration of intervention and intervention design. Publication bias was visually evaluated using the funnel plot, supplemented by Egger's regression test.^{49 50} Sensitivity analysis was performed due to the high degree of heterogeneity and risk of bias. Review Manager of the Cochrane Collaboration (RevMan V.5.4, Cochrane Organization) was used to perform the meta-analysis.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Selection of studies

The search of the six databases yielded 1183 articles, and 4 articles were retrieved manually through a review of reference lists. After eliminating duplicates, 457 articles remained. Three hundred seventy-two studies were removed after reading the abstract and title, leaving 85 articles for full screening. Following 66 exclusions at the full-text level (mainly due to non-randomised controlled trials ($n=34$), or reporting mixed population (type 1 and type 2 diabetes) ($N=7$)), 19 studies were incorporated in the final review. The flow diagram for study selection is shown in figure 1.

Characteristics of the included studies

In the current meta-analysis, a total of 19 articles met the inclusion criteria with 2708 study participants. Of these, nine included articles reported glycaemic control and knowledge of diabetes as a common outcome variable. Regarding location, two were from Brazil,^{51 52} three from China,^{53–55} two from Germany,^{56 57} five from Iran,^{58–62} two

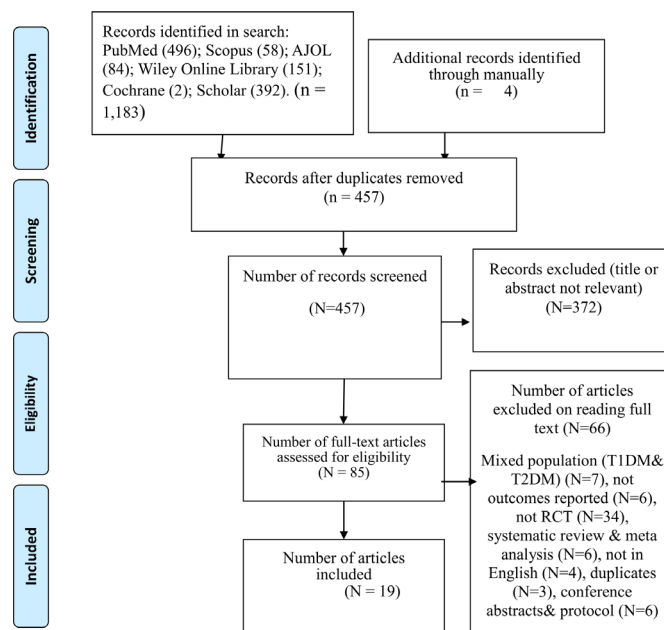


Figure 1 PRISMA flow chart for selection of studies. PRISMA, Preferred Reporting Items for Systematic Review and Meta-Analysis; RCT, randomised controlled trial; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

from Malaysia,^{63 64} two from Sweden,^{65 66} and one each from Thailand,⁶⁷ Sri Lanka,⁶⁸ and Australia.⁶⁹ The sample size varied from 60⁵³ to 300 participants.⁵⁵ Educational interventions in the review were guided by the following theories or models: three studies used the theory of self-efficacy,^{54 63 67} three studies^{56 61 66} used empowerment theory, two studies^{60 68} used theory of self-efficacy and motivational interviewing, and one study used either chronic care model,⁵⁵ PRECEDE-PROCEED model,⁶² BASNEF model⁵⁹ or behavioural theory.⁶⁴ However, the remainder of the articles^{51–53 57 58 65 69} used non-theory or model-based approaches.

The educational interventions comprised of face-to-face counselling,^{54 55 63 68 69} diabetes education sessions,^{51 52 55 60 63 67} group discussion,^{56 58–60 67} telephone follow-ups,^{54 60 63 67 69} home visits,⁶⁷ demonstrations,^{53 54 59} as well as questions and responses^{58 59} as among the most common approaches. The control groups of all studies were the current standard of care. The duration of educational interventions varied from 4 weeks^{54 58 59} to 12 months.^{52 66} Intervention groups obtained the information by different healthcare professionals such as physicians,^{54 55 66} nurses,^{52 56 58 67 69} nutritionists,^{61 64} health managers,⁵⁵ public health assistants⁵⁵ and pharmacists.⁵¹ In most included studies, intervention processes were group-based education^{52 54–63 65–67} and combined education^{53 68 69}; however, in the remainder, web-based⁶⁴ and individual-based⁵¹ education approaches were used. The main results and features of the selected studies are presented in table 2.

Risk of bias in the included studies

The random sequence generation for allocation was evaluated as low risk of bias in 12 studies,^{52–54 56 57 60 61 63 64 66–68}

Table 2 Characteristics of the included studies

Authors	Country	Number of subjects (baseline)	Health education provider	Theory/model used	Group/individual	Intervention	Components of intervention	Duration of intervention	Outcome measures	Outcome indicators
Wichit <i>et al</i> ⁶⁷	Thailand	I=70 C=70	Trained nurse	Self-efficacy	Group	Education classes (3 sessions), discussions, a home visit and a telephone follow-up	Programme focused on: meal planning, foot hygiene, physical activities, problem-solving, diabetes-related complications, enhancing competence and diabetes knowledge	9 weeks	At baseline, week 5 and week 13	①②③④⑤⑥
Fan <i>et al</i> ⁶⁹	Australia	I=138 C=138	Trained nurse	Empirical	Mixed	Face-to-face counselling over 1 hour, self-care plan, a 10 min telephone call before the appointment, a 3-month forum for about 2 hours	Education emphasises on diet modification, exercise, SMBG, psychological and adherence to medication	6 months	At each follow-up and the end of 6 months	①
Grillo <i>et al</i> ⁵²	Brazil	I=68 C=68	Trained generalist nurse	Empirical	Group	Structured diabetes self-management education; the course consisted of weekly 2-hour meetings for 5 weeks, reinforcement meetings every 4 months (7 sessions)	The course content included: (1) identification of modifiable risk factors for T2DM, (2) non-pharmacological treatment, emphasising diet and exercise, (3) pharmacological therapy, (4) an overview of chronic diabetes complications and (5) foot care	12 months	At baseline, 4, 8 and 12 months	①④
Cani <i>et al</i> ⁶¹	Brazil	I=37 C=41	Pharmacist	Empirical	Individual	Diabetes education (5 sessions), pharmacotherapeutic care plan and written guidance	Education on acute and chronic complications, the importance of lifestyle changes, foot care, the importance of home blood glucose monitoring and other topics, advice focused on the indication, proper dosage, side effects and adequate storage of medication	6 months	At baseline and 6 months	①③④⑥
Zheng <i>et al</i> ⁶³	China	I=30 C=30	Therapist guidance	Empirical	Mixed	Two-session diabetes self-management education which is theory and practical course, lecture, video, exercise, food simulation model and vivid models	Theory course focuses on knowledge of diabetes and self-management strategies, such as diet guidance, exercise guidance, and knowledge of hypoglycaemia treatment, foot care, medication, and blood glucose monitoring; the practice course focuses on one-on-one nutrition guidance and individualised exercise guidance	3 months	At baseline and 3 months	①③⑤
Jiang <i>et al</i> ⁶⁴	China	I=133 C=132	Trained nurses and physicians	Self-efficacy	Group	Structured education programme, patients' experience sharing, peer modelling, demonstration; the intervention was given 4 weekly sessions for 1 month and then face-to-face/telephone meetings every 3 months	Diabetes-related knowledge and diabetes self-management skills based on self-efficacy theory	4 weeks	At baseline, 3 and 6 months	①②③④⑤
Kong <i>et al</i> ⁶⁵	China	I=150 C=150	Physician, health manager and public health assistant	Chronic care model (CCM)	Group	Pamphlets and face-to-face communication, continuous medical education; education was 9 sessions every month	Received the five components CCM-based intervention, awareness of the chronic disease management, self-management support included goals setting, planning, doing, checking and assessing	9 months	At baseline and 9 months	①③⑥
Braun <i>et al</i> ⁶⁷	Germany	I=83 C=72	Not stated	Empirical	Group	Diabetes teaching and treatment programme, 7 educational classes of 45 min duration	Self-monitoring, diabetes treatment	6 months	Before (t0), immediately after (t1) and 6 months after (t2)	①④⑤

Continued

Table 2 Continued

Authors	Country	Number of subjects (baseline)	Health education provider	Theory/model used	Group/individual	Intervention	Components of intervention	Duration of intervention	Outcome measures	Outcome indicators
Hermanns <i>et al</i> ⁵⁸	Germany	I=92 C=92	Certified diabetes nurse	Empowerment self-management approach	Group	Lecture, discussion and a nutrition game; the education is given for 10 lessons of 90 min each, 5-week period, 2 sessions per week	Lifestyle modification, blood glucose self-monitoring, metabolic risk factors, individual goals of diabetes treatment, nutrition game, physical exercise and complications	5 weeks	At baseline and 6 months after the intervention	①②③④⑤⑥
Didarloo <i>et al</i> ⁵⁹	Iran	I=45 C=45	Trained nurse	Empirical	Group	Interactive approach such as discussion, brainstorming, question-and-response techniques for 60min/week for 4weeks; used specific training such as verbal persuasion and modelling	Promoting self-efficacy of diabetics; the educator used specific training approaches such as verbal persuasion, modelling and performance accomplishments Definition, signs, symptoms, and consequences of T2DM and diet	4 weeks	At baseline and 3 months after the end of the intervention	①②③④⑤
Askari <i>et al</i> ⁶⁰	Iran	I=54 C=54	Researcher	BASNEF model	Group	Training in 8 sessions (2 sessions in a week), each session lasted for 70min; question and answer, exercise, discussion, image and messages were sent to the patients each week	Presented content was about diabetes; signs and symptoms, diet, food composition tables, partitioning, proper use of fruits, vegetables, and grains as sources of dietary fibre	4 weeks	At baseline and 3 months after the end of the intervention	①②③④⑤
Ebrahimi <i>et al</i> ⁶¹	Iran	I=53 C=53	Nurse with the endocrinologist and nutritionist	Empowerment model	Group	Education training, 5-7 weekly regular meetings were held for about 60-90min	The content of education was diet, exercise, medication and foot care The structural model was perceived threat, self-efficacy and evaluation	8 weeks	Baseline and 3 months after the end of the intervention	①
Nejhaddadgar <i>et al</i> ⁶²	Iran	I=43 C=43	Trained professional	PRECEDE-PROCEED model	Group	The education programme with 8 weekly sessions; training workshops were also conducted among patients' families and health workers	Education based on the variables of the PRECEDE model such as predisposing factors are genetic and environmental factors such as knowledge, attitudes and self-efficacy	8 weeks	Baseline and 6 months after the education programme	③④⑤
Azami <i>et al</i> ⁶⁰	Iran	I=71 C=71	Trained nurse	Self-efficacy and motivational interviewing	Group	Usual care plus a 12-week nurse-led diabetes self-management education, booklet, watching movie clips, group-based educational session, telephone follow-up calls	Self-care behaviours, including healthy eating, being active, monitoring, taking medication, problem-solving, reducing risk and healthy coping are the core components of the intervention	12 weeks	At baseline, and 12 weeks and 24 weeks post-randomisation	①②③⑥
Tan <i>et al</i> ⁶³	Malaysia	I=82 C=82	Not stated	Self-efficacy	Group	Structured education consisted of monthly sessions for 3 months about 30min each session, 2 were face-to-face individual education sessions and 1 was a telephone follow-up; printed educational materials	The first session, healthy eating, being active, medication adherence and self-monitoring of blood glucose; the second and third sessions on problem-solving skills related to hyperglycaemia, sick day and emotional episodes	3 months	At baseline and 12 weeks	①②④
Ramadas <i>et al</i> ⁶⁴	Malaysia	I=66 C=62	Nutritionist	Behavioural theory	Web-based	Web-based dietary intervention, 12 lesson plans were made available to the patients one after another for 6 months with updates every fortnight	The dietary lesson plans in the intervention package were personalised according to the patients' dietary stages of change and were expected to improve their diabetes, knowledge, attitude and behaviour; the participants also send their queries to the study nutritionist via the website	6 months	At baseline, 6 months post-intervention and 12-month follow-up	①②③④
Adolfsson <i>et al</i> ⁶⁵	Sweden	I=50 C=51	Nurse and physician	Empowerment	Group	Empowerment group education, counselling using videotaping, presentation and discussion, 1 follow-up session was given within 7 months	About the disease, treatment, prevention of complications, blood glucose monitoring, diet, physical activity and daily foot care	12 months	At baseline and at 1-year follow-up	①②④⑥

Continued

Table 2 Continued

Authors	Country	Number of subjects (baseline)	Health education provider	Theory/model used	Group/individual	Intervention	Components of intervention	Duration of intervention	Outcome measures	Outcome indicators
Hörnsten <i>et al</i> ⁶⁵	Sweden	I=44 C=60	Nurse with special education in diabetes care	Empirical	Group	Education and group discussion with 10 2-hour group sessions over 9 months	Patients' understanding of the illness	9 months	Before and each year after the intervention	①
Jayasuriya <i>et al</i> ⁶⁸	Sri Lanka	I=43 C=42	Medical officer and trained nurse	Self-efficacy and motivational interviewing	Mixed	Self-management education through face-to-face meeting and lecturing The first four sessions within 6 weeks, following monthly (4 weekly) for 5 more visits	Physical activity and healthy dietary intake and more recently in 'avoidance behaviours' to reduce unhealthy eating	6 months	At baseline and at 6 months	①,②,⑤

Outcome indicators: ① metabolic controls, ② self-efficacy, ③ behaviour, ④ knowledge, ⑤ other psychological indicators and ⑥ quality of life.
C, control; I, intervention; SMBG, Self-Monitoring of Blood Glucose; T2DM, type 2 diabetes.

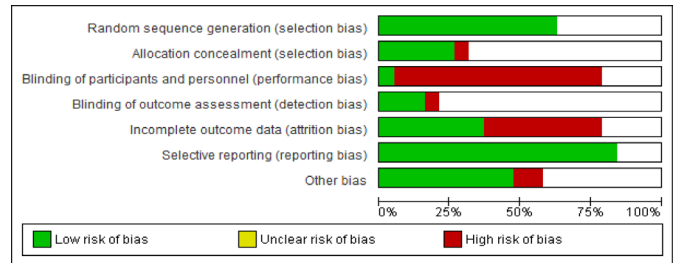


Figure 2 Risk of bias graph: review of authors' judgements about each risk of bias item presented as percentages across all included studies.

with 7 studies measured as having some concerns of bias.^{51 55 58 59 62 65 69} Allocation concealment was a low risk of bias in five studies.^{53 54 58 60 67} On the other hand, a high risk of allocation bias was reported in one study.⁵⁹ The remaining studies^{51 52 55-57 61-66 68 69} were evaluated to have some concerns of bias. Blinding of participants and educators was considered a problem in such interventions; however, one study blinded participants and educators.⁶⁰ Outcome assessors were blinded in three studies.^{52 61 67} Regarding incomplete outcome data reporting, seven studies^{51 52 54 58 60 67 69} were evaluated as low risk of bias. The risk of bias due to selective reporting was confirmed low for 16 studies^{51 53-63 65 67-69}; however, there were some concerns of bias in three studies.^{52 64 66} Nine studies^{52-54 56 60 64 66 67 69} were evaluated as low risk of other potential biases, two studies^{58 65} were confirmed to be high risk of bias and eight studies^{51 55 57 60-63 68} were evaluated to have some concerns of bias. The risk of bias for studies overall is summarised in [figure 2](#) and the risk of bias in each study is reported in [figure 3](#).

Effect of educational intervention on glycaemic control

The effects of educational interventions on glycaemic (HbA1c) level reduction are presented in [figure 4](#). The results of the meta-analysis using random-effects model revealed that educational interventions significantly decreased HbA1c levels (MD: -0.83%; 95% CI: -1.17% to -0.49%; p<0.001, I²=88%) compared with standard care groups. A sensitivity analysis was employed by omitting three studies^{53 56 58} because of high risk of heterogeneity. When these studies were omitted, the results demonstrated that the pooled effect on HbA1c reduction remained statistically significant with an MD of -0.70% (95% CI: -0.96% to -0.44%, p=0.001). The I² statistic among the studies was 73%, indicating a moderate risk of heterogeneity.

Subgroup analysis

In the present review, subgroup analysis was conducted based on the duration of intervention and intervention design (theory-based vs empirical approach) to explore the potential source of heterogeneity between trials. The results of the subgroup analysis showed that the greater effect size was reported in studies with intervention duration of ≤3 months (MD: -1.09, 95% CI: -1.60 to -0.57, p<0.00) with a significant evidence of heterogeneity

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Adolfsson ET W-EM , 2017	+		+		+		+
Askari A, 2018		+	+			+	
Azami G SK et al, 2018	+	+	+		+	+	+
Braun AK et al, 2009	+		+		+	+	
Cani CG et al, 2015			+		+	+	
Didarloo A , 2016		+	+		+	+	+
Ebrahimi H, 2016	+		+	+	+	+	
Grillo MdFF et al, 2016	+		+	+	+	+	+
Hermanns N , 2012	+				+	+	+
Hörnsten Å SH , 2008			+			+	+
Jayasuriya R PM et al, 2015	+		+		+	+	
Jiang XJ et al, 2019	+	+			+	+	+
Kong J-X et al, 2019					+	+	
Min-Hua Fan et al, 2016			+		+	+	+
Nejhaddadgar N, 2019						+	
Ramadas A CC, 2018	+		+	+	+		+
Tan MY MJ et al, 2011	+		+		+	+	
Wichit N et al, 2017	+	+	+	+	+	+	+
Zheng F , 2019	+	+	+			+	+

Figure 3 Risk of bias summary: review of authors' judgements about each risk of bias item for each included study.

among studies ($I^2=88\%$) (figure 5). Additionally, the results of the subgroup analysis revealed that interventions with an empirical approach had greater effects in

terms of reducing glycaemic levels (MD: -1.03 , 95% CI: -1.90 to -0.15 , $p<0.00$). Because of a significant degree of heterogeneity between studies ($I^2=88\%$), a random-effects analysis was used (figure 6).

The effect of educational interventions on diabetes knowledge

Ten out of the 19 studies reported knowledge of diabetes as an outcome variable.^{51 52 54 56–59 62 64 67} The pooled effect size of the 10 trials demonstrated an improvement in knowledge of T2DM (SMD: 1.16, 95% CI: 0.7 to 1.60, $p<0.001$; figure 7) compared with standard care groups. A random-effects model was used because of significant heterogeneity. The Dietary Knowledge Questionnaire⁶⁴ and the Diabetes and Medication Knowledge Questionnaire^{52 54 57 58 67} were used to estimate the level of knowledge in individuals with T2DM. The number of items was between 8⁶² and 24 items.⁶⁷ There was a significant variation in knowledge of T2DM scores across different studies.

Publication bias

The presence of publication bias was visually evaluated using a funnel plot for the primary outcome (glycaemic control), and the results also reported there was no publication bias (figure 8). Likewise, Egger's test also showed no publication bias ($p=0.732$). On the other hand, there were insufficient data to generate funnel plots to assess for the potential presence of publication bias for the second outcome (knowledge about T2DM).

Overall quality of the evidence

The overall quality of evidence was assessed using the GRADE approach and the results are presented in the summary of findings for the main comparison. Findings showed that the overall certainty of the evidence for glycaemic control was moderate, which suggests further studies will increase our confidence in the estimate of effect size. The quality of evidence for diabetes knowledge was low, which reflects that the effect size is limited

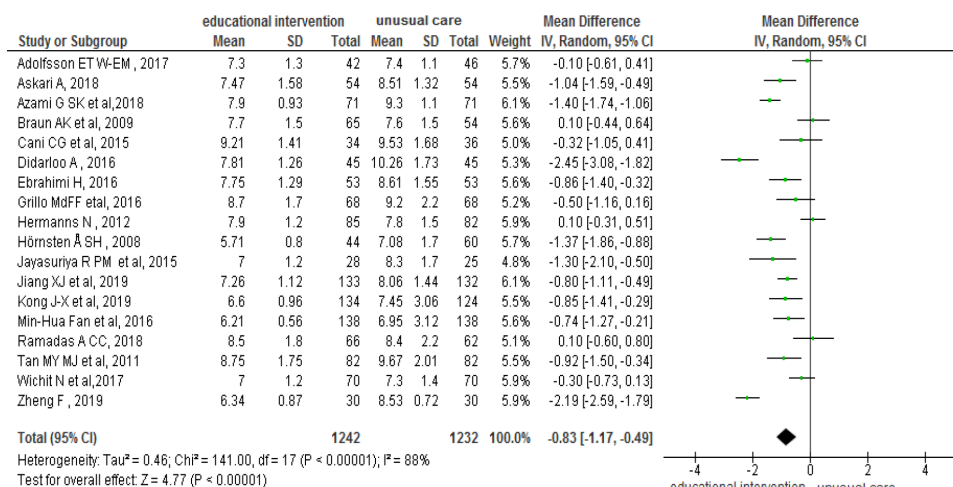


Figure 4 The pooled effect of education interventions on HbA1c levels in patients with T2DM. HbA1c, glycosylated haemoglobin; T2DM, type 2 diabetes mellitus.

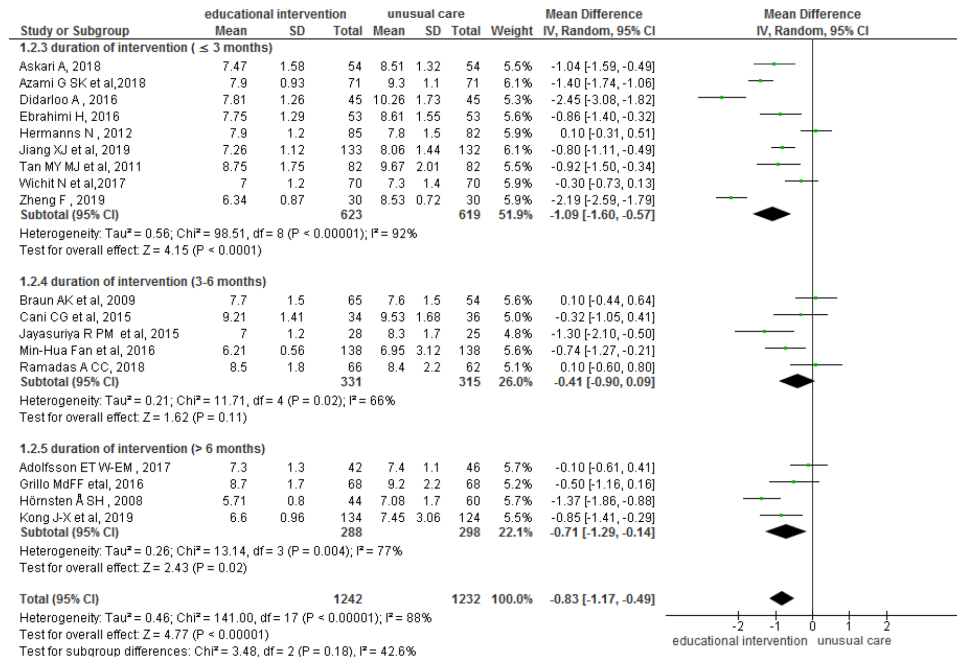


Figure 5 Subgroup analysis based on the duration of the intervention.

and the true effect may be substantially different from the estimate of the effect size (table 3).

DISCUSSION

Currently, diabetes has emerged as a public health problem that needs effective educational interventions which apply across age, ethnicities and socioeconomic levels. Evidence showed that appropriate self-management education is a vital component of clinical care to improve glycaemic levels and change behavioural outcomes.⁷⁰ In the current meta-analysis, to generate high-quality evidence, only clinical trial studies were included.

This review summarises 19 RCT studies of educational interventions involving 2708 study participants with T2DM that took place in different global regions and health systems. In the present meta-analysis, findings

demonstrated that educational intervention has a promising effect on glycaemic control and diabetes knowledge. The finding revealed that educational interventions reduced HbA1c levels by 0.83% (95% CI: 1.17 % to 0.49%) among patients with T2DM. This finding has a substantial degree of heterogeneity (I²=88%) indicating variation between included studies. However, there was a slight reduction of MD after sensitivity analysis, 0.70% (95% CI: 0.96 % to 0.44%), with a moderate degree of heterogeneity (I²=73%). Our findings are supported by previous meta-analyses, which reported that behavioural and self-management education have a significant benefit in the reduction of HbA1c levels in patients with diabetes.^{28 37 38}

The improvement in glycaemic levels is considered to be clinically essential. The UK Diabetes Study revealed

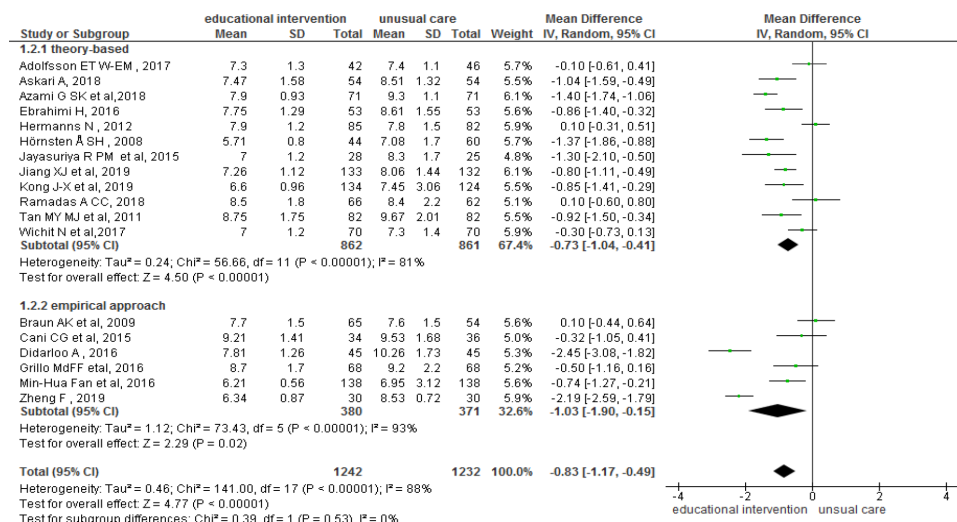


Figure 6 Subgroup analysis based on intervention design.

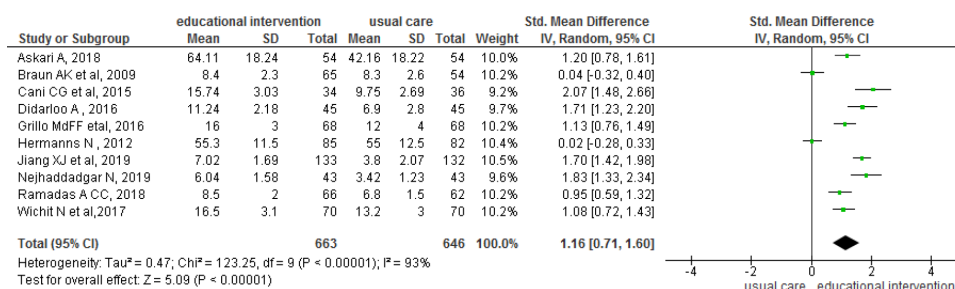


Figure 7 The pooled effect of education interventions on disease knowledge in patients with type 2 diabetes.

that with each 1% reduction in HbA1c, there is a likelihood of reducing the risk of diabetes complications by 21%.⁷¹ Similarly, a previous study showed that achieving optimal glycaemic level is likely to reduce the risk of deaths from diabetes complications, such as cardiovascular and cerebrovascular problems.⁷² Moreover, the ADA recognises that diabetes self-management has a vital role in improving glycaemic levels and reducing diabetes-related complications.⁷³

In the current meta-analysis, a subgroup analysis was conducted based on the duration of the educational interventions. Concerning duration of interventions, there was a variation between <3 months, 3–6 months and >6 months in the reduction of HbA1c levels. In this meta-analysis, the pooled effect size for short educational interventions (duration ≤3 months) was better than the effect size of longer interventions (duration 3–6 months and >6 months), -1.09 (95% CI: -1.60 to -0.57 , $p < 0.001$). One possible explanation may be associated with the initial motivation of the participant to be empowered to obtain positive results in a short period.⁷⁴ In contrast, previous studies reported that longer duration of interventions was more likely related to a significant reduction in HbA1c levels.^{28 75 76} Similarly, a meta-analysis study showed that more contact hours were associated with a reduction of HbA1c level.³³ Moreover, evidence also supported that the duration of contact hours between trainer and patient has a substantial impact on HbA1c levels.¹⁸ The current findings reflect that the duration of intervention would influence the effectiveness of the educational

intervention among patients with T2DM. Therefore, this disparity should be considered when developing future educational interventions.

In the present review, a subgroup analysis was conducted based on intervention design (theory-based vs empirical educational). Our study indicated that educational interventions benefited all patients regardless of the intervention design. In the current findings, empirical educational intervention showed improvement in glycaemic control level, -1.03 (95% CI: -1.90 to -0.15 , $p < 0.001$). Similarly, evidence showed that interactive self-management interventions through evidence-based approaches and structured curricula are crucial to improve glycaemic control and behavioural outcomes.⁷⁷ However, another review indicates that in patients with T2DM, theory-based self-management educational interventions improved HbA1c.³⁶ Although one-third of the included studies used an empirical approach in designing interventions, and favourable results on glycaemic control were obtained, their specific role in educational interventions has been debated.

In this review, diabetes knowledge showed a significantly higher standardised mean score of correct knowledge of diabetes among the intervention group as compared with the standard care group (SMD=1.16; 95% CI: 0.71 to 1.60, $p < 0.001$). Similarly, educational interventions were associated with significant improvements in knowledge of diabetes being reported in the previous meta-analyses.^{78 79} Moreover, there is evidence that education improves knowledge and subsequently promotes behavioural changes among patients with end-stage renal disease.⁸⁰ Though significant changes were observed in diabetes knowledge, this finding should be interpreted with caution due to the significant degree of heterogeneity among included studies.

Limitations

Our study has some limitations that need to be considered in the future. First, studies published in the English language were only considered for this systematic review. Second, there was variation in the included studies in terms of healthcare providers, component of interventions, outcome measures and intervention methods. Third, global representativeness must be considered as it was not possible to identify evidence from all countries of the globe. Fourth, although all the included studies were

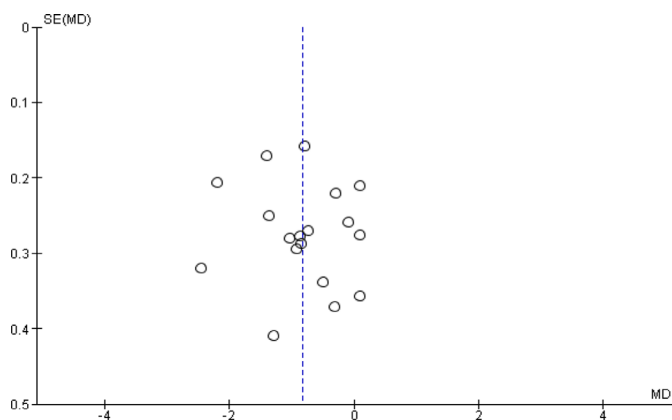


Figure 8 Funnel plot for HbA1c, glycosylated haemoglobin; MD, mean difference.

Table 3 GRADEpro level of quality evidence assessment

Educational intervention compared with usual care for patients with type 2 diabetes

Patient or population: patients with type 2 diabetes

Setting:

Intervention: educational interventions

Comparison: usual care

Outcomes	Anticipated absolute effects*		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with comparison	Risk with intervention				
Glycaemic control (HbA1c) measured with difference in mean HbA1c level after intervention	–	MD 0.83 lower (1.17 lower to 0.49 lower)	–	2474 (19 RCTs)	⊕⊕⊕○ Moderate ^{a,b}	a. Majority of studies had high or unclear risks of bias for allocation concealment and blinding of participants or investigators. One out of two studies reported low-risk methods for blinding of outcome assessment. b. The certainty in the evidence was downgraded due to imprecision in the intervention, inconsistent with duration of intervention and intervention design.
Scale from 1 month to 12 months	–	SMD 1.16 SD higher (0.71 higher to 1.6 higher)	–	1309 (10 RCTs)	⊕⊕○○ Low ^{c,d}	c. Bias was judged to be at 'high risk' in this trial. d. Heterogeneity was high in this trial.

GRADE Working Group grades of evidence: **high certainty** – we are very confident that the true effect lies close to that of the estimate of the effect. **Moderate certainty** – we are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. **Low certainty** – our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect. **Very low certainty** – we have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

GRADE, Grading of Recommendations Assessment, Development and Evaluation; HbA1c, glycosylated haemoglobin; MD, mean difference; RCTs, randomised controlled trials; SMD, standardised mean difference.

randomised controlled trials, some trials had biases, such as lack of allocation concealment, blinding and intention-to-treat analysis.

CONCLUSION

This systematic review adds to the body of knowledge that suggests that structured diabetes self-management education and support contribute to improving glycaemic outcomes and diabetes knowledge. Therefore, clinicians could make an effort to provide such care to ensure glycaemic control and to improve knowledge of T2DM. Further research is needed to determine the clinical significance of these improvements and their cost-effectiveness.

Implications for practice

Overall, these data revealed that educational interventions provide a basic benchmark to reduce glycaemic levels and to improve knowledge of T2DM. Importantly, to implement a successful education intervention, it is necessary to consider the duration of intervention and intervention design (empirical education is more effective) in patients with T2DM. Therefore, clinicians should use educational interventions to improve glycaemic control and diabetes knowledge among patients with T2DM. However, before making a practice decision based on the current review, further information from other reviews considering how the role of educational intervention reduced glycaemic level and improved diabetes knowledge should be taken into account. Hence, the certainty of this evidence is not adequate to conclude that interventions will be effective among patients with T2DM.

Implications for research

Further research is likely to change the estimated effect size of educational interventions in glycaemic control and knowledge of patients with T2DM. Knowledge of diabetes was assessed using different tools, outcome data were measured in heterogeneous ways. Based on this review, future studies of educational interventions would increase our certainty of evidence whether these interventions improve knowledge of diabetes or not by overcoming limitations of existing studies. Therefore, future educational intervention studies should be designed to evaluate individual-centred outcomes and become new priorities to support in clinical decision-making.

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