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The effect of educational interventions on knowledge of the disease and glycemic control in patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials

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3 **The effect of educational interventions on knowledge of the disease and glycemc control in**
4 **patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized**
5 **controlled trials**
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Abstract

Background and aims: Globally, type 2 diabetes has become increasing which accounting for over 90% of all diabetes cases. Though the magnitude of uncontrolled glycemetic levels in patients with Type 2 diabetes is steadily rising, evidence showed that effectively controlled glycemetic levels can prevent complications and improve the quality of life of patients. As little is known about the effect of educational intervention on this population, this systematic review and meta-analysis evaluated the effectiveness of educational interventions on glycemetic control and disease knowledge among Type 2 diabetes patients.

Methods: PubMed, Google Scholar, Cochrane Library, Scopus, African Journals Online, and Wiley Online Library were searched. The Cochrane Collaboration tool was used to evaluate risk of bias of among eligible studies. 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 (GRADE) approach.

Results: A total of 19 trials with 2,708 study participants included in the review. Primary outcomes (glycemetic control) were reported in eighteen trials. The pooled estimated impact of educational intervention on glycemetic levels using the random effect model was -0.83 (95% CI: -1.17, -0.49, $p < 0.001$). Subgroup analyses revealed greater A1C reductions in those studies with intervention durations of up to three months and with empirical intervention designs. Educational interventions led to significant increases in participants' knowledge of type 2 diabetes (SMD: 1.16; 95% CI: 0.71, 1.60; $I^2 = 93\%$).

Conclusion: In the current review overall, educational interventions can potentially lead to improved glycemetic 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 Type 2 diabetes patients.

Keywords: educational intervention, Type 2 diabetes, diabetes knowledge, glycemetic control

Strengths and limitations of this study

- This systematic review will provide a comprehensive search of the literature the effect of educational intervention on glyceimic control and knowledge of type 2 diabetes.
- An extensive search of multiple databases (i.e, PubMed, African Journals online, Web of Science, Scopus, and Google scholar) were 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 the worldwide which could be in several other languages such as Spanish, French, or Portuguese.
- It may be lacked global representativeness because no data were found from all countries of the globe.

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 living with DM [2]. According to International Diabetes Federation (IDF) projection approximately 629 million peoples will be affected by 2045 [3]. Of these, approximately 80% of affected individuals live in low-income countries [4]. In particular, Type 2 diabetes (T2DM) is responsible for more than 90% of all diabetes cases [5]. The increasing burden is due to several risk factors such as sedentary behaviors, obesity, unhealthy diet, lack of exercise, family history, and age [6-8].



Maintaining optimal glyceimic levels is vital to diabetes control [9]. However, evidence showed that poor glyceimic control ($HbA1c \geq 7\%$) has 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 glyceimic targets, minimize adverse events, and prevent complications [15, 16]. Therefore, lifestyle modification such as diet and exercise have been reported to reduce the complication of uncontrolled glyceimic levels in T2DM patients [17].

Evidence has revealed that self-management education can reduce the glyceimic level by 30–80% [18]. Besides, diabetes education can improve glyceimic control, changing people's behaviors,

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3 promoting self-care, reducing complications, and progression of the disease [19-21]. Moreover,
4 numerous studies suggest that diabetes educational interventions can increase knowledge of
5 diabetes [22, 23], medication compliance [24], and improve glycemc control [25, 26].
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9 Though knowledge about diabetes has paramount benefit to patients' self-care management;
10 insufficient diabetes knowledge is unfavorable to the patients' health due to most of the
11 complications that arise can be prevented through self-care practice [27, 28]. Besides, inadequate
12 knowledge of diabetes is responsible for poor self-care practice and uncontrolled glycemc levels
13 [29]. However, numerous studies have shown that improving patient knowledge about T2DM
14 and its complications has substantial benefits to maintain optimal glycemc levels, enhance
15 treatment adherence, reduces treatment cost, and decreases the progression of disease [30-32].
16 Previously several review on the effect of self-management interventions for patients with
17 T2DM have been employed [33-35]. However, most review has been included inadequate
18 number of articles, not address the effect of education on knowledge of diabetes, and
19 interventions were poorly described. Thus, research is required to estimate the effect of
20 educational interventions with sufficient methodological quality and substantive statistical
21 analysis. Hence, the present review and meta-analysis aimed to evaluate the effect of educational
22 interventions on glycemc control and disease knowledge in patients with T2DM.
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33 34 **Review questions**

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36  Does a structured educational intervention increase diabetes knowledge in patients with
37 T2DM?
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39  Does a structured diabetic educational intervention reduce HbA1c levels among T2DM
40 patients?
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44 **Methods**

45 **Protocol and registration**

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47 Initially, PROSPERO was searched to confirm for other reviews on the effect of educational
48 interventions on glycemc control and disease knowledge among patients with T2DM. But, no
49 such reviews were identified. Then, the protocol was registered on Prospero
50 (www.crd.york.ac.uk/PROSPERO/) as recommended by the PRISMA statement [36] with the
51 number (CRD42020205838).
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Search strategy and data sources

We did a compressive systematic search to collect all relevant articles using the Peer Review of Electronic Search Strategies (PRESS) for systematic reviews [37]. The search was limited to studies published in peer-reviewed journals from January 2000 to July 2020 (as authors are interested in up-to-date data). The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines were used to conduct and report the present review [36]. The literature was searched from 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 wont to combine search terms. The MeSH terms employed in the PubMed search engine in various combinations are shown in Table 1. To access all articles on this study goal, it was decided to manually review all references to reduce publication bias. Searches were performed in 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: are educational intervention (I) in type 2 diabetes people (P), when compared to people who had not taken part in the educational intervention or had standard care (C), associated with improved glycemic control and disease knowledge (O)?.

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]	183,620
#2	Education [tw] OR intervention [tw] OR behavioral intervention[tw] OR self-management [tw]	1,473,053
#3	Glycemic control [tw] OR glycosylated hemoglobin[tw] OR HbA1c[tw]	59,352
#4	Knowledge [tw] OR behavioral outcomes[tw]	775,760
#5	#1 AND #2 AND #3 AND #4	4,888
#6	#5; Limits: studies done with Humans, English language, full text, RCT, and publication year (2000 to 2020)	447

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, diabetic clinics, and hospitals within the catchment. Children or those with T1DM were excluded from the review.

Types of Interventions

The review considered an educational intervention as intervention provided to adult patients with T2DM in diabetic care settings receiving standard or routine care. Intervention could be provided by any health care provider, involved any medium (written, oral, video, and computer), at the individual or group-level, theory-based or empirical, and we did not impose to restrict the duration of intervention. Studies lacking an education intervention, unclear information respecting to 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 health care 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 randomized controlled trials. Full text articles were included, whereas studies published with only abstract or unpublished data were excluded. Besides, nonrandomized controlled trials, quasi-experimental, before and after, cohort, case-control, and cross-sectional studies were excluded because uncontrolled trials and observational studies leads to a greater risk of biased estimates of effect size [38].

Type of outcome

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

Study selection

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3 After database exploration, all recognized studies were uploaded into EndNote version 8, and
4 duplicates articles were removed. Clinical trials studies were included for this systematic review.
5 Predefined selection criteria were used to select relevant full-text articles during the screening
6 process. Two authors (WSS & YAA) independently screened the title, abstract, and keywords of
7 the studies identified for possible eligibility in the review. Afterward, all full-text articles were
8 evaluated carefully for inclusion and data extraction. Further screening of full text was done by
9 two (TYA & YAA) independent authors to select the studies which satisfied the eligibility
10 standards. The possible justification for the exclusion of full-text studies was documented and
11 reported in the systematic review. Any uncertainties about study eligibility were discussed
12 between authors.
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23 **Data extraction**

24 After identifying studies for eligibility, data abstraction was conducted by two (AMK & WSS)
25 independently authors using Microsoft™ Excel for Windows. The first author made the data
26 abstraction, whereas the second author control the quality of extracted and entered data. The data
27 extracted from each study included first/corresponding author, year of publication, study setting,
28 education provider, duration of intervention, the intensity of intervention, components of the
29 intervention, number of participants in each arm (intervention and standard care group),
30 intervention design, outcome measures, before and after intervention HBA1c levels and
31 knowledge scores. The outcome measures in this review were reported as the variation from
32 starting point to closing date of follow-up in the intervention and standard care groups. If the
33 standard deviation (SD) of mean difference was not reported in each included study, the values
34 were recalculated according to the guideline in the Cochrane Handbook [39].
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44 **Assessment of risk of bias in included studies**

45 Two (MD & PMP) independently authors assessed within trial risk of bias in each included study
46 using Cochrane's Risk of Bias assessment tool [40]. The Cochrane's Risk of Bias tool has seven
47 evaluation domains that are used to evaluate validity and bias in studies of clinical trials in (1)
48 random sequence generation, (2) allocation concealment, (3) blinding of participants and
49 personnel, (4) blinding of outcome assessor, (5) incomplete outcomes reporting, (6) the
50 selectivity of outcome reporting, and (7) other possible sources of bias. For this review, the risk
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3 of bias item was rated as “low risk” if it had been unlikely that a bias would significantly change
4 the results; “unclear” if it had been likely that a bias would raise some uncertainty about the
5 results; or “high risk” if it had been likely that a bias would seriously change the results. Any
6 disagreement was resolved through discussion and consensus.
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10 **Assessment of certainty of the evidence**

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12 To evaluate the quality of the evidence, the authors used the Grading of Recommendations
13 Assessment, Development, and Evaluation (GRADE) approach[41]. GRADE pro-GDT was
14 employed to summarize the quality of evidence [42]. The certainty of the evidence encompasses
15 consideration of the within-study risk of bias which comprising methodological worth,
16 indirectness of evidence, unexplained heterogeneity, imprecision, and the probability of
17 publication bias. The GRADE approach has four levels of quality such as high-quality evidence
18 recommends that additional study is very unlikely to change our confidence in the estimate of
19 effect size; moderate-quality reflects further research as likely to have a vital impact on the
20 estimate of effect size and may alter the estimate; low quality reveals that further research is
21 very unlikely to have a significant influence on the current estimate of effect size and is likely to
22 change the estimate; and very low quality suggests one is precise indeterminate about the
23 estimate.
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34 **Data synthesis and analysis**

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36 The primary and secondary outcomes were reported as mean difference (MD) and standardized
37 mean difference (SMD) with a 95% confidence interval (CI), using a random-effects model [43]
38 respectively. Degree heterogeneity was examined with the I^2 statistic, which expresses the
39 amount of heterogeneity between studies [44]. To interpreting the effect sizes, authors followed
40 Cohen's guidelines where $d \leq 0.2$ was small, $d \approx 0.5$ was medium, and $d > 0.8$ was large
41 variation among intervention and control groups [45]. We performed subgroup analyses to
42 reduced the level of heterogeneity for the primary outcomes using duration of intervention and
43 intervention design. Publication bias was visually evaluated using the funnel plot, supplemented
44 by Egger's regression test [46, 47]. Sensitivity analysis was performed due to high degree
45 heterogeneity and risk of bias. Review Manager of the Cochrane Collaboration (RevMan 5.4,
46 Cochrane Organization) was used to perform the meta-analysis.
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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 1, 134 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 full articles for full screening. Following 66 exclusions at the full-text level (mainly due to nonrandomized control 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 2,708 study participants. Of these 9 included articles have reported glycemic control and knowledge of diabetes as a common outcome variable. Regarding location, two were from Brazil [48, 49], three from China [50-52], two from Germany [53, 54], five from Iran [55-59], two from Malaysia [60, 61], two from Sweden [62, 63], and one each from Thailand [64], Sri Lanka [65], and Australia [66]. The sample size varied from 60 [50] to 300 participants [52]. Educational interventions in the review was guided by the following theories or models; three studies used the theory of self-efficacy [51, 60, 64], three studies [53, 58, 63] used empowerment theory, two studies [57, 65] used theory of self- efficacy and motivational interviewing, each one study used chronic care model [52], Precede-Proceed model [59], BASNEF Model [56], and behavioral theory [61]. However, the remainder of the articles [48-50, 54, 55, 62, 66] used non-theory or model based approaches.

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3 The approach of providing educational interventions comprises of face-to-face counseling [51,
4 52, 60, 65, 66], diabetes education sessions [48, 49, 52, 57, 60, 64], group discussion [53, 55-57,
5 64], telephone follow-up [51, 57, 60, 64, 66], home visit [64], demonstration [50, 51, 56],
6 question and response [55, 56] were among the most common. The control groups of all studies
7 had the current standard of care. The duration of educational interventions varied from 4 weeks
8 [51, 55, 56] to 12 months [49, 63]. Interventionl groups were obtained the information by
9 different health care proffessionals such as physicians [51, 52, 63], nurses [49, 53, 55, 64, 66],
10 nutritionist [58, 61], health manager [52], public health assistant [52], and pharmacists [48]. In
11 most of the included studies, intervention processes were group based education [49, 51-60, 62-
12 64], combined education [50, 65, 66]; however, in the rest of the studies, web-based [61], and
13 individual-based [48] education approaches were used. The main results and the features of the
14 selected studies are presented in Table1.
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Table 2. Characteristics of the included studies

Authors	Country	No of subjects (baseline)	Health education provider	Theory/model used	Group/individual	Intervention	Components of intervention	Duration of intervention	Outcome measures	Outcome indicators
Wichit et al [64]	Thailand	I=70 C=70	Trained Nurse	Self-efficacy	Group	Education classes (3 session), discussions, a home visit, and a telephone follow-up	Program focus on; meal planning, foot hygiene, physical activities, problem solving, diabetes-related complications, enhancing competence, and diabetes knowledge	9 week	at baseline, week 5, and week 13	①② ④⑤ ⑥
Fan et al, [66]	Australia	I=138 C=138	Trained Nurse	Empirical	Mixed	Face-to-face counseling over 1 h, and self-care plan, a 10-min telephone before the appointment, attend a 3-monthly forum about 2 h.	Education emphasizes on such as diet modification, exercise, SMBG, psychological and adherence to medication	6 months	At each follow-up and the end of the 6-month	①
Grillo et al, [49]	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 type 2 diabetes mellitus, (2) non-pharmacological treatment, emphasizing 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 et al, [48]	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-month	At baseline and 6 months	①③ ④⑥
Zheng et al, [50]	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 hypoglycemia treatment, foot care, medication, and blood glucose	3 months	At baseline and 3 months	①③ ⑤

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							monitoring. The practice course focus on one-on-one nutrition guidance and individualized exercise guidance.			
Jiang et al, [51]	China	I=133 C=132	Trained nurses and physicians	Self-efficacy	Group	Structured education program, patients' experience sharing, peer modeling, demonstration, the intervention was given four 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-month	①② ③④ ⑤
Kong et al, [52]	China	I=150 C=150	Physician, health manager, and public health assistant	Chronic Care Model	Group	Pamphlets and face-to-face communication, continuous medical education, education was 9 session every month.	received the five components CCM (chronic care model)-based intervention, awareness of the chronic disease management, Self-management support included goals setting, planning, doing, checking, and assessing,	9 months	At baseline, & 9 months	①③ ⑥
Braunet al, [54]	Germany	I=83 C=72	Not stated	Empirical	Group	Diabetes teaching and treatment program, seven educational classes of 45 min duration,	Self-monitoring, Diabetes treatment,	6 months	Before (t0), immediately after (t1), and 6 months after (t2)	①④ ⑤
Hermanns et al [53]	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, two 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	①② ③④ ⑤⑥
Didarloo A et al [55]	Iran	I=45 C=45	Trained nurse	Empirical	Group	Interactive approach such as discussion, brainstorming, question and response techniques for 60 min/week for 4 weeks, utilized	Promoting self-efficacy of diabetics, the educator utilized specific training approaches such as verbal persuasion, modeling,	4 weeks	At baseline, and 3 months	①② ③④ ⑥

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						specific training such as verbal persuasion, and modeling	and performance accomplishments. Definition, signs, symptoms, and consequences of T2DM, and diet		after the end of the intervention	
Askari[56]	Iran	I=54 C=54	Researcher	BASNEF Model	Group	Training in eight sessions (two sessions in a week); each session lasted for 70 min, question and answer, exercise, discussion, image, and messages were sent to the patients each week	Presented content was about diabetes, sign & symptoms, diet, food composition tables, partitioning, proper use of fruits, vegetables, and grains as sources of dietary fiber.	4 week	At baseline, and 3 months after the end of the intervention.	①② ③④ ⑤
Ebrahimi et al [58]	Iran	I=53 C=53	Nurse with the endocrinologist, and nutritionist	Empowerment model	Group	Education training, 5–7 weekly regular meetings were held about 60–90 min.	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 et al [59]	Iran	I=43 C=43	Trained professional	Precede-proceed model	Group	The education program with eight 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 program	②③ ④⑤
Azami et al, [57]	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 behaviors, 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-week and 24-week post-randomization	①② ⑤⑥
Tan et al, [60]	Malaysia	I=82 C=82	Not stated	Self-efficacy	Group	Structured education consisted of monthly sessions for 3 months	The first session, healthy eating, being active, medication adherence and	3 months	At baseline,	①② ④

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						about 30 min each session, two were face-to-face individual education sessions and one was a telephone follow-up, Printed educational materials	Self-monitoring of blood glucose. 2 nd and 3 rd session on problem-solving skills related to hyperglycemia, hypoglycemia, sick day, and emotional episodes		and 12 weeks	
Ramadas [61]	Malaysia	I=66 C=62	Nutritionist	Behavioral 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 personalized according to the patients' dietary stages of change and were expected to improve their diabetes, knowledge, Attitude, and behavior, the participants also send their queries to the study nutritionist via the website.	6-months	At baseline, 6-month post-intervention and 12-months follow-up	①② ③④
Adolfsson, [63]	Sweden	I=50 C=51	Nurse and physician	Empowerment	Group	Empowerment group education, counseling using videotaping, presentation and discussion, one follow-up session has 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	①② ④⑥
Hörnsten, [62]	Sweden	I=44 C= 60	Nurse with special education in diabetes care	Empirical	Group	Education and group discussion with ten two hour group sessions over 9 months	Patients' understanding of the illness.	9 months	Before and each year after the intervention	①
Jayasuriya et al, [65]	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 six weeks, following monthly (4 weekly) for five more visits.	Physical activity and healthy Dietary intake and more recently in "avoidance behaviors" to reduce unhealthy eating	6 months	At baseline and at 6 months	①② ⑤

Notes: Outcome indicators: ①metabolic controls, ②self-efficacy, ③behavior, ④knowledge, ⑤other psychological indicators, and ⑥quality of life.

Risk of bias in the included studies

The random sequence generation for allocation was evaluated as low risk of bias in 12 studies [49-51, 53, 54, 57, 58, 60, 61, 63-65] and the rest 7 studies were measured as unclear risk of bias [48, 52, 55, 56, 59, 62, 66]. Allocation concealment was a low risk of bias in five studies [50, 51, 55, 57, 64]. On the other hand, a high risk of allocation bias was reported in one study [56]. The remaining other studies [48, 49, 52-54, 58-63, 65, 66] were evaluated to have an unclear risk of bias. Blinding of participants and educators was considered a problem in such interventions; however, one study blinded participants and educators [57]. Outcome assessors were blinded in three studies [49, 58, 64]. Regarding incomplete outcome data reporting seven studies [48, 49, 51, 55, 57, 64, 66] were evaluated as low risk of bias. The risk of bias due to selective reporting was confirmed low for 16 studies [48, 50-60, 62, 64-66], however, unclear risk of bias in three studies [49, 61, 63]. Nine studies [49-51, 53, 57, 61, 63, 64, 66] were evaluated as low risk of other potential biases, two studies [55, 62] were confirmed to be high risk for bias, and eight studies [48, 52, 54, 57-60, 65] were evaluated to have unclear risks of bias. The risk of bias for studies overall is summarized in Figure 2 and the risk of bias in each study is reported in Figure 3.

Effect of educational intervention on glycemic control

The effects of educational interventions on glycemic (HbA1C) level reduction are presented in Figure 4. The results of the meta-analysis revealed that educational interventions significantly decreased HbA1c levels (MD: -0.83%; 95% CI: -1.17, -0.49; $P < 0.001$) compared to standard care groups. A random-effect model was used due to significant heterogeneity ($I^2=88\%$). A sensitivity analysis was employed by omitting three studies [50, 53, 55] because of a 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%, -0.44%, $p = 0.001$). The I^2 statistics 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 versus 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 an intervention duration of ≤ 3 months (MD: -1.09, 95% CI: -1.60, -0.57, $p < 0.00$) with a significant evidence of heterogeneity among studies ($I^2 = 88\%$) (Fig. 5). Additionally, the results of the subgroup analysis revealed that interventions with an empirical approach had greater effects in terms of reducing glycemic levels (MD: -1.03, 95% CI: -1.90, -0.15, $p < 0.00$). Because of a significant degree of heterogeneity between studies ($I^2 = 88\%$) random effect analysis was used (Fig. 6).

The effect of educational interventions on diabetes knowledge

Ten out of the 19 studies were reported knowledge of diabetes as outcome variable [48, 49, 51, 53-56, 59, 61, 64]. The pooled effect size of the ten trials demonstrated an improvement in knowledge of T2DM (SMD: 1.16, 95% CI: 0.7, 1.60, $p < 0.001$; Fig.7) compared to standard care groups. A random-effect model was used because of significant heterogeneity. The Dietary Knowledge Questionnaire [61] and the Diabetes and Medication Knowledge Questionnaire [49, 51, 54, 55, 64] used to estimate the level knowledge in individuals with T2DM. The number of items was between eight [59] and 24 items [64]. There was a significant variation in knowledge of type 2 diabetes scores across different studies.

Publication bias

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

The 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 glycemic 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 and the true effect may be substantially different from the estimate of the effect size.

Summary of findings 1:

[educational intervention] compared to [usual care] for [type 2 diabetes patients]

Patient or population: [patients with type 2 diabetes]

Setting:

Intervention: [educational interventions]

Comparison: [usual care]

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with [comparison]	Risk with [intervention]				
glycemic control (HbA1c) measured with: difference in mean HbA1c level after intervention Scale from: 1 month to 12 months	-	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.
diabetes knowledge assessed with: diabetes and medication knowledge 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.

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

CI: Confidence interval; MD: Mean difference; SMD: Standardized mean difference

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

Discussion

Currently diabetes has been becoming a public health problem that needs effective educational interventions which apply across age, ethnicities, and socioeconomic levels. Evidence showed that appropriate self-management education are suggested as a vital component of clinical care to improve glycemic levels and change behavioral outcomes [67]. In the current meta-analysis to generate high quality of evidence, only clinical trials studies were included.

This review summarises 19 RCT studies of educational interventions involving 2,708 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 glycemic control and diabetes knowledge. The finding revealed that educational interventions reduced HbA1c levels by 0.83% (95% CI: 1.17 %, 0.49%) among T2DM patients. This finding has substantial degree heterogeneity ($I^2 = 88\%$) indicating variation between included studies. However, there was a slight reduction of mean difference after sensitivity analysis, 0.70% (95% CI: 0.96 %, 0.44%), with a moderate degree of heterogeneity ($I^2=73\%$). Our findings are supported by previous meta-analysis, which reported that behavioral and self-management education have a significant benefit in the reduction of HbA1c levels in patients with diabetes [26, 34, 35].

The improvement in glycemic levels is considered to be clinically essential. The UK Diabetes Study revealed that with each 1% reduction in HbA1c is a likelihood to reduce the risk of diabetes complications by 21% [68]. Similarly, study showed that achieving optimal glycemic level is likely to reduce the risk of deaths from diabetes complications such as cardiovascular and cerebrovascular problems [69]. Moreover, the American Diabetes Association recognizes that diabetes self-management has vital role to improve glycemic levels and reduce diabetes related complications [70].

In the current meta-analysis, subgroup analysis was conducted based on the duration of the educational interventions. Concerning duration of intervention, there was a variation between ≤ 3 months, 3-6 months, and > 6 months to the reduction of HbA1c levels. In this meta-analysis, the pooled effect size for short educational interventions (duration ≤ 3 -month) was better than the effect size of longer interventions (duration 3-6 month and >6 -month) -1.09 (95% CI; $-1.60, -$

0.57, $P < 0.001$). One possible explanation maybe associated with the initial motivation of the participant to be empowered to obtain positive results in a short period [71]. In contrary, previous studies reported that longer duration of interventions were more likely related with a significant reduction in HbA1c levels [26, 72, 73]. Similarly, a meta-analysis study showed that more contact hours were associated with a reduction of HbA1c level [30]. Moreover, evidence also supported that the duration of contact hours between trainer and patient have a substantial impact on glycated hemoglobin levels [18]. The current findings reflects that the duration of intervention would influence the effectiveness of the educational intervention among T2DM patients. Therefore, this disparity should be considered when developing future education interventions.

In the present review subgroup analysis was conducted based on interventions design (theory-based versus empirical educational). Our study indicated that educational interventions benefited all patients regardless of the intervention design. In the current findings empirical educational intervention showed better improvement in glycemic control level -1.03 (95% CI; $-1.90, -0.15$, $P < 0.001$). Similarly, evidence showed that interactive self-management interventions through evidence-based approaches and structured curricula is crucial to improve glycemic control and behavioral outcomes [74]. However, other review indicates that, in patients with T2DM, theory-based self-management educational interventions improved HbA1c [33]. Although one-third of the included studies used an empirical approach in designing interventions, and favorable results on glycemic control were obtained; their specific role in educational interventions has been debated.

In this review diabetes knowledge showed significantly a higher standardized mean score of correct knowledge of diabetes among the intervention group as compared to the standard care group (SMD = 1.16; 95%CI: 0.71, 1.60, $p < 0.001$). Similarly, educational interventions were associated with significant improvements in knowledge of diabetes being reported in the previous meta-analyses [75, 76]. Moreover, there is evidence that education improve knowledge and subsequently promoting behavioral changes among patients with end-stage renal disease [77]. Though significant changes were observed in diabetes knowledge, this finding should be applied with caution due to the significant degree of heterogeneity among included studies.

Limitations

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3 Our study has some limitations that need to be considered in the future. First, studies published
4 in the English language were only considered for this systematic review. Second, there was
5 variation in the included studies in terms of healthcare providers, component of interventions,
6 outcome measure, and intervention methods. Third, it may be lacked global representativeness
7 because no data were found from all countries of the globe. Fourth, although all the included
8 studies were randomized controlled trials, some trials had the following biases; lack of allocation
9 concealment, blinding, and intention-to-treat analysis.
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16 **Conclusion**

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18 Our study findings showed that educational intervention have significant benefits over routine
19 care in terms of reducing glycemic levels and improving diabetes knowledge. Therefore,
20 clinician should make an effort to provide such care to ensure glycemic control and to improve
21 knowledge of T2DM. Further research is needed to determine the clinical significance of these
22 improvements and their cost-effectiveness.
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28 **Implications for practice**

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

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50 Further research is likely to change the estimated effect size of educational interventions in
51 glycemic control and knowledge of T2DM patients. Knowledge of diabetes was assessed using
52 different tools, outcome data was measured in heterogeneous ways. Based on this review, future
53 studies of educational intervention would increase our certainty of evidence either these
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3 interventions improve knowledge of diabetes or not by overcome limitations of existing studies.
4 Therefore, future educational interventions studies should be designed to evaluate individual
5 centered outcomes and that are becoming new priorities to support in clinical decision-making.
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8 9 **List of abbreviations**

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11 GRADE: Grading of Recommendations Assessment, Development, and Evaluation; HbA1c:
12 glycosylated hemoglobin level; IDF: International Diabetes Federation; PRESS: Peer Review of
13 Electronic Search Strategies; PRISMA: Preferred Reporting Items for Systematic Review and
14 Meta-Analysis statement; T2DM: type 2 diabetes mellitus; WHO: World Health Organization.
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19 **Declaration**

20 21 **Ethics approval and consent to participate**

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23 Not applicable.
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26 27 **Consent for publication**

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29 Not applicable.
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32 33 **Availability of data and materials**

34 All relevant data are within the paper and supporting information files. There is no separate data
35 set to share.
36
37

38 39 **Competing interests**

40 The authors declare that they have no competing interests.
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42

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45 Not applicable.
46
47

48 49 **Authors' contributions**

50 WSS, YAA, and TYA developed the protocol and were involved in the design, selection of
51 study, data extraction, statistical analysis, and developing the initial drafts of the manuscript.
52 AMK, WSS, PMP, and MD were involved in data extraction, quality assessment, statistical
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3 analysis, and revising. WSS and YAA prepared and edited the final draft of the manuscript. All
4 authors read and approved the final draft of the manuscript.
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9 Not applicable
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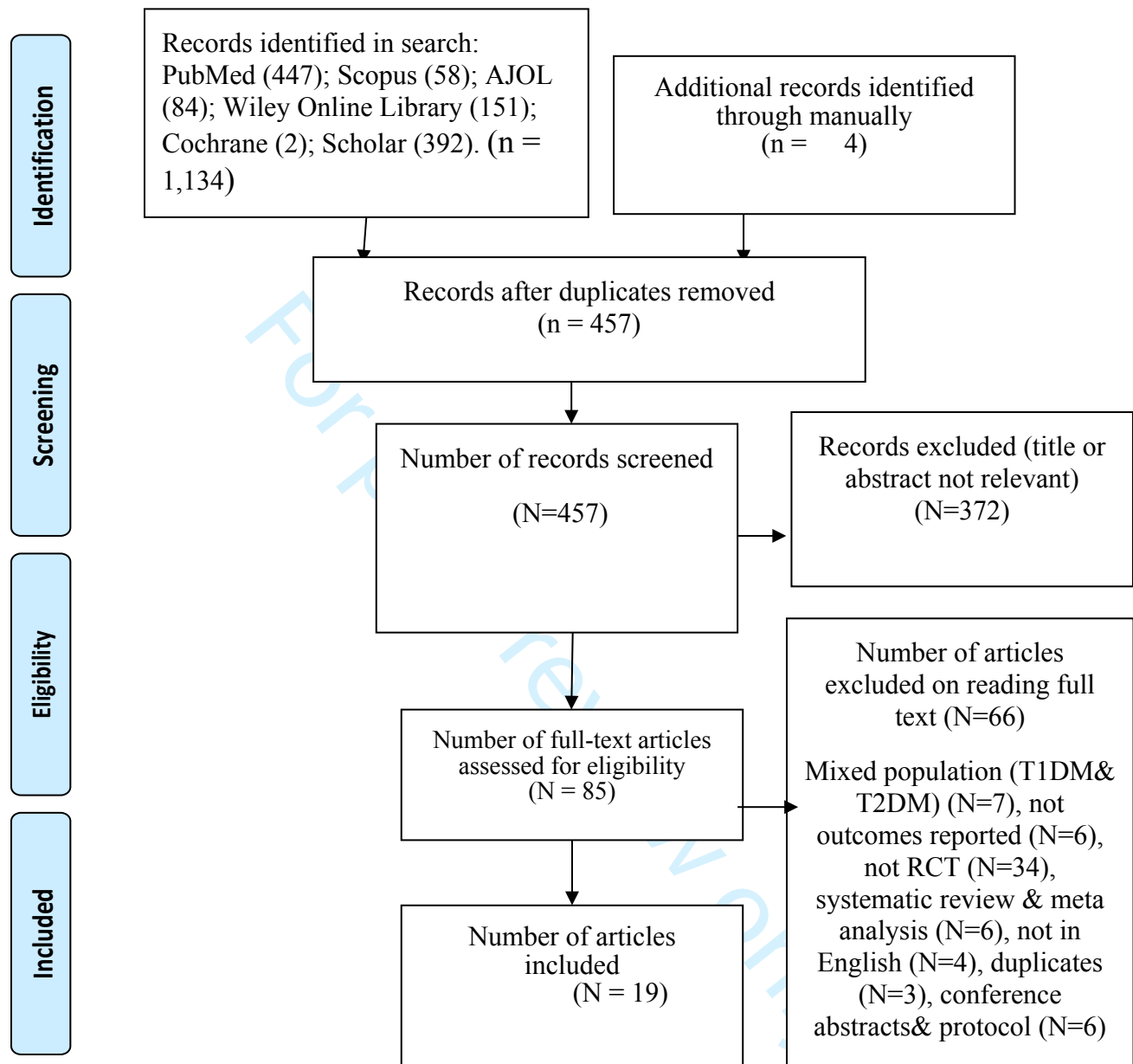


Figure 1. PRISMA flow chart for selection of studies

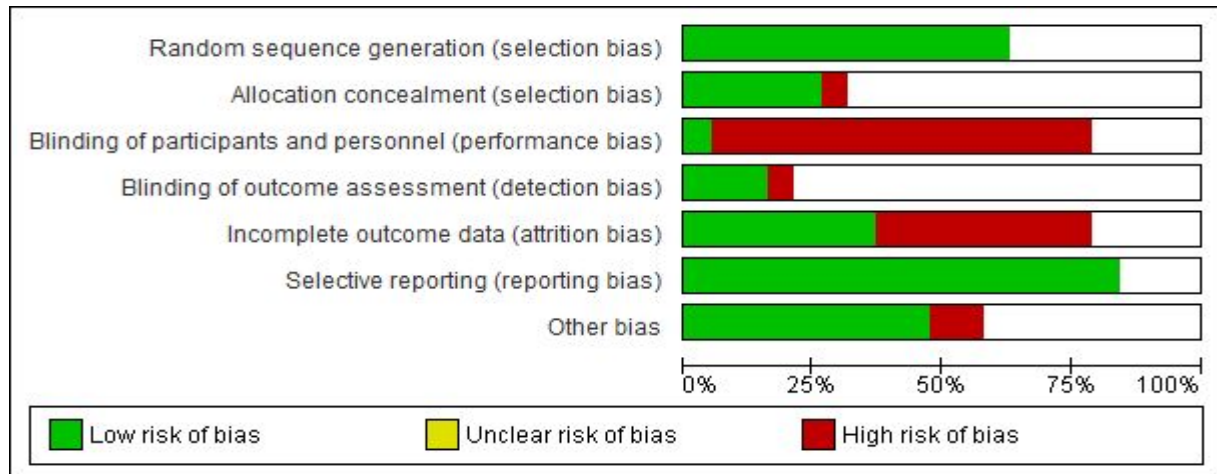


Figure 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

	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 etal, 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 authors' judgments about each risk of bias item for each included study.

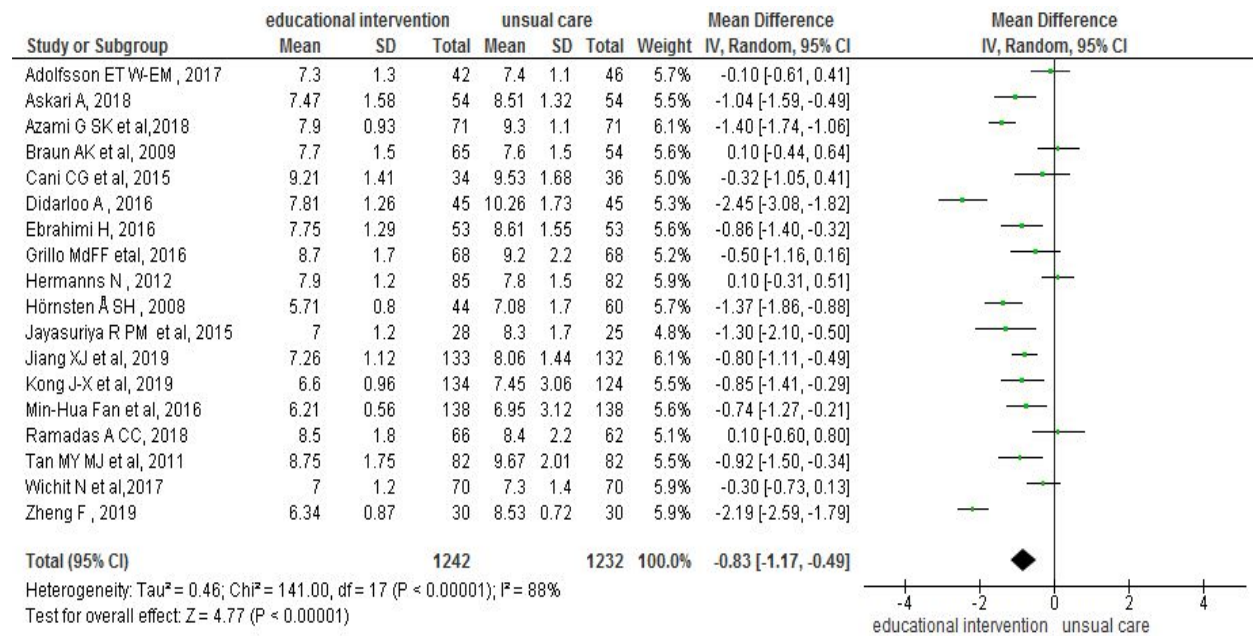


Figure 4. The pooled effect of education interventions on HbA1c levels in patients with T2DM

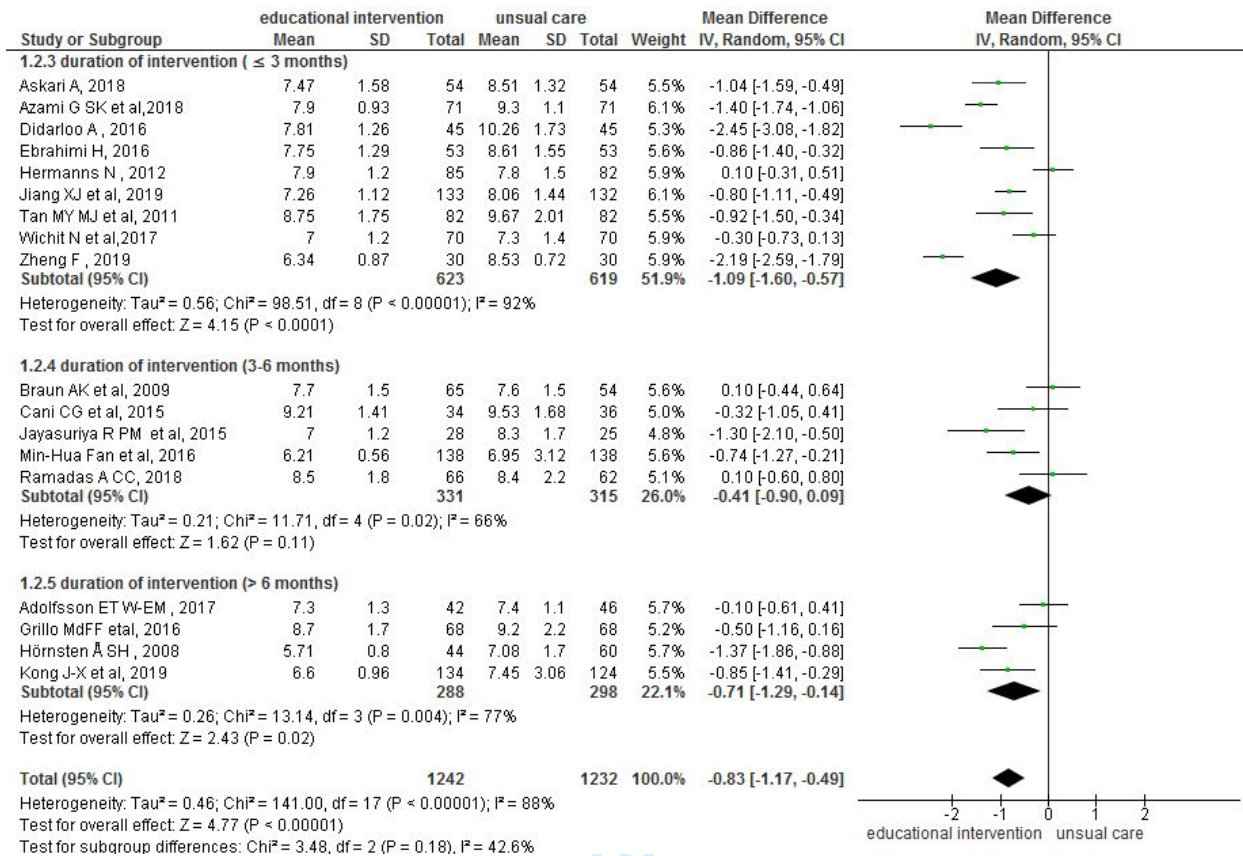


Figure 5. Subgroup analysis based on the duration of the intervention

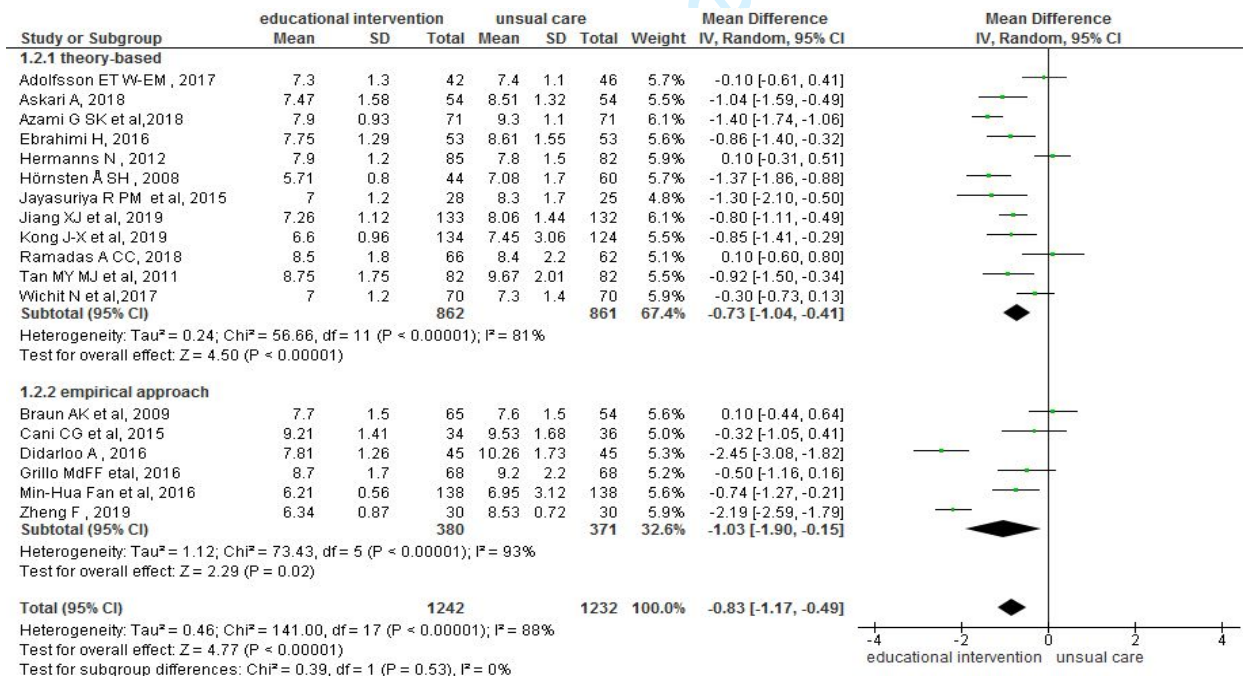


Figure 6. Subgroup analysis based on intervention design

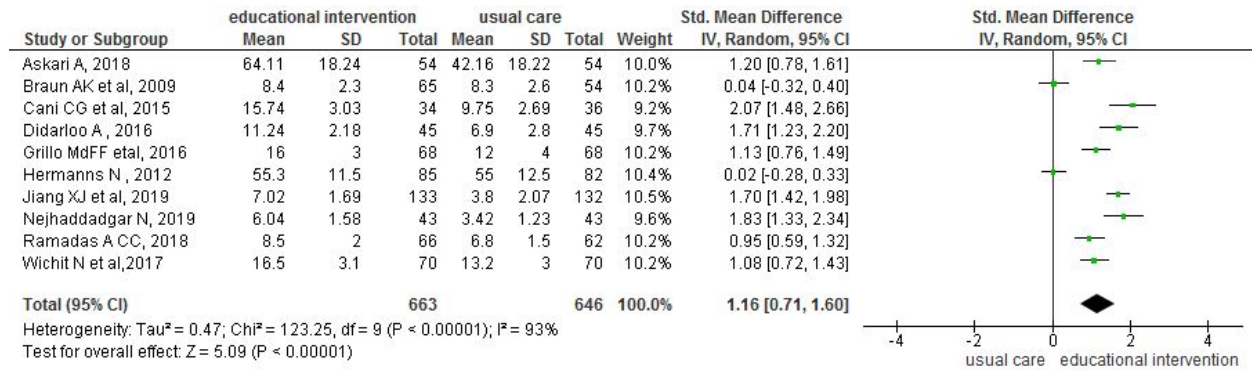


Figure 7. The pooled effect of education interventions on disease knowledge in patients with T2DM.

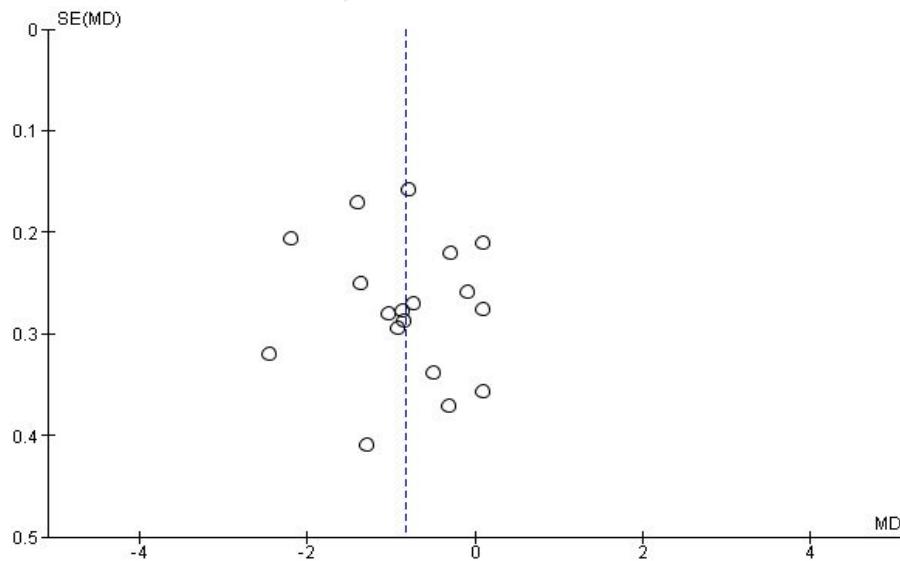


Figure 8. Funnel plot for HbA1c results.



PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	CRD42020205838
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	NA
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis	8



PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	14
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	14
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	14-15
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	15
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	14-15
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	18-19
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	20
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	NA

PRISMA checklist the paper entitled the effect of educational interventions on knowledge and glycemic control in patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials



PRISMA 2009 Checklist

For more information, visit: www.prisma-statement.org.

Page 2 of 2

For peer review only

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BMJ Open

The effect of educational interventions on knowledge of the disease and glycemic control in patients with Type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials

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Primary Subject Heading:	Diabetes and endocrinology
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Keywords:	EDUCATION & TRAINING (see Medical Education & Training), Diabetes & endocrinology < INTERNAL MEDICINE, General diabetes < DIABETES & ENDOCRINOLOGY, DIABETES & ENDOCRINOLOGY

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3 **The effect of educational interventions on knowledge of the disease and glycemc control in**
4 **patients with Type 2 diabetes mellitus: a systematic review and meta-analysis of**
5 **randomized 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 Type 2 diabetes patients.

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 randomized trials (RoB 2). 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 (GRADE) approach.

Results: A total of 19 trials with 2,708 study participants were included in the review. Primary outcomes (glycaemic control) were reported in eighteen trials. The pooled estimated impact of educational intervention on glycaemic levels using the random effect model was -0.83 (95% CI: -1.17, -0.49, $p < 0.001$). Subgroup analyses revealed greater A1C reductions in those studies with intervention durations of up to three months and with empirical intervention designs. Educational interventions led to significant increases in participants' knowledge of Type 2 diabetes (SMD: 1.16; 95% CI: 0.71, 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 Type 2 diabetes patients.

PROSPERO registration number CRD42020205838.

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2
3 **Keywords:** educational intervention, Type 2 diabetes (T2DM), diabetes knowledge, glycaemic
4 control
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6 7 **Strengths and limitations of this study** 8

- 9
- 10 ➤ This systematic review will provide a comprehensive search of the literature the effect of
11 educational intervention on glycaemic control and knowledge of Type 2 diabetes.
12
 - 13 ➤ An extensive search of multiple databases and search engines (i.e., PubMed, African
14 Journals Online, Web of Science, Scopus, and Google Scholar) were performed to ensure
15 a comprehensive review; nevertheless, potentially relevant articles from other/additional
16 databases may be missed.
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 - 18 ➤ We only used English language articles. although our target was global, which could be
19 in several other languages such as Spanish, French, or Portuguese.
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25 **Background** 26

27
28 Diabetes mellitus (DM) is increasingly becoming an extensive non-communicable health
29 problem, leading to significant morbidity and mortality [1]. Globally, a recent estimate showed
30 that approximately 422 million adults living with DM [2]. According to International Diabetes
31 Federation (IDF) projection approximately 629 million peoples will be affected by 2045 [3]. Of
32 these, approximately 80% of affected individuals live in low-income countries [4]. In particular,
33 Type 2 diabetes (T2DM) is responsible for more than 90% of all diabetes cases [5]. The
34 increasing burden is due to several risk factors such as sedentary behaviors, obesity, unhealthy
35 diet, lack of exercise, family history, and age [6-8].
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38
39 Maintaining optimal glycaemic levels is vital to diabetes control [9]. However, evidence showed
40 that poor glycaemic control ($HbA1c \geq 7\%$) contributes to kidney failure, myocardial infarction,
41 stroke, retinopathy, hypertension, increasing costs for patient care, and reduced quality of life
42 [10-14]. The aims of T2DM management are to attain glycaemic targets, minimize adverse
43 events, and prevent complications [15, 16]. Therefore, lifestyle modifications, such as diet and
44 exercise, have been reported to reduce the complications of uncontrolled glycaemic levels in
45 T2DM patients [17].
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Evidence has revealed that self-management education can reduce the glycaemic level by 30–80% [18]. Besides, diabetes education can improve glycaemic control, changing people's behaviors, promoting self-care, reducing complications, and progression of the disease [19-21]. Moreover, numerous studies suggest that diabetes educational interventions can increase knowledge of diabetes [22, 23], medication compliance [24], decreasing readmissions [25, 26], reducing length of stay and mortality rate [25], and improve glycaemic control [27, 28]. In addition, the American Diabetic 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 4 critical times to provide diabetic 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 unfavorable 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, reduces treatment cost, and decreases 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 with 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 diabetic educational intervention reduce HbA1c levels among T2DM patients?

Methods

Protocol and registration

Initially, PROSPERO was searched to confirm for other reviews on the effect of educational interventions on glycemic 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] with the number (CRD42020205838).

Search strategy and data sources

We did a comprehensive systematic search to collect all relevant articles using the Peer Review of Electronic Search Strategies (PRESS) 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 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 in August 20, 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: are educational intervention (I) in people with T2DM (P), when compared to people who had not taken part in the educational intervention or had standard care (C), associated with improved glycemic control and disease knowledge (O)?.

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]	199,276

#2	Education [tw] OR intervention [tw] OR behavioral intervention[tw] OR self-management [tw]	1,587,693
#3	Glycemic control [tw] OR glycosylated hemoglobin[tw] OR HbA1c[tw]	65,114
#4	Knowledge [tw] OR behavioral outcomes[tw]	851,164
#5	#1 AND #2 AND #3 AND #4	5,428
#6	#5; Limits: studies done with Humans, English language, full text, RCT, and publication year (2000 to 2020)	496

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, diabetic 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 diabetic care settings receiving standard or routine care. Intervention could be provided by any health care 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 durations. 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 health care 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 randomized controlled trials. Full text articles were included, whereas studies published with only abstract or unpublished data were excluded. Of note, nonrandomized controlled trials, quasi-experimental, before and after, cohort,

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3 case-control, and cross-sectional studies were excluded because uncontrolled trials and
4 observational studies lead to greater risk of biased estimates of effect size [41].
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7 **Type of outcome**

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

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17 After database exploration, all recognized studies were uploaded into EndNote version 8, and
18 duplicates articles were removed. Predefined selection criteria were used to select relevant full-
19 text articles during the screening process. Three authors (WSS, PMP & YAA) independently
20 screened the title, abstract, and keywords of the studies identified for possible eligibility in the
21 review. Afterward, all full-text articles were evaluated carefully for inclusion and data extraction.
22 Further screening of full text was done by two (TYA & YAA) independent authors to select the
23 studies which satisfied the eligibility standards. The possible justification for the exclusion of
24 full-text studies was documented and reported in the systematic review. Any uncertainties about
25 study eligibility were discussed between authors.
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34 **Data extraction**

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37 After identifying studies for eligibility, data abstraction was conducted by two (AMK & WSS)
38 independently authors using Microsoft™ Excel for Windows. The first author undertook the data
39 abstraction, whereas the second author assumed control for the quality of extracted and entered
40 data. The data extracted from each study included first/corresponding author, year of publication,
41 study setting, education provider, duration of intervention, intensity of intervention, components
42 of the intervention, number of participants in each arm (intervention and standard care group),
43 intervention design, outcome measures, before and after intervention HBA1c levels, and
44 knowledge scores. The outcome measures in this review were reported as the variation from
45 starting point to closing date of follow-up in the intervention and standard care groups. If the
46 standard deviation (SD) of mean difference was not reported in an included study, the values
47 were recalculated according to the guideline in the Cochrane Handbook [42].
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Assessment of risk of bias in included studies

Two (MD & PMP) independently authors assessed within trial risk of bias in each included study using revised Cochrane risk-of-bias tool for randomized trials (RoB 2)[43]. The Cochrane's Risk of Bias 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 summarize the quality of evidence [45]. The certainty of the evidence encompasses consideration of the within-study risk of bias which comprising 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 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 mean difference (MD) and standardized mean difference (SMD) with a 95% confidence interval (CI), using a random-effects model [46] respectively. Degree heterogeneity was examined with the I^2 statistic, which expresses the amount of heterogeneity between studies [47]. To interpreting the effect sizes, authors followed Cohen's guidelines where $d \leq 0.2$ was small, $d \approx 0.5$ was medium, and $d > 0.8$ was large variation among intervention and control groups [48]. We performed subgroup analyses to reduced 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

heterogeneity and risk of bias. Review Manager of the Cochrane Collaboration (RevMan 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 1,183 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 nonrandomized control 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 2,708 study participants. Of these 9 included articles reported glycemic 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 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 60 [53] to 300 participants [55]. Educational interventions in the review was 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 Model [59], or behavioral theory [64]. However, the remainder of the articles [51-53, 57, 58, 65, 69] used non-theory or model based approaches.

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3 The educational interventions were comprised of face-to-face counseling [54, 55, 63, 68, 69],
4 diabetes education sessions [51, 52, 55, 60, 63, 67], group discussion [56, 58-60, 67], telephone
5 follow-ups [54, 60, 63, 67, 69], home visits [67], demonstrations [53, 54, 59], as well as
6 questions and responses [58, 59] were among the most common approaches. The control groups
7 of all studies were the current standard of care. The duration of educational interventions varied
8 from 4 weeks [54, 58, 59] to 12 months [52, 66]. Interventionl groups obtained the information
9 by different health care professionals such as physicians [54, 55, 66], nurses [52, 56, 58, 67, 69],
10 nutritionists [61, 64], health managers [55], public health assistants [55], and pharmacists [51]. In
11 most included studies, intervention processes were group based education [52, 54-63, 65-67],
12 combined education [53, 68, 69]; however, in the remainder, web-based [64] and individual-
13 based [51] education approaches were used. The main results and features of the selected studies
14 are presented in Table 2.
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Table 2. Characteristics of the included studies

Authors	Country	No of subjects (baseline)	Health education provider	Theory/ model used	Group/ Individual	Intervention	Components of intervention	Duration of intervention	Outcome measures	Outcome indicators
Wichit et al [67]	Thailand	I=70 C=70	Trained Nurse	Self-efficacy	Group	Education classes (3 session), discussions, a home visit, and a telephone follow-up	Program focus on; meal planning, foot hygiene, physical activities, problem solving, diabetes-related complications, enhancing competence, and diabetes knowledge	9 week	at baseline, week 5, and week 13	①② ④⑤ ⑥
Fan et al, [69]	Australia	I=138 C=138	Trained Nurse	Empirical	Mixed	Face-to-face counseling over 1 h, and self-care plan, a 10-min telephone before the appointment, attend a 3-monthly forum about 2 h.	Education emphasizes on such as diet modification, exercise, SMBG, psychological and adherence to medication	6 months	At each follow-up and the end of the 6-month	①
Grillo et al, [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, emphasizing 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 et al, [51]	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-month	At baseline and 6 months	①③ ④⑥
Zheng et al, [53]	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 hypoglycemia treatment, foot care, medication, and blood glucose	3 months	At baseline and 3 months	①③ ⑤

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							monitoring. The practice course focus on one-on-one nutrition guidance and individualized exercise guidance.			
Jiang et al, [54]	China	I=133 C=132	Trained nurses and physicians	Self-efficacy	Group	Structured education program, patients' experience sharing, peer modeling, demonstration, the intervention was given four 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-month	①② ③④ ⑤
Kong et al, [55]	China	I=150 C=150	Physician, health manager, and public health assistant	Chronic Care Model	Group	Pamphlets and face-to-face communication, continuous medical education, education was 9 session every month.	Received the five components CCM (chronic care model)-based intervention, awareness of the chronic disease management, Self-management support included goals setting, planning, doing, checking, and assessing,	9 months	At baseline, & 9 months	①③ ⑥
Braunet al, [57]	Germany	I=83 C=72	Not stated	Empirical	Group	Diabetes teaching and treatment program, seven educational classes of 45 min duration,	Self-monitoring, Diabetes treatment,	6 months	Before (t0), immediately after (t1), and 6 months after (t2)	①④ ⑤
Hermanns et al [56]	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, two 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	①② ③④ ⑤⑥
Didarloo A et al [58]	Iran	I=45 C=45	Trained nurse	Empirical	Group	Interactive approach such as discussion, brainstorming, question and response techniques for 60 min/week for 4 weeks, utilized	Promoting self-efficacy of diabetics, the educator utilized specific training approaches such as verbal persuasion, modeling,	4 weeks	At baseline, and 3 months	①② ③④ ⑥

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						specific training such as verbal persuasion, and modeling	and performance accomplishments. Definition, signs, symptoms, and consequences of T2DM, and diet		after the end of the intervention	
Askari[59]	Iran	I=54 C=54	Researcher	BASNEF Model	Group	Training in eight sessions (two sessions in a week); each session lasted for 70 min, question and answer, exercise, discussion, image, and messages were sent to the patients each week	Presented content was about diabetes, sign & symptoms, diet, food composition tables, partitioning, proper use of fruits, vegetables, and grains as sources of dietary fiber.	4 week	At baseline, and 3 months after the end of the intervention.	①② ③④ ⑤
Ebrahimi et al [61]	Iran	I=53 C=53	Nurse with the endocrinologist, and nutritionist	Empowerment model	Group	Education training, 5–7 weekly regular meetings were held about 60–90 min.	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 et al [62]	Iran	I=43 C=43	Trained professional	Precede-proceed model	Group	The education program with eight 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 program	②③ ④⑤
Azami et al, [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 behaviors, 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-week and 24-week post-randomization	①② ⑤⑥
Tan et al, [63]	Malaysia	I=82 C=82	Not stated	Self-efficacy	Group	Structured education consisted of monthly sessions for 3 months	The first session, healthy eating, being active, medication adherence and	3 months	At baseline,	①② ④

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						about 30 min each session, two were face-to-face individual education sessions and one was a telephone follow-up, Printed educational materials	Self-monitoring of blood glucose. 2 nd and 3 rd session on problem-solving skills related to hyperglycemia, hypoglycemia, sick day, and emotional episodes		and 12 weeks		
9 10 11 12 13 14 15 16 17 18	Ramadas [64]	Malaysia	I=66 C=62	Nutritionist	Behavioral 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 personalized according to the patients' dietary stages of change and were expected to improve their diabetes, knowledge, Attitude, and behavior, the participants also send their queries to the study nutritionist via the website.	6-months	At baseline, 6-month post-intervention and 12-months follow-up	①② ③④
19 20 21 22 23 24	Adolfsson, [66]	Sweden	I=50 C=51	Nurse and physician	Empowerment	Group	Empowerment group education, counseling using videotaping, presentation and discussion, one follow-up session has 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	①② ④⑥
25 26 27 28 29	Hörnsten, [65]	Sweden	I=44 C= 60	Nurse with special education in diabetes care	Empirical	Group	Education and group discussion with ten two hour group sessions over 9 months	Patients' understanding of the illness.	9 months	Before and each year after the intervention	①
30 31 32 33 34 35 36	Jayasuriya et al, [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 six weeks, following monthly (4 weekly) for five more visits.	Physical activity and healthy Dietary intake and more recently in "avoidance behaviors" to reduce unhealthy eating	6 months	At baseline and at 6 months	①② ⑤

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Notes: Outcome indicators: ①metabolic controls, ②self-efficacy, ③behavior, ④knowledge, ⑤other psychological indicators, and ⑥quality of life.

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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] with seven studies were 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, 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 for 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 summarized in Figure 2 and the risk of bias in each study is reported in Figure 3.

Effect of educational intervention on glycemic control

The effects of educational interventions on glycemic (HbA1C) level reduction are presented in Figure 4. The results of the meta-analysis using random-effect model revealed that educational interventions significantly decreased HbA1c levels (MD: -0.83%; 95% CI: -1.17, -0.49; $P < 0.001$, $I^2=88\%$) compared to 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%, -0.44%, $p = 0.001$). The I^2 statistics 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 versus 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 an intervention duration of ≤ 3 months (MD: -1.09, 95% CI: -1.60, -0.57, $p < 0.00$) with a significant evidence of heterogeneity among studies ($I^2 = 88\%$) (Fig. 5). Additionally, the results of the subgroup analysis revealed that interventions with an empirical approach had greater effects in terms of reducing glycemic levels (MD: -1.03, 95% CI: -1.90, -0.15, $p < 0.00$). Because of a significant degree of heterogeneity between studies ($I^2 = 88\%$) random effect 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 ten trials demonstrated an improvement in knowledge of T2DM (SMD: 1.16, 95% CI: 0.7, 1.60, $p < 0.001$; Fig.7) compared to standard care groups. A random-effect model was used because of significant heterogeneity. The Dietary Knowledge Questionnaire [64] and the Diabetes and Medication Knowledge Questionnaire [52, 54, 57, 58, 67] were used to estimate the level knowledge in individuals with T2DM. The number of items was between eight [62] 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 (glycemic 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 was 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 glycemic 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 and the true effect may be substantially different from the estimate of the effect size (Table 3).

Table 3. GRADEpro level of quality evidences assessment**[educational intervention] compared to [usual care] for [Type 2 diabetes patients]**

Patient or population: [patients with Type 2 diabetes]

Setting:

Intervention: [educational interventions]

Comparison: [usual care]

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with [comparison]	Risk with [intervention]				
glycemic control (HbA1c) measured with: difference in mean HbA1c level after intervention Scale from: 1 month to 12 months	-	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.
diabetes knowledge assessed with: diabetes and medication knowledge 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.

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

CI: Confidence interval; MD: Mean difference; SMD: Standardized mean difference

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

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 glycemic levels and change behavioral outcomes [70]. In the current meta-analysis to generate high quality evidence, only clinical trials studies were included.

This review summarises 19 RCT studies of educational interventions involving 2,708 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 glycemic control and diabetes knowledge. The finding revealed that educational interventions reduced HbA1c levels by 0.83% (95% CI: 1.17 %, 0.49%) among T2DM patients. This finding has a substantial degree heterogeneity ($I^2 = 88\%$) indicating variation between included studies. However, there was a slight reduction of mean difference after sensitivity analysis, 0.70% (95% CI: 0.96 %, 0.44%), with a moderate degree of heterogeneity ($I^2=73\%$). Our findings are supported by previous meta-analyses, which reported that behavioral and self-management education have a significant benefit in the reduction of HbA1c levels in patients with diabetes [28, 37, 38].

The improvement in glycemic levels is considered to be clinically essential. The UK Diabetes Study revealed that with each 1% reduction in HbA1c there is a likelihood to reduce the risk of diabetes complications by 21% [71]. Similarly, a previous study showed that achieving optimal glycemic level is likely to reduce the risk of deaths from diabetes complications, such as cardiovascular and cerebrovascular problems [72]. Moreover, the American Diabetes Association recognizes that diabetes self-management has a vital role to improve glycemic levels and reduce diabetes related complications [73].

In the current meta-analysis, 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 to the reduction of HbA1c levels. In this meta-analysis, the pooled effect size for short educational interventions (duration \leq 3-month) was better than the

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3 effect size of longer interventions (duration 3-6 month and >6-month) -1.09 (95% CI; $-1.60, -$
4 0.57 , $P < 0.001$). One possible explanation maybe associated with the initial motivation of the
5 participant to be empowered to obtain positive results in a short period [74]. In contrast, previous
6 studies reported that longer durations of interventions were more likely related with a significant
7 reduction in HbA1c levels [28, 75, 76]. Similarly, a meta-analysis study showed that more
8 contact hours were associated with a reduction of HbA1c level [33]. Moreover, evidence also
9 supported that the duration of contact hours between trainer and patient has a substantial impact
10 on glycated hemoglobin levels [18]. The current findings reflects that the duration of intervention
11 would influence the effectiveness of the educational intervention among T2DM patients.
12 Therefore, this disparity should be considered when developing future education interventions.
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21 In the present review subgroup analysis was conducted based on interventions design (theory-
22 based versus empirical educational). Our study indicated that educational interventions benefited
23 all patients regardless of the intervention design. In the current findings, empirical educational
24 intervention showed improvement in glycemic control level -1.03 (95% CI; $-1.90, -0.15$, $P <$
25 0.001). Similarly, evidence showed that interactive self-management interventions through
26 evidence-based approaches and structured curricula is crucial to improve glycemic control and
27 behavioral outcomes [77]. However, another review indicates that, in patients with T2DM,
28 theory-based self-management educational interventions improved HbA1c [36]. Although one-
29 third of the included studies used an empirical approach in designing interventions, and favorable
30 results on glycemic control were obtained, their specific role in educational interventions has
31 been debated.
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41 In this review, diabetes knowledge showed significantly a higher standardized mean score of
42 correct knowledge of diabetes among the intervention group as compared to the standard care
43 group (SMD = 1.16 ; 95%CI: $0.71, 1.60$, $p < 0.001$). Similarly, educational interventions were
44 associated with significant improvements in knowledge of diabetes being reported in the
45 previous meta-analyses [78, 79]. Moreover, there is evidence that education improves knowledge
46 and subsequently promotes behavioral changes among patients with end-stage renal disease [80].
47 Though significant changes were observed in diabetes knowledge, this finding should be
48 interpreted with caution due to the significant degree of heterogeneity among included studies.
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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 randomized 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 Diabetic self management education and support (DSMES) contributes to improving glycemic outcomes and diabetes knowledge. Therefore, clinician could make an effort to provide such care to ensure glycemic 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 glycemic 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 glycemic control and diabetes knowledge among T2DM patients. However, before making a practice decision based on the current review, further information from other reviews considering how the role of educational intervention reduced glycemic 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 T2DM patients.

Implications for research

Further research is likely to change the estimated effect size of educational interventions in glycemic control and knowledge of T2DM patients. Knowledge of diabetes was assessed using different tools, outcome data was measured in heterogeneous ways. Based on this review, future

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3 studies of educational intervention would increase our certainty of evidence either these
4 interventions improve knowledge of diabetes or not by overcome limitations of existing studies.
5 Therefore, future educational interventions studies should be designed to evaluate individual
6 centered outcomes and that are becoming new priorities to support in clinical decision-making.
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10 **List of abbreviations**

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13 GRADE: Grading of Recommendations Assessment, Development, and Evaluation; HbA1c:
14 glycosylated hemoglobin level; IDF: International Diabetes Federation; PRESS: Peer Review of
15 Electronic Search Strategies; PRISMA: Preferred Reporting Items for Systematic Review and
16 Meta-Analysis statement; T2DM: Type 2 diabetes mellitus; WHO: World Health Organization.
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21 **Declaration**

22 **Ethics approval and consent to participate**

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24 Not applicable.
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28 **Consent for publication**

29
30 Not applicable.
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33 **Availability of data and materials**

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35 All relevant data are within the paper and supporting information files. There is no separate data
36 set to share.
37
38

39 **Competing interests**

40
41 The authors declare that they have no competing interests.
42
43

44 **Funding**

45
46 Not applicable.
47
48

49 **Authors' contributions**

50
51 WSS, YAA, and TYA developed the protocol and were involved in the design, selection of
52 study, data extraction, statistical analysis, and developing the initial drafts of the manuscript.
53
54 AMK, WSS, PMP, and MD were involved in data extraction, quality assessment, statistical
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57

analysis, and revising. WSS and YAA prepared and edited the final draft of the manuscript. All authors read and approved the final draft of the manuscript.

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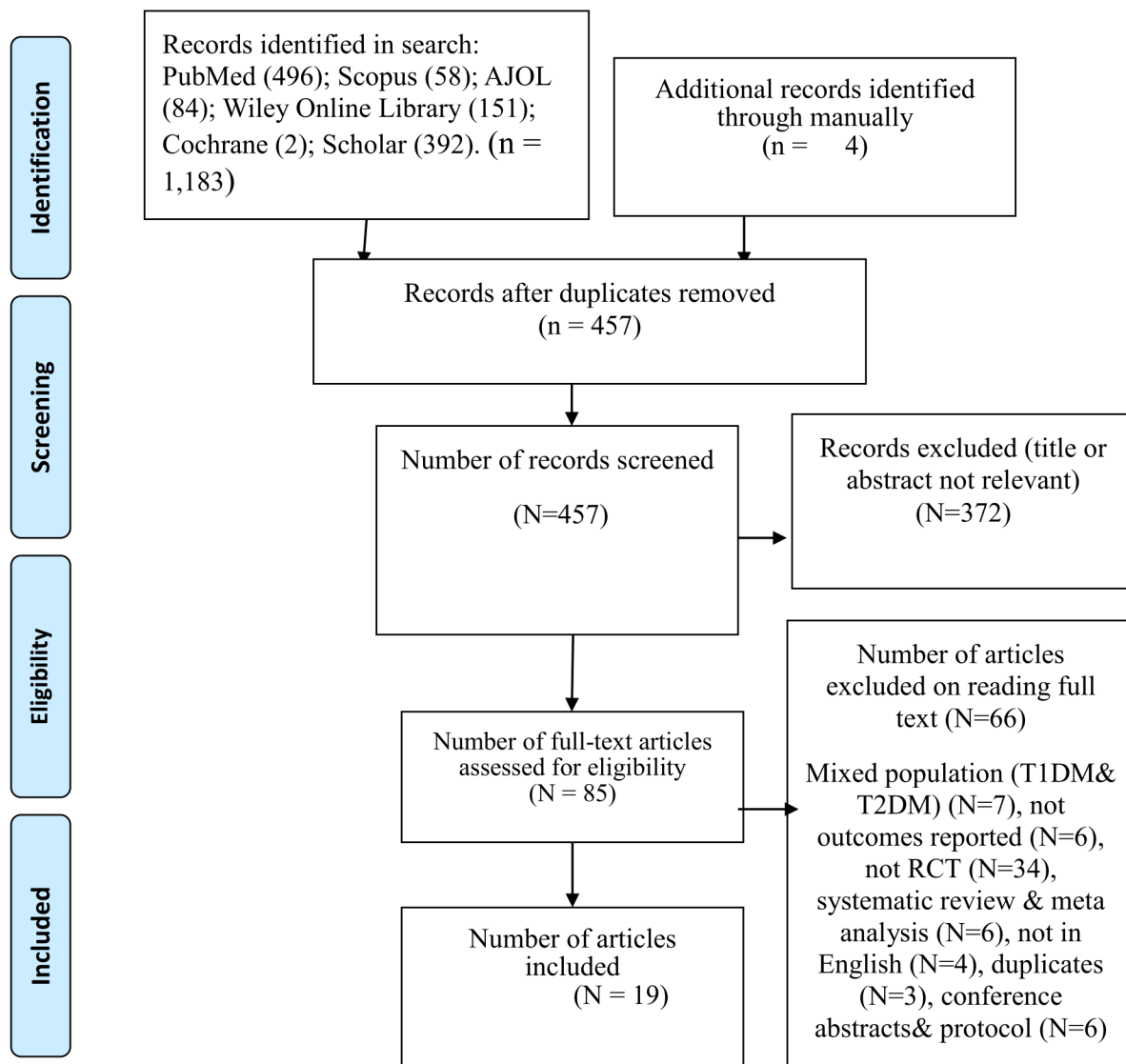


Figure 1. PRISMA flow chart for selection of studies

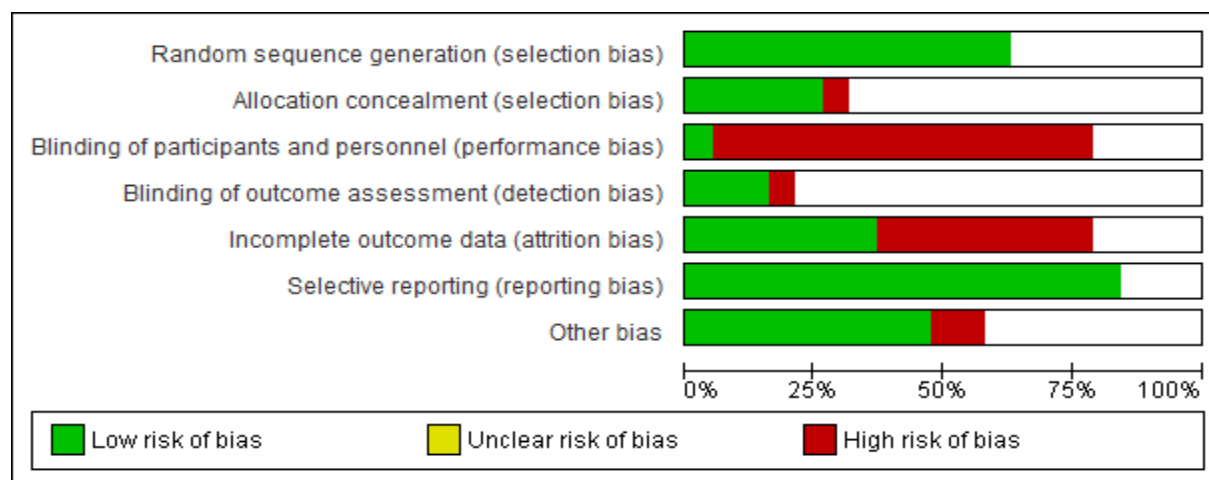


Figure 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

	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 authors' judgments about each risk of bias item for each included study.

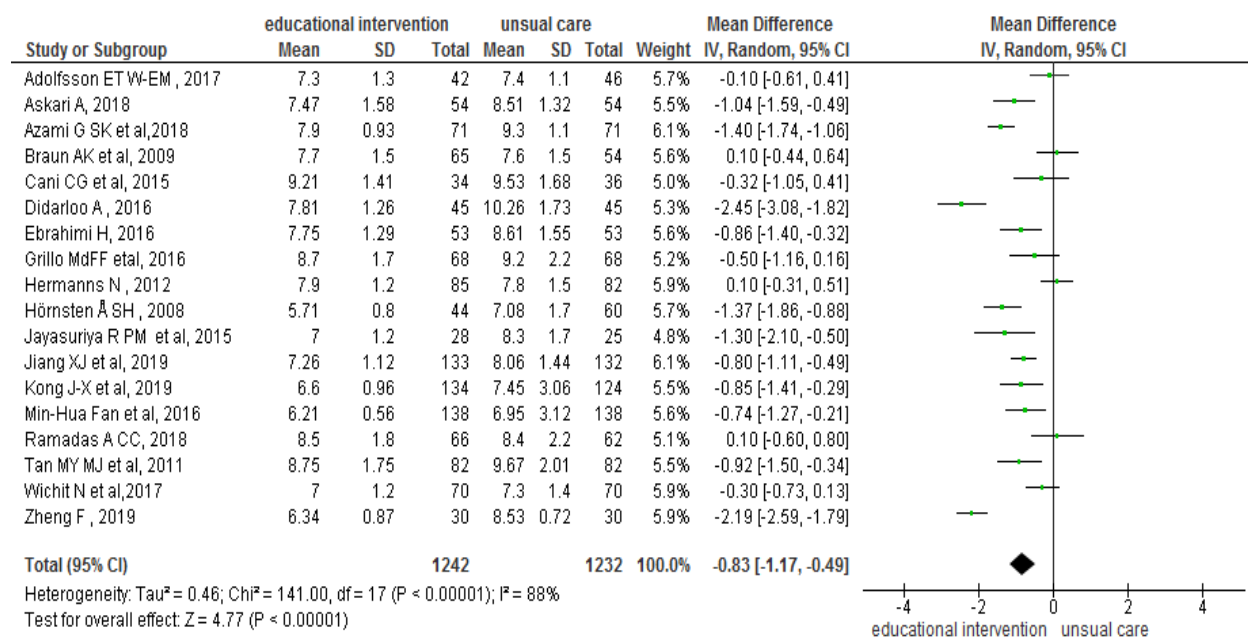


Figure 4. The pooled effect of education interventions on HbA1c levels in patients with T2DM

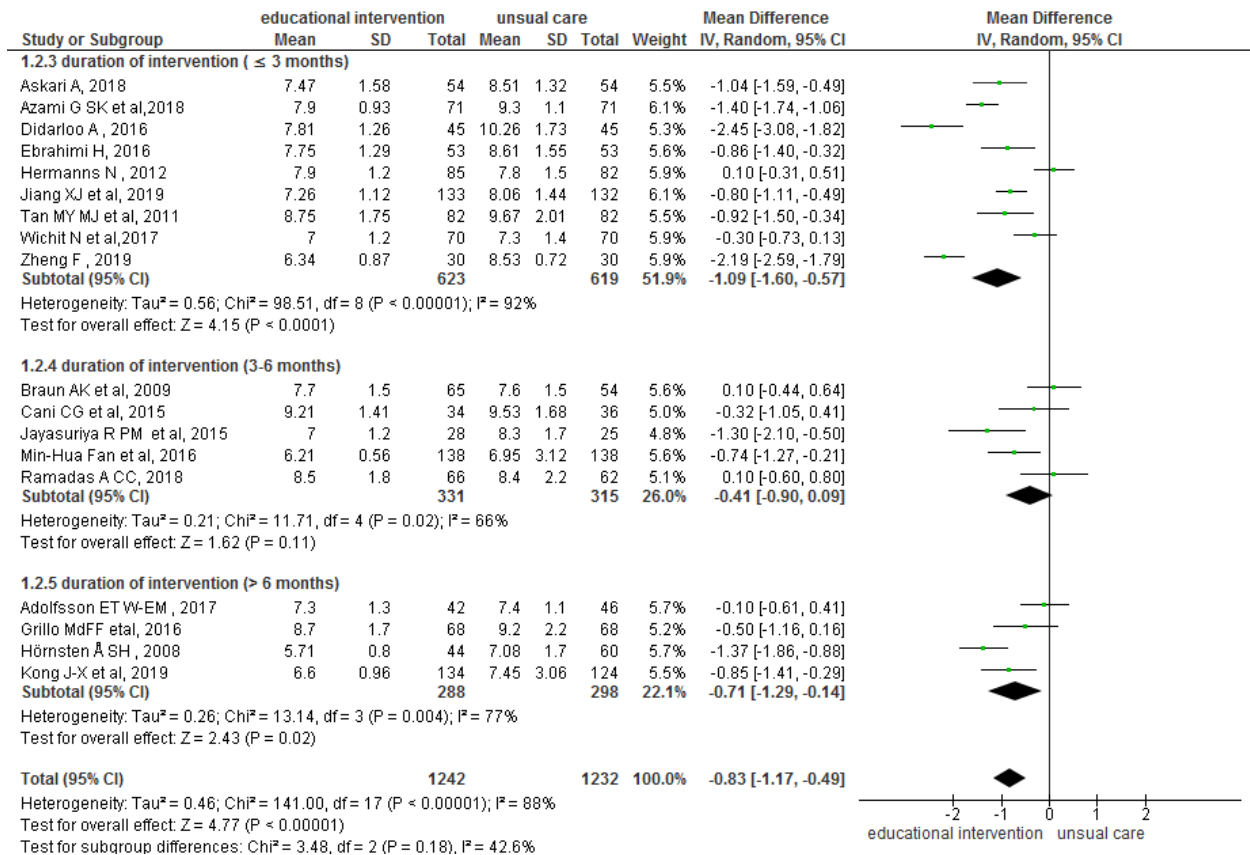


Figure 5. Subgroup analysis based on the duration of the intervention

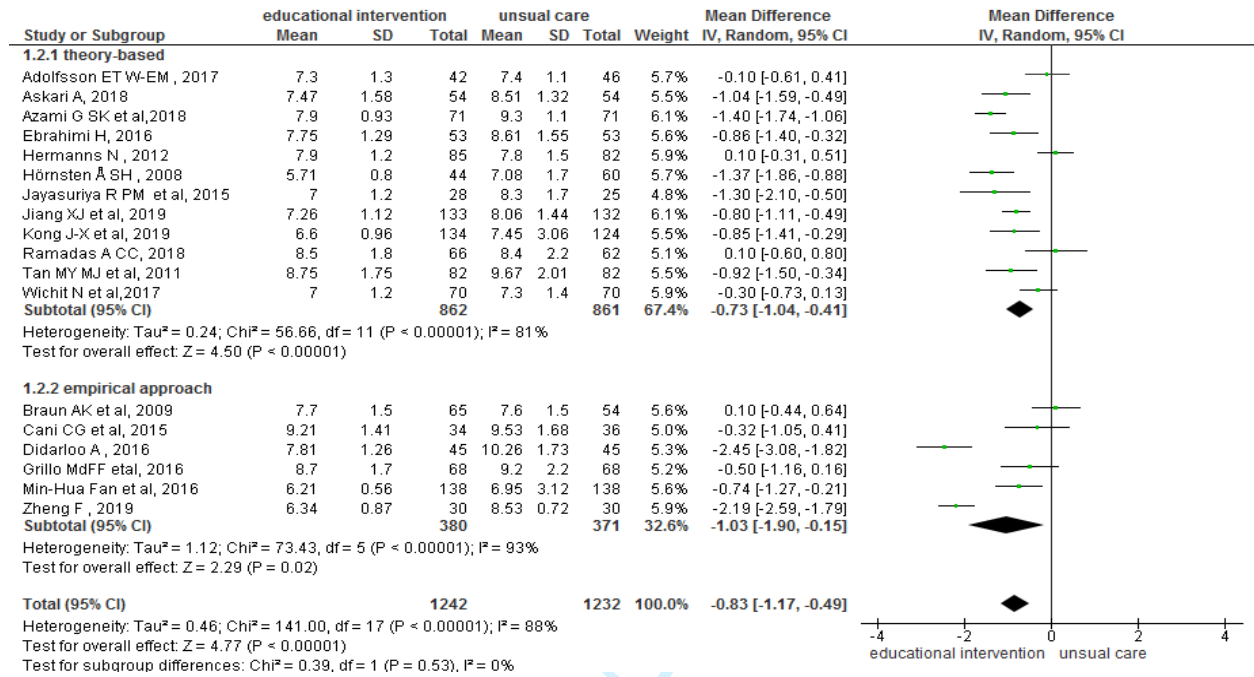


Figure 6. Subgroup analysis based on intervention design

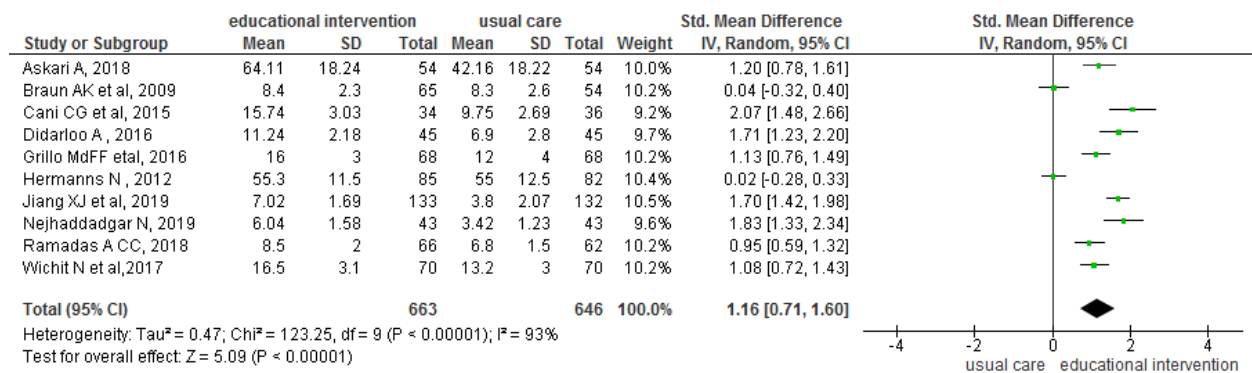


Figure 7. The pooled effect of education interventions on disease knowledge in patients with Type 2 Diabetes.

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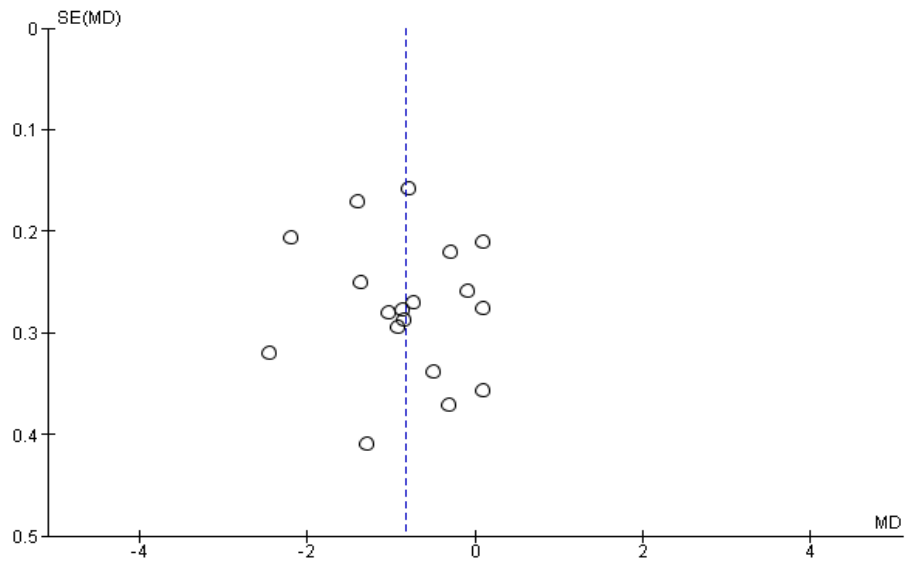


Figure 8. Funnel plot for HbA1c results.

review only



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	CRD42020205838
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis	8



PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	14
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	14
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	14-15
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	15
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	14-15
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	18-19
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	20
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	NA

PRISMA checklist the paper entitled the effect of educational interventions on knowledge and glycemic control in patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials



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