

# The comparison of self-management group education and the standard care for patients with type 2 diabetes mellitus: An updated systematic review and meta-analysis

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## ABSTRACT

To investigate the efficacy of self-management group education versus the standard care for patients with type 2 diabetes mellitus (DM). An electronic search was performed in nine databases including PubMed for selecting eligible studies. Meta-analysis was used for pooling of the results. Of 3446 records screened, we included ten studies for this systematic review and meta-analysis. Regarding assessment of effectiveness, there was a significant superiority reported in the intervention group when compared to the usual/standard care (standardized mean difference [95% confidence interval] = 0.24 [0.15; 0.32]). The intervention group had a significant reduction in the levels of hemoglobin A1C (HbA1C), fasting blood glucose, low-density lipoprotein, total cholesterol, and body mass index compared to the usual/standard care ( $p < 0.05$ ). Moreover, no significant difference was observed in the levels of high-density lipoprotein, systolic blood pressure (SBP), or diastolic blood pressure (DBP) between the two groups ( $p > 0.05$ ). Self-management group education interventions are recommended in patients with type 2 DM for their effectiveness in different clinical aspects.

**Keywords:** DM, education, self-management

## Introduction

Diabetes mellitus (DM) is considered as a global health issue in the clinical society. The most common types of DM are DM type 1 (which is driven by auto-immunity against  $\beta$  cells of the

pancreas) and DM type 2 (which is multi-factorial in origin).<sup>[1]</sup> It is estimated that 8.3% of global populations are affected with DM type 2 in 2013 with an expected dramatic rise in its prevalence to affect 10% globally in 2035; the highest prevalence was reported in middle and low-income countries.<sup>[2]</sup> Diagnosis of diabetes usually occurs after several years of affection, which hardens its management. The International Diabetes Federation (IDF) demonstrated that approximately half of the diabetic patients are undiagnosed.<sup>[1]</sup>

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DM type 2 patients are commonly associated with several complications such as cardiovascular, renal, and retinal diseases and mortality in severe stages of the disease.<sup>[3-5]</sup> Knowledge of DM among healthy individuals is essential for the prevention and controlling of risk factors and among patients for better disease control and prevention of developing of the hazards of DM.<sup>[6]</sup> Diabetes self-management education (DSME) constitutes an important strategy for better improvement in patients' behavior against diabetes.<sup>[7]</sup> Group-based self-education, computer-based programs, and telephone messages were identified as the common sources for DSME.<sup>[8-10]</sup>

It is well known that diabetes is associated with frequent hospital admission because of its complications; DSME decreases the rates of hospital admission and thereby decreases the health care cost.<sup>[11,12]</sup> Moreover, the application of DSME resulted in a significant decrease in hemoglobin A1C (HbA1C) and fasting blood glucose (FBG) level and a significant increase in high-density lipoprotein (HDL) compared to controls.<sup>[13]</sup> To our knowledge, physical inactivity is a major risk factor for developing cardiovascular disorders; DSME plays a significant role in increasing the physical activity among diabetic patients.<sup>[14,15]</sup> Furthermore, group education in addition to usual care indicated a significant improvement in the quality of life among DM patients.<sup>[16]</sup> Additionally, DSME was associated with an improvement in the psychological life of diabetic patients.<sup>[17]</sup> Al Hayek *et al.*<sup>[17]</sup> indicated a significant decrease in depression levels among diabetic patients. Moreover, there was a significant increase in the levels of medication adherence after the application of DSME for a duration of 6 months. In this meta-analysis, we aim to compare the effectiveness of self-management group education and the usual/standard diabetic.

## Methods

### Search strategy and study selection

The study process was conducted following the accepted methodology recommendations of the PRISMA checklist for systematic review and meta-analysis where registration of the protocol is not mandated.<sup>[18]</sup> A systematic electronic database search was conducted for relevant studies published after 2010 and till 25 December 2019 in nine databases including Google Scholar, System for Information on Grey Literature in Europe (SIGLE), Scopus, Web of Science (ISI), PubMed, Virtual Health Library (VHL), Clinical trials.gov, metaRegister of Controlled Trials (mRCT), and The WHO International Clinical Trials Registry Platform (ICTRP) databases using keywords, medical subject (MeSH) terms, and publication types based on the PICO framework (participants, comparison, intervention, and outcomes). Participants were any patients with type 2 diabetes; the intervention was the self-management group education, the comparison was usual/standard care, and all possible outcomes were included. "Usual/standard care" could consist of usual primary care assignment to a wait list or no intervention, whereas any studies considering another educational intervention (even minimal) as a comparison group

have been excluded. "Effectiveness" was defined as the positive change (whether an increase or decrease) from baseline values to the last follow-up point. In the case of multiple outcomes, effectiveness is measured by the change in the outcome that has been reported to be the main outcome of the study or most relevant to the diabetic control (to maintain homogeneity).

We further did a manual search of references in our included papers to avoid missing any relevant studies.<sup>[19]</sup> Included study designs were randomized-controlled trials or quasi-experimental studies with a matched control group comparing self-management group education interventions (in type 2 diabetics) to usual care. The inclusion of quasi-experimental study designs was consistent with the Cochrane Consumers and Communication Review Group standards for the evaluation of complex interventions.<sup>[20,21]</sup> There were no restrictions on the country, language, or publication date.

Papers were excluded if there were one of the following exclusion criteria: i) individual self-management education; ii) *in vitro* or animal studies; iii) data duplication, overlapping, or unreliably extracted or incomplete data; iv) abstract only articles, reviews, thesis, books, conference papers, or articles without available full texts (conferences, editorials, author response, letters, and comments). The title and abstract screening was performed by four independent reviewers. Furthermore, three independent reviewers performed full-text screening to ensure the inclusion of relevant papers in our systematic review. Any disagreement was done by discussion and consulting the senior member when necessary.

### Data extraction

Two authors developed the data extraction using a Microsoft Excel file. Data extraction was done by three independent reviewers using the Excel sheet. The fourth independent reviewer performed data checking to ensure the accuracy of data extraction. All the disagreements and discrepancies were resolved by discussion and consultation with a senior member when necessary.

### Quality assessment

Three independent reviewers evaluated the risk of bias in included studies. The National Institutes of Health (NIH) quality assessment tool was used to assess the quality of observational studies.<sup>[22]</sup> Quality assessment of each study was obtained through a scoring system including 14 questions. The criterion was judged as follows: a score of 13 to 14 was good, a score of 9 to 12 was fair, and studies scoring below 9 are considered of poor quality for cohort studies.<sup>[23]</sup> Furthermore, the Cochrane quality assessment tool was used to determine the quality of randomized studies.<sup>[24]</sup> Any discrepancy between the reviewers was solved by discussion.

### Statistical analysis

All data were analyzed using R software version 3.6.1.<sup>[25]</sup> Using a "meta" package, changes from the baseline for

both intervention and control were analyzed to compute the standardized mean difference (SMD) and the corresponding standard errors (SEs).<sup>[26]</sup> For easier interpretation (of the heterogeneous data presentation in the studies), the results were standardized to be in a positive direction, and it was detailed in the results whether it is a reduction or an increase. The SMD was used because of the difference in measurement methodology among included studies plus it is more generalizable than mean difference.<sup>[27]</sup> The corresponding 95% confidence intervals (CI) of pooled effect size were calculated using a fixed-effects or random-effects model depending on the presence of heterogeneity. Heterogeneity was assessed with Q statistics and I<sup>2</sup> test considering it significant with I<sup>2</sup> value >50% or P value < 0.05.<sup>[28]</sup> The publication bias was assessed using Egger's regression test<sup>[29,30]</sup> and represented graphically by Begg's funnel plot<sup>[31]</sup> when there were ten or more studies. Egger's regression test P value < 0.10 was considered significant. Whenever publication bias was found, the trim and fill method of Duvall and Tweedie was applied to add studies that appeared to be missing<sup>[32]</sup> to enhance the symmetry. In the case of statistically significant results, a leave-one-out sensitivity analysis was performed by iteratively removing one study at a time to confirm that our findings were not driven by any single study.<sup>[33]</sup>

## Results

### Study characteristics

Our search identified 3446 after excluding of 1435 duplicated by endnote software version X9. Title and abstract screening was performed and resulted in the inclusion of 115 reports for further full-text screening. Eight studies were included after the exclusion of 107 reports. An additional two papers were found after performing a manual search. Finally, we included ten studies for this systematic review and meta-analysis<sup>[13,34-42]</sup> [Figure 1].

There were eight randomized controlled trials (RCTs) and two prospective cohorts [Table 1]. The total sample size was 2346. The follow-up duration was reported in nine studies. The follow-up duration was 12 months in three studies, 6 months in two studies, 3 months in one study, 9 months in one study, 24 months in one study, and 30 months in one study. Regarding the risk of bias, five RCTs were identified as high risk of bias, two as the moderate risk of bias, and one as low risk of bias; meanwhile, the two cohorts were of fair quality.

### Assessment of effectiveness

Ten studies assessed the effectiveness in both intervention and usual/standard care groups with a total of 2346 patients. There was

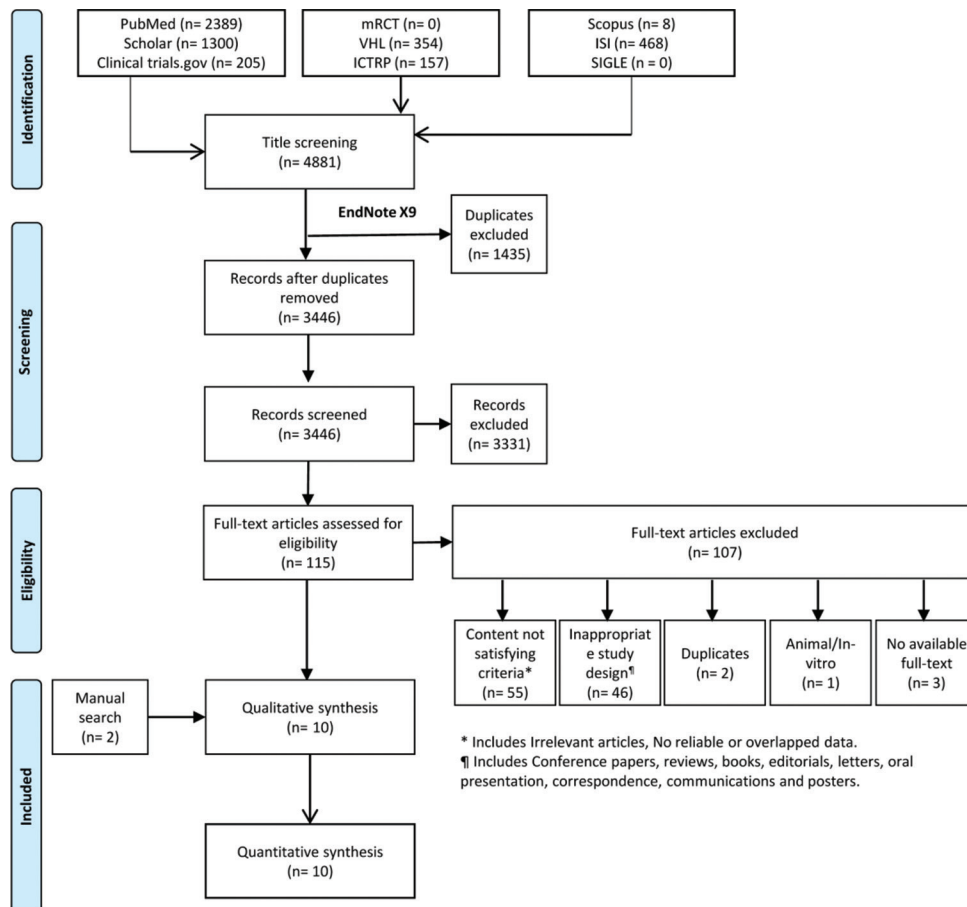
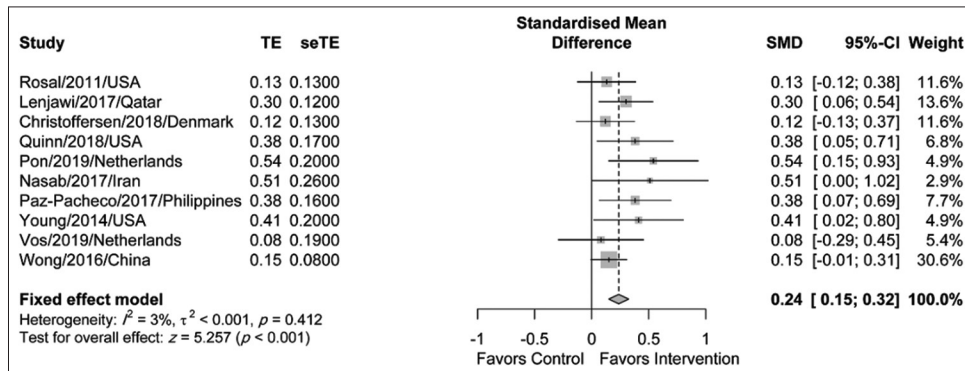


Figure 1: PRISMA flow diagram showing the process of the review

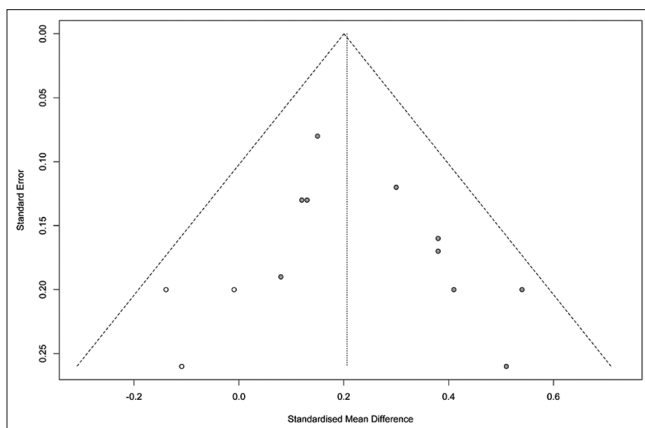
**Table 1: Study characteristic table**

Reference ID	Study design	Compared groups	Sample size	Age in months (mean (SD))	Male (event)	Follow-up duration	QA
Rosal/2011/USA	RCT	I	124	18-25 <sup>#</sup>	27	12 months	Moderate risk
		C	128		32		
Lenjawi/2017/Qatar	RCT	I	215	52 (8.9)	NR	12 months	Low risk of bias
		C	215	55 (9.7)	NR		
Christoffersen/2018/Denmark	PC	I	234	62.3 (10.4)	109	12 months	Fair
		C	76	63.1 (11.6)	38		
Quinn/2018/USA	RCT	I	82	53.5 (7.5)	43	NR	High risk of bias
		C	25	49.6 (8.9)	10		
Pon/2019/Netherlands	RCT	I	56	50->80 <sup>#</sup>	38	6 months	Low risk of bias
		C	52		34		
Nasab/2017/Iran	RCT	I	30	NR	16	3 months	High risk of bias
		C	30	NR	13		
Paz-Pacheco/2017/Philippines	RCT	I	85	57.6 (11.5)	25	6 months	High risk of bias
		C	70	56.5 (11.7)	21		
Young/2014/USA	RCT	I	51	>35->70 <sup>#</sup>	29	9 months	High risk of bias
		C	50		31		
Vos/2019/Netherlands	RCT	I	56	62.9 (8.3)	27	30 months	High risk of bias
		C	52	61.7 (7.4)	33		
Wong/2016/China	PC	I	390	62.9 (9.13)	177	24 months	Fair
		C	325	68.54 (10.1)	123		

<sup>#</sup>Range, NR=not reported, I=intervention, C=control, RCT=randomized controlled trial, PC=cohort study



**Figure 2:** Forest plot of effectiveness comparison in intervention and usual/standard care groups. TE: standardized mean difference; seTE: standard error of the standardized mean difference



**Figure 3:** Funnel plot with the trim and fill method for the effectiveness outcome (three studies are added on the left side)

a significant ( $P < 0.001$ ) superiority reported in the intervention group when compared to the usual/standard care (SMD [95% CI] =

0.24 [0.15; 0.32]). Moreover, there was no significant heterogeneity across the included studies with  $I^2 = 3\%$  and  $P = 0.412$  [Figure 2]. Furthermore, the leave-one-out sensitivity analysis did not affect the significance or the direction of the results, indicating that they were not driven by any single study [Supplementary Figure 1].

Nevertheless, there was a significant ( $P = 0.0366$ ) risk of bias using Egger's regression test. On adjusting the results for risk of bias, using the trim and fill method, three missing studies were added and the adjusted SMD was 0.21 with a 95% CI of 0.11–0.30 [Figure 3]. Noteworthy, the significance was not affected after adjustment ( $P < 0.001$ ), and the superiority of the intervention group was maintained.

### HbA1c and fasting blood glucose

Five studies have assessed the change in HbA1c in both groups. The intervention group was significantly ( $P < 0.001$ ) better than



the usual/standard care group (SMD [95% CI] = 0.25 [0.13; 0.38]). Moreover, there was no significant heterogeneity across the included studies with  $I^2 = 0\%$  and  $P = 0.551$  [Figure 4a]. However, the leave-one-out sensitivity analysis has eliminated the significance with the removal of any of the included studies, indicating that the results may have been driven by any single study [Supplementary Figure 2].

In the same context, four studies have evaluated the change in FBG. The overall results have showed a significant ( $P = 0.002$ ) benefit of the intervention in FBG reduction in comparison to the usual/standard care group (SMD [95% CI] = 0.27 [0.10; 0.43]) [Figure 4b]. Additionally, no significant heterogeneity was detected with  $I^2 = 0\%$  and  $P = 0.433$ . The leave-one-out sensitivity analysis did not affect the significance or the direction of the results, indicating that they were not driven by any single study [Supplementary Figure 3].

### Serum lipid profile

There was a significant ( $P = 0.020$ ) reduction in the low-density lipoprotein (LDL) levels in the intervention group when compared to the usual/standard care group (SMD [95% CI] = 0.20 [0.03; 0.37]). In the same context, total cholesterol (TC) levels have also shown more reduction in the intervention group (SMD [95%CI] = 0.16 [0.00; 0.32];  $P = 0.046$ ) [Figure 5]. In both outcomes (LDL and TC), the leave-one-out sensitivity analysis has eliminated the significance with the removal of any of the included studies, indicating that the results may have been driven by any single study.

In contrast, there was no significant difference between the intervention and the usual/standard care groups in aspects of high-density lipoproteins (HDL) (SMD [95% CI] = 0.22 [-0.10; 0.53];  $P = 0.176$ ) and triglyceride (TG) levels (SMD [95%CI] = 0.16 [-0.01; 0.33];  $P = 0.058$ ). For all outcomes, there was no significant heterogeneity among included studies ( $I^2 = 0\%$  and  $P > 0.1$ ).

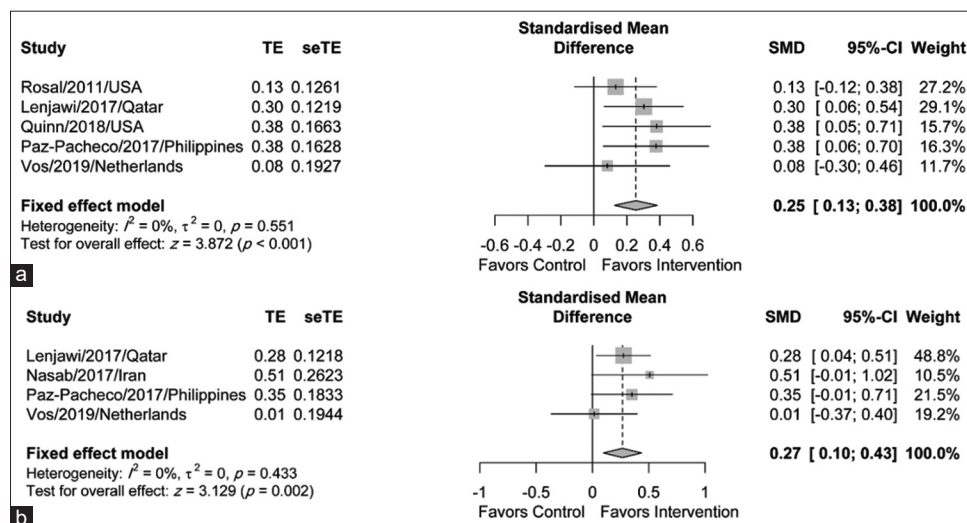
### Body mass index (BMI) and blood pressure (BP)

Four studies have assessed changes in BMI in the intervention and the usual/standard care groups. There was a statistically significant ( $P = 0.004$ ) reduction in the BMI in the intervention group compared to the usual/standard care one SMD [95% CI] = 0.25 [0.08; 0.41]). Moreover, there was no significant heterogeneity across the included studies with  $I^2 = 0\%$  and  $P = 0.385$  [Figure 6]. However, the leave-one-out sensitivity analysis has eliminated the significance with the removal of Paz-Pacheco *et al.*[39], indicating that the results may have been driven by this study [Supplementary Figure 4].

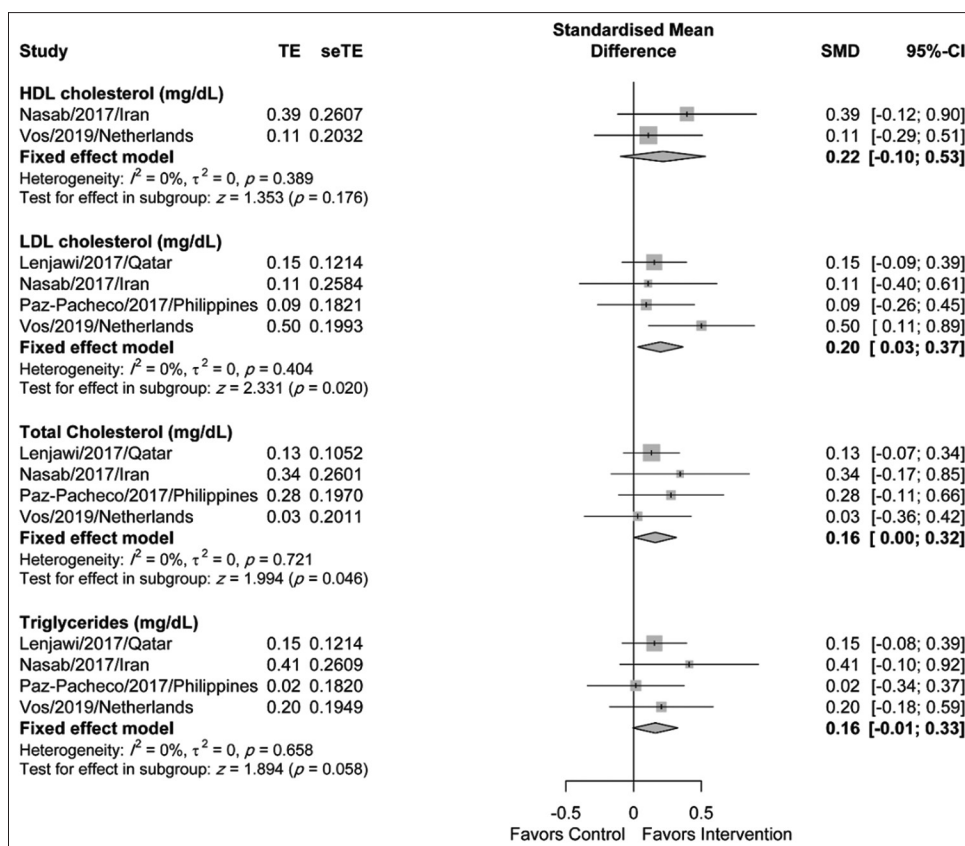
For BP, three studies have assisted both DBP and SBP changes. There was no significant difference between the intervention and the usual/standard care groups in either the DBP (SMD [95%CI] = 0.09 [-0.09; 0.27];  $P = 0.335$ ) or the SBP (SMD [95%CI] = 0.15 [-0.02; 0.31];  $P = 0.085$ ). There was no significant heterogeneity among the included studies for both DBP ( $I^2 = 0\%$  and  $P = 0.972$ ) and SBP ( $I^2 = 0\%$  and  $P = 0.399$ ) [Figure 7].

### Discussion

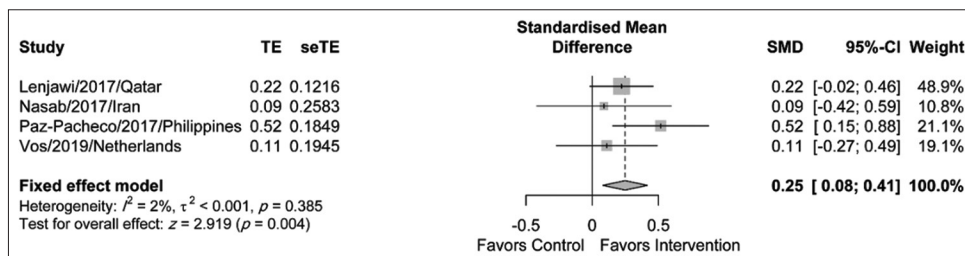
In general, the current results support the use of group-based, self-management educational interventions, which have shown significant consistent effectiveness when compared to the usual/standard care. This is consistent with the previous studies which have shown a cost-effective benefit of the diabetes self-management education intervention.<sup>[43,44]</sup> They were associated with a reduction in the hospitals' admission and re-admission rates, health care costs, and risk of developing diabetic complications.<sup>[11,43,44]</sup> By 2050, one in three individuals in the United States would develop type 2 diabetes with the associated burden of costs; hence, the importance of the aforementioned interventions, in reducing costs, would emerge.<sup>[43-45]</sup>



**Figure 4:** (a) Forest plot of HbA1c change comparison in intervention and usual/standard care groups; (b) forest plot of FBG reduction in intervention and usual/standard care groups. TE: standardized mean difference; seTE: standard error of the standardized mean difference



**Figure 5:** Forest plot of changes in the serum lipid profile in intervention and usual/standard care groups. TE: standardized mean difference; seTE: standard error of the standardized mean difference

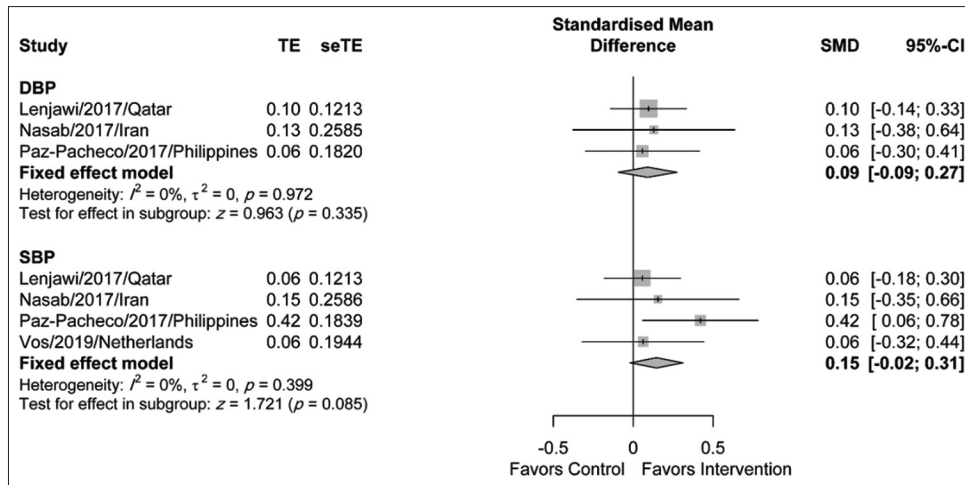


**Figure 6:** Forest plot of changes in the BMI in intervention and usual/standard care groups. TE: standardized mean difference; seTE: standard error of the standardized mean difference

In terms of diabetic control, our results showed a significant improvement in fasting blood glucose levels among the intervention group, which seems to be a long-term one since the HbA1C levels showed a significant drop as well. This is supported by evidence in many other studies where glycemic control was much better with the self-management groups.<sup>[46-50]</sup> A reduction of 1% in HbA1c levels was noted in type 2 diabetics using such interventions.<sup>[8,51-55]</sup> The previously conducted meta-analysis assessing the effectiveness of different types of self-management have come to the same conclusion.<sup>[56-58]</sup> In contrast, a recent meta-analysis has found no significant effect of the self-management interventions on HbA1c in African-Americans.<sup>[21]</sup> This conflict may be explained by the short-term effects that can be eliminated with longer follow-ups.<sup>[49,55,59]</sup> This can also be evident in our results where the

significance eliminated on applying the leave-one-out sensitivity analysis the HbA1c outcome (long-term) but maintained the FBG outcome (short term).

An adjuvant improvement in the serum lipid profile was observed in terms of LDL and TC levels, whereas HDL and TG levels were not affected significantly. Moreover, the body weight showed a significant reduction in the intervention group with a drop in the BMI with no significant effect on BP.<sup>[55]</sup> This was consistent with many of the previously published literature studies, except for the BP, where a few studies have shown a small effect on BP.<sup>[48,60-62]</sup> Moreover, diabetic self-management interventions have shown a positive effect on the quality of life,<sup>[8,16,56,63-65]</sup> adopting more healthful eating patterns, regular physical activity,<sup>[66]</sup> reduction in the diabetes-related distress,<sup>[54,67]</sup>



**Figure 7:** Forest plot of changes in BP in intervention and usual/standard care groups. TE: standardized mean difference; seTE: standard error of the standardized mean difference

and healthier coping with reduced depression.<sup>[68-70]</sup> All of these improvements would explain the positive impact on the serum lipid profile, body weight, and to some extent BP. Any conflict between the results of different studies may be explained with the time spent with the diabetic educator and the last point of follow-up, where better outcomes have been observed with spending more time.<sup>[43,55,56,71]</sup>

The current study has many strengths with the absence of heterogeneity among the included studies, making the results more reliable. Moreover, the standardization of treatment effects and excluding studies with minimal intervention as a control group have increased the reliability and the homogeneity of the results. The effectiveness outcome has shown a risk of bias; nevertheless, the adjustment of the results did not change the significance. In contrast, there are some other limitations that can raise concern. Although most of the studies are randomized controlled studies, the quality of the included studies is questionable. Despite the standardization of the treatment effects, the methodology of the included studies is heterogeneous and the follow-up durations are different. Large studies with good quality and a long follow-up duration are suggested for better generalizability and validity.

### Conclusion

We recommend the usage of self-management education for patients with type 2 DM because of its effectiveness in the diabetic control of the patients along with other health benefits.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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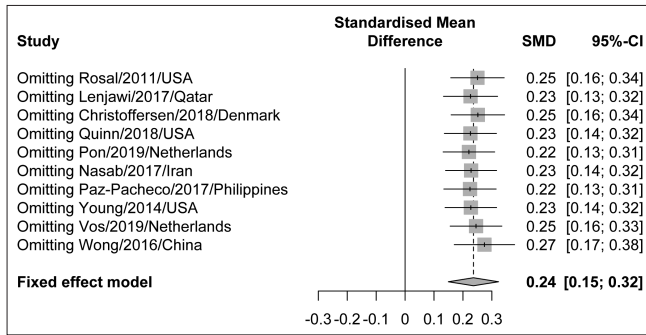
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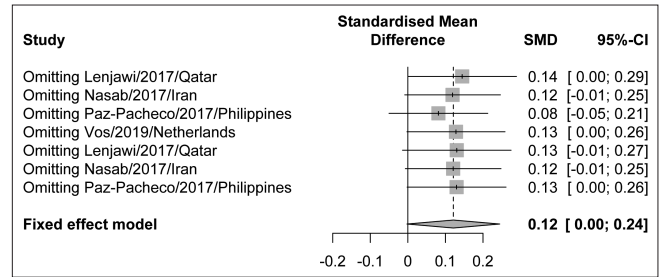


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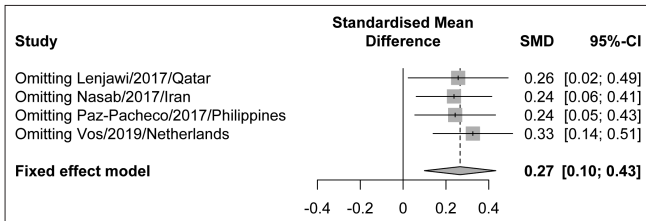
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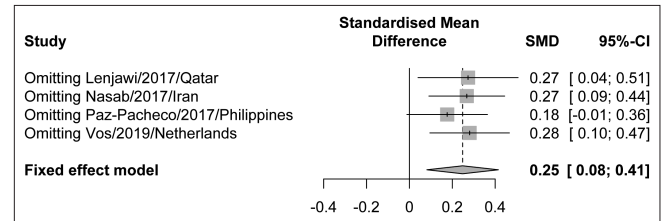
**Supplementary Figure 1:** Leave-one-out sensitivity analysis for the effectiveness outcome



**Supplementary Figure 2:** Leave-one-out sensitivity analysis for the HbA1c change



**Supplementary Figure 3:** Leave-one-out sensitivity analysis for the FBG change



**Supplementary Figure 4:** Leave-one-out sensitivity analysis for the BMI change