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REVIEW ARTICLE

The effect of family involvement in diabetes self-management education on glycemic control in patients with type 2 diabetes mellitus: a systematic review and meta-analysis

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ABSTRACT

Diabetes self-management education (DSME) is an essential part of diabetes care. It is possible to deliver DSME in many forms and components. In this case, family support is known to be a critical component of social support in self-care and glycemic control. This study aimed to systematically review the effectiveness of family involvement in diabetes self-management education for glycemic control in patients with type 2 diabetes mellitus. The researchers searched PubMed, SpringerLink, Science Direct, Google Scholar, and EBSCO for English and Indonesian articles published between 2000 and 2020 describing randomized controlled trials involving family components. The primary outcome of this review was HbA1c changes. The pooled standard mean differences (SMD) or effect size between intervention and control groups with 95% confidence interval (CI) were calculated using a random-effects model. Meanwhile, heterogeneity of HbA1c findings was assessed with Cochran's Q and I2. Seventeen randomized controlled trials with a total of 2644 participants were obtained from a comprehensive search procedure. The intervention was effective in reducing HbA1c (SMD= -0.31 95%CI= -0.46 to -0.16;) than the control group, and it was statistically significant (p<.001). Due to heterogeneity (I2 = 71%), a meta-analysis of the random-effects model was employed. Intervention program with baseline HbA1c < 9% (SMD= -0.55; 95%CI= -1.05 to -0.05; p=.030), duration of intervention ≥ 6 month (SMD= -0.26; 95%CI= -0.37 to -0.15; p<.001), intervention delivery mode of combination type (SMD= -0.73; 95%CI= -1.42 to -0.03; p=.040), contact hour ≥10 (SMD= -0.37; 95%CI= -0.59 to -0.14; p=.001), and frequency of contact (SMD= -0.75; 95%CI= -1.39 to -0.12; p=.020) were effective to reduce HbA1c level. According to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method, the quality of evidence was classified as moderate. Family involvement in the DSME program was effective in improving glycemic control in patients with type 2 diabetes. Further research on baseline HbA1c, delivery mode, contact hours, and intervention frequency may provide useful information to determine the most effective treatment.

Key words: family involvement, randomized controlled trial, type 2 diabetes, meta-analysis

INTRODUCTION

Type 2 diabetes mellitus is recognized as a global public health issue with a substantial effect on the cost of living and human health. In many areas of the world, rapid economic growth and urbanization have contributed to a growing burden of diabetes[1].

People with diabetes are at greater risk of experiencing a number of severe life-threatening health complications, renal disease, paralysis, heart attacks, strokes, and lower-limb amputations, resulting in a high socio-economic burden and quality of life, leading to higher medical care expenses, lower quality of life, and increased mortality[2]. Besides, type 2 diabetes tends to escalate the prevalence, severity, and leading cause of human suffering and death. Approximately 462 million people had type 2 diabetes in 2017, equivalent to 6.28% of the world's population. As many as 4.4% of them are aged 15–49 years, 15% are aged 50–69, and 22% are more than 70 years old[3].

If no effective preventive measures are adopted, the International Diabetes Federation (IDF) has projected a rise of 693 million people with diabetes by 2045[4]. For people with diabetes, there is a marginally higher chance of mortality than in the population without diabetes. Body Mass Index (BMI), systolic blood pressure, total cholesterol and HDL, increased intake of unhealthy foods, sedentary lifestyle, and smoke culminated in elevated fasting plasma glucose. These factors, separately, show a strong association with mortality rates[5].

Furthermore, diabetes is a complex chronic disease that requires continuing medical care. Risk prevention strategies by education and self-management are essential to prevent acute complications and reduce the risk of long-term complications[6]. Self-management of people with type 2 diabetes can be accomplished by improving understanding of risk factors, symptoms, nutrition, physical exercise, glycemic monitoring, and insulin prescription and utilization. The cornerstone of diabetes is to improve the patient's diet by effective treatment recommendations to minimize disease-related mortality and morbidity[7].

Diabetes self-management education (DSME) is a crucial element in caring for both people with diabetes and those at risk of developing the condition. Besides, diabetes complications need to be avoided or postponed in the effective management of people with diabetes[8]. The initial stage of DSME is to promote the awareness, expertise, and ability of pre-diabetes and diabetes self-care practitioners to control their diabetes[9]. Regarding this, the American Diabetes Association (ADA) encourages self-management education and support at least yearly to avoid acute complications of diabetes mellitus and minimize the risk of long-term complications[10]. Previous studies have revealed that DSME is associated with increased diabetes awareness and decreased HbA1c[11–13].

The hemoglobin A1c test (glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c) is used to determine an individual’s glucose regulation level. The test indicates the average blood sugar level for the last 90 days or three months. HbA1c level greater than 6.5 percent is known to be uncontrolled glycemia[14].

On the other hand, diabetes treatment can be relatively difficult for patients. They must attend multiple medical appointments per year, adhere to a number of different medications to manage their disease, engage in several forms of self-care, including home glucose screening and a healthy diet and lifestyle, and negotiate maintenance costs[6]. As a chronic disease, most treatments for this

disease are performed at home and within the family. Thus, diabetes is often referred to as a family disorder, and its controls and demands influence all family members as such social support, especially family support, can be a significant part of effective diabetes and glycemic control[15].

Further, family members are known to be a key source of social support for adults with diabetes and an effective and critical component in self-care and disease control[16]. It is also vital for these patients, their families, and the health care teams to be engaged in the treatment process to manage the disease. Both approaches from family and health care professionals are combined with the recommendations on diabetes and the determination of patients to adhere to a diet plan, exercise, medical therapy, support, and supervision from both.

Previous systematic review findings have demonstrated that family-supported DSME increases clinical outcomes for patients with untreated glycemia[17]. The author included 22 experiments conducted between 2008 and 2016. The research findings found that family support improved the clinical conditions of patients with untreated glycemia. Despite systematic reviews of family support in DMSE have been published, no meta-analyses have specifically analyzed the impact of family involvement in DSME with type 2 diabetes. Furthermore, no studies have examined and described the characteristics, such as baseline HbA1c, type of delivery, contact hours, or intervention frequency, that might yield better glycemic control outcomes for patients with type 2 diabetes. There is limited knowledge about the impact of such self-management intervention for patients with type 2 diabetes. Therefore, this systematic review and meta-analysis were carried out to identify the knowledge gaps and to make recommendations for primary research. This study aimed to assess the effect of family involvement in DSME compared to usual treatment on glycemic control in DSME programs in type 2 diabetes patients. Several characteristics of family involvement in DSME were also investigated in subgroup analyses to identify who have better or worse glycemic control. The findings will promote the preparation of evidence-based interventions and help inform future studies.

MATERIALS AND METHODS

Design

This research applied a systematic review and meta-analysis. All similar studies, including topic and design studies, were gathered through a systematic review and meta-analysis, after which study findings were checked and reanalyzed. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) were used to establish and publish systematic review and meta-analysis[18]. Besides, a systematic review and meta-analysis approach was employed to comply with the principles of the Cochrane handbook for systematic reviews of interventions [19].

Search strategy

This study was carried out by searching and selecting data from clinical trial results conducted across ethnicities, races, and countries worldwide. 2000-2020 was the selected study outcome period. Multiple journal databases, including PubMed, SpringerLink, Science Direct, Google Scholar, and EBSCO, were utilized to search for study results. Besides, medical subject (MeSH) terms and publications of the PICO framework (participants, intervention, comparison, and outcomes) were employed for the search strategy. The search keywords used were "type 2 diabetes" AND "self-management" AND "diabetes self-management education" AND "family support" AND "HbA1c" AND/OR "glycemic".

To find additional studies adequate for this study's purposes, the researchers reviewed the articles' reference lists. The researcher selected articles published in Indonesian and English. Meanwhile, other qualifying experiments were manually scanned for references from the chosen studies.

Inclusion and exclusion criteria

In this meta-analysis study, the inclusion criteria were that: (1) the study design was a randomized controlled trial (RCT); (2) the study subjects were people with type 2 diabetes mellitus; (3) a comparison group without any active DSME component was used, such as routine treatment that may consist of regular primary care, a waiting list, or limited intervention. Studies eligible for inclusion were also required to meet the DSME definition by the National Standards for Diabetes Self-Management Education and Support, (4) there was family participation involved in DSME interventions, (5) the intervention time was at least three months as HbA1c represents a mean glycemia of approximately three months, (6) improvements in Glycohemoglobin A1c were recorded, and (7) in this review, the papers chosen were in full text.

Moreover, Diabetes Self-Management Education (DSME) is the method to promote the awareness, knowledge, and skills required for self-care for diabetes [20]. This definition is not prescriptive but more process-oriented; DSME interventions should provide elements and practices to strengthen participants' awareness, expertise, and capacity to carry out self-management activities that can enhance glycemic control. Eligible for inclusion were DSME treatments delivered in any environment, by any method or provider, and for any period and contact hour.

Meanwhile, the exclusion criteria included that (1) abstracts, dissertations, and conference papers were excluded because they included inadequate details. (2) Articles were excluded in the absence of randomized control trials. (3) Pilot studies, single cohort feasibility studies, or policy reviews were excluded. (4) Studies that did not involve type 2 diabetes mellitus as a primary disease were excluded, including type 1 diabetes, asthma, or arthritis (4). The study step was carried out with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA)[18]. In Figure 1, the selection study flow chart is presented.

Study selection

A screening method and objective evaluation for the chosen papers were performed by two reviewers (AA and TH). Based on predefined inclusion and exclusion criteria, the reviewers obtained information from the abstracts and full texts. Meanwhile, both duplicate citations and documents from the same article found were deleted. The reviewers extracted information from the abstract into a structured table independently. To compare the findings obtained, the two reviewers read and graded the full-text articles. Through discussion and agreement, the differences in the resulting outcomes were resolved. Articles that qualify for a systematic analysis were included.

Data extraction

Selected articles were evaluated and extracted separately. The data were obtained from the selected articles, including the first author's name, publication year, the study's design, country, respondents' age, sample size, delivery program, contact hour, contact frequency, intervention duration, and HbA1c.

Furthermore, several subgroups analyses were carried out for HbA1c. The intervention duration was classified as <six

months and ≥ six months. The contact frequency was calculated based on the recorded intervention procedure and when it was available. The participants' HbA1c levels were at baseline, whereas the contact frequency was categorized into three levels: low (less than one contact per one month per patient), moderate (one or two contacts per one month per patient), and high (more than two contacts a month per patient). Contact hours were grouped as <10 and 10 hours, while the type of program delivery was measured for individual, group, or a combination of individual and group deliveries.

Bias and quality appraisal

The Cochrane Collaboration tool was utilized in the bias risk assessment, with the following categories: selection bias (random sequence generation and allocation concealment), performance bias (blinding participants and researchers to the intervention received by participants), detection bias (blinding of knowledge result assessment of what intervention a participant received), attrition bias, reporting bias, and other bias [19]. This tool used the relevant criteria for classification as low, unclear, or high risk. As suggested, "low risk of bias" is advised if the consistency requirements for the least bias are completely reached; "unclear" if it is probable that a bias poses some concern about the results; "high risk of bias" if it is possible that a bias severely weakens confidence in the outcomes.

Determining the quality of the research obtained is crucial in choosing the studies to be included in the systematic review. Therefore, the researchers used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE). In the GRADE System, the assessment results can be categorized as high, medium, low, or very low. Research with a randomized controlled trial design is considered high quality, whereas observational studies are of low quality. However, factors such as limitations in design, heterogeneity, indirectness, imprecision, and publication bias can reduce the assessment of the article's quality[21]. Thus, specifically, publication bias was assessed by funnel plot, Egger's test, and Begg's test. The funnel plot is a scatter plot based on the predicted effect size on the sample size. The funnel plots will be distributed symmetrically if there is no publishing bias. On the other hand, if the funnel is asymmetrical, publication bias is indicated [22]. Furthermore, p-values of less than 0.05 in Begg's test and Egger's test were considered statistically significant if there was potential publication bias [23,24].

Meta-analysis

Typically, statistical analysis is performed in Review Manager 5.2 and Stata version 16. In this study, the meta-analysis utilized the Review Manager (REVMAN) version 5.2 to determine the intervention's effect on the HbA1c. Data analysis used the mean and standard deviation of the results of measuring the HbA1c level before and after the intervention. Meta-analysis was also conducted to determine the differences in baseline HbA1c between the intervention and control groups. Besides, the mean HbA1c values for the intervention and control groups were presented as differences in standard mean, 95% CI, and heterogeneity (I^2). Then, the data heterogeneity employed Cochran's Q and I^2, with p-values <.05 for Cochran's Q values and $I^2 \geq 50\%$, suggesting substantial heterogeneity [25].

The results were calculated and aggregated in random-effects meta-analysis. The observed random-effects meta-analysis varied across experiments due to variations in each study's treatment effects and heterogeneity in sampling[26]. The meta-analysis findings were presented in the form of a forest plot for change in

HbA1c. A forest plot is a diagram displaying each experiment's details in the meta-analysis and predictions of the total effects. The forest plot visually reveals the large variation (heterogeneity) between the outcomes. Apart from assessing the magnitude of variation in the forest plot, it also shows the strength of the relationship[27].

RESULTS

Study Characteristics

Figure 1 exhibits the PRISMA diagram in the article selection process. The initial search process resulted in 991 articles obtained from PubMed, SpringerLink, Science Direct, Google Scholar, and EBSCO databases. After removing duplicate articles, 889 articles remained. After the abstract review process, 74 articles were selected for further full review. Then, there were 25 articles left for critical appraisal. In the end, 17 of the 25 articles were selected for a systematic review.

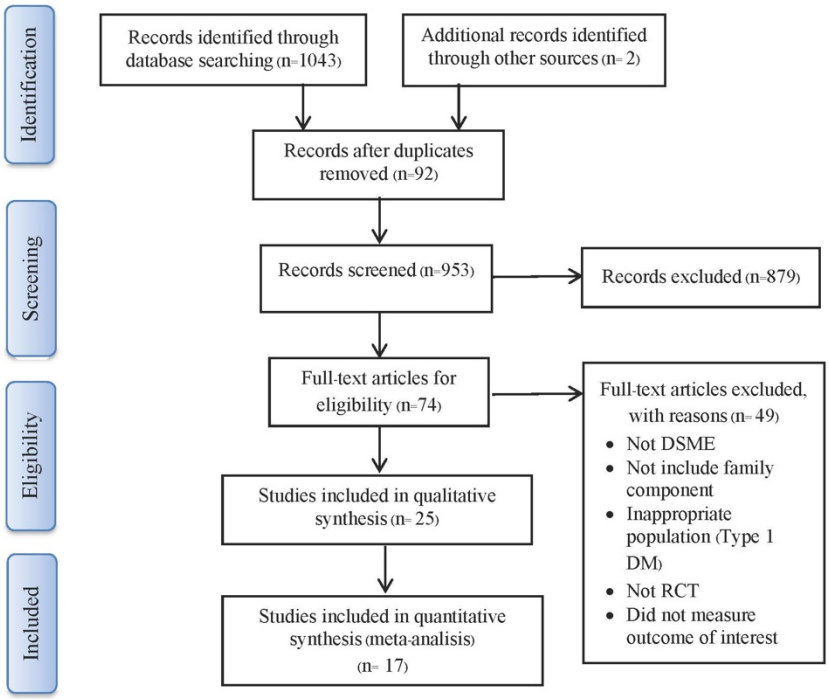

Figure 1 PRISMA flow chart

Table 1 shows the characteristics of the studies included in systematic reviews. Publication time ranged from 2000 to 2020. All articles were randomized controlled trials (RCTs). Articles varied in sample size, duration, and DSME interventions with family involvement. The number of respondents from all articles included in this systematic review totaled 2644 respondents. The respondents' mean age was 56.16 years (ranging from 61.3 to 49.1 years). The sample sizes were diverse from

17 to 286. All respondents considered patients with type 2 diabetes. The mean length of diabetes was 8.2 years (ranging from 3.8 to 16 years). DSME interventions with family involvement were different in setting, structure, content, type, duration, frequency, contact hours and providers. The intervention location was heterogenous from primary care offices, hospitals, community health centers, diabetes education centers, and patient homes. DSME interventions with family involvement were delivered by various experts, such as diabetes educators, nurse educators, nurse case managers, registered dieticians, pharmacists, and peer educators. All these interventions involved the family in their implementation.

The majority of the studies were carried out in the United States[28–37], Iran[38,39], and Thailand[40,41], followed by Ireland[42], Taiwan [43], and Brazil [44]. Six studies had baseline of < 9[29,31–33,39,40], and eleven studies had baseline HbA1c of ≥ 9[28,30,44,34–38,41–43]. Four studies had intervention duration of <6 months[29,32,39,40], and 13 studies had an intervention duration of ≥ 6 months[28,30,42–44,31,33–38,41]. Five studies were conducted individually[33,37,41,42,45]; eight studies were carried out in groups[28,29,31,35,38–40,44]; four were done in combination with individuals and groups in the delivery of the DSME intervention[30,32,36,43]. Six articles had contact hours of < 10[39–44], and 11 articles had contact hours of ≥ 10[28,29,38,30–37]. Four studies had a low contact frequency[39–41,43], four studies were moderate[32,37,38,44], and nine studies had a high contact frequency[28–31,33–36,42].

Table 1 Summary of 17 randomized controlled trials family involvement in DSME on glycemic control in patients with type 2 diabetes included in the analysis

Author	Year	Country	Design	Sample (N)		Diabetes duration (yrs)		Mean age		Definition of Family	Contact hour/frequency contact		Type of delivery	Family involvement in DSME intervention	Control	Duration	Mean HbA1c	
				IG	CG	IG	CG	IG	CG								IG (Mean/SD)	CG (Mean/SD)
Brown[28]	2002	US	RCT	126	126	7.6	8.1	54.7	53.3	First degree relative	>10	>2	Group	DSME was provided by bilingual Mexican American nurses, dietitians, and community workers accompanied by a family member or friend. The intervention involved: (1) 3 months of weekly instructional sessions on nutrition, self-monitoring of blood glucose, exercise, and other self-care topics; and (2) 6 months of biweekly support group sessions to promote behavior changes. The approach was culturally competent in terms of language, diet, social emphasis, family participation, and incorporation of cultural health beliefs	Usual care	12 month	10.89 (2.56)	11.64 (2.85)
Vincent[29]	2009	US	RCT	9	8	7,9	7,8	56.67	55.25	Friends and family	>10	>2	Group	The intervention delivered by physician or nurse consisted of eight weekly 2-hr group sessions, which included didactic content, cooking demonstrations, and group support (friends and family). Participants were encouraged to bring a support person to the sessions.	Usual care	3 month	6.14 (0.5)	6.84 (1.3)
Kang[43]	2010	Taiwan	RCT	33	34	3.8	4.4	55.3	51.7	Family members, parent, significant other, or additional important relative.	<10	1	Both	This intervention/ FPIC group consisted of three brief individual educational sessions, 2-day long group educational sessions, a monthly 25–30 min telephone discussion. All patients and family members also received diabetes handouts about diet, medication, physical activity and exercise, and eye and foot self-care at the first IES. Each education session lasted 20–40 min. Intervention delivered by physician, nurse, dietitian, pharmacist, physiotherapist, social worker	Usual care	6 month	7.9(1.36)	8.12(1.21)

Author	Year	Country	Design	Sample (N)		Diabetes duration (yrs)		Mean age		Definition of Family	Contact hour/frequency contact		Type of delivery	Family involvement in DSME intervention	Control	Duration	Mean HbA1c	
				IG	CG	IG	CG	IG	CG								IG (Mean/SD)	CG (Mean/SD)
Keogh[42]	2011	Ireland	RCT	60	61	9.17	9.65	59.96	57.29	Family members in the same home as patients	<10	>2	Individual	The intervention consisted of 3 weekly sessions consisted of 2 sessions delivered by a health psychologist to the patient and a family member in the patient's home. The first 2 sessions lasted 45 minutes each. The third session involved a 10- to 15-minute follow-up telephone call.	Usual diabetes care	6 month	8.41 (0.99)	8.80 (1.36)
Rosal[30]	2011	US	RCT	124	128	5 to 10 years	5 to 10 years	>18 years	>18 years	Family members in the same home as patients	>10	>2	Both	The intervention consisted of 12 weekly and 8 monthly sessions. Cultural tailoring included the use of an educational soap opera to introduce self-management. The first session was conducted as an individual 1-h meeting in the participant's home. Group sessions lasted for approximately 2.5h. The intervention delivered by a trained team (either a nutritionist or health educator and trained lay individuals).	Usual care	12 month	8.39(1.29)	8.91 (0,80)
Toobert[31]	2011	US	RCT	142	138	8.4	10.4	55.6	58.7	Not-mentioned	>10	>2	Group	The intervention delivered by physician consist of weekly meetings the intervention continued with 4-h facilitator-led meetings, providing 1 h each of instruction and practice of diet, stress management, physical activity, and support groups (1 h for each component=4 h). Meetings were held weekly for 6 months, then faded to twice monthly for 6 months	Usual care-only	12 month	8.3 (1.9)	8.3 (1.6)
Castejon[32]	2014	US	RCT	19	24	-	-	54	55	Family member or a friend Attending partners were a spouse, friend, sibling, or child	>10	1-2	Both	The intervention included a focused discussion (3-h) and two individual pharmacist counseling sessions (1-h) on medication, nutrition, exercise, and self-care to promote behavior changes. Sessions were culturally adapted for language, diet, family participation, and cultural beliefs. patients were asked to come back for three educational sessions every two weeks during the first six weeks and a follow- up clinical screening three months later. The family member was asked to come with the study participant for every clinical screening and educational session, as appropriate.	The control group had The same timeline but no educational sessions were given	3 month	7.3 (0.3)	88.0 (0.2)

Author	Year	Country	Design	Sample (N)		Diabetes duration (yrs)		Mean age		Definition of Family	Contact hour/frequency contact		Type of delivery	Family involvement in DSME intervention	Control	Duration	Mean HbA1c	
				IG	CG	IG	CG	IG	CG								IG (Mean/SD)	CG (Mean/SD)
Tabasi[39]	2014	Iran	RCT	45	46	9.71	11.39	52.93	54.13	Family members have blood relative and living with patient	<10	1	Group	The instruction about the importance of medication adherence and family support behavior was carried out about 45–60 minutes in 3 sessions. In every session 30–45 minutes considered for teaching and 15 minutes answering the questions and exchanging of views between family members.	Family did not receive any instruction	3 month	7.7 (1.1)	8.1 (8.0)
Garcı´a[33]	2015	US	RCT	39	33	6.2	7.2	50	49.1	Not-mentioned	>10	>2	Individual	Participants received eight weekly, in-home, one-on-one educational and behavior modification sessions with a registered nurse focusing on symptom awareness, glucose self-testing and appropriate treatments, followed by eight biweekly support telephone sessions. each session lasting30–60 min. Family members were encouraged to attend the sessions	Wait-listed control	6 month	7.9 (1.87)	8.5 (1.72)
Shakibazadeh[38]	2015	Iran	RCT	140	140	5–9 years	5–9 years	58.73	58.57	First degree relative	>10	1-2	Group	A nurse educator, dietitian and counselor conducted the program. Eight 2½-h educational workshops offered over a 4-week period and followed by two sessions, each 2 weeks apart. Researcher set up group-based classes and invited a family member to enhance the self-efficacy of the patients and improve family support.	Usual Lecture-based non-interactive Educational sessions.	18-21 month	8.1 (1.6)	8.9 (2.2)
Trief[34]	2016	US	RCT	104	82	12.8	12.6	57.8	56.9	Couples was defined as his/her partner in a committed relationship ≥ 1 year	>10	>2	Individual	A comprehensive Diabetes Education (DE) delivered in two telephone sessions (mean length of calls 75 min) followed with couple calls (cc). CC had 10 additional calls (mean length: CC 57 min/call). Couples were encouraged to provide mutual support for change. Calls occurred weekly for 12 weeks. Educators were dietitians	Usual care	12 month	8.5 (1.5)	8.5 (1.4)

Author	Year	Country	Design	Sample (N)		Diabetes duration (yrs)		Mean age		Definition of Family	Contact hour/frequency contact		Type of delivery	Family involvement in DSME intervention	Control	Duration	Mean HbA1c	
				IG	CG	IG	CG	IG	CG								IG (Mean/SD)	CG (Mean/SD)
Ing[35]	2016	Hawai	RCT	25	22	-	-	54.62	54.42	Not-mentioned	>10	>2	Group	1-hour weekly group meetings, providing information on diabetes self-management and encouraging participants to work with their diabetes team that includes the individual, their family, physician, and other diabetes experts	Usual care	6 month	8.96 (1.82)	9.47 (2.69)
Gomes[44]	2017	Brazil	RCT	108	114	15.7	7.82	60.43	60.43	A family member when patients do have blood relatives.	<10	1-2	Group	Participants received in four sessions with an average duration of 2 h each in groups of up to 10 people. a family caregiver who was considered a source of SS for the patient was included in the Education Program in Diabetes Mellitus	Usual care without family/caregiver	12 month	8.73 (1.72)	8.94 (1.68)
McEwen[36]	2017	US	RCT	83	74	11.92	11.05	53.64	53.41	Lived in same house as participant with T2DM or saw them weekly	>10	>2	Both	The 12-week intervention program included 3 successive components: (1) six 2-hour educational and social support group sessions conducted weekly for 6 weeks, (2) three 2-hour home visits scheduled weekly for 3 weeks, and (3) three 20-minute telephone calls scheduled weekly for 3 weeks. A nurse who is a certified diabetes educator (CDE) conducted the educational sessions, and a promotor conducted the social support sessions, home visits, and telephone calls.	Waitlist control group	9 month	9.19 (2.1)	9.20 (2.0)
Wichit[40]	2017	Thailand	rct	70	70	6.0	5.4	61.3	55.5	Living in the same residence and relative,	<10	1	Group	The intervention group received routine care plus a family-oriented program that included education classes, group discussions, a home visit, and a telephone follow-up. The education consisted 2 hour sessions were provided in a group of 8–12 dyads (individual and family member) per group and the facilitator. The program consisted of three education sessions delivered at baseline, Week 5, and Week 9. The facilitator of the education session was a Thai National and a registered nurse.	Usual care /routine care	13 Week	7.0 (1.2)	7.3 (1.4)

Author	Year	Country	Design	Sample (N)		Diabetes duration (yrs)		Mean age		Definition of Family	Contact hour/frequency contact		Type of delivery	Family involvement in DSME intervention	Control	Duration	Mean HbA1c	
				IG	CG	IG	CG	IG	CG								IG (Mean/SD)	CG (Mean/SD)
Withidpanyawong[41]	2018	Thailand	RCT	98	98	5.61	6.35	60.53	58.13	Living in the same Household as or significant relative of the participant	<10	1	Individual	Beyond the usual care, the intervention group received an education package for participants and their relatives. The intervention was administered by one research pharmacist during 4 visits within a 9-month period, at approximately 3-month intervals. Each intervention lasted 40-50. A pharmacist delivered the educational sessions and encouraged family members to take an active role in self-management practices.	Usual care	9 month	7.84 (1.96)	8.87 (1.81)
McElfish[37]	2019	US	RCT	110	111	-	-	52.2	52.2	Same households	>10	1-2	Individual	The adapted DSME included 10 h of content delivered over an 8-week period and covered eight core elements of DSME. the adapted DSME curriculum engaged family members in the educational sessions delivered by certified educators.	Usual care without family members	12 month	9.64 (1.74)	10.36 (1.85)

Meta-analysis results

A meta-analysis was conducted using data from the final sample size of 17 studies with 2644 participants. Compared to the control group, Figure 2 displays the HbA1c forest plot of the DSME intervention with family involvement. The effect size obtained was -0.31 (95% CI -0.46 to -0.16; 2644 participants; 17 study studies). The heterogeneity was high (I^2 = 71%), and it was statistically significant ($p<.001$). The random-effects meta-analysis was used to evaluate differences between the intervention and control groups in the baseline HbA1c. Compared to the control group, there was also a significant difference in HbA1c in the intervention group. There was no evidence for publication bias in the funnel plot (Figure. 3), the Egger's test (p = .123), or the Begg's test (p = .458).

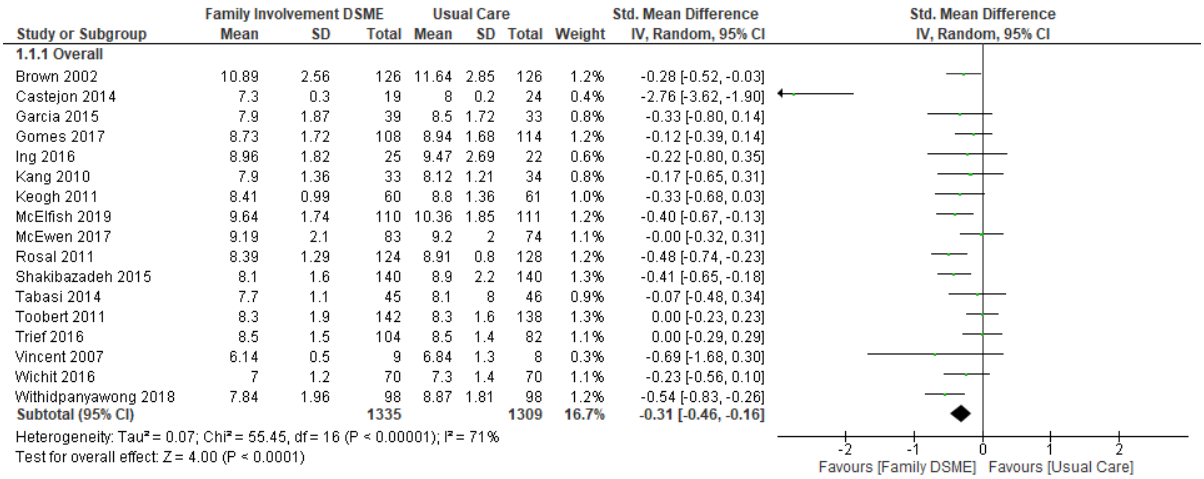

Figure 2 Forest plot for HbA1c meta-analysis

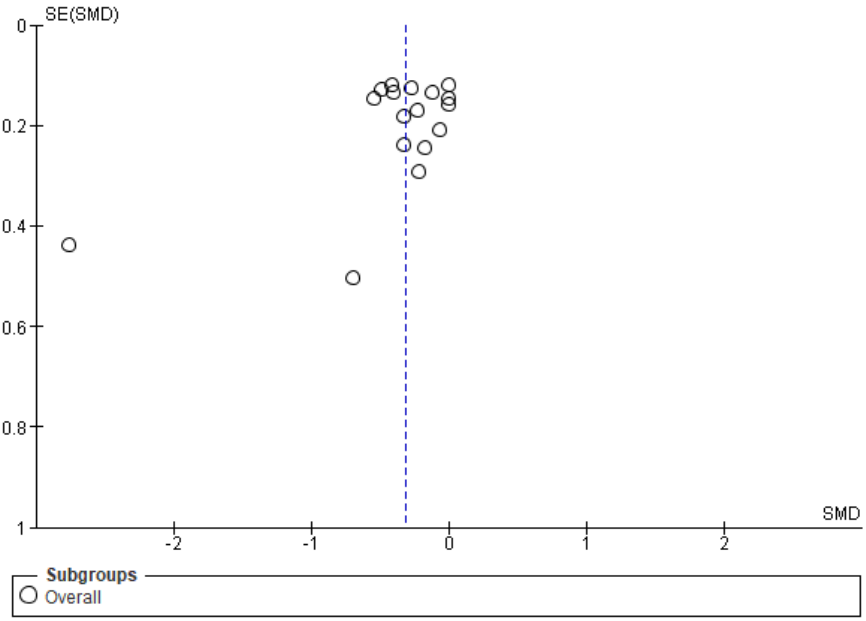

Figure 3 Funnel plot

Subgroup analysis

Subgroup analysis was conducted to explore possible differences between studies based on their characteristics, participants' baseline HbA1c levels, intervention duration, type of intervention delivery, contact hour, and contact frequency (Table. 2).

Particularly, a subgroup analysis of HbA1c values to explore the source of heterogeneity between studies was carried out to provide a more detailed overview of the findings. Subgroup analysis of HbA1c values was performed based on the baseline HbA1c grouping (<9% with ≥ 9%), intervention duration (<6 months with ≥6 months), contact hour (<10 with ≥ 10), contact frequency (low, moderate, high), and program delivery (individual, group, and combination).

Table 2 Subgroup analysis for the standard mean difference of HbA1c

Variables	No Studies	Std. Mean Difference of HbA1c	95% CI	p	I^2
All studies	17	-0.31	-0.46 to -0.16	<.001	71%
Baseline HbA1c					
< 9%	6	-0.55	-1.05 to -0.05	.030	87%
≥ 9%	11	-0.29	-0.40 to -0.17	<.001	37%
Duration of intervention					
< 6 month	4	-0.87	-1.78 to 0.04	.060	91%
≥ 6 month	13	-0.26	-0.37 to -0.15	<.001	44%
Type of intervention delivery					
Individual	5	-0.32	-0.52 to -0.12	.001	46%
Group	8	-0.20	-0.32 to -0.09	<.001	13%
Combination	4	-0.73	-1.42 to -0.03	.040	92%
Contact Hour					
< 10	6	-0.26	-0.41 to -0.11	<.001	16%
≥ 10	11	-0.37	-0.59 to -0.14	.001	80%
Frequency of Contact					
Low	4	-0.29	-0.51 to -0.07	.010	33%
Moderate	4	-0.75	-1.39 to -0.12	.020	91%
High	9	-0.23	-0.38 to -0.08	.002	49%

Subgroup analysis based on the baseline HbA1c

A subgroup analysis was performed for the baseline HbA1c <9% and ≥ 9%. There was statistically significant difference in baseline HbA1c <9% (SMD= -0.55; 95%CI -1.05 to -0.05; p=.030) and ≥ 9% (SMD= -0.29; 95%CI 0.40 to -0.17; p<.001). Study heterogeneity was high and statistically significant for the baseline HbA1c <9% (I^2 = 87%; p< .001), but for the baseline HbA1c ≥ 9%, it was low and statistically non-significant (I^2 = 37%; p= .10) (Figure. 4). There was evidence of potential publication bias according to Egger's test (p= .078) and Begg's test (p=.038) for the baseline HbA1c <9%. Meanwhile, there was no evidence of publication bias for the baseline HbA1c ≥ 9% according to Egger's test (p= .409) and Begg's test (p=.311). Previous studies indicated that less than 9 percent of baseline HbA1c was associated with greater improvement in glycemic control interventions than more than 9 percent of baseline HbA1c[46].

Subgroup analysis based on the intervention duration

A subgroup analysis was then conducted for the <6 months and ≥6-month of intervention duration. There was no statistically significant difference in HbA1c for <6-month duration of intervention (SMD= -0.87; 95%CI -1.78 to 0.04; p=.060), but there was statistically significant difference in HbA1c for ≥6-month duration of intervention (SMD= -0.26; 95%CI -0.37 to -0.15; p<.001). Study heterogeneity was high and statistically significant for the <6-month duration of the intervention (I^2 = 91%; p<.001), but low and statistically significant for the ≥6-month duration of the intervention (I^2 = 44%; p=004) (Figure. 5). There was no evidence of publication bias for <6-month duration of intervention according to Egger's test (p= .296) and Begg's test (p=.496); however, there was no evidence of publication bias for ≥the 6-month duration of intervention according to Egger's test (p= .846) and Begg's test (p=.807). The intervention duration was related to glycemic control. Previous studies have found that interventions carried out for six months resulted in significant changes in blood sugar control[47].

Subgroup analysis based on the type of intervention delivery

A subgroup analysis was carried out based on the type of intervention delivery for individual, group, and combination. There were statistically significant differences in HbA1c for individual delivery (SMD= -0.32; 95%CI -0.52 to -0.12; p=.001), group delivery (SMD= -0.20; 95%CI -0.32 to -0.09; p<.001), and combination delivery (SMD= -0.73; 95%CI -1.42 to -0.03; p=.040). Study heterogeneity was low and statistically non-significant for the individual delivery (I^2 = 46%; p=.12) and group delivery (I^2 = 13%; p=.33), but it was high and statistically significant for the combination delivery (I^2 = 92%; p<.001) (Figure. 6). There was no evidence of publication biases for individual delivery according to Egger's test (p= .933) and Begg's test (p=.624), for group delivery based on Egger's test (p= .644) and Begg's test (p=.804), and for combination delivery as shown by Egger's test (p= .356) and Begg's test (p=.496).

Subgroup analysis based on the contact hours

A subgroup analysis was done for contact hours <10 and ≥10. There were statistically significant differences in HbA1c for contact hours <10 (SMD= -0.26; 95%CI -0.41 to -0.11; p<.001) and contact hours ≥10 (SMD= -0.37; 95%CI -0.59 to -0.14; p= .001). Study heterogeneity was low and statistically non-significant for

contact hours <10 (I^2 = 16%; p=.031), but for contact hours ≥10, it was high and statistically significant (I^2 = 80%; p<.001) (Figure. 7). There were no evidence of publication biases for contact hours <10 according to Egger's test (p= .604) and Begg's test (p=.851) and for contact hours ≥10 based on Egger's test (p= .126) and Begg's test (p=.483).

Subgroup analysis based on the contact frequency

A subgroup analysis was conducted based on low, moderate, and high contact frequency. There were statistically significant differences in HbA1c for low contact frequency (SMD= -0.29; 95%CI -0.51 to -0.07; p=.010), moderate contact frequency (SMD= -0.75; 95%CI -1.39 to -0.12; p=.020), and high contact frequency (SMD= -0.23; 95%CI -0.38 to -0.08; p=.002). Study heterogeneity was low and statistically non-significant for the low contact frequency (I^2 = 33%; p=.12), high and statistically significant for the moderate contact frequency (I^2 = 91%; p<.001), and low and statistically significant for the high contact frequency (I^2 = 49%; p=.002) (Figure. 8). There was no evidence of publication biases for the low contact frequency according to Egger's test (p= .183) and Begg's test (p=.174), for moderate contact frequency based on Egger's test (p= .073) and Begg's test (p=.496), and for a high contact frequency as found in Egger's test (p= .501) and Begg's test (p=.297).

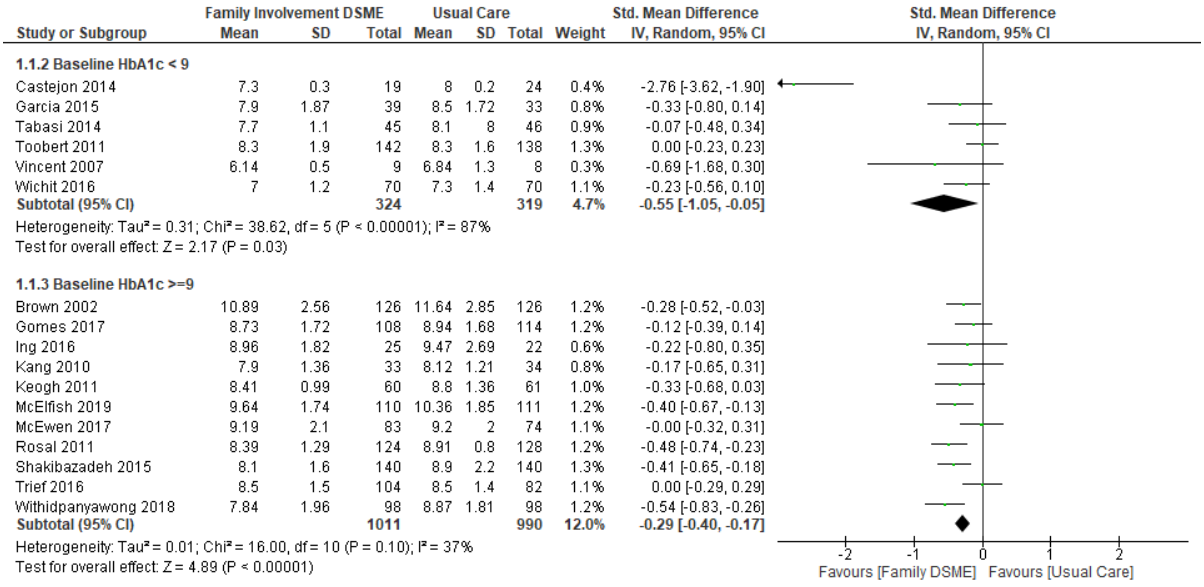

Figure 4 Forest plot for Subgroup analysis based on the HbA1c baseline

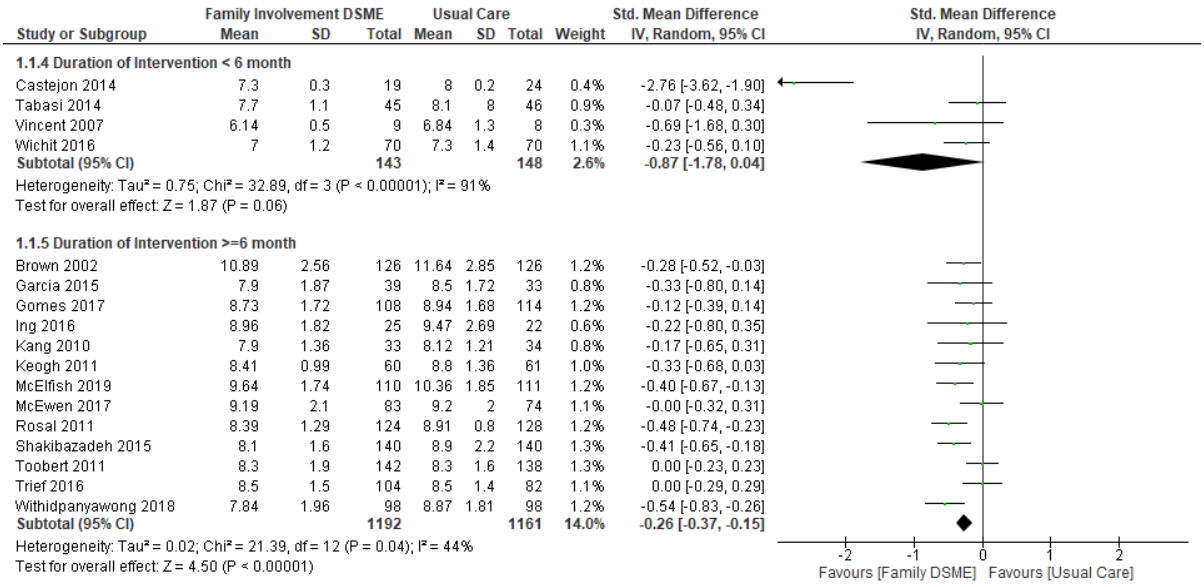

Figure 5 Forest plot for Subgroup analysis based on duration of intervention

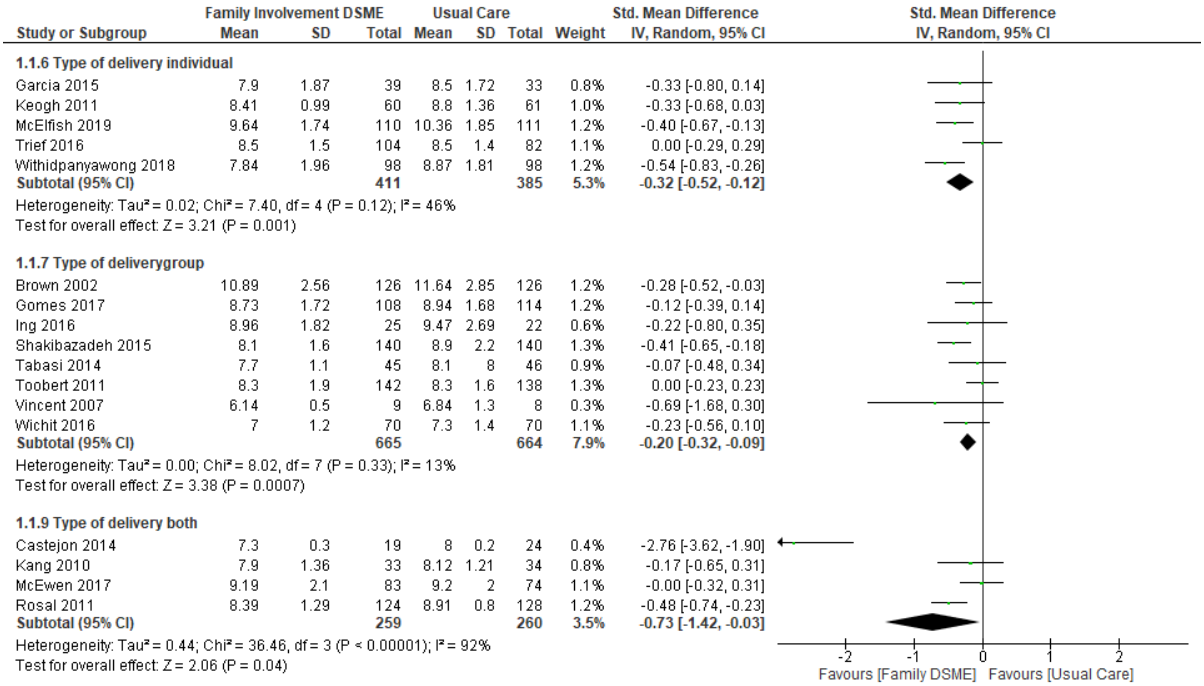

Figure 6 Forest plot for Subgroup analysis based on type of intervention delivery

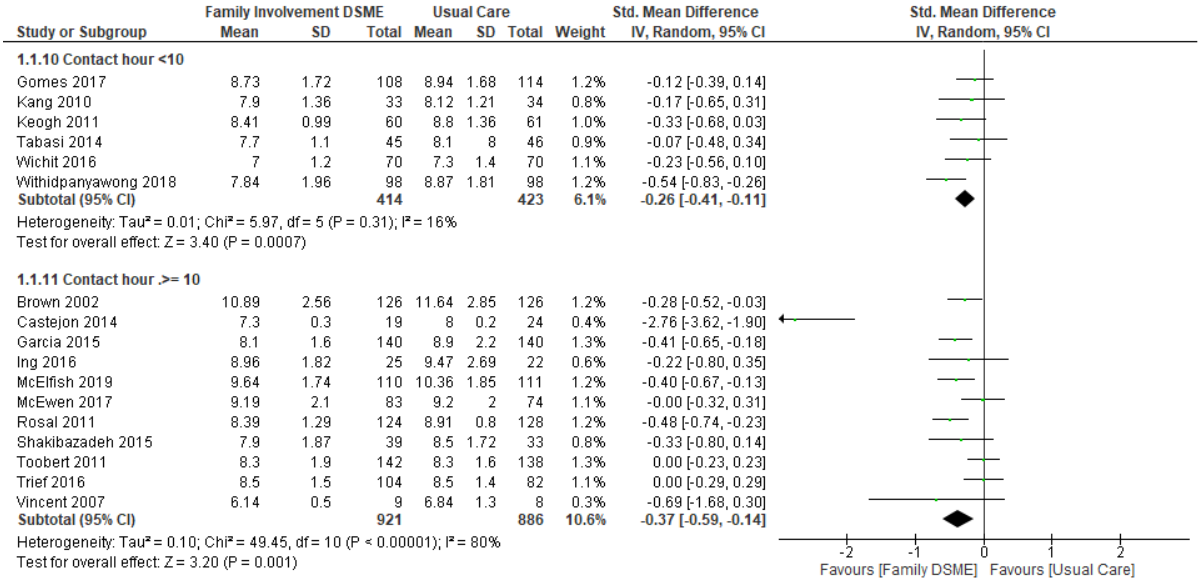

Figure 7 Forest plot for Subgroup analysis based on contact hour

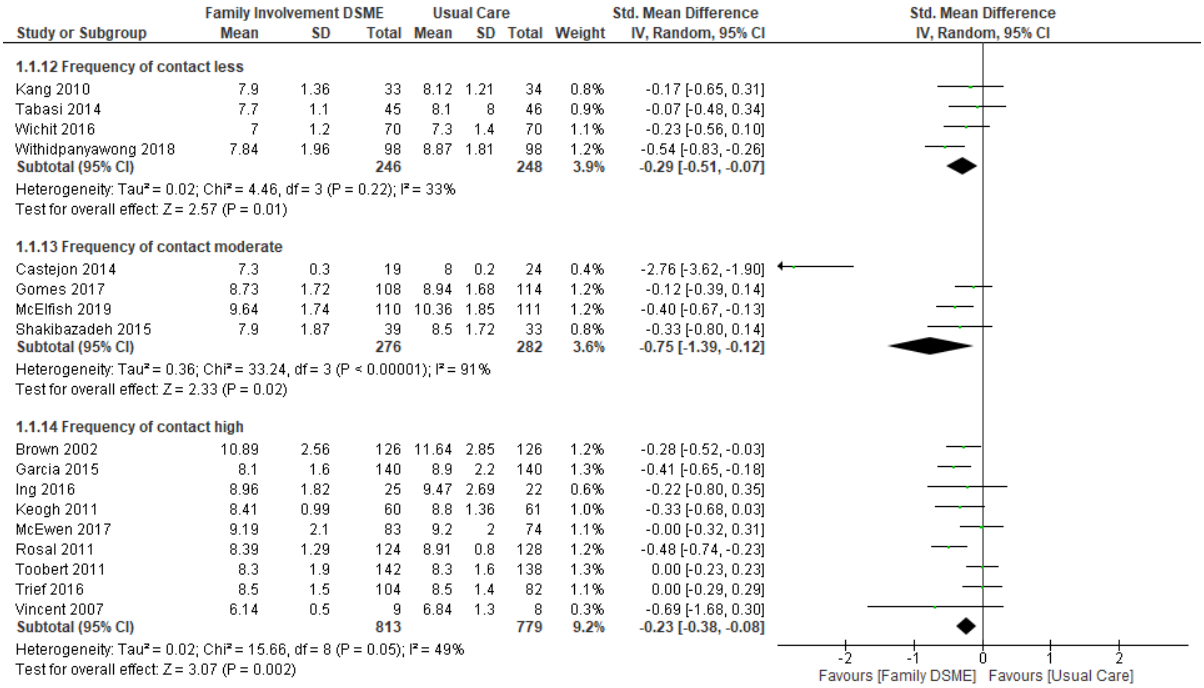

Figure 8 Forest plot for Subgroup analysis based on frequency of contact

DISCUSSION

This study's primary purpose was to review studies on improving glycemic control using family involvement in diabetes self-management education (DSME). The researchers conducted a meta-analysis to estimate intervention effects and identify variables contributing to glycemic control in type 2 DM. In this meta-analysis, only randomized control trials were included. This review included seventeen randomized control trial studies with 2644 participants. This review's results indicated that family involvement in

DSME intervention positively affected HbA1c levels in type 2 diabetes.

A total of seven articles showed a significant value in reducing HbA1c to control[28,30,32,37,38,41,42]. This meta-analysis suggested that family involvement in DSNE had a favorable effect on improving glycemic control, with a pooled mean reduction of -0,31 (95% CI -0.46 to -0.16) in HbA1c levels compared with usual care, and it was statistically significant (p<.001). This finding is consistent with prior systematic review and meta-analyses about group-based DSME compared to routine treatment, which found HbA1c reductions in the general population[48]. The estimated -0.31% reduction in HbA1c in patients with type 2 diabetes was modest. There is also some evidence from observational studies, which disclosed a decrease in HbA1c reduced the risk of complications. According to a prior study, each 1% reduction in HbA1c was associated with reductions in risk of 21% for any endpoint related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction, and 37% for microvascular complications[49].

This study has essential implications for current clinical and public health practice and research. Glycemic control is a vital predictor of many chronic complications of diabetes. Another study stated that every 1% reduction in HbA1c was associated with 14%, 12%, and 16% reductions in the relative risk (RR) of myocardial infarction, stroke, and heart failure, respectively[50]. Moreover, according to the prior study, significantly increased risks of complications for every 1% higher HbA1c level were associated with a 38% higher risk of a macrovascular event, a 40% higher risk of a microvascular event, and a 38% higher risk of death[51].

In this study, there was a high value of heterogeneity, and it was statistically significant (I^2= 71%; P<.001). This high heterogeneity value might be due to the substantial variations in intervention characteristics. The random-effects model was used because of this heterogeneity value. Various subgroup studies were conducted not only to clarify the heterogeneity (I^2) between studies and identify the most effective intervention aspects but also to explore the effects. The current study indicated that larger effects were found in interventions with a longer duration and contact hours, delivered in the combination between individual and group format, and with interventions of lower baseline HbA1c and interventions of a moderate contact frequency.

Subgroup analysis revealed that studies involving patients with lower baseline HbA1c (< 9%) showed a higher greater effect size (SMD= −0.55) after intervention than ≥ 9% of baseline HbA1c. The results are contrary to the previous study, which found that a higher baseline HbA1c (< 9%) was reported, a greater decrease in HbA1c[52,53]. The low baseline HbA1c in the other study had the best clinical predictor of HbA1c attainment at 7.0%. A higher risk of hypoglycemia was also associated with the low baseline HbA1c[54]. Efforts to reach the HbA1c target should be balanced with quality of life preservation and protection against excessive hypoglycemia, according to the ADA statement[55].

Besides, the results from subgroup analysis based on the intervention duration showed that the ≥6 months effectively reduced HbA1c, and it was statistically significant (p<.001). There was evidence to suggest that a longer intervention duration was associated with a reduction in HbA1c levels. In a previous review, outcome measures were primarily collected at 6 and 12 months. The HbA1c reduction results varied. Of the seven studies, a decrease in HbA1c levels was found in four studies, while the other three studies did not show a significant decrease in HbA1c levels[56]. The factors responsible could hardly be

identified because they limited the available knowledge about the interventions' long-term effects and needed additional research.

Further, the chosen studies were divided into three subgroups based on the type of intervention delivery, including individual, group, and a combination of individual and group. In this current review, the effect size between the combination between individual and group delivery was greater than that between the individual or group delivery only. The entire category was statistically significant. The current findings are consistent with the previous review, which uncovered that a combination of group and individual involvement resulted in the largest decreases in A1C than only group and individual[57]. A combination of individual and group education can provide interactive, participatory, and collaborative learning to positively affect health outcomes from planning and problem solving and improving health behavior.

Based on intervention contact hours between < 10 hours and 10 hours, subgroup analyses were also conducted. In this study, contact hour ≥10 had a greater effect size than < 10 hours in reducing HbA1c, and it was statistically significant (p=.001). Similar to these findings, the previous meta-analysis study suggested that the reduction in HbA1c values was associated with more contact hours, and it was statistically significant [57]. The previous review also noted that contact hours of ≥10 hours had a major effect on reducing the risk of mortality and improving health outcomes[58,59].

Moreover, the subgroup analysis based on the contact frequency was classified into three levels: low (less than one contact per month per patient), moderate (one or two contacts per month per patient), and high (more than two contacts in a month per patient). The highest effect size in HbA1c was observed in the moderate category. All contact frequency categories were statistically significant. These results corroborate with the previous meta-analysis study, stating that moderate and high contact frequency intervention programs indicated a significant glycemic control improvement. Contact frequency seemed to be a vital feature of intervention efficacy. Therefore, a program with a moderate or intensive contact frequency should be implemented[60].

As explained, this meta-analysis used GRADE to assess quality evidence of the effect of the family involvement in DSME on glycemic control in patients with type 2 diabetes. According to GRADE, there was moderate-quality evidence for the effects of family involvement in DSME on glycemic control in patients with type 2 diabetes, and the reasons for providing the moderate quality of evidence among the four levels (high, moderate, low, and very low) were the possible risk of performance bias. The risk from performance bias was unavoidable as it is very difficult to provide allocation concealment and blind the patients and provider to random assignment, although few studies successfully blinded participants to randomization.

This methodological quality assessment result is in line with the previous meta-analysis. Winkley et al. found that the quality of evidence in studies involving adults with type 2 diabetes was rated as moderate quality for the primary outcome (HbA1c). The reasons for moderate quality were the inconsistency and high heterogeneity in most subgroups of psychological interventions and interventionist subgroups. Otherwise, the quality of evidence was rated as high quality for the secondary outcomes, such as BMI and blood pressure[61].

Strengths and limitations

The study's strengths are a comprehensive systematic review and meta-analysis to examine the effect of family involvement in DSME on glycemic control. Only randomized controlled trials were included in this analysis to assure high validity. The researchers selected studies by two independent reviewers. This study is the first empirical review to explore the effectiveness of family involvement in DSME on glycemic control to the best of the researchers' knowledge. The researchers also performed subgroup analysis to answer clinically relevant and essential questions that had not previously been addressed. For all risks of bias assessed, most studies had a low risk of bias, and the overall body of evidence was rated to be moderate quality per the GRADE criteria.

This meta-analysis has several limitations. First, the researchers limited the selection of publications only to articles in the English and Indonesian language. Second, only peer-reviewed and published papers were evaluated. There was no assessment of grey literature, unpublished work, or dissertation studies. Third, the number of studies is frequently limited by the selective publication such as language, so only English and Indonesian articles were included in the meta-analysis. Fourth, there were considerable variations found in the intervention programs' components.

Furthermore, if the components between the trials were similar, variations could exist considering the intervention's strength or that the providers' education techniques would vary. Such variations might have contributed to the observed heterogeneity, reflected by the large CIs and I^2 values. There was a lack of clear definitions of "usual care" in most of the studies included, and there were also differences in the DSME methods in various studies. Although there were differences in the diabetes treatment methods provided for patients, it is clear that patients assigned to family DSME groups received more diabetes education than those in control groups.

CONCLUSION

In conclusion, the current evidence suggests that family involvement in DSME improves glycemic control in patients with type 2 diabetes. There are indications that less than 9% of baseline HbA1c, interventions delivered by individual and group combination, delivered in more than six months, contact hours longer than 10 hours, and moderate to high contact frequency give the best glycemic control results.

RECOMMENDATION

Further research with baseline HbA1c, intervention duration, delivery type, contact hour, contact frequency, and other characteristics can shed more light on the subject and provide useful information about DSME that will help determine the most successful regime. Secondly, research heterogeneity was high in this meta-analysis, indicating the need for more rigorously designed family DSME trials for patients with type 2 diabetes in the future. Thirdly, as in all meta-analyses, the risk of publication and selection bias must be considered. Finally, since the number of studies on family-based DSME is limited, further research with a large number of participants and a longer time of follow-up is required to gather further evidence.

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AUTHOR CONTRIBUTION

AA, BM, and DT had conceived the meta-analysis idea and were guarantors of the general content. AA and BM selected appropriate papers, retrieved them, and evaluated each trial. AA was responsible for the statistical analysis. AA and DT drafted the manuscript. All the authors revised the final manuscript and approved it.

CONFLICT OF INTEREST

There was no conflict of interest in this study.

THE AUTHORS DECLARE THAT THEY HAVE NO COMPETING INTERESTS.

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ETHICAL APPROVAL

This article does not contain any studies with human participants performed by any of the authors.

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