# **REVIEW ARTICLE**

# Effectiveness of Family-focused Interventions in Patients with Type 2 Diabetes Mellitus in Family and Community Practice: A Systematic Review and Meta-Analysis

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**Background**: Type 2 DM is a chronic disease and is increasing in prevalence and incidence worldwide. In developing nations like the Philippines, it affects patients and their families. Family-oriented interventions, like family counseling, meetings, interviews, and home visits, can support commitment to change and enhance medication adherence, health behavior, and knowledge ensuring adherence to the multifaceted diabetes type 2 management. Patients and families should be permitted to make decisions about lifestyle modifications and medication interventions and finding the appropriate family-focused intervention that works for managing type 2 diabetes is essential. With this information, family physicians can provide more effective care to patients hence, improving their quality of life.

**Objective**: This review's objective was to determine the effectiveness of family-focused intervention among patients with type 2 diabetes in terms of glycemic control (HbA1c and FBS) and in terms of improving the quality of life.

**Methods**: This is a meta-analysis that included clinical trials randomized involving adult participants that were diagnosed to have type 2 DM. The interventions tested was family-based interventions and the primary outcomes included are HbA1c and FBS. A systematic review was conducted for secondary outcome, patients' quality of life. Reviewers used the RevMan5 software in the analysis of data.

**Results**: Seven studies met the inclusion criterion. The overall mean difference in post-treatment HbA1c was -0.54%(95%Cl [-0.82,-0.25];p=0.0003) for the 1,265 participants included, showing an overall significant benefit of reducing HbA1c favoring intervention, especially on the 3-month follow-up. On subgroup analysis, the results were as follows: 3-months, -0.45%(95%Cl [-0.73,-0.16];p=0.002); 6-month, -0.15%(95%Cl[-0.51,0.22];p=0.44), and 12-month, -0.77%(95%Cl[-1.75,0.21], p=0.12). The overall difference in mean change in FBS showed a result of -7.8(95%Cl[-17.52,1.92],p=0.12) showing benefit, though not statistically significant, favoring intervention in decreasing FBS.

**Conclusion**: Family-focused interventions among Type 2 DM patients shows significant benefit on improving glycemic control and OOL.

**Key words**: type 2 diabetes mellitus, family-oriented, family, family-based, family-focused

# Introduction

Type 2 diabetes mellitus is a chronic disease and is increasing in both prevalence and incidence worldwide. It has a major impact on patients and families in third-world countries like the Philippines. In the 2014 prevalence study in the Philippines published by the International

Diabetes Federation, estimated that there are 3.2 million cases, with a 5.9% prevalence rate in adults between the ages of 20 and 79 years. Type 2 diabetes used to be known as adult-onset diabetes, is now also seen in more children probably due to the rise in childhood obesity. The family's lifestyle can strongly influence this. Aside from increasing prevalence, a major concern is the high cost of diagnosis, monitoring and treatment. There is no cure for type 2 diabetes, but losing weight, dieting and exercising can help manage the disease. This is based on existing guidelines that emphasize lifestyle changes, moderate weight

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loss (7% body weight), regular physical activity (150 min/week), reduced calories, sugar and dietary fat intake must be started. If diet and exercise are not enough to control blood sugar, oral diabetes medications or insulin therapy may be needed. The management plan should be formulated in collaboration with the patient, family, physician, and other members of the health care team. Implementation of the management plan requires that every aspect is understood and agreed upon by the patients and the care providers and that the goals and treatment plan are feasible. Any plan should consider the patient's age, work schedule and conditions, physical activity, eating patterns, social situation and cultural factors and presence of complications of diabetes or other medical conditions.4 Unfortunately, these multifaceted approaches are not easy to follow and require strong selfdetermination and discipline for adherence. To ensure adherence to the multi-faceted intervention for diabetes type 2, family participation is necessary. Patients and families should be allowed to make the decisions regarding lifestyle changes and the pharmaceutical interventions they will take. Type 2 diabetes as a lifestyle disease can be prevented by changing behaviors towards diets, physical activities, smoking and use of other substances. In this modern age, family involvement is important in managing the patients as they are the primary care giver and can also influence the behavior of the patients towards chronic diseases like diabetes mellitus. Having a family member engaged in patient care will help in self-care, self- efficacy and changing behaviors as this will also change the patient's environment.

Filipinos have a strong family unit. Family members provide robust support to those facing illnesses, ensuring that affected individuals are not subjected to discrimination within the family. Accompanied by a family member, those dealing with health issues regularly attend outpatient clinic visits. The financial responsibilities, including expenses for medications and laboratory tests, are collectively borne by siblings. Nursing homes are not a standard practice, family members take on the responsibility of providing disease support, particularly in cases like diabetes and its associated complications.<sup>6</sup> Central to the achievement of control of chronic lifestyle disease is the patient's knowledge and adoption of an appropriate lifestyle. To achieve this, interventions should be an ongoing process of improving the knowledge, skills and ability of the patient for diabetes self-care as well as assist a family member in implementing and sustaining patient behavior needed to manage their illness on an ongoing basis. The persistent and close social influence by a family member, a diabetic patient will be able to adopt and adhere to these changes. Family-oriented intervention, including family counseling, meetings, interviews, and home visits, can reinforce commitment to change and eventually improve medication adherence, health behavior, and knowledge. A study in Wuhan, China, concluded that family-based diabetes interventions, including health teaching, had significant improvements in glycemic control, body mass index, waist circumference, diabetes knowledge, self-efficacy, and selfcare activities among family members. Family involvement in managing lifestyle diseases like diabetes is important, as the goal is to change existing behaviors for an appropriate one. Patients with diabetes who received more support from their families could identify and implement self-care behaviors more efficiently than those with lesser family support.

As Type 2 diabetes is also considered a familial disorder that can be present in the next family generation, it is therefore necessary to identify the appropriate family-focused intervention that is effective in controlling type 2 diabetes mellitus. With this information, family physicians will be able to provide effective care to their patients with this condition and further improve their quality of life. This will also avoid the unnecessary complications that might result from poor management and control of the disease. Involving the patient's family will allow them to handle the medical, social, and economic burden of this disease that might also be present in the next generations. This will also provide the needed information to the Department of Family and Community Medicine, Batangas Medical Center, and the Philippine Academy of Family Physicians in strengthening the role of the family in managing type 2 Diabetes Mellitus in the pre-existing clinical practice quidelines.

This systematic review and meta-analysis was conducted with the objective of determining the effectiveness of family-focused interventions among adult patients with type 2 diabetes in terms of blood sugar control (HbA1c and Fasting Blood Sugar) as the primary outcome and in terms of improvement in quality of life (QOL) as a secondary outcome.

#### METHODS

# **Protocol Review and Registration**

This systematic review protocol was registered with the Research Committee of the Philippine Academy of Family Physician. It was also registered to Batangas Medical Center where the investigators are affiliated. It was conducted following the guidelines of Cochrane Handbook for Systematic Reviews of Interventions and reported following the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA). If there are any adjustments throughout the study, the authors have fixed and updated the details in the final report.

#### **Inclusion Criteria of Studies**

Study Design

This systematic review and meta-analysis only included comparative clinical trials, randomized clinical trial design involving humans as the clinical subjects. Published studies in peer reviewed journals of PubMed, clinical trials registered Cochrane Central Register of Controlled Trials and the grey literature were also included. Foreign language studies were included if the authors could obtain additional information necessary for the evaluation and extraction of relevant data from the article. Non-comparative clinical trials, outcomes research or real-world data, animal experiments, reviews and case reports were excluded in this review.

## **Participants**

The participants in the study were diagnosed to have diabetes mellitus type 2 based on the presence of any of the following criteria:

1) A1c≥6.5%; 2) FPG≥126 mg/dL (7.0 mmol/L); 3) 2h plasma glucose≥200mg/dL (11.1mmol/L) during an OGTT; and 4) In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose≥200 mg/dL (11.1 mmol/L)³ and have been appropriately evaluated and eligible to receive the interventions. The authors can also include studies with participants who have other comorbidities.

#### Interventions

One of the interventions tested was the family-based intervention. Clinical trials where the intervention described involved the family or labelled as 'family therapy'. The main categories of family therapy approaches considered were: 1) structural or systems intervention; 2) strategic family therapy that is focused on family issues; 3) family-based therapy and its variants like educational and behavioral interventions; and 4) others like approaches that use family involvement in therapy as treatment partner or therapeutic ally. These family interventions were delivered as monotherapy or in conjunction with other interventions including standard care.

The control intervention could be placebo or the currently accepted standard treatment. This is usually described in the literature as:

1) standard care or usual treatment; 2) pharmacologic interventions;

3) patient-only directed educational, psychological, or behavioral interventions; and 4) alternative or complementary interventions. Both the intervention and control groups should have similar other co-interventions and did not receive any other intervention that might interfere with the outcome of the study.

For the electronic search, the researcher used the combination of terms ("family oriented" OR "family-oriented" OR "family-based" OR "family") AND ("type 2 diabetes" OR "diabetes type 2"). The authors then limited the search to the following study types "clinical trials" OR "randomized controlled trials". Other limits were not utilized to maximize the yield of their initial search.

PubMed (https://pubmed.ncbi.nlm.nih.gov/) and Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (https://www.cochranelibrary.com/central/about-central) were the databases used for the primary studies. Cross reference search was also utilized by the researchers. The references listed in the included articles were reviewed to determine if there are available citations that can included. A grey literature search was also done to identify studies that are not indexed in the cited database. The following grey literature databases such as Open Grey (www.opengrey.eu), Grey Literature Report of the New York Academy of Medicine (www.greylit.org), Agency for Healthcare Research and Quality (www.ahrq.gov), National Institute for Health and Clinical Excellence (www.nice.org.uk) were used.

## **Data Collection and Analysis**

Three review authors independently carried out all aspects of study selection, risk of bias assessment and data extraction and then resolved any disagreement through a discussion.

#### **Selection of Studies**

The researcher downloaded all titles and abstracts retrieved by electronic searching and were duplicated. Three independent reviewers initially screened the titles and abstracts that meet the criteria. Then the full text copy of all the articles that met the criteria after evaluating the title and abstract by each reviewer were retrieved. The three reviewers read the full text article and arrived at a consensus if the study should be included or not. The decision to include or exclude was cross-checked by each reviewer. If there was a disagreement in the selection process, the reviewers made further discussion until an agreement was reached. Assessors identified and recorded reasons for exclusion of the ineligible studies. A list of studies that initially appeared to meet the inclusion criteria but later excluded was noted in the 'Characteristics of excluded studies' table. PRISMA flow diagram was used to show the screening process of the study inclusion and exclusion.

#### Risk of Bias Assessment

The risk of bias for each study was assessed using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions. Authors assessed the risk of bias according to Bias arising from the randomization process, due to deviations from intended interventions, missing outcome data, measurement of the outcome, selection of the reported result, and any other source of bias. The researchers judged each potential source of bias as "high", "low", or "unclear" and provided a quote from the study report together with a justification for their judgment in the "Risk of bias" table. The risk of bias judgements were summarized across different studies for each of the domains listed. An overall risk of bias assessment (low risk of bias; some concerns; or high risk of bias) was assigned to each of the included studies. Specifically, studies with low risk of bias for all key domains, or where it seems unlikely for bias to seriously alter the results, to have a low risk of bias. Those studies are considered to have some concerns where the study is judged to raise some concerns in at least one domain. but not to be at a high risk of bias for any domain. Studies with a high risk of bias in at least one domain or judged to have serious concerns for multiple domains in a way that substantially lowers confidence in the result, are considered to have a high risk of bias. Studies were not excluded on the grounds of their risk of bias but the risk of bias when presenting the results of the studies was clearly reported.

# **Data Extraction and Management**

A data collection form in hard copy and MS Excel form for data collection was utilized wherein, study characteristics and data outcomes were extracted. The data collection on at least one study in the review was piloted. The main data extracted from the included studies were Methods (study design, number of study centers and location, study setting, withdrawals, date of study, follow-up), Participants (number, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria, other relevant characteristics), Interventions (intervention components, comparison, fidelity assessment), Outcomes (main and other outcomes specified). This data

was extracted by three reviewers and there was no disagreement with the extracted data. The authors were also contacted for clarification. All the extracted data were cross-checked by these three reviewers.

#### **Variables**

The primary outcome of this meta-analysis is the control of blood sugar either HbA1c or FBS. Secondary outcome like the patients' quality of life were also investigated. Measures of family function scale, and satisfaction to care should have been included in the secondary outcomes but such were not seen in the reviewed studies. Negative events as secondary outcomes like hospital admission, appearance of complications or mortality were also considered but no such outcomes were present in the included studies.

## **Analysis**

RevMan5 software was utilized in the analysis of the extracted data. Different evaluation methods were used according to the different efficacy indicators. This study assessed the effectiveness of intervention by determining the difference in post-treatment HbA1c and FBS between the treatment groups, and also explored the impact on the improvement of Quality of Life. The mean difference or standardized mean difference, together with the 95% associated confidence interval for continuous data was used.

## **Assessment of Heterogeneity**

Heterogeneity was assessed by Chi-squared test and  $I^2$  test. If  $I^2$  is < 50%, p>0.1, it is considered that there is no statistical heterogeneity between each study and choose a fixed effect model (FEM) to synthesize the data. If  $I^2$  is  $\leq$  50%, p<0.1, indicating that there is a statistical heterogeneity, the data is then integrated by the random effect model (REM).

#### **Subgroup Analysis**

The results in the primary outcome, HbA1c, was heterogeneous, and because of that subgroup analysis for the follow-up schedule (3 months, 6 months, and 12 months) was conducted.

## **Grading the Quality of Evidence**

In this systematic review, the quality of evidence for the entire study was assessed using the "Grades of Recommendations Assessment, Development and Evaluation (GRADE)" standard established by the World Health Organization and international organizations. The authors assessed the certainty of the evidence (high, moderate, low, and very low) using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias).

#### RESULTS

# **Study Selection**

In the initial database search while using the search terms mentioned above, a total of 152 studies were identified. After removing the duplicates, 82 studies remained and needed to be further evaluated. Sixty-eight studies were further removed after reading the titles. Abstracts of sixteen studies were then screened further and the reviewer excluded one as it was a study for the pediatric age group. Full-text for the remaining 15 studies were retrieved for review and eight studies were excluded due to the following reasons: four studies were protocols only and did not have results yet, three were Quasi-Experimental studies, and one study focused on a patient outcome that is not relevant to this review. For the final meta-analysis, seven studies met the inclusion criterion and were included. (Figure 1)

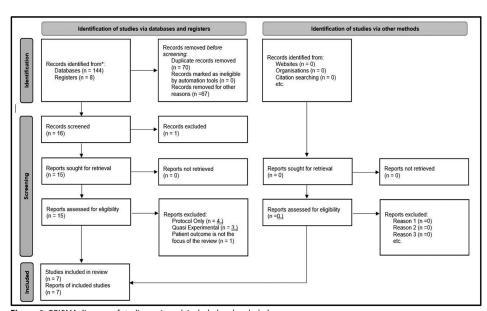


Figure 1. PRISMA diagram of studies reviewed, included and excluded.

## **Characteristics of the Selected Studies**

Seven studies with a total of 1,265 participants met the inclusion criteria. (Table 1) Assigned to the intervention group and the control group are 627 and 638, respectively. All included studies were randomized control trials<sup>12,13,14</sup> two being single-blinded ones<sup>15,16</sup> and another as an experimental repeated<sup>13</sup> measure with publication years between 2011-2018. The follow-up period in the

said studies ranged from 3 months to 12 months. The control group in all the studies included in this meta-analysis underwent the usual standard diabetic care which included: 1) blood glucose monitoring, and 2) basic education that does not involve a family member or a caregiver. The ages ranged from 49 to 61 years old, the baseline HbA1C and FBS ranged from 6.3% to 9.99% and 147.3 to 163.76 respectively. Patients included in the studies were diagnosed with Type 2 Diabetes mellitus for 5.4 to 11.9 years.

Table 1. Table of included studies.

Author, Year Study Design Country	Study Samples/ Age in years Mean (SD)	Intervention/Duration	Outcome Measures	Results
Keogh, 2011	T2DM patients, >18 years old N=121	Psychological family-based intervention (motivational interviewing) – 3 weekly sessions lasting 45 minutes	HbA1c	There were no significant differences in follow-up A1C between groups in block 1 or block 2.
USA	IG= 60/59.96(11.67) CG=61/57.29(11.34)	with a family member and a 10-minute follow-up telephone call	<u> </u>	In block 3 there was a statistically significant difference of 1.2% in follow-up A1C levels between the groups (intervention mean of 8.70% [SD =1.16%], n = 15, vs control mean of 9.95%
	IG: intervention group CG: control group	CG: Usual diabetes care  12 months		[SD = 1.31%], n = 15; B = -1.28, SE (B) = 0.49; P = .01; 95% confidence interval, = -2.29 to - 0.26).
Gomes, 2017 Single-blind RCT	T2DM patients aged >40, lacks complications N=222/60.43 (8.38)	IG: Educational intervention and motivational counseling with a participation of family/caregiver through telephone contact	HbA1c, FBS	The clinical variables based on the results of the laboratory tests also showed no differences between groups at both T6 and T12.
Brazil	IG = 108 CG= 114	CG: Educational intervention without family/caregiver		However, clinical improvement was evident in the comparison analysis between study times within groups; the IG showed a greater reduction in HbA1c at both T6 and T12, whereas the CG only showed a reduction at T12 that was smaller than
Maslakpak, 2017	T2DM patients, 18-55, no	In the face-to-face family-	HbA1c, FBS	that of the IG.  Both HbA1c and FBS, despite showing a
RCT Iran	underlying conditions N= 90	oriented education group, the subjects were subsequently divided into 3 smaller groups to		decreasing trend in the intervention groups, this change did not reach statistical significance.
	IG (F2F)=30/49.9(4.98) IG (PB)=30/49.46(4.76) CG=30/50.6(3.74)	attend the educational classes face-to-face classes was between 8 A.M. and 2 P.M. from Saturday to Wednesday. These classes lasted for 20–30		HbA1c CG: 7.8 (1.7) → 7.8 (1.5)
		minutes.		IG:
	F2F: Face-to-face TB: phone-based	the telephone-based family- oriented education group, they performed the educational		Phone group: 8.2 (1.1) → 7.3 (1.2)
		session. The time of the telephone call was set at 9 A.M.		Face to face group: 7.9 (1.5) → 7.2 (1.2)
		to 10 P.M., lasting for 15 to 30 minutes, twice a week in the		FBS (mg/dl)
		first and second months and once a week in the third month.		CG: 147.3 (42.56)→ 150.9 (38.69)
		the control group received the paper-based educational materials of the teaching		IG (phone): 154.5 (46.7) → 138.33 (33.43)
		sessions.		(face to face): 163.76 (50.63) → 144.3 (37.65)
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McEwen, 2017 RCT USA	T2DM patients  N= 157/53.53(9.0)  IG= 83/53.64(9.6)  CG= 74/53.42(8.4)	IG: 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)	HbA1c	Participants' A1c did not significantly change over time (group by time interaction). For both groups, A1C decreased slightly from baseline to T2(3 months), with the decrease greater for the intervention group. The control group continued to decrease from T2 to T3(6 months) while the intervention group increased slightly.
		three 20-minute telephone calls scheduled weekly for 3 weeks.		

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Study Samples/ Age in years Mean (SD)	Intervention/Duration	Outcome Measures	Results
	CG: Two-hour educational sessions provided weekly for 3 weeks		
Adults diagnosed with T2DM , at diabetes outpatient clinic N=140 IG=70/61.3(11.6) CG=70/55.5(10.5)	12 weeks Intervention consists of three education sessions delivered at baseline, week 5 and week 13.  Control group received standard care from clinical staff which includes blood sugar testing, medical and nursing physical examinations and medication follow-up	HbA1c, QOL QOL was measured using the Thai version of the 12-item short form health survey (SF12) – physical and mental aspect only	A significant increase in HbA1c was noted in the control group (indicating a deterioration)  No associations between the family-oriented self-management intervention and better quality of life or improved glycemic control was found.
T2DM patients, >30 years old  N= 196 IG=98 CG=98	Intervention group received usual care, and education package for participants and their relatives. It was administered during 4 visits within a 9-month period, at approximately 3-month interval. Each intervention lasted 40-50 minutes and was carried in a private room. Followed by counseling and telephone follow-up.  Control group received usual diabetes service every 3 months. Only patients with very poor glycemic control of blood glucose levels were educated mainly by nurses. Intervention to 10-15 minutes without the involvement of family members	HbA1c	Over the 9-month intervention period, the intervention group showed superiority over the control group in glycemic control, with HbA1c reductions of -1.37% (-14.99mmol/mol, P < 0.001) and -0.21% (-2.28 mmol/mol, P = 0.270), respectively.  Between-group difference in the changes of HbA1c was -1.16 % (-12.71 mmol/mol, P< 0.001)
At least 6 months diagnosed with Type 2 DM patients, at least 30 years old  N=80 IG =40/58.61(7.69) CG =40/53.50 (9.22)	9 months  The IG has undergone routine care with an additional family-oriented program that included education classes, group discussions, a home visit, and a telephone follow-up (every 2 weeks)  CG: 3-week period (1.5 hour each session, without family member/caregiver present)  12 weeks	Quality of Life  45 item questionnaires with 5 dimensions  Physical, mental, social, economic and disease and treatment issues  Likert scale from 1-5  Highest score =	A significant increase in the mean QOL scores of patients in the IG at posttest on the physical, mental, social, and disease and treatment dimensions as well as the total score (p=0.001)
	Adults diagnosed with T2DM, at diabetes outpatient clinic N=140 IG=70/61.3(11.6) CG=70/55.5(10.5)  T2DM patients, >30 years old N=196 IG=98 CG=98  At least 6 months diagnosed with Type 2 DM patients, at least 30 years old N=80 IG=40/58.61(7.69)	Adults diagnosed with T2DM, at diabetes outpatient clinic  N=140  IG=70/61.3(11.6) CG=70/55.5(10.5)  T2DM patients, >30 years old  N= 196  T2DM patients, >30 years old  N= 196  CG=98  T2DM patients, >30 years old  N= 196  Adults diagnosed with T2DM patients, at least 30 years old  At least 6 months diagnosed with Type 2 DM patients, at least 30 years old  N= 80  N=80  IG=40/53.50 (9.22)  Intervention consists of three education sessions delivered at baseline, week 5 and week 13.  Control group received standard care from clinical staff which includes blood sugar testing, medical and nursing physical examinations and medication follow-up  13 weeks  Intervention group received usual care, and education package for participants and their relatives. It was administered during 4 visits within a 9-month period, at approximately 3-month interval. Each intervention lasted 40-50 minutes and was carried in a private room. Followed by counseling and telephone follow-up.  Control group received usual diabetes service every 3 months. Only patients with very poor glycemic control of blood glucose levels were educated mainly by nurses. Intervention to 10-15 minutes without the involvement of family members  At least 6 months diagnosed with Type 2 DM patients, at least 30 years old  CG: 3-week period (1.5 hour each session, without family member/caregiver present)	Adults diagnosed with T2DM, at diabetes outpatient clinic N=140 Control group received standard care from clinical staff which includes blood sugar testing, medical and nursing physical examinations and medication follow-up  T2DM patients, >30 years old N= 196 CG=98 T2DM patients, >30 years old CG=98 T2DM patients, at least 30 years old CG=40/53.50 (9.22) T2DM patients, at least 30 years old CG=40/53.50 (9.22) T2DM patients, at least 30 years old CG=30-80 CG=30-80 CG=30-80 CG=30-80 CG=40/53.50 (9.22) CCG: 3-week period (1.5 hour each session, without family member/caregiver present) CCG: 3-weeks CGG=40/53.50 (9.22) CCG: 3-week period (1.5 hour each session, without family member/caregiver present) CCG: 3-weeks CCG: 3-week period (1.5 hour each session, without family member/caregiver present) CCG: 3-weeks CCG: 3-weeks CCG: 3-week period (1.5 hour each session, without family member/caregiver present) CCG: 3-weeks CCG: 3-week period (1.5 hour each session, without family member/caregiver present) CCG: 3-weeks CCG: 3-week

Among the seven studies included in this meta-analysis, one was a three-arm interventional study, having two intervention groups and one control group.<sup>12</sup> All studies included in this review utilized educational interventions as one of the family-based interventions. These training and educational programs were conducted by trained healthcare workers such as doctors, nurses, and pharmacists to the participants and proclaimed family member/caregiver. 10,12-17 Relevant topics included were adherence to medication, blood sugar monitoring, diet, foot hygiene, physical activity, and coping with diabetes-related complications.<sup>17</sup> Motivational interview and counseling were also used in three studies. Through this, facilitators of the training program were able to encourage and modify participants' practices with family support. 12,13,15 This type of intervention also aimed to encourage discussion between the patients and their families thus increasing the caregiver's interest in DM-related matters and DM care. 13 To reinforce the key points of the educational interventions, six out of seven studies used telephone calls that lasts from 15-20 minutes to follow-up on participant's progress and identify the barriers in attaining the treatment goal. 10,12-15,17 Another intervention is the use of group discussion among participants and partner relatives. Group discussions were conducted to emphasize self-care practices as participants exchange ideas and share experiences among them. 13,14,16 Three studies used a workbook and pamphlet in patient education, two were used as a supplement for the educational training and the other as a control. 12,14,16 One study used home visits to match the knowledge and skills acquired from the group session designed to the family concept. 10

## **Risk of Bias in Studies**

Among the seven included studies, overall risk of bias assessment shows high risk of bias on performance, attrition, reporting and other bias. (Figure 2). Performance bias or the blinding of both participants and personnel is at high risk as two studies were single-blinded (personnel only was blinded) and the other one is an experimental repeated RCT wherein there was no blinding. In terms of attrition bias, two studies have high dropout rates which contributed to the outcome data to be incomplete. With this, there was also a noted selective reporting as those who are lost to follow-up were excluded in the analyzing of result. One study offered grocery certificates to some participants and their corresponding family members. After a thorough review and assessment of the risk of bias of all the included studies in this meta-analysis, all are considered low risk for selection bias as these studies used randomization in selecting and allocating their participants.

The studies of Keogh et al. (2011), Witchit et al. (2017), and McEwen et al.(2019) have high risk in terms of performance as these studies did not completely blind the participants and the personnel involved in facilitating the said intervention due to the following reasons: 1) the psychological nature of the intervention (motivational interview), the psychologist involved was not blinded<sup>15</sup>, 2) Prior to commencement of the study, participants were verbally informed that they will be allocated into treatment and control group 16, and 3) a nurse educator conducted the sessions for the intervention group.<sup>17</sup> Studies low risk for performance bias took extra steps to make sure that participants and personnel were blinded by doing the same procedure as telephone calls for the control group too. 13 Withidpanyawong et al.(2018) has unclear risk as only the personnel (physicians and nurses) were blinded while participants and family members were not blinded to the intervention.

Unlike the other six studies that were assessed to be low risk for detection bias, the study of McEwen et al (2019) did not mention if there was blinding for the assessor of the study. 17 As for the assessment

Blinding of participants and personnel (performance

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Incomplete outcome data (attrition bias)

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sequence generation (selection bias)

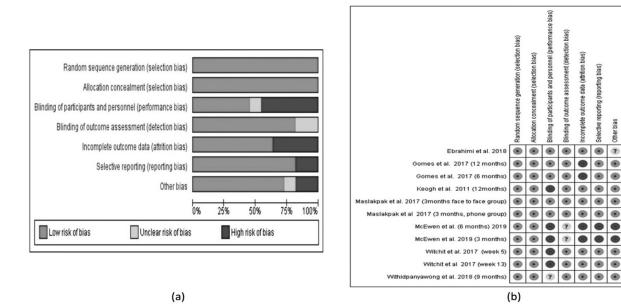


Figure 2. Risk of bias assessment. (a) Overall assessment, (b) Individual assessment

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of the risk for attrition bias, two studies were found to have a dropout rate of more than 20%, the study of McEwen had 55% and Gomes have 24% and 28% dropout rates for the intervention and control group, respectively. Studies with a low risk for attrition bias have dropout rates that range from 0% to 18%.

Attrition bias indicates that all participants even the dropouts were analyzed and accounted for. In this review, only the study of McEwen et al. (2019) had excluded results of the dropouts, hence, it was high risk for this bias. For other biases (i.e., conflict of interest), all but one study mentioned that they have no conflict of interests. McEwen et al., stated in their methods that adult participants and their corresponding family members were given grocery certificates for participating in the said study without giving the same treatment to the control group. 17

## **Effect of Family-based Intervention on Glycemic Control**

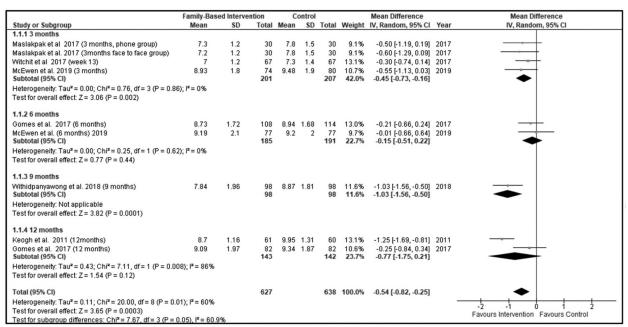
Glycosylated hemoglobin (HbA1C)

Figure 3 is a forest plot of HbA1C changes in the intervention groups compared with the control groups. Of the seven studies in this review, six studies observed glycemic control by taking note of HbA1c level at baseline and on the subsequent follow-ups. No significant change over time was reported in 4 out of the 6 studies between groups.  $^{12,13,16,17}$  The two other studies that reported a significant change were the studies of Withidpanyawong et al. (2018) which stated that in over the 9-month intervention period, the intervention group showed superiority over the control group in glycemic control, with HbA1c reductions of -1.37% (-14.99mmol/mol, p < 0.001) and -0.21% (-2.28 mmol/mol, p = 0.270), respectively  $^{14}$ ; and the study of Keogh et al (2011) reported statistically

significant difference of 1.2% in follow-up A1C levels between the groups (intervention mean of 8.70% [SD=1.16%], vs control mean of 9.95% [SD = 1.31%]). <sup>15</sup> The overall difference in mean post--treatment HbA1c was -0.54% (95% CI [-0.82%,-0.25%], p=0003) for the total of 1,265 participants (IG=627, CG=638). A heterogeneity Chi<sup>2</sup>=20.00, df=8 (p=0.001);  $I^2$ =60%. As for the overall effect of the test, a Z=3.65 (P=0.0003). To address the heterogeneity issue  $(I^2=60\%)$ , a subgroup analysis was done by grouping all the extracted results in accordance to the time of follow-up (3,6 and 12 months). After analyzing each subgroup, results were as follows: for the 3 month subgroup the HbA1c change at 95% CI was -0.45% [-0.73, -0.16] p=0.002; for the 6 month subgroup it was noted to be -0.15% [-0.51,-0.22] p=0.44, and at 12 month subgroup it was -0.77%[-1.75,0.21] p=0.12. Overall pooled result showed significant benefit in favor of the family-based interventions in terms of improving HbA1c. Subgroup analysis based on duration of treatment showed significant benefit only in the 3-month follow-up.

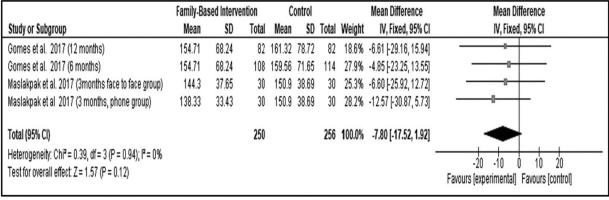
# Fasting Blood Glucose

FBS is another primary outcome that was investigated in this review. The forest plot for the comparison of the difference in mean change in FBS. Of the seven reviewed studies, only two studies had FBS as one of their outcome measures. (Figure 4) This was taken at baseline and then on follow-up to monitor the efficiency of glycemic control using family-based intervention. Maslakpak et al.(2017) measured FBS after a 3-month follow-up on two intervention arms. At a 95% confidence interval, these are the results: face to face -6.60 [-25.92, 12.72] and telephone based -12.57[-20.87,5.73] intervention. <sup>12</sup> Gomes et al. (2017) also assessed the mean difference in FBS at 6



\*Mean Difference (MD) = mean post-treatment HbA1c in IG – mean post-treatment HbA1c in CG

Figure 3. Analysis of effectiveness on HbA1c of family-based interventions



\*Mean Difference (MD) = mean post-treatment FBS in IG - mean post-treatment FBS in CG

Figure 4. Analysis of Effectiveness on FBS of Family-Based

and 12-month post-intervention which were -4.85 [-23.25,13.55] and -6.61[29.16,15.94] respectively.<sup>13</sup> The overall difference in mean post-treatment FBS for these two studies was -7.8 [-17.52, 1.92] Though there was a notable decrease in trend for the FBS levels in the intervention groups, this value did not reach statistical significance.

## Effect of Family-based Intervention on Patient's Quality of life (QOL)

Two studies assessed the effect of family-based intervention on the Quality of life. One of these studies is the study of Ebrahimi et al (2018). In this study, intervention was an educational training program attended by both the patient and designated caregiver or relative. There was no significant difference noted in an individual t-test between the intervention and control groups. However, there was a noted improvement in the mean scores of QOL patients on pretest and post-test in favor of the intervention group in all dimensions except in the economic (p = 0.27) aspect.<sup>10</sup> No associations between the family-oriented self-management intervention and better quality of life was found in a study conducted by Witcht et al (2017). Better self-management significantly increased self-efficacy (p < 0.001), both physical (p = 0.03) and mental (p = 0.002) components of quality of life. Estimates of the effect of family-based interventions for QOL were not pooled as the two studies included used different tools in measuring the outcome.

#### Grading The Quality of Evidence

Assessing for the Grades of Recommendations Assessment, Development and Evaluation (GRADE) resulted in high certainty for the 9-months follow-up but low certainty for the HbA1C outcome for 3-, 6-, and 12-months follow-up. This is attributed to the lack of blinding, not doing the intention to treat analysis, and due to an increased rate of dropouts. Studies that were appraised for the FBS outcome, also got low certainty quality of evidence, and this is also due to attrition bias. On the other hand, for the effect of family interventions to quality of life, certainty quality of evidence is high as risks for biases were not serious.

#### Discussion

This review evaluated the effectiveness of a family-oriented intervention in improving glycemic control and quality of life. The interventions used in the studies involved a family member or a caregiver to undergo special training/education and motivational interviewing to aid diabetic patients in self-sufficiency and self-care. The overall effect of these interventions on HbA1c levels of diabetic patients (-0.54% [95%Cl 0.82,-0.25]) showed a significant benefit in terms of lowering HbA1c levels, most especially in the 3-month followup (-0.45 [95% CI [-0.73, -0.16). This significant decrease in the HbA1c levels in patients can reduce the risk of developing complications like cardiovascular diseases, nephropathies, neuropathies, retinopathies and amputations. In the effect on FBS, though there is noticeable decreasing trend in blood glucose levels, results showed no statistically significant difference in glycemic control between the two groups. In addition, patients' self-efficiency scores and quality of life are also improved. It is also worth noting that with an increased adherence to management, there is also an increase in prevention of complications and hospitalizations. A longer follow-up should have been utilized to prove how family-based interventions can be sustained on their own. Though strengthening the family and support is significant in patient's adherence to management, negative or adverse effects like family conflicts may also arise. For example, the patient might perceive the tight-knit bond as "controlling" and in effect, become a barrier in diabetic care. In this review, there was no mention of the said adverse effects, but it should be noted or reported to understand fully the effect of the said intervention.

The implications derived from the results of this review bear significant relevance to family and community practice in the context of diabetes management. This study, focusing on the effectiveness of a family-focused intervention, revealed promising outcomes in terms of improved glycemic control and enhanced quality of life. These findings suggested that interventions targeting the familial unit can play a pivotal role in positively influencing health outcomes for individuals with diabetes. Family-focused strategies may prove instrumental in fostering a supportive environment that encourages healthier lifestyle

choices, medication adherence, and overall well-being. Furthermore, the positive impact on quality of life implies a broader societal benefit, as healthier and more satisfied individuals contribute not only to their immediate families but also to the community at large. Integrating family-focused approaches into community healthcare practices could thus represent a valuable avenue for enhancing the effectiveness of diabetes management and promoting holistic well-being. It can be noted that involving a family member in managing a diabetic patient, in general, can positively affect patient adherence to management, and in effect, improve glycemic control and the patient's quality of life.

This review covered only seven studies, hence results may not represent all family focused interventions that other institutions or countries are practicing. Since studies are based internationally, the interventions used may have a different effect if applied in the local setting. But considering that Filipinos are more family-centered, the intervention can be utilized in the local setting and may lead to a greater benefit.

#### Conclusion/Recommendations

This systematic review was undertaken to assess the effectiveness of a family-oriented intervention in enhancing glycemic control and quality of life yielded notable findings. Meta-analysis showed that incorporating family-oriented intervention into the management of a diabetic patient may have significant positive impact with an overall significant benefit in favor of the family-based interventions in terms of lowering HbA1c levels. This involvement was observed to enhance patient adherence to management strategies, subsequently leading to improvements in glycemic control. Moreover, the study highlighted a parallel enhancement in the overall quality of life for the patients. These results emphasize the importance of a family-focused approach in diabetes care, and its potential to bring about tangible benefits in both glycemic control and the overall well-being of individuals managing diabetes.

The findings of this study bear significant implications for practical application in family and community practice. Firstly, the demonstrated effectiveness of the family-oriented intervention in enhancing glycemic control and quality of life suggests that healthcare practitioners should consider incorporating such interventions into routine family and community care protocols. Implementing these strategies could prove instrumental in managing and preventing type 2 diabetes within familial contexts. Additionally, practitioners should note the importance of family engagement and support in diabetes management during patient consultations. Furthermore, as this study provides valuable insights into the positive outcomes of family-focused interventions, it also highlighted the need for further research in this domain. Future studies, hopefully local ones, can delve deeper into specific components of family-oriented interventions, evaluate longterm sustainability, and explore variations in effectiveness across diverse demographic groups. Such continued research efforts will not only refine current understanding of effective family-based approaches but also contribute to the development of tailored interventions that address the unique dynamics of family and community settings in the context of diabetes care.

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