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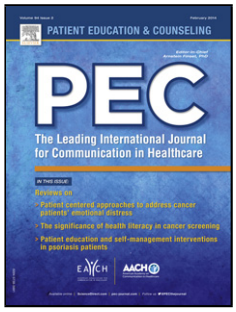

Title: Family-based intervention by pharmacists for type 2 diabetes: A randomised controlled trial

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Short title: Family intervention by pharmacists for type 2 diabetes

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Highlights

- A study investigating family involvement for type 2 diabetes is conducted.
- Family intervention improves glycaemic control and health-related outcomes.
- Involvement of spouses or women as caregivers has effects on glycaemic improvement.
- Family-involvement intervention should be promoted in diabetes care.

Abstract

Objectives: To investigate the effectiveness of family intervention for type 2 diabetes and to examine predictors of glycaemic control.

Methods: This was a prospective randomised controlled trial. Participants with type 2 diabetes were randomly assigned to an intervention group (n = 98) or a control group (n = 98). A pharmacist delivered the educational sessions and encouraged family members to take an active role in self-management practices for the intervention patients. The control patients received usual care.

Results: At the end of the study (9-month follow-up), greater reduction in glycosylated haemoglobin (HbA_{1c}) occurred in the intervention group than in the control group (-1.37% and -0.21%, respectively; $P < 0.001$). Between-group differences in the improvements of low-density lipoprotein cholesterol (LDL-C) and blood pressure were found ($P < 0.05$). Higher scores in diabetes knowledge of patients, family support, medication adherence, self-management and self-efficacy were seen in the intervention group than in the control group ($P < 0.05$). Multivariable analysis showed family members who were spouses or women were strong predictors of improved glycaemic control.

Conclusion: Family-involvement intervention is helpful in diabetes management, especially having spouses or women as caregivers.

Practice implications: Family involvement should be encouraged in diabetes care.

Keywords: Family intervention, pharmacist, type 2 diabetes

1. Introduction

Diabetes is a public health crisis worldwide. The global burden of diabetes was 425 million in 2017 and may swell to 629 million by 2045 [1]. Type 2 diabetes accounts for 90-95% of all cases [2].

Good glycaemic control is necessary to prevent the progression of microvascular and macrovascular complications. Nonetheless, a high proportion of patients (at least 30%) do not meet the glycaemic target (glycosylated haemoglobin (HbA_{1c}) level of < 7.0% (< 53 mmol/mol) [2]. The reasons for poor control of diabetes include lack of knowledge about the illness and low levels of social support from family members [3, 4]. Several studies have focused on how to improve patients' knowledge or awareness on diabetes and management using educational interventions [5, 6]. Social support has been shown to have a positive association with health outcomes. Social support is a perception that one is able to receive assistance from others or actual support. The resources for social support include health professionals, friends and family members [7, 8]. Family factors have been important for helping patients with self-management tasks [9]. Better adherence to self-management is correlated with well-controlled glycaemic level [10]. Accordingly, the role of family is a necessary aspect of intervention for patients with diabetes. Numerous randomised controlled trials have investigated family involvement in caring for people with type 1 diabetes but similar studies in type 2 diabetes are limited. Moreover, most previous studies regarding family-based intervention for diabetes care did not thoroughly examine adherence to treatment regimens [11-13]. Improvement in medication compliance has a positive effect on glycaemic control [14]. Apart from the evaluation of biological outcomes,

no studies have comprehensively investigated the other aspects of outcomes covering medication adherence, diabetes knowledge of patients and their family members, family support behaviours, self-management and self-efficacy. In addition, pharmacist-led intervention is rarely targeted in family support for adults with diabetes. Health intervention by pharmacists has been shown to improve clinical outcomes in diabetes [15, 16]. The objectives of this study, therefore, were to investigate the effectiveness of family intervention by pharmacists on diabetes control and other health-related outcomes including medication adherence, diabetes knowledge of patients and their family members, family support behaviours, self-management and self-efficacy in type 2 diabetes and to assess the determinants of glycaemic improvement.

2. Methods

2.1. Study design and setting

A randomised controlled trial was conducted with a 9-month follow-up period (from June to March 2015). The study site was the outpatient diabetes clinic at a hospital located in the south of Thailand.

2.2. Ethical approval

Ethical approval for this study was obtained from the Research Ethics Committee, Faculty of Pharmaceutical Sciences, Prince of Songkla University (ST.0521.1.07/902). All participating patients and their family members gave written

informed consent before recruitment into the study. The clinical trial registration was Thai Clinical Trial Registry TCTR20140526002.

2.3. Participants

Potential participants were identified from the database of the diabetes clinic at the study site by a research pharmacist.

Inclusion criteria included (1) being at least 30 years of age, (2) having diagnosis of type 2 diabetes, (3) presence of oral hypoglycaemic therapy, (4) poor glycaemic control (HbA_{1c} > 7.0% or > 53 mmol/mol), (5) ability to attend regular visits at the diabetes clinic, and (6) having one family member who was willing to help in diabetes management. Family members were those of age at least 18 years, living in the same household as participants and being a spouse or significant relative of the participant. Exclusion criteria for patients included (1) history of severe complications or life-threatening illnesses such as renal failure or cancer, (2) use of insulin, and (3) pregnancy or lactation.

Sample size estimation was based on HbA_{1c} values from the study by Kang et al. [11]. The levels of HbA_{1c} at the end of the study for the intervention group and the control group were 7.9 + 1.4% and 8.1 + 1.2%, respectively. Detection of 0.6% between group difference in HbA_{1c} with a significant level of 0.05 and a power of 80% required a sample size of 73 per group. To account for 15% dropouts, target sample size was increased to 85 per group. The participants were assigned to the intervention group or the control group via stratified randomisation using participants' age, duration of diabetes and HbA_{1c} levels by a research pharmacist.

2.4. Study instruments

All the instruments in the English version were translated into Thai. The questionnaires were assessed for content validity by three experts in clinical pharmacy and were tested for reliability in 65 participants with diabetes.

The diabetes knowledge questionnaire was derived from the General Knowledge of Patients with Diabetes (in Thai) by Wongwiwatthananukit et al. [17]. The test consists of 16 items with a 3-point response (true/false/don't know). The content validity index (CVI) was 0.98 and Cronbach's alpha was 0.68. The Family behaviour measurement was derived from the Diabetes Family Behaviour Checklist (DFBC) by Glasgow et al. [18]. The instrument included 9 items on supportive and non-supportive family behaviours with a 5-point scale from "none" to "at least once a day". The DFBC had a CVI of 0.92 and a Cronbach's alpha of 0.81.

Adherence to diabetes medications was measured with the self-reported Morisky Medication Adherence Scale (MMAS) [19-21]. The MMAS is composed of eight items with a dichotomous scale (yes/no) for seven items and a five-point scale (never to all the time) for one item. Cronbach's alpha of the scale was 0.72. The diabetes self-management activities questionnaire was derived from the Summary of Diabetes Self-Care Activities Measure by Toobert et al. [22]. The 9-item measurement determined the frequency of performing self-management activities in the last 7 days. The CVI and Cronbach's alpha of the questionnaire were 1.00 and 0.55, respectively. The self-efficacy test was derived from the Self-Efficacy for Diabetes by Stanford Patient Education Research Center [23]. The 7-item test is rated on a 10-point scale (not at all confident to totally confident). The CVI and Cronbach's alpha were 0.95 and 0.77, respectively.

2.5. Control and the intervention groups

2.5.1. The control group

The control patients received the usual diabetes service provided by physicians, nurses and pharmacists during their outpatient visits to the hospital approximately every 3 months. At each visit, blood pressure and weight were monitored and documented by the hospital staff. Additionally, the assessment of HbA_{1c} and lipid profile (low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglyceride and total cholesterol) was performed in the control patients at the beginning and at the end of 9-month follow-up period. The patients were asked to bring the medications remaining with them at every visit. Adherence to diabetes medications was determined using pill count and the MMAS at every clinical visit. The percentage pill count was calculated by [(number of pills needed to take as prescribed - number of pills remaining)/number of pills needed to take as prescribed]x100.

In usual care, only patients who had a very poor control of blood glucose levels were educated mainly by nurses. The nurses assessed the reasons for poor glycaemic control and then gave advice. The intervention took approximately 10-15 minutes and mostly without the participations of their family members.

2.5.2. The intervention group

The goals of the family intervention were to enhance family members' knowledge on diabetes and their active support in assisting the participants in self-care practices. Physicians and nurses were blinded to the intervention.

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 minutes and was carried out in a private room. At the initial visit, the pharmacist interviewed participants individually in order to identify medication adherence, self-care practices, barriers to adherence to medications and self-care, other problems leading to inadequate glycaemic control and family behaviours in diabetes care. Then, the participants were offered the counselling and encouraged to modify their inappropriate practices with family support.

At the next 3 follow-up visits, the participants along with their family members were educated on diabetes, the importance of adherence to medications, appropriate nutrition for diabetes, hypertension and dyslipidaemia and also proper physical activity. A booklet covering information on diabetes as presented in the educational sessions was given to the participants and their family members. The pharmacist continued to identify non-compliance as well as problems on drug use and inappropriate lifestyle behaviours from each patient and their family member. Subsequently, such information was used to design a family intervention. The intervention was tailored for the family member individually to take an active role in the care of their relative particularly in improving adherence to treatment and healthy lifestyle including diet and physical activity. Then, group discussion was conducted in 3-4 families to exchange the ideas and to share the experiences on how to perform the appropriate self-care practices.

To ensure continuity of family support, follow-up visits with their family members were supplemented with two phone calls at one month after the second and the third

visits. The pharmacist telephoned the family members to discuss and provide counselling on patient care, to remind them of the medical appointments and to answer the questions. The duration of each phone call was 15-20 minutes.

2.6. Outcomes

The parameters of interest were determined at baseline and at the end of the study. Primary outcome of the intervention was the change in HbA_{1c} level. Secondary outcomes were the changes in lipid profile, blood pressure, body mass index (BMI), diabetes knowledge of patients and family members, and health-related outcomes including positive family support (i.e., supportive family behaviour), negative family support (i.e., negative approach to the patients such as nagging or arguing in order to reinforce them to adhere recommended self-care practices), medication adherence using pill count and MMAS, self-management and self-efficacy.

2.7. Statistical analysis

Demographic characteristics and study outcomes of participants (i.e., changes from baseline to 9 months) in the intervention and the control groups were compared using independent samples *t*-test for continuous data and chi-square test for categorical data. The within-group differences were analysed using paired *t*-test. Multivariable linear regression in the intervention group was performed to test which characteristics of patients and family members significantly predicted the changes in HbA_{1c} over the 9-month period. Significance level for all statistical inferences was set at 0.05. Data analyses were carried out using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Loss to 9-month follow-up was 10 participants (10.2%) in the intervention group and 6 participants (6.1%) in the control group (Fig. 1). A total of 180 participants with type 2 diabetes (88 intervention and 92 control) completed the study.

At baseline, the intervention and the control groups were not significantly different in demographic data (Table 1). Women comprised the majority of participants (intervention group 72.7% and control group 75.0%, P = 0.729). More than half of the family members were spouses (62.5% and 62.0%, respectively; P = 0.124).

3.1. Clinical outcomes

At baseline, the levels of HbA_{1c}, lipid profile, blood pressure and BMI were similar for the intervention and the control groups (P > 0.05) (Table 2).

3.1.1. HbA_{1c}

Over the 9-month intervention period, the intervention group showed superiority over the control group in glycaemic control, with HbA_{1c} reductions of -1.37% (-14.99 mmol/mol, P < 0.001) and -0.21% (-2.28 mmol/mol, P = 0.270), respectively. Between-group difference in the changes of HbA_{1c} was -1.16 % (-12.71 mmol/mol, P < 0.001)

3.1.2. Lipid profile, blood pressure and BMI

LDL-C level was more greatly reduced in the intervention group (P = 0.002) than in the control group (P = 0.534), with between-group difference being significant (P = 0.041). No between-group differences in the changes of HDL-C, triglyceride, total cholesterol or BMI were found. Decreases in systolic and diastolic blood pressure were observed in the intervention group in contrast to the control group, who reported increased blood pressure. The changes in blood pressure differed significantly between the groups (P < 0.05).

3.2. Diabetes knowledge and health-related outcomes

Family members in the intervention group at the end of the study experienced significant increases in diabetes knowledge from baseline levels (P < 0.001) (Table 3). Patients in the intervention group showed greater increases in scores of diabetes knowledge and health-related outcomes (including positive and negative family support, medication adherence using pill count and MMAS, self-management and self-efficacy) than did those in the control group. Of these changes, between-group differences achieved statistical significance (P < 0.05) in all except negative family support and adherence by MMAS.

3.3. Predictors of glycaemic improvement

The regression analysis indicated that patients' gender, age, education and duration of diabetes were not significantly associated with glycaemic improvement (P > 0.05) (Table 4). On the other hand, having spouse as the family member in the intervention

was the strongest predictor of improvement in glycaemic control, followed by family member being a woman.

4. Discussion and conclusion

4.1. Discussion

This trial showed that family involvement in health education for patients with type 2 diabetes improved glycaemic control and health-related outcomes including diabetes knowledge, family support, medication adherence, self-management and self-efficacy.

Patients with family involvement in diabetes care had significantly greater reductions in HbA_{1c} levels compared to the control patients. The improvement in glycaemic control in this study was consistent with that in a previous study of family involvement in type 2 diabetes management, which indicated an effect of 2.62% (28.64 mmol/mol) reduction in HbA_{1c} [13]. On the contrary, a family intervention study by Kang et al. [11] indicated no significant differences in HbA_{1c} between the intervention and the control groups (the intervention effect of 0.42% (4.58 mmol/mol), P = 0.460). The lack of significant improvement in blood glucose level may have been due to the smaller sample size (n = 56) and the shorter period of follow-up (6 months) compared to the larger sample size (n = 180) and the longer period of follow-up (9 months) in this study. In addition, the family intervention in the study of Kang et al. [11] focused on the educational programme on diabetes and self-management and also family involvement and support. The programme consisted of three individual educational sessions and 2-day group educational sessions. The contents were delivered by various health providers such as nurses, dietarians,

physicians, pharmacists, physiotherapists, foot therapists and social workers. Conversely, the family intervention in the present study emphasised not only education but also identification and solutions of the problems related to poor glycaemic control of the patients. The intervention consisted of the following four sessions: the first session for identifying barriers associated with poor diabetes outcomes and the next three sessions for providing patients and their family members with educational interventions on diabetes and self-management. Importantly, the research pharmacist still made an intensive effort to identify and to resolve the problems in patients individually and also supported the family members to participate in self-care. Afterwards, group discussions were carried out to share the ideas and experiences. The strategies in family intervention in the current study may have a greater impact on diabetes control than those in the previous study.

Kang et al. [11] also demonstrated the changes in LDL-C did not differ between the groups (P = 0.860) following family-partnership intervention. Conversely, in the current study the improvement of LDL-C in the intervention group was significantly greater than that in the control group. However, in this study the LDL-C in the intervention group was higher than the goal of < 100 mg/dL (2.59 mmol/L). To yield more favourable lipid outcomes, future family intervention should include more dyslipidaemia education and support on adherence to cholesterol-lowering therapy. In this study blood pressure in both groups was below the targets of < 140/90 mmHg according to the American Diabetes Association guidelines in 2017 [2]; nonetheless the blood pressure improvements in the intervention group were significantly better than those in the control group. The findings may reflect the effects of family-involvement intervention in patients with diabetes.

Family is increasingly recognised as an important source of social support in the care of patients with diabetes [24]. However, many family members had inadequate awareness on diabetes self-management and their roles in caring for their relatives [25]. In the present study, the research pharmacist provided family members with the information on disease management and their role in supporting diabetes care. The results showed significantly improved scores in family members' knowledge and positive family supportive behaviours compared to baseline. The positive family support was also significantly greater in the intervention group than that in the control group. Family members who were more knowledgeable about diabetes would perform more supportive behaviours for the patients [4]. Supportive family behaviours were associated with patient adherence to diabetes medications and other self-management practices including diet control and adequate physical activity [4, 9]. In the current study, the intervention group showed significantly greater improvement in medication adherence using pill count than the control group. Adherence to diabetes medications is a potential determinant of glycaemic control [14]. Furthermore, our finding revealed a significantly larger increase in self-management and self-efficacy in the intervention group compared to the control group. Better patient self-efficacy was related to better family support [24]. Family members providing better support may result from not only gaining diabetes knowledge but also perceiving how to play a role in self-management as mentioned above. Self-efficacy was potentially associated with self-management [8]. Diabetes self-management had a direct effect on disease control. Likewise, existing evidence supports the association between improved glycaemic control and family support [24]. The significant increments in knowledge, adherence by Morisky scores, self-management and self-efficacy were also detected in the control group compared to baseline. The control group may receive additional

care from other health providers. Moreover, there may be the potential for the Hawthorne effect in this study.

Multivariable regression analysis showed that there were no significant associations between patient characteristics and improved glycaemic control among the intervention group. Notably, spouse involvement was found to be the strongest predictor of glycaemic improvement. August et al. [26] also pointed out that patients with type 2 diabetes named their spouses most commonly as sources of social control. Furthermore, married men were reported to receive the highest levels of social control, followed by married women and unmarried women and men [26]. Having women acting as family caregivers was confirmed as a significant determinant of glycaemic improvement in this study. A study by Bidmon et al. [27] reported that women possessed more health and nutrition awareness than men. Accordingly, women may provide more health-related social control to their relatives living with diabetes in order to support self-care goals and glycaemic control compared to men.

The strengths of this study were having a larger sample size compared to the previous studies on family involvement in type 2 diabetes [11-13]. The present study also assessed many variables including biochemical and health-related outcomes (e.g., HbA_{1c}, lipid profile, blood pressure, BMI, diabetes knowledge of patients and family members, family support, medication adherence, self-management and self-efficacy) providing more comprehensive information on effectiveness of family involvement. In addition, multivariable regression analysis was used to examine whether characteristics of patients and family members were associated with glycaemic improvement. These associations were not reported in the earlier studies [11-13]. The multivariable model supported the benefit of spouses or women acting as caregivers of patients with diabetes.

The important limitations of the present study were, firstly, the participants were recruited from a single hospital thus limiting the generalisability of the results. Secondly, even though the overall sample size was large, sample size in the intervention group was not large enough for multivariable regression analysis to examine relationships between all measured variables in the study and improvement in HbA_{1c}. As a result, we evaluated only the effects of characteristics of patients and their caregivers. Thirdly, the reliability of self-management questionnaire was rather low; however, other questionnaires showed acceptable or good reliability. Lastly, family members' knowledge was not measured in the control group. Hence, we did not evaluate the difference in family knowledge between the intervention and the control groups. Future studies should compare family knowledge between the groups to determine whether this variable is a significant predictor of glycaemic improvement in patients with type 2 diabetes.

4.2. Conclusion

Our results highlight the importance of family involvement in type 2 diabetes management. Family support was meaningful for patients with diabetes to achieve better diabetes outcomes. The findings also illustrated that having spouses as family caregivers had the greatest potential for disease control, followed by having female caregivers. Accordingly, the participation of family members, especially those who are spouses or women should be encouraged in the control of diabetes.

4.3. Practice implications

The present study demonstrates that pharmacist-led family intervention for type 2 diabetes is helpful to improve glycaemic control, diabetes knowledge, family support, medication adherence, self-management, and self-efficacy. Involvement of spouses or women as family caregivers has positive effects on glycaemic improvement. The findings reflect the potential role that family involvement may play in the care of diabetes particularly when this includes spouses or women. Accordingly, family support should be encouraged in diabetes care. Identification of the key mechanisms of family participation in the health care process for diabetes management should be taken into account in further studies.

Informed consent and patient details

The authors confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Author contributions

Urawan Withidpanyawong worked on the data acquisition, data analysis and revised the manuscript. Sanguan Lerkiatbundit participated in data analysis and also reviewed and revised the manuscript. Woranuch Saengcharoen developed the research design and performed data analysis, interpretation of data, research summary and recommendations and wrote the manuscript. All authors approved the final manuscript.

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Conflict of interests

All authors declare no conflicts of interest.

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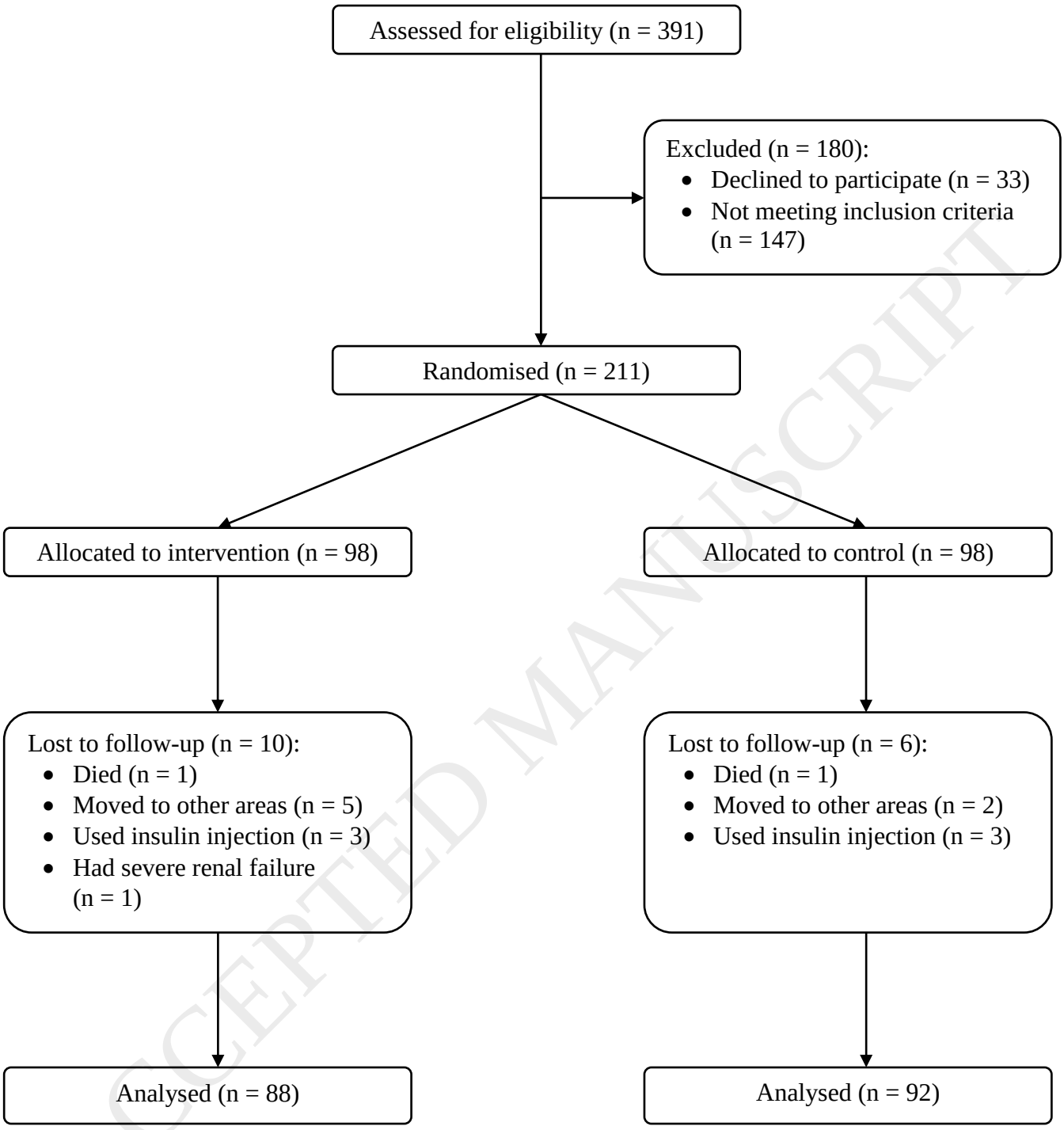

Fig. 1. Flow chart of the study participants.

Table 1
Demographic characteristics of the study patients and their relatives.

	Intervention group (n = 88)	Control group (n = 92)	P value
Patient			
Gender			0.729[a]
Male	24 (27.3)	23 (25.0)	
Female	64 (72.7)	69 (75.0)	
Age (mean ± SD)	60.53 ± 10.71	58.13 ± 10.10	0.123[b]
Education			0.505[a]
≤ Primary school	75 (85.2)	75 (81.5)	
> Primary school	13 (14.8)	17 (18.5)	
Marital status			0.117[a]
Unmarried	0	4 (4.3)	
Married	71 (80.7)	66 (71.7)	
Divorced	17 (19.3)	21 (22.8)	
Widowed	0	1 (1.1)	
Co-morbidity			
Hypertension	62 (70.5)	59 (64.1)	0.366[a]
Dyslipidaemia	80 (90.9)	78 (84.8)	0.210[a]
Cardiovascular disorder	7 (8.0)	1 (1.1)	0.032[a]
Duration of diabetes (mean ± SD) (years)	5.61 ± 4.34	6.35 ± 4.37	0.259[b]
Oral hypoglycaemic agent			
Metformin	82 (93.2)	87 (94.6)	0.699[a]
Glipizide	63 (71.6)	63 (68.5)	0.649[a]
Pioglitazone	18 (20.5)	20 (21.7)	0.833[a]
Family member			
Gender			0.679[a]
Male	48 (54.5)	53 (57.6)	
Female	40 (45.5)	39 (42.4)	
Age (mean ± SD)	48.94 ± 15.04	50.05 ± 15.59	0.627[b]
Education			0.188[a]
≤ Primary school	54 (61.4)	65 (70.7)	
> Primary school	34 (38.6)	27 (29.3)	
Relationship			0.124[a]
Husband/wife	55 (62.5)	57 (62.0)	
Son/daughter	30 (34.1)	25 (27.2)	
Others (e.g., nice, nephew)	3 (3.4)	10 (10.9)	

[a] Chi-square test
[b] Independent samples *t*-test

Table 2
Changes in clinical outcomes within and between groups (mean ± SD).

	Intervention group (n = 88)	Control group (n = 92)	Group difference (95% CI)	P value[a]
HbA_{1c} (%)				
Baseline	9.21 ± 1.84	9.08 ± 1.47	0.13 (-0.36, 0.62)	0.595
9 months follow-up	-1.37 ± 1.96	-0.21 ± 1.81	-1.16 (-1.72, -0.61)	< 0.001
P value[b]	< 0.001	0.270		
HbA_{1c} (mmol/mol)				
Baseline	77.19 ± 20.14	75.75 ± 16.03	1.44 (-3.90, 6.79)	0.595
9 months follow-up	-14.99 ± 21.47	-2.28 ± 19.73	-12.71 (-18.77, -6.65)	< 0.001
P value	< 0.001	0.270		
LDL-C (mmol/L)				
Baseline	3.50 ± 1.13	3.30 ± 0.97	0.20 (-0.11, 0.51)	0.196
9 months follow-up	-0.43 ± 1.28	-0.07 ± 1.07	-0.36 (-0.71, -0.02)	0.041
P value	0.002	0.534		
HDL-C (mmol/L)				
Baseline	1.20 ± 0.26	1.22 ± 0.26	-0.02 (-0.10, 0.05)	0.515
9 months follow-up	-0.02 ± 0.21	-0.04 ± 0.18	-0.02 (-0.08, 0.04)	0.546
P value	0.353	0.045		
Triglyceride (mmol/L)				
Baseline	1.80 ± 0.84	1.81 ± 0.91	-0.01 (-0.27, 0.25)	0.949
9 months follow-up	-0.03 ± 0.99	-0.01 ± 0.77	-0.02 (-0.28, 0.24)	0.879
P value	0.775	0.901		
Total cholesterol (mmol/L)				
Baseline	5.50 ± 1.19	5.38 ± 1.10	0.12 (-0.21, 0.46)	0.469
9 months follow-up	-0.45 ± 1.34	-0.15 ± 1.19	-0.30 (-0.67, 0.08)	0.116
P value	0.002	0.226		
Systolic blood pressure (mmHg)				
Baseline	136.73 ± 13.31	134.14 ± 12.08	2.59 (-1.15, 6.32)	0.174
9 months follow-up	-2.64 ± 15.13	3.20 ± 14.25	-5.83 (-10.15, -1.51)	0.008
P value	0.106	0.034		
Diastolic blood pressure (mmHg)				
Baseline	78.45 ± 11.12	76.09 ± 10.71	2.37 (-0.84, 5.58)	0.147
9 months follow-up	-2.95 ± 12.03	1.11 ± 10.00	-4.06 (-7.31, -0.82)	0.015
P value	0.024	0.290		
BMI (kg/m^2)				
Baseline	27.68 ± 4.70	27.60 ± 3.87	0.08 (-1.19, 1.34)	0.901
9 months follow-up	-0.14 ± 1.03	0.07 ± 1.14	-0.21 (-0.53, 0.11)	0.198
P value	0.215	0.545		

HbA_{1c} = Glycosylated haemoglobin; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; BMI = body mass index.
[a] Between group differences were analysed using independent samples *t*-test.
[b] Within group differences were analysed using paired *t*-test.

Table 3
Changes in diabetes knowledge and health-related outcomes within and between groups (mean ± SD).

	Intervention group (n = 88)	Control group (n = 92)	Group difference (95% CI)	P value[a]
Knowledge about diabetes[b]				
Patient				
Baseline	11.50 ± 2.40	11.62 ± 2.37	-0.12 (-0.82, 0.58)	0.737
9 months follow-up	3.83 ± 2.43	1.43 ± 2.21	2.40 (1.71, 3.08)	< 0.001
P value[c]	< 0.001	< 0.001		
Family member				
Baseline	9.31 ± 3.12	-	-	-
9 months follow-up	5.71 ± 3.09	-	-	
P value	< 0.001			
Positive family support[d]				
Baseline	12.55 ± 4.17	11.62 ± 4.58	0.93 (-0.36, 2.22)	0.158
9 months follow-up	2.92 ± 4.46	-0.26 ± 4.80	3.18 (1.82, 4.55)	< 0.001
P value	< 0.001	0.604		
Negative family support[e]				
Baseline	5.33 ± 2.62	5.25 ± 2.38	0.08 (-0.66, 0.82)	0.832
9 months follow-up	0.58 ± 3.26	-0.17 ± 2.92	0.75 (-0.16, 1.66)	0.104
P value	0.099	0.569		
Medication adherence				
Pill count (%)				
Baseline	95.01 ± 7.13	95.21 ± 8.23	-0.20 (-2.46, 2.08)	0.867
9 months follow-up	3.52 ± 8.31	-0.32 ± 12.70	3.83 (0.66, 7.01)	0.018
P value	< 0.001	0.811		
Morisky score[f]				
Baseline	6.48 ± 1.55	6.09 ± 1.82	0.39 (-0.11, 0.89)	0.124
9 months follow-up	0.97 ± 1.56	0.68 ± 1.77	0.28 (-0.21, 0.77)	0.261
P value	< 0.001	< 0.001		
Self-management[g]				
Baseline	4.70 ± 0.88	4.91 ± 0.87	-0.21 (-0.47, 0.05)	0.111
9 months follow-up	1.04 ± 0.99	0.34 ± 0.96	0.70 (0.41, 0.98)	< 0.001
P value	< 0.001	0.001		
Self-efficacy[h]				
Baseline	6.01 ± 1.48	6.52 ± 1.81	-0.51 (-1.00, -0.03)	0.038
9 months follow-up	1.67 ± 1.78	0.68 ± 1.93	0.98 (0.44, 1.53)	< 0.001
P value	< 0.001	0.001		

[a] Between group differences were analysed using independent samples *t*-test.
[b] 16 items with score of 0-16.
[c] Within group differences were analysed using paired *t*-test.
[d] 6 items with score of 6-30.
[e] 3 items with score of 3-15.
[f] 8 items with score of 0-8.
[g] 9 items with score of 0-7.
[h] 7 items with score of 1-10.

Table 4
Prediction of glycaemic improvement in the intervention group by multivariable regression analysis*.

	B	95% CI for B	SE	Beta	P value
Patient					
Gender	-10.472	-24.459, 3.515	7.030	-0.218	0.140
Age (years)	-0.171	-0.634, 0.292	0.233	-0.085	0.464
Education	-4.178	-17.570, 9.215	6.731	-0.069	0.537
Duration of diabetes (years)	0.916	-0.093, 1.924	0.507	0.185	0.074
Family member					
Spouse	-20.788	-32.247, -9.329	5.759	-0.471	0.001
Woman	-15.047	-27.535, -2.558	6.277	-0.351	0.019

*The dependent variable was the change of HbA_{1c} level at the end of the intervention from baseline.
B = Unstandardised coefficient; CI = confidence interval; SE = standard error; Beta = standardised coefficient.