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Effects of the tailored intervention program in lowering blood glucose levels and diabetes distress among patients with diabetes in Indonesia: a randomized controlled trial

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ABSTRACT

Introduction: Blood glucose levels and diabetes distress are the foremost factors contributing to diabetes treatment outcomes and managements. No tailored intervention program was implemented for patients with diabetes in Indonesia. This study aimed to investigate the effectiveness of a tailored intervention program in lowering blood glucose levels and diabetes distress among patients with diabetes patients in Indonesia.

Methods: A randomized controlled trial (RCT) with pre-test and post-tests was applied. A total of 163 people with diabetes were collected for both intervention (n=80) and control (n=83) groups: A diabetes-tailored intervention program was attempted in the intervention group. Descriptive statistics, Analysis of Variant (ANOVA) and inferential statistics were used to analyze the data (significance level <0.05)..

Results: The mean blood glucose levels and diabetes distress before and after in the intervention group were 255.19 mg/dl, and 245.60 mg/dl (p-value >0.05); 2.46 and 2.01 (p-value <0.01). While the control group's mean of blood glucose levels and diabetes distress before and after the intervention was were 227.81 mg/dl, and 245.94 mg/dl (p-value <0.05); and 2.37 (p-value >0.05).

Conclusions: The diabetes-tailored intervention program is effective on decreasing blood glucose levels and diabetes distress, and showed a significant result to diabetes distress.

Keywords: blood glucose, diabetes, diabetes distress, personalized

Introduction

Diabetes is considered a major global health problem that causes diabetes distress (Hu et al., 2020; Jeong & Reifsnider, 2018; Young et al., 2020). Diabetes distress happens because of unstable blood glucose levels and medication needed for a long time (Young et al., 2020). Blood glucose levels and diabetes distress are the most important factors contributing to treatment outcomes and management of diabetes (Hu et al., 2020). Diabetes distress releases the excessed glucocorticoid hormone that impairs glucose production in the liver and reduces

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the cell's sensitivity to insulin which causes hyperglycemia (Farm et al., 2017).

The prevalence of distress was high among patients with diabetes (Batais et al., 2021). Simultaneous increases in blood glucose levels due to diabetes distress have also been reported (Dekkers & Hertroijs, 2018; Pranata et al., 2022). Moreover, the routine interventions implemented by health professionals for glycemic control and distress management in several countries are health education (Suciana & Arifianto, 2019). Health education alone is not enough, we need to understand health-seeking behaviors based on patient culturally (Seligman et al., 2018; Widayanti, 2018). Moreover, support from various groups, especially families and health professionals, is needed (Pranata et al., 2021). However, health professionals' health education and support in the hospital for patients with diabetes did not meet the patient's personal needs (Cimo & Dewa, 2019; Kolb, 2021).

Health education and support should be tailored to patients' requirements (social-cognitive factors, intention, and behaviour) (Pranata et al., 2022). Every patient has the obligation and right to participate in individual and group healthcare planning and implementation. Additionally, patient-centred education and support increase satisfaction and is crucial for efficient patient education (Sassen, 2018).

Four thousand years ago, a collection of sacred Indian literature, a tailored intervention, was first addressed (Dekkers & Hertroijs, 2018). Its goal was to customize treatment through education and support to each person to establish a balance between body, mind, and spirit. At the time, it was known as Ayurvedic medicine. Today, tailored intervention aims to improve patients' health outcomes and care experience by taking their unique requirements and preferences into consideration while creating a treatment plan (Dekkers & Hertroijs, 2018; Hertroijs et al., 2018). Such an approach might be a personalized strategy based on patient phenotyping. According to this method, patients' biopsychosocial characteristics are used to distinguish subgroups of patients with comparable care requirements, capacities, and preferences so that customized treatment plans can be constructed (Dekkers & Hertroijs, 2018; Pranata et al., 2022).

The increasing rates of morbidity and death now seen in the diabetes community may be reduced by modifying program delivery for education and support programs customized to that population (Cimo et al., 2020). Patient preferences, cultural sensitivity, patient center, and support reference to tailored intervention (Hertroijs et al., 2018; Mayor, 2017). All components of tailored intervention are allowing clients' requirements to direct diabetes education, adapting instruction to match individual needs, and supporting and empowering clients to self-manage (Cimo & Dewa, 2019). There is a lot of opportunity for personalized care in tailored intervention to be implemented in Indonesia as an innovation in enhancing health services for diabetic patients (Pranata et al., 2021). A tailored intervention plan for managing diabetes may help patients control their condition, provide tools to manage it more successfully, and lower blood glucose levels and diabetes distress simultaneously. Thus, this study's objective was to assess how effective a tailored intervention program is for diabetic patients. The evaluation focused on lowering blood glucose levels and diabetes distress.

Materials and Methods.

Design of the study

A randomized controlled trial (RCT) with two groups for the pre-and post-test design was used to examine a repeated measure with a single-blind for a tailored intervention program. The study was carried out from January 7 to April 7, 2021.

Population and sample of the study

Laboratory testing of blood glucose levels, as well as a doctor's diagnosis, were used to diagnose the diabetes population in this study. The laboratory data were assessed by the medical records. People with diabetes who visited and registered at primary healthcare in Sumbawa City, West Nusa Tenggara, Indonesia, were included as study samples. Respondents were recruited from patient list data that had been recorded at the hospital and further randomized using the ABAB pattern. Group A is included in the intervention and group B is included in the control. The level of significance or alpha (α) = 0.05, population effect size (ES) = 0.5, and power ($1-\beta$) = 0.80 were used to calculate the sample size for the study (Kim, 2016). The calculations showed that a sample size of 126 people (64 in each group) was necessary. To account for the possibility that a person would withdraw, the researcher increased the number of participants by 30%. Consequently, 168 volunteers were required for this investigation (84 per group). Simple randomization by computerized random numbers were used in this study. After randomization by researchers, each respondent received a different inform concern from one another. The intervention group received informed concerns about the implementation of tailed care and the control

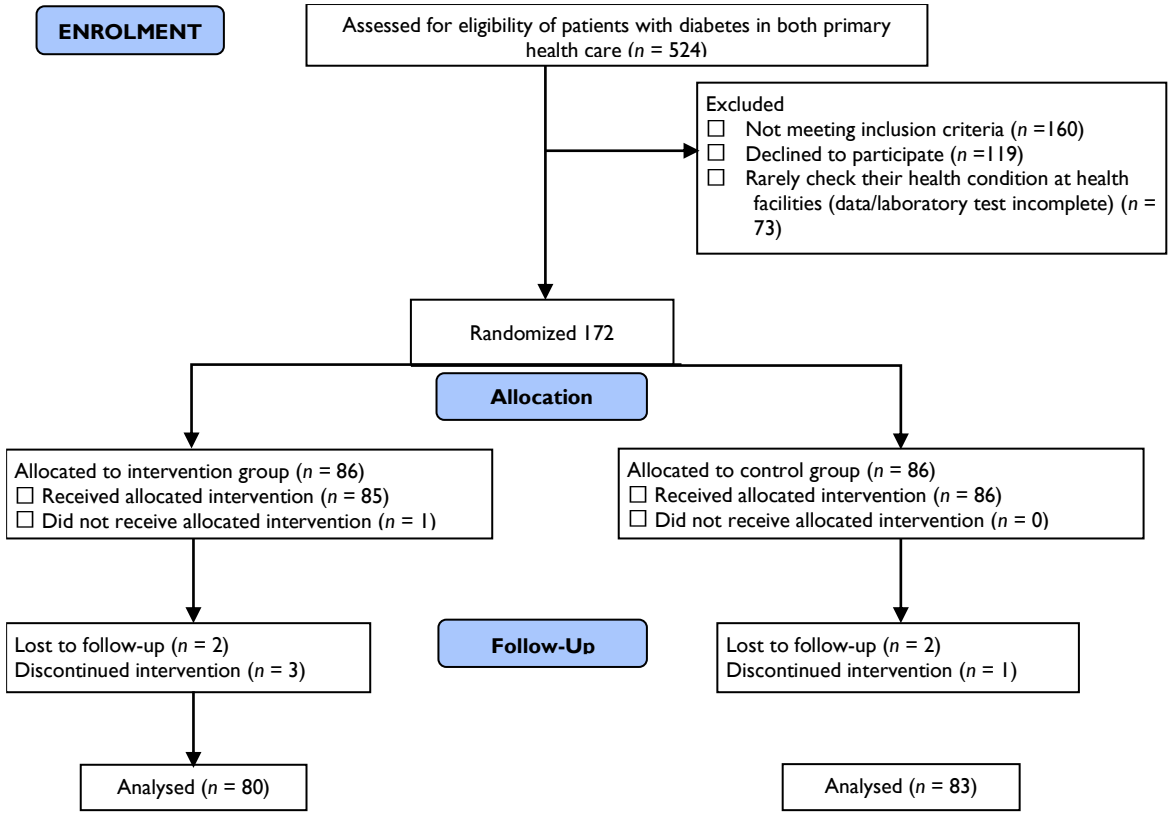

Figure 1 The recruitment process for the randomized controlled trial

group received traditional health education informed concerns.

The study included respondents older than 20 at the time of recruitment, identified as the Indonesian citizen, willing to participate, had a mobile device, and lived with the family. Twenty years is a mature age in which a person can make their own decisions (Icenogle, 2019). If patients reside with their families, the researcher will find it easier to contact them afterwards or to call them to remind them to follow the study protocol. The study excluded those have a history of or a diagnosis of ischemic heart disease, transient ischemic attack (TIA), peripheral vascular disease, or persistent mental health concerns. Medical condition is used as a criterion to reduce the risk of dropout.

Standard care

Standard care from the hospital includes routine blood sugar monitoring, blood pressure assessments, and monthly health counselling for each group (Suciana & Arifianto, 2019). The standard care services provided to diabetic patients typically concentrate on five key areas: diet, medications, physical activity, health education, and routine blood sugar monitoring (Sujana, 2019). Although many other media are used to provide health advice, a leaflet or booklet was primarily utilized in standard care (Srikartika et al., 2019). Advice on how to alter one's diet, use drugs like insulin or oral medications, and notice clinical signs of blood sugar swings are frequently included in leaflets and booklets (Nanda et al., 2018; Srikartika et al., 2019). Participants who received standard care are blinded to the allocation. It avoids those elements that have potentially influenced the outcomes from allocations. Participants were also blinded as to their group assignment to avoid their expectations for that treatment.

Tailored intervention program

The tailored intervention program strategies for diabetes were divided into seven steps: 1. Brief deducting teaching; 2. Assessment for self-management level; 3. Brainstorming through a support group for sharing patient's difficulty on glycaemic target and specific target behaviour; 4. Making a list of patients' needs and then ranking the priorities; 5. Setting a goal and writing action; 6. Follow-up; and 7. Report of goals attempt.

As presenters, brief deducting teaching activities were carried out by health professionals (nurse, physician and dietitian). Previously, health professionals had been briefed in detail to ensure that they delivered topics according to patient needs and research needs. the researchers also assessed the material they conveyed to the respondents. Health professionals explained about 1) treatment options for high or low blood sugar levels; 2) Proper nutritional treatment based on culturally sensitive dietary information; 3) How to combine daily physical activity and exercise; 4) A condition in which patients are required to consume drug or insulin medication; 5) teach patients for blood glucose self-monitoring test; 6) Acute comorbidity prevention, detection, and treatment; 7) chronic comorbidity prevention, detection, and treatment; 8) goal-setting and achievement-based health promotion; and 9) integration of psychological adjustment for daily living and problem-solving advice.

After the brief deductive teaching has been transferred, the respondent was assessed on his level of self-management. The level of self-management will determine the small group of each respondent. Respondents with a good level of self-management are grouped with good levels in small groups, moderate levels are grouped with moderate levels in small groups and so on. When they are in small groups, respondents exchange information with each other through the support group. In support groups, respondents learn from each other from the experience of group members to maintain glucose control. after they exchanged information, each respondent then made personal targets according to their respective abilities along with how long it would take them to reach these targets. The explanation in the support group is adjusted to the respondent's preferred language. The tailored care and support group target from the small group was evaluated twice a month for three months.

Research assistants were employed to deliver the support group and brainstorming after a brief deducting teaching. Two research assistants were selected from each primary health facilities where the study was conducted because they had a better understanding of the patients and conditions in the local area. The research assistant's qualifications were a bachelor's degree level and a working period of more than five years.

Before the assistant carried out the planned intervention, the research assistant was trained. This process was to ensure that they have the same understanding of each other about the study process and intervention.

Blinding

Each respondent received a different inform concern from one another. The intervention group acknowledged that they received the implementation of tailed care and the control group received traditional health education. It has been confirmed that there was no communication between participants in the intervention and the control group. The area of Sumbawa Island is quite large, with a less population, therefore, the distance between respondents was quite far and minimized the probability of them doing interaction. Further, applying a blinding process to the trial was important since it can be reduced perceptions of the impact of the treatment on the mental or physical responses among participants.

Instruments

Blood glucose level and diabetes distress were measured twice: at M1 (baseline, before the intervention) and M2 (3 months after the intervention). The laboratory test of blood glucose levels and the diabetes distress scale were used to collect the data.

Blood glucose levels

Blood glucose level was measured after the patient's blood sample is collected by the research assistant and further laboratory equipment analysis of the blood sample. Laboratory test was used to evaluate the participants' blood glucose levels in this study.

Diabetes distress scale (DDS)

DDS was developed by William H. Polonsky from the Problem Areas in Diabetes (PAID) instrument and has since become well-established and widely recommended for assessing the level of distress in patients with diabetes (Farm et al., 2017; Polonsky et al., 2005). However, the DDS has a more precise and cross-culturally consistent factor structure (Polonsky et al., 2005). The DDS consists of 17 items that measure patients' feelings in four general domains. First, the interpersonal distress domain (3 items) reflects the psychological emotions and feelings of patients with diabetes during their interaction with families, friends, or people around them. Second, the physician distress domain (4 items) portrays the distress patients with diabetes experience during interaction with their physician. The third domain, regimen distress (5 items), describes the distress felt by patients with diabetes because of the need to adhere to a therapy management plan. The last is the emotional burden domain (5 items), which describes the distress related to the personal emotions of the patients suffering from

type 2 diabetes, including fear of the possibility of diabetes-related complications (Farm et al., 2017; Polonsky et al., 2005).

The factor analysis of DDS instrument revealed a correlation among the four factors ranging from 0.40 to 0.67. The factor loadings of selected items from the four factors ranged from 0.41 to 0.98. The internal consistency for the four domains ranged from 0.78 to 0.83 (Farm et al., 2017). The DDS17 Bahasa Indonesia provides an initial psychometric validation study, factor structure, and internal consistency for assessing the distress of Indonesian type 2 diabetes outpatients (Farm et al., 2017). Diabetes distress data assessed by research assistants. the two research assistants did not know which was the intervention group and which was the control group. they only know that group one received tailored care interventions while the other group received traditional health education.

Demographic and disease characteristics

The demographic characteristics included the patient's age, time since the diagnosis of diabetes, sex, religion, educational level, marital status, occupation, and smoking status.

Process of participant recruitment

The current study was approved by Indonesia Centre for Health Resources and Services Research and Development (Registry number: INA-KFQZKG). Figure 1 shows the recruitment process for this study.

Data analysis

IBM SPSS Statistics for Windows v. 20.0 (IBM Corporation, Armonk, NY, USA) was used for archiving and statistically analyzing. The statistical methods included descriptive statistics (frequency distributions, percentages, means, and standard deviations), ANOVA and also inferential statistics (independent sample t-tests and paired t-tests) with significance level of 0.05.

Ethical considerations

To protect the human rights of the study participants, the current study was approved by the institutional review board No. 235/EA/KEPK-BUB-2020. Participants were invited to participate in the study after the researchers gave them an overview of it and completed an informed consent form. Participants in the study were all chosen voluntarily. For the creation of the questionnaire and data analysis, their information was coded anonymously. The participants were given the researcher's phone numbers and were told they may leave the research at any time without any consequences. After the study was completed, the control group also received tailored care interventions from a team of research assistants.

Results

Baseline respondent characteristics

There were no significant differences between the two groups on sex, religion, education level, marital status, complication and smoking status in the intervention and control groups. This indicates that in terms of respondent characteristics for both groups were similar.

The majority of respondents in this study were 78.75% female in the intervention group and 79.14% in the control group. Education level was 66.25% primary school in the intervention group and 63.86% in the control group, 98.75% married in the intervention group and 98.79% in the control group, 98.75% without complication in the intervention group and 97.59% in

Table 1 Respondents characteristics

Variables	Intervention		Control		n= 163 (%)	Significance
	n=80	(%)	n=83	(%)		
Sex						
Male	17	21.25%	17	20.48%	34 (20.86%)	0.905*
Female	63	78.75%	66	79.52%	129 (79.14%)	
Education level						
Illiteracy	1	1.25%	2	2.4%	3 (1.84%)	0.726*
Primary school	53	66.25%	53	63.86%	106 (65.03%)	
Junior high school	7	8.75%	5	6.03%	12 (7.36%)	
Senior high school	11	13.75%	13	15.66%	24 (14.73%)	
College	8	10%	10	12.05%	18 (11.04)	
Marital status						
Single	0	0%	1	1.21%	1 (0.61%)	0.179*
Married	79	98.75%	82	98.79%	161 (98.78%)	
Complication						
None	79	98.75%	81	97.59%	160 (98.16%)	0.585*
Hypertension	1	1.25%	2	2.41%	3 (1.84%)	
Smoking						
Smoking	8	10%	6	7.23%	14 (8.59%)	0.531*
No smoking	72	90%	77	92.77%	149 (91.41%)	

Table 2 Participant characteristics

Variables	Intervention				Control				P-value
	Mean	SD	Min-max	CI 95%	Mean	SD	Min-max	CI 95%	
Age	55.53	9.237	37-76	53.47-57.58	57.61	9.243	33-79	55.60-.63	0.151*
Time since the diagnosis of diabetes in year	3.345	2.4770	1-11	2.794-3.896	3.837	3.3057	1-15	3.116-559	0.285*

* =ANOVA test

the control group, 90% smoking in the intervention group and 92.77% in the control group (Table 1).

In Table 2, there were no observable changes in age or the amount of time since diabetes diagnosis between the intervention and control groups. This indicates that in terms of participant characteristics, both groups shared similarities. Moreover, the mean age of respondents in this study was 55.53 years in the intervention group and 57.61 years in the control group. In addition, the mean of the diagnosis of diabetes in the intervention group was 3.3 years, while the control group was 3.8 years.

Description and comparison of the outcome indicators for the two groups in the pre-test and post-test

Before the intervention, there were no appreciable variations in blood glucose levels and diabetes distress between the intervention and control groups (Table 3) by ANOVA tested. This indicates that before the intervention, the participant characteristics of both groups were comparable.

The mean blood glucose levels before the intervention group received a tailored intervention program was 255.19 mg/dl, then decreased to 245.60 mg/dl. Furthermore, the diabetes distress scale from 2.46 (moderate) and then decreased to 2.01 (moderate). On the other hand, the mean blood glucose levels before the control group received traditional health education intervention program was 227.81 mg/dl, then increased to 245.94 mg/dl, and the diabetes distress scale from 2.40 (moderate) then decreased to 2.37 (moderate).

Blood glucose levels and diabetes distress between groups before the intervention did not significantly change but did differ significantly after the intervention, according to independent t-test analysis in (Table 4). Therefore, it is required to conduct additional tests using the paired t-test to compare the effectiveness of traditional health education before and after the intervention with a tailored intervention program.

The paired t-test analysis (Table 5) showed that the intervention and control group's blood glucose levels decreased before and after treatment. Still, the decrease in blood glucose levels was bigger in the intervention group compared to the control group. Both groups were not statistically significant, with a p-value >0.05. However, the diabetes distress scale in the intervention group significantly decreased, namely 0.441, with a p-value <0.05. While in the control group, the decrease was only 0.036 with a p-value > 0.05.

Discussions

Both groups for blood glucose tested were not statistically significant with p-value 0.984. However, the blood glucose levels of participants in the intervention group who received a tailored intervention program were better than the control group who received traditional health education. Based on the study, traditional diabetes education models did not translate

Table 3 Description of the outcome indicators for the two groups

Variables	Baseline		P-value	Follow-Up (3-month)		P-value
	Intervention	Control		Intervention	Control	
Blood Glucose			Pre-test = 0.134 *			Post-test= 0.984 *
Mean	255.19	227.81		245.60	245.94	
Median	253.50	205		218	237	
SD	109.867	121.905		116.650	105.207	
Min-Max	76-512	72-594		84-595	91-595	
95% CI	230.74-279.64	201.19-254.43		219.64-271.56	222.97-268.91	
Diabetes Distress			Pre-test = 0.638 *			Post-test= 0.000 *
Mean	2.46	2.40		2.01	2.37	
Median	2.40	2.40		1.90	2.50	
SD	0.743	0.716		0.585	0.607	
Min-Max	1-5	1-4		1-4	1-4	
95% CI	2.29-2.62	2.25-2.56		1.88-2.15	2.23-2.50	

*=ANOVA test

Table 4 Comparison of blood glucose levels and diabetes distress in both groups (independent t-test)

Variable	Significance (p)
Blood glucose levels	
Pre-test	0.807
Post-test	0.356
Diabetes distress	0.688
Pre-test	0.000
Post-test	

appropriately and did not meet patients' needs. The tailored care intervention program was better and more successful to improve the diabetes self-management through blood glucose indicator. Participants in the studies perceived themselves as becoming more informed about their disease and diabetes complications through tailored care intervention program. This encourages them to keep their blood glucose levels stable within normal limits. Evidenced by the blood glucose data in the intervention group which decreased compared to the control group. Intervention based on the participant's preferred language and incorporated culturally sensitive dietary information by the same cultural group was the key in the tailored care intervention program (Navodia et al., 2019). Ideal members of each small group no more than ten members (Pranata et al., 2022).

Education programs that do not support behaviour change are potentially ineffective and inaccurate (Choi et al., 2017). On the other hand, intervention based on the participant's preferred language and incorporating culturally sensitive dietary information and the same cultural group through tailored intervention program potentially influence participants' engagement in behavioural changes, uptake adherence and further decrease the blood sugar level among respondents (Navodia et al., 2019). From our study, after 3 months of implementation of the tailored care intervention program, respondents became more active in seeking information from health professionals and regularly monitoring blood sugar in health facilities. With regular monitoring, respondents know more about their condition so they are able to make the best preventive choices towards the risk of complications in the future.

Table 5 Comparison of blood glucose levels and diabetes distress for the two groups (Paired t-test)

Variables	Mean difference	SD	P-value
Blood glucose			
Pair 1 pre-post	9.588	140.597	0.544
Pair 2 pre-post	-18.133	110.646	0.139
Diabetes distress	0.441	0.688	0.000
Pair 1 pre-post	0.036	0.284	0.250
Pair 2 pre-post			

Diabetes forces people to manage their diet and sometimes need medication for glycemic control. In the long course of treatment therapy, patients with diabetes might suffer from diabetes distress. To avoid these situations, some efford is required. Our study proved that tailored intervention program is better at reducing diabetes distress in the diabetes population compared to traditional health education. Diabetes distress in the intervention group before receiving the tailored intervention program was 2.46 (moderate), then decreased to 2.01 (moderate) with a p-value of 0.000.

Meanwhile, in the control group who received traditional health education, the diabetes distress score was 2.40 (moderate), decreased to 2.37 (moderate), and was not statistically significant. Our data related to another study by Lutes et al. (2018) was that tailored integrated intervention among uncontrolled type 2 diabetes patients has a good impact on reducing the level of diabetes distress (Lutes et al., 2018). Diabetes distress comprises several domains, such as emotional distress, distress with health professionals, medication and interpersonal distress (Farm et al., 2017). The decrease in diabetes distress shown by participants in this study is closely related to good communication between patients and health workers. In the tailored intervention program, professional staff is faced with conditions to place the expected intervention outcome by the profile of each patient (Cummings et al., 2019; Lake et al., 2020; Navodia et al., 2019). In addition, patient preferences are a determinant in the choice of medication. In the tailored intervention program, participants feel more valued for their opinions, which impacts a sense of responsibility for what they choose in medication (Hertroijs et al., 2018; Tinetti et al., 2016). Awareness of healthy behaviour that began to emerge among each respondent made them start doing self-management voluntarily without coercion from anyone. This condition makes each diabetic patient feel much more empowered, further affecting the reduction in diabetes distress.

Limitations

The single-blind design may appear to be biased in that participants may exaggerate the data they provide. In addition, blood glucose examination in this study was limited to the pre-test at the beginning of the test and the post-test after three months. Blood glucose examination was not able to accurately show blood glucose results in the previous three months but only at the time of examination. Bias results can happen if we just used blood glucose tested in this case. We suggest

that the HbA1c examination be carried out in future studies in order to observe the respondents' average blood glucose levels for the last three months.

Conclusions

Both the experimental and control groups' mean blood glucose levels were not statistically significant. Conversely, diabetes distress in the intervention group statistically decreased compared to the control group. This approach can be an important concern for improving the quality of services by health professionals, particularly nurses for diabetes distress prevented. Longer follow-up studies are required to see if there are any benefits over the course of the disease. In the future, more than 3 months of follow-up research will be needed.

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Conflict of Interest

The authors affirm no conflict of interest in this study.

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