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Effectiveness of Tailored Care Program on Diabetes self-care activity, risk of CVD and HbA1C among Patients with Diabetes in Indonesia: A Randomized Controlled Trial

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ABSTRACT

Background: A tailored care intervention program implemented related to diabetes self-care activity, HbA1c, and the risk of cardiovascular disease (CVD) complications was not undertaken in Indonesia. Thus, the purpose of this study was to evaluate the effectiveness of a tailored care intervention program for patients with diabetes in Indonesia. **Methods:** A randomized controlled trial (RCT) with pre- and post-testing was conducted from January to April 2021 with a total of 163 participants: 80 in the intervention group and 83 in the control group (undertaken at three months following baseline collection). The intervention group received a tailored care intervention program that included: (1) brief deducting teaching; (2) assessment for self-care activity and CVD risk; (3) brainstorming and support group; and (4) follow-up. The control group received standard education in the primary health care facilities (Moyo Hilir and Moyo Hulu Primary Health Care). **Results:** Improvements in diabetes self-care activity, HbA1c, and a lower risk of CVD among patients in the intervention group were the advantages of the tailored care intervention program after the three-month evaluation. Blood pressure, body weight, body mass index (BMI), triglycerides, blood glucose, cholesterol, and a triglyceride glucose index showed no differences in change over time between the intervention and control groups. **Conclusion:** The tailored care intervention program improved diabetes self-care activity, HbA1c, and decreased the percentage of CVD risk. Moreover, it is culturally acceptable to the Indonesian community with diabetes.

Keywords: CVD Risk; Diabetes; Diabetes Self-Care Activity; Hba1c; Tailored Care

INTRODUCTION

The number of people with diabetes in Indonesia continues to increase every year. The number of diabetic adults aged 20–79 years in 2019 was 463 billion, further increasing to 537 million in 2022 (IDF, 2021). The increase in the number of patients was followed by an increase in the number of diabetic patients with complications The most common complications due to diabetes in Indonesia are neuropathy, retinopathy, nephropathy, and cardiovascular disease, where cardiovascular disease is one of the deadliest diseases among other complications (Papatheodorou *et al.*, 2018).

Recently, interventions to reduce the number of complications due to diabetes in hospitals have included health education (Hailu *et al*., 2019; Sassen, 2018). However, health education provided by hospitals to diabetic patients has not achieved maximum results (Sherifali *et al.*, 2016). Data on diabetics with complications is still the

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main homework for health workers and the government to improve health services.

A study in 2022 mentions that health education in hospitals remains focused on a population-based approach, even though health education should be tailor-made and tuned into the individual needs (social-cognitive determinants, intention, and behavior) of the individual patient (Pranata *et al.*, 2022). Every patient has the right and duty to participate individually and collectively in the planning and implementation of their health care (Sassen, 2018; World Self-medication Industry, 2010). Moreover, patient-centered education leads to more satisfaction, which is important for effective patient education (Sassen, 2018).

In recent years, research efforts in this direction have been labeled tailored care (Dekkers & Hertroijs, 2018). It was then called Ayurvedic medicine, and its aim was to tailor treatment to each person's prakriti (or constitution) in order to maintain a balance between body, mind, and spirit by taking their individual needs and preferences into account in developing a treatment plan (Dekkers & Hertroijs, 2018; Hertroijs *et al.*, 2018). A tailored approach based on the phenotyping of patients may be such an approach. In this approach, patients' biopsychosocial characteristics are used to identify subgroups of patients with similar care needs, abilities, and preferences for whom tailored solutions can be developed (Dekkers & Hertroijs, 2018; Hertroijs *et al.*, 2018; Lutes *et al.,* 2020; Osborn *et al.*, 2010). Modifying program delivery for education programs tailored to diabetes may help to curtail the increasing rates of morbidity and mortality currently observed in the diabetes population (Cimo *et al.*, 2020). Patient care and preference, patient-oriented, cultural, and patient-centered care are referred to as tailored care, (Cimo *et al.*, 2020; Dekkers & Hertroijs, 2018; Hertroijs *et al*., 2018; Lutes *et al.*, 2020; Osborn *et al.*, 2010; Solano *et al.*, 2020). Tailored care is an approach that includes letting clients' needs guide diabetes education, applying flexibility in teaching to meet individual needs, and empowering clients to self-manage (Cimo & Dewa, 2019a). Personalized care in tailored care programs has been developed by various countries and has great potential to be applied in Indonesia as a new innovation in improving health services for patients with diabetes (Pranata et al., 2021). A tailored care program for the self-management of diabetes might enhance patients' perception of their level of control of diabetes and enable them to apply more effective self-management and self-care activities, decrease the risk of cardiovascular disease (CVD), and improve HbA1C.

Purpose

The purpose of this study was to evaluate the effectiveness of a tailored care program among patients with diabetes. The evaluation focused on improvements in diabetes self-care activity, risk of CVD, and HbA1C.

METHODOLOGY

Design

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

Study Population and Sample Size

People with diabetes who visited and registered at primary healthcare facilities in Sumbawa City, West Nusa Tenggara, Indonesia, were included as study samples. The level of significance, or alpha (α)= 0.05, population effect size (ES)= 0.5, and power (1-β) = 0.80 were used to compute the sample size for the study (Kim, 2016). Consequently, 168 volunteers were required for this investigation (84 per group).

The inclusion criteria for the study include being more than 20 years old at the time of recruitment, owning a mobile device, and residing with family members. On the other hand, those who could not consent for themselves or had a history or diagnosis of ischemic heart disease, transient ischemic attack (TIA), peripheral vascular disease, or persistent mental health issues were deemed unsuitable for the trial and excluded.

Usual Care

The basic health care services offered to diabetic patients generally focus on five key areas: diet, medications, physical activity, health education, and routine blood sugar monitoring (Suciana & Arifianto, 2019); moreover, assessments of blood pressure, urine protein levels, and monthly health counseling for each group (Sujana, 2019).

Various media are used to give health counseling, but in basic health care, a pamphlet or booklet is typically used (Srikartika *et al.*, 2019).

Tailored Care Intervention Program

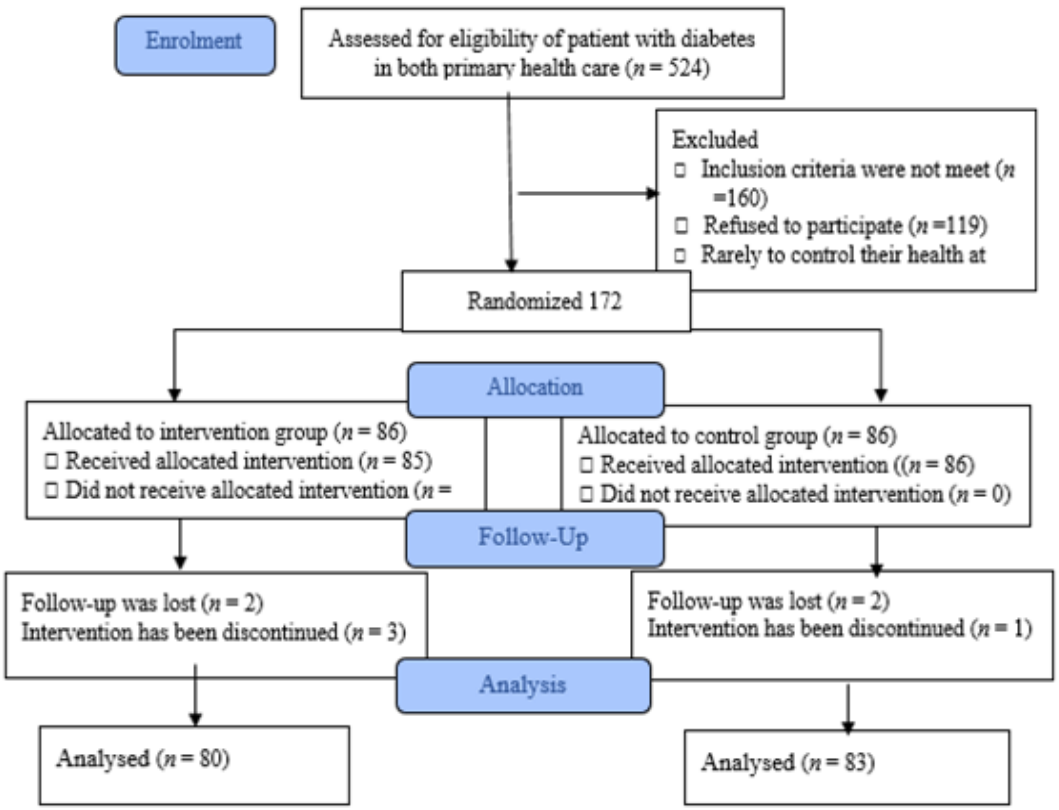
The strategies for tailored care for diabetes were divided into seven steps: 1. Brief deducting teaching; 2. Assessment for self-management level and risk of cardio vascular disease among patients; 3. Brainstorming among patients to share their difficulty on glycaemic target and specific target behavior; 4. Making a list of patients' needs and ranking the priorities; 5. Setting a goal and writing action; 6. Follow-up; and 7. Report of goals attempted.

Instruments

Diabetes self-care activity, CVD risk, and HbA1C were assessed at two different times: M1 (baseline: before the intervention) and M2 (3 months from the commencement of the intervention). The following instruments were used to gather the data: HbA1C by laboratory testing, ISH CVD risk chart, and summary of diabetes self-care activity (SDSCA). The demographic characteristics included the patients' age, time since the diagnosis of diabetes, sex, religion, education level, and marital status. The laboratory tests included HbA1c.

Process of Participant Recruitment

The current study was approved by the Indonesia Center for Health Resources and Services Research and Development (Registry number: INA-KFQZKG). The recruitment process for this randomized control trial is depicted in Figure 1.



Data Analysis

IBM SPSS Statistics for Windows v. 20.0 (IBM Corporation, Armonk, NY, USA) was used for archiving and statistical analysis. The statistical methods included descriptive statistics (frequency distributions, percentages,

means, and standard deviations) and inferential statistics (independent sample *t*-tests, paired *t*-tests, and chi-squared tests).

Ethical Consideration

The current study was approved by the institutional review board of Universitas Muhammadiyah Semarang on December 26, 2020 with the number 0073/KEPK/XII/2021. The current study was approved by the Indonesia Center for Health Resources and Services Research and Development (Registry number: INA-KFQZKG).

RESULTS

Baseline participant characteristics

Table 1: Participant 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%)	
Religion						
Islam	80	100%	83	100%	163 (100%)	
Education Level						
Illiteracy	1	1.25%	2	2.4%	3 (1.84%)	0.726
Primary school	53	66.25%	53	63.86%	100.6 (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						0.179
Married	0	0%	1	1.21%	1(0.61%)	
Widower/widow	79	98.75%	82	98.79%	161(98.78%)	

Respondents in this study were female 79.14%, education level was primary school 65.03% in the intervention group and 63.86% in the control group, married 98.78%, (Table 1).

Table 2: Participant Characteristics

Variables	Intervention				Control				Significance
	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	55.60-0.63	0.151
Time since the diagnosis of diabetes	3.345	2.4770	1-11	2.794-3.896	3.837	3.3057	1-15	3.116-559	0.285

In this study, the mean age of respondents in the intervention group was 55.53 years and 57.61 years in the control group. Furthermore, the intervention group's mean time since diabetes diagnosis was 3.3 years, while the control group was 3.8 years (Table 2).

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

Table 3: Description of the Outcome Indicators for The Two Groups

Variables	Intervention		Control		Significance
	Pre-test	Post-test	Pre-test	Post-test	
HbA1c					
Mean	10.64	9.92	10.59	11.54	Pre-test=0.916
Median	10.35	10.05	10.10	12	Post-test=0.000
SD	2.928	2.265	2.807	2.301	
Min-Max	5-15	6-14	5-15	7-16	
95% CI	9.98-11.29	9.41-10.42	9.98-11.20	11.03-12.04	
SDSCA					
Mean	45.68	60.96	46.08	47.31	Pre-test=0.798
Median SD	45.50 10.271	62 11.573	45 10.106	48 10.482	Post-test=0.000
Min-Max	25-75	34-89	24-75	27-76	
95% CI	43.39-47.96	58.39-63.54	43.88-48.29	45.02-49.60	

The mean HbA1c before the intervention group received a tailored care intervention program was 10.64, then decreased to 9.92, and summary diabetes self-care activity went from 45.68 to 60.96, the higher the better. On the other hand, the mean HbA1c before the control group received the traditional health education intervention program was 10.59, then decreased to 11.54, and the summary diabetes self-care activity was 46.08, then increased to 47.31; the higher the better. (Table 3)

Table 4: Comparison of HBA1C and SDSCA for The Two Groups (Independent T-Test)

Variable	Group n=163	*F*	*t*	*P*-value	Status
HbA1c					
Pre-test	Intervention and control group	0.280	0.106	0.916	ns
Post-test	Intervention and control group	0.129	-4.526	0.000	*significant
Diabetes Self-Care Activity					
Pre-test	Intervention and control group	0.044	-0.256	0.798	ns
Post-test	Intervention and control group	0.069	7.897	0.000	*significant

ns= non-significant

HbA1c and diabetes self-care activity between groups before the intervention did not change substantially but did differ significantly after the intervention, according to independent t-test analysis in Table 4. 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 care program.

Table 5: Comparison of HBA1C and SDSCA for The Two Groups (Paired T-Test)

Variables	Mean difference	SD	*t*	*p*-value	Status
HbA1c					
Pair 1 pre-post	0.720	2.578	2.498	0.015	*significant
Pair 2 pre-post	-0.946	1.612	-5.350	0.000	ns
Diabetes Self-Care Activity					
Pair 1 pre-post	-15.288	11.249	-12.156	0.000	*significant
Pair 2 pre-post	-1.229	4.043	-2.769	0.007	*significant

Note: pair 1= intervention group before and after, pair 2= control group before and after; ns= non-significant

According to paired *t*-test analysis (Table 5), the intervention group's HbA1c level was 0.70 with a p-value of 0.05 before and after treatment, whereas the control group's level increased by 0.946, or significantly in the opposite direction. Furthermore, with a *p*-value of 0.05, the intervention group's involvement in diabetes self-care improved significantly by 15,288. In the control group, there was a rise of 1,229 with a *p*-value greater than 0.05. As a result, the intervention group outperformed the control group in terms of diabetic self-care activity.

Table 6: Description and Comparison of CVD Risk of Groups (Chi-Square)

	Intervention group n=80 (49.1%)	Control group n=83 (50.9%)	Value	df	Asymp.Sig (2-sided)
Risk of CVD before Intervention			0.015	4	1.000
<10%	63(78.75%)	66(79.52%)			
10-<20%	9(11.25%)	9(10.84%)			
20-<30%	4(5%)	4(4.82%)			
30-<40%	2(2.5%)	2(2.41%)			
>40%	2(2.5%)	2(2.41%)			
Risk of CVD after Intervention			45.892	4	0.000
<10%	60(75%)	19(22.89%)			
10-<20%	13(16.25%)	50(60.24%)			
20-<30%	4(5%)	9(10.84%)			
30-<40%	1(1.25%)	3(3.62%)			
>40%	2(2.5%)	2(2.41%)			

DISCUSSION

The tailored care intervention was successful in lowering HbA1c in the intervention group, while it was unsuccessful in the control group. An increase of 1% in HbA1c concentration among individuals with diabetes was associated with a 30% increase in all-cause mortality, a 40% increase in cardiovascular or ischemic heart disease mortality, and a 37% increase in microvascular diseases such as nephropathy and retinopathy (Boussageon *et al.*, 2011; Sherwani *et al*., 2016). Whereas reducing the HbA1c level by 0.2% could lower mortality by 10% (Sherwani *et al*., 2016). These results are in line with research conducted by Patel (2017) about

"a Group-Based Culturally Tailored Lifestyle that is able to improve lifestyle and have an impact on decreasing HbA1c values among his respondents (Patel *et al.*, 2017). Moreover, culturally tailored community health worker home-visiting interventions in patients with diabetes had a mean reduction of 0.53% in HbA1c (Huang *et al*., 2019). The success of a tailored care intervention program in reducing the HbA1c level among patients with diabetes is expected to be a solution to prevent complications due to diabetes in the future.

The tailored care intervention program was better at improving the diabetes self-care activity of participants in the intervention group if compared with participants in the control group who received traditional health education. Tailored care activities included general diet, specific diet, exercise, footcare, blood glucose monitoring, and smoking (Hailu *et al.*, 2019). Tailored care intervention can improve patients' adherence to treatment satisfaction and knowledge regardless of their clinical status, further improving self-care behavior or activity (Alfian *et al.*, 2020; Cummings *et al*., 2019; Hu *et al*., 2016; Navodia *et al*., 2019; O'Neil *et al*., 2016). Other studies mention that tailored care through education and support programs effectively changes knowledge, attitudes, and medication-taking behaviors when compared to the non-provision of tailored care (Caro-Bautista *et al.*, 2021; Choi *et al.*, 2017; Cimo & Dewa, 2019b; Iovane *et al*., 2017). The main components of the implementation of tailored care intervention programs carried out by researchers consist of the implementation of brief deductive teaching or education and brainstorming with support groups. Educational programs play a significant role in enabling patients to undertake self-care activities (Hailu *et al*., 2019). Moreover, education needs self-management support to make patients' health behaviors last for a long time (Cimo & Dewa, 2019a, 2019b; Koetsenruijter *et al.*, 2014; Panagioti *et al*., 2014). Good self-efficacy affects self-care behavior, increased self-efficacy by approaching cognitive functions, like providing health education about self-care management and health education that presents social or family support (Wahyuni, & Ramayani, 2020).

Diabetes was referred to as the mother of various dangerous chronic diseases. The risk of CVD complications is one of them. The statistical results of this study indicate that the tailored care intervention program is proven to be able to reduce the percentage of CVD risk when compared to traditional health education among the diabetes population. The findings if another study reveal that development of a health education package intended for selfcare to prevent diabetes is necessary (. A patient-centered communication style and treatment decisions based on patient preferences, values, and needs that address cultural barriers have become fundamental approaches in tailored care (Choi *et al.*, 2017; Cimo & Dewa, 2019b; Hertroijs *et al*., 2018; Holmen *et al*., 2017; Prato *et al.*, 2010). The approach makes a person more confident and responsible for every decision they make (Cimo & Dewa, 2019b; Hertroijs *et al*., 2018; Prato *et al*., 2010). Glycaemic control from the HbA1c indicator has a big impact on the risk of developing diabetes complications (Boussageon *et al.*, 2011; Sherwani *et al.*, 2016). The better the HbA1c, the risk of developing diabetes complications will also be decreased, and vice versa. (Sherwani et al., 2016). Therefore, the decrease in HbA1c among respondents who received tailored care program interventions was closely related to the decrease in CVD risk in the intervention group. Moreover, how much a person will suffer from CVD can also be identified from data on age, gender, smoking or non-smoking status, blood pressure, and cholesterol levels (Chaudhary *et al*., 2016; Otgontuya *et al.*, 2013; Raghu *et al.*, 2015). Age and gender are variables that cannot be controlled. Meanwhile, variables such as blood pressure in the intervention group that received the tailored care intervention program decreased. A good blood pressure indicator will reduce the risk of CVD complications due to diabetes in the future (Otgontuya *et al.*, 2013).

CONCLUSION

The tailored care intervention was successful in lowering HbA1c, improving diabetes self-care activity. Moreover, the tailored care intervention program was proven to be able to reduce the percentage of CVD risk when compared to traditional health education among the diabetes population in Indonesia.

Conflict of Interest

The authors state that there is no conflict of interest in this study.

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