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Self-regulatory-based compliance module improve chronic kidney failure patients condition

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ABSTRACT

Adherence is very important to pay attention to in health management and the quality of life among end-stage renal disease (ESRD) patients, in the fact that adherence is still lacking. This study aimed to analyze the effect of self-regulatory-based compliance modules improving interdialytic weight gains (IDWG), blood pressure (BP), sodium levels, and functional independence. A quantitative research design with a quasi-experiment approach (pre and post-test control study). A total of 28 samples for each group were taken using purposive sampling. Self-regulation based on health promotion was given using module and IDWG, sodium levels, BP measured with laboratories and physical examination, and Functional Independence measured using a questionnaire. Wilcoxon signed-rank test and Mann-Whitney test were the selected analyses for this study. There was a significant effect on self-regulation-based compliance to IDWG (p=0.012), sodium levels (p=0.001), systolic pressure (p=0.003), and functional independence (p=0.002) in the intervention group. A significant difference was also shown between the two groups (p<0.05). The self-regulation-based compliance module showed improved patient compliance in terms of fluid restriction, taking drugs, paying attention to diet, and managing activities. Adherence to patients increases good outcomes in controlling IDWG, BP, sodium levels, and functional independence in ESRD patients.

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1. INTRODUCTION

Adherence is very important in patients with end-stage renal disease (ESRD) to manage the health and quality of life [1], Until now, compliance in patients with ESRD still shows that not all of them are maximal [2]. The implementation of hemodialysis (HD) which is carried out routinely and continuously must be supported by patient compliance in order to produce good and stable clinical outcomes [3]. Patients with HD treatment face difficulty in health management and it causes complicated [4], they have difficult managing fluid restriction [5], diet [6], treatment [2], and physical activity [7], [8]. The patient's low self-awareness puts the patient often in a worse condition and can enter a critical phase that requires rapid treatment to prevent death [9]. Self-care compliance in patients is shown by interdialytic weight gain (IDWG)

[9], blood pressure (BP) [10], sodium levels [11], and functional independence [11]. So far, research with the intervention of developing a model of compliance theory based on self-regulation has not been carried out.

Previous Research conducted showed that 30-60% ESRD patients undergoing hemodialysis failed to comply with restriction of salt and fluid [12], and it cause 74% ESRD patient do not adherence [4]. Non-adherence rates in ESRD patients with HD is still high, in medication reached 26-53%, food and fluid restriction ranged from 41.4-67%, and physical activity about 64-70% [13], therefore, non-adherence patients impact in HD failed [14]. In globally 10% of adult population survive for ESRD, but 9 out of 10 people are on-adherence [15]. In Indonesia ESRD cases reached 0.38% [16]. According to WHO in 2015, patient compliance in undergoing a series of long-term treatment in developed countries is only 50% [17], while lower numbers are found in developing countries, so there are many treatment failures in ESRD patients [18]. ESRD patient that not adherence will get several complications and will increase mortality cases. HD therapy is one of the successful therapy to prevent the complication [4], during HD patient should manage in diet [7], fluid and salt restriction [5], and physical activity [8], non-adherence in diet and physical activity contributes to loss of muscle strength and mass [8], limits the quality of life [19], abnormal body composition and impaired physical capacity, all complications lead to hospitalization increasing, morbidity and mortality [20].

ESRD patient who do not compliance will have a negative impact, the patient's age which is expected to last longer becomes shorter because of self-regulation that is not maintained [21]. Restriction of fluids, diet, activity and taking drugs should be routinely carried out, many patients also begin to show boredom and ignore these conditions [21]. Non-compliance in ESRD patients requires treatment in the form of implementing education through learning media to improve patient compliance [13]. One of the educational media that can be used is a module, so that it can be used by health workers through an educative approach to ESRD patients to increase compliance. This study combines the Information Motivation and Behavioral Skill models in the formation of compliance [22]. Based on the information motivation and behavioral skills theory, someone change their behavior if they have sufficient knowledge and motivation [23], blended with appraisal and coping strategy from Lazarus state that health management is related to patient's perception and coping [24], [25]. The concept of this theory helps to understand the influence of psychosocial (primary appraisal, secondary appraisal, and coping strategies) on the decision making of HD patients to increase self-regulation [26]. This self-regulation-based compliance model can be used as an alternative solution to replace the belief-based compliance model that has been used so far and is considered ineffective. Therefore, researchers are interested in conducting a study implementing a self-regulation-based compliance module intervention in controlling IDWG, BP, sodium levels and functional independence in patients with ESRD.

2. METHOD

2.1. Research design

A quasi experiment with the research design used is pre-test and post-test with control group design. This type of research design was chosen because it was to find a cause-and-effect relationship involving the control group in addition to the treatment group.

2.2. Respondents' recruitments

The population of this study were all hemodialysis patients who underwent hemodialysis in the hemodialysis room of Sultan Agung Islamic Hospital for a period of one month. The samples in this study were hemodialysis patients who participated in the Phase 1 study and met the following criteria: i) adult patients (over 18 years); ii) patients with stable oxygen saturation (98-100% on the oximeter); iii) able to speak and write Indonesian as well as communicative; iv) undergo hemodialysis 2 times a week for more than 3 months; v) not the patient is in an emergency condition; and vi) patients with IDWG and unstable BP. Samples were randomized to determine the treatment group and the control group. Determination of the sample size in this study using the G-Power software with statistical test: difference between two independent means (two groups), with the degree of error used is 5% and power 95%. The mean group I has an assumed value of 6.29 and a standard deviation (SD) of 1.03, while the mean group II has an assumed value of 5.24 and an SD of 1.66. The measurement of the sample size using the G-Power software resulted in a sample size of 28 samples for each group which were taken using purposive sampling.

2.3. Data collection

The independent variable in this study is self-regulation based on health promotion. While the dependent variable is the compliance behavior of hemodialysis patients (fluid management). Data was collected using the Self-regulatory-based compliance module instrument for IDWG, sodium levels, BP, and functional independence in hemodialysis patients. Measurement of IDWG was performed by calculating the

patient's weight after (post) HD in the first hemodialysis period (measurement I). In the second hemodialysis period, the patient's weight was weighed again before (pre) HD (measurement II), then calculated the difference between measurement II minus measurement I divided by measurement II multiplied by 100%. Graph of the range of the percentage increase in the range of increase in the study: a) Mild 2%, b) Moderate 5%, and c) 8% weight. BP is measured by examining vital signs and sodium levels seen from laboratory results. Functional independence is measured by functional independence measure (FIM), this questionnaire consists of 18 statement items that are felt in the past month. Respondents were asked to put a mark (x) on the answer that was chosen as the statement that was put forward with the following scale; TB: No assistance (score 5); BMin: minimum assistance (<25% assistance) (score 4); BS: medium assistance (25%-49% assistance) (score 3); BMax: maximum assistance (50%-75% assistance) (score 2); BT: total assistance (more than 75% support) (score 1).

2.4. Data analysis

Data analysis on differences in outcome IDWG, BP, sodium levels, and functional independence in hemodialysis patients in the control and treatment groups was carried out using the Wilcoxon signed rank test because the data obtained were not normally distributed. The delta value difference test in this study was carried out using the Mann-Whitney test because the data obtained were not normally distributed.

2.5. Ethical clearance

The protocol has been declared ethically feasible by KEPK RSI Sultan Agung with no: 12/EC/KEPK/2020 with due observance of the principles of self-determination, anonymity, confidentiality, justice, beneficence, and non-maleficence.

3. RESULTS AND DISCUSSION

3.1. Sociodemographic characteristic of respondents

The sociodemographic characteristics of the research respondents indicated that the majority of the two age groups ranged from 46-55 years and were male. The highest educational status in the treatment and control groups was high school with the most types of work being self-employed. Most of the respondents in this study were married, see the details in Table 1. The average Hb level of the respondents in the treatment group was 8.74 and 8.38 in the control group, see Table 2. Previously the data had been tested for homogeneity and normality, the test results showed homogeneous data, whereas based on the normality test using Kolmogorov Smirnov it showed that the data obtained for all variables in this study did not have a normal distribution, see Table 3.

Table 1. Sociodemographic characteristics of respondents

Sociodemographic characteristic	Treatment		Control		Homogeneity
	n	%	n	%	
Age					0.736
18-25 years	2	7.1	2	7.4	
26-35 years	3	10.7	5	18.5	
36-45 years	3	10.7	6	22.2	
46-55 years	13	46.4	8	29.6	
56-65 years	6	21.4	5	18.5	
>65 years	1	3.6	1	3.7	
Gender					0.912
Male	17	60.7	16	59.3	
Female	11	39.3	11	40.7	
Educational background					0.896
Elementary school	4	14.3	6	22.3	
Junior high school	10	35.7	9	33.3	
Senior high school	13	46.4	11	40.7	
University	1	3.6	1	3.7	
Job					0.052
Do not working	16	57.2	14	51.9	
Privat sector	0	0	6	22.2	
Entrepreneur	9	32.1	6	22.2	
Civil servant	3	10.7	1	3.7	
Marital status					0.147
Married	27	96.4	23	85.2	
Single	1	3.6	4	14.8	

Table 2. Hemoglobin level of the respondents

Characteristics	Treatment		Control		Homogeneity
	Mean	SD	Mean	SD	
Hb level	8.74	1.44	8.38	1.45	0>358

Table 3. The results of the normality and homogeneity test of the initial data for IDWG variables, sodium levels, BP, and functional independence

Variable	Group				Homogeneity	Normality
	Treatment		Control			
	Mean	SD	Mean	SD		
IDWG	2.11	1.57	2.06	1.55	0.903	0.004
Natrium level	133.36	3.16	133.22	3.87	0.888	0.001
Systole blood pressure	139.64	20.45	142.93	20.48	0.555	0.044
Diastole blood pressure	81.79	11.89	85.56	11.51	0.167	0.001
Functional independence	75.54	22.11	80.19	18.41	0.400	0.001

3.2. Research variable characteristics

The results of the different test showed that there was a significant difference between the mean IDWG values before and after the intervention in the treatment group (p=0.012). Similarly, sodium levels also showed significant differences before and after the intervention in the treatment group (p=0.001). BP showed unequal results between systole and diastolic, there was a difference before and after the intervention with p=0.003 for systolic pressure and p=0.197 for diastolic pressure, so the diastolic pressure did not show a significant difference. While the functional independence of the patients also showed a difference before and after the intervention (p=0.002), see Table 4.

The results of the different IDWG delta value test showed a significant difference between the treatment and control groups (p=0.003). Similarly, the delta values for sodium levels, systolic BP and functional independence also showed a significant difference between the two groups (p<0.05). However, there was no significant difference between the two groups (p<0.05), see Table 5.

Table 4. Differences in IDWG values in hemodialysis patients before and after intervention

Variable	IDWG				*p*-value
	Pre-test		Post-test		
	Mean	SD	Mean	SD	
IDWG					
Treatment group (n=28)	2.11	1.57	1.64	1.91	0.012
Control group (n=27)	2.06	1.55	2.18	1.15	0.145
Natrium level					
Treatment group (n=28)	133.36	3.16	132.36	1.87	0.001
Control group (n=27)	133.22	3.87	133.33	3.53	0.518
Systole blood pressure					
Treatment group (n=28)	139.64	20.45	132.21	15.27	0.003
Control group (n=27)	142.93	20.48	140.37	18.29	0.079
Diastole blood pressure					
Treatment group (n=28)	81.79	11.89	80.00	7.20	0.197
Control group (n=27)	85.56	11.51	85.19	8.49	0.705
Functional independence					
Treatment group (n=28)	75.54	22.11	77.14	20.44	0.002
Control group (n=27)	80.19	18.41	80.07	17.95	0.716

Table 5. The results of the different delta values of all variables between the two groups

Variable	Group				p-value
	Treatment		Control		
	Mean	SD	Mean	SD	
IDWG	-0.46	0.89	0.130	0.83	0.003
Natrium level	-1.00	1.63	0.11	0.89	0.021
Systole blood pressure	-7.43	6.92	-2.56	7.08	0.011
Diastole blood pressure	-1.79	7.22	-0.37	5.17	0.350
Functional independence	1.61	2.18	-0.11	1.18	0.001

ESRD patients who were given module training showed improved clinical outcomes compared to the group that did not receive intervention, this resulted in stability in IDWG values, sodium levels, systolic BP and functional independence. ESRD patients to be able to achieve good outcomes require high

self-regulation to generate self-motivation from patients in order to comply with therapy and fluid control properly [14], [27], so as to prevent interdialytic weight gain. IDWG was used as an outcome to evaluate the compliance of hemodialysis patients in regulating fluid balance [28]. It is important to do this that IDWG monitoring is associated with limiting fluid intake in patients with chronic kidney disease [29]. Water that enters the body is made in balance with water that comes out either through urine, insensible water loss. This can help to prevent such occurrences through excessive monitoring of IDWG to improve clinical outcomes in HD patients [30]. Based on the foregoing, efforts are needed to monitor and suppress the increase in IDWG values in hemodialysis patients.

ESRD patients who are unable to regulate themselves in consuming sodium are the cause of increased sodium levels [31]. Restriction of sodium intake is one of the dietary requirements of hemodialysis patients, which aims to control BP and edema [32]. BP of hemodialysis patients almost always increases, the mechanism of increasing BP is due to accumulation of salt and water or the Renin Angiotensin Aldosterone (RAA) system [33]. Patients with early-stage renal failure are also advised to limit sodium intake. This is due to the association between sodium intake, kidney disease, and hypertension. Fluid volume status in hemodialysis patients depends on several factors, one of which is sodium intake [34]. In ESRD patients, limiting salt intake is very important because it can result in inadequate renal sodium excretion [35]. Excess dietary sodium increases extracellular osmolarity, leading to the movement of water from the intracellular to the extracellular compartment, resulting in volume expansion. The cornerstone of volume management is restriction of salt and fluid intake [36].

Non-adherence to the treatment regimen is one of the causes of uncontrolled BP in hemodialysis patients [37]. BP in dialysis patients can predict target organ damage or all-cause mortality in relatively healthy dialysis patients. Thus, in dialysis patients BP measurements and treatment should be carried out more often than in general patients. From this, it is necessary to monitor BP in hemodialysis patients. In this study, BP is an outcome in evaluating the adherence of hemodialysis patients to the recommended series of care and treatment for hemodialysis patients. Therefore, an intervention that aims to improve medication or medication adherence in hemodialysis patients is needed, the self-regulation-based adherence module in this study is considered effective in helping patients self-regulate to adhere to treatment, so that the increase in BP in hemodialysis patients can be avoided properly. The results of this study are in line with previous study that explanation hemodialysis patient compliance has a close relationship with the patient's own functional independence [38]. Webster also said that adhering to a fluid and salt diet, adhering to medication, and adhering to activity patterns could improve functional independence in ESRD patients undergoing hemodialysis [39].

Based on the foregoing, efforts are needed to assist ESRD patients undergoing hemodialysis in increasing functional independence, because according to functional independence in ESRD patients undergoing hemodialysis can be used as an indicator of the success of hemodialysis therapy itself. We believe that the success of treatment is not solely the responsibility of the patient, but must be seen how other factors influence a person's behavior in completing their treatment and complying with their treatment. In general, things that need to be understood in increasing the level of adherence is that patients need support and not blame. Improving adherence of hemodialysis patients is the best intervention in order to achieve successful treatment of ESRD patients.

The implementation of the research is inseparable from the limitations of the study as obstacles experienced by researchers during conducting research. The limitation of this study is the difficulty of collecting data during the pandemic which requires the use of personal protective equipment. The use of personal protective equipment (PPE) and the lack of tactile contact with patients make personal emotional bonds decrease, this causes chemistry between education providers and recipients to be difficult to build. Respondents are also less than optimal in receiving education due to the limitation of communication time to prevent the chain of transmission, so further education is carried out through WA and social media if there are things that are not understood.

4. CONCLUSION

The self-regulation-based compliance module improve hemodialysis patient’s adherence. Adherence to patients increases good outcomes, namely controlling IDWG, BP, sodium levels and functional independence in ESRD patients undergoing HD. The self-regulation-based compliance module can be applied by nurses in hospitals as a specialist intervention to improve the condition of chronic kidney failure patients. In addition, the module can increase patient compliance while at home, so that patients are more routine in carrying out fluid checks, diet, medication and therapy, as well as increasing their functional independence in addition to having caregivers providing care.

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