

## Development and validation of a self-management module for patients with excess fluid volume undergoing hemodialysis

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### Abstrak

Excess fluid volume is a critical issue faced by patients undergoing hemodialysis and is associated with increased morbidity and reduced quality of life. Effective self-management is essential in controlling fluid intake; however, tailored educational modules are limited. This study aimed to develop and validate a self-management module to improve fluid restriction behavior among patients undergoing hemodialysis. A Design-Based Research (DBR) approach using a modified Borg & Gall model was employed. The study was conducted in three phases: (1) preliminary research through an integrative literature review to define domains and construct the module framework; (2) design and development of the module and supporting handbook based on evidence and theory; and (3) content validation by a panel of five experts in nephrology and patient education. Content validity was assessed using the Item-Level Content Validity Index (I-CVI), with a cut-off value of  $\geq 0.80$ . The module covered key domains of fluid self-management, including knowledge enhancement, behavioral strategies, and self-monitoring tools. Expert validation confirmed high content relevance, with all items achieving I-CVI  $\geq 0.80$ . Feedback from experts also supported the cultural appropriateness and practical applicability of the module for use in hemodialysis settings. The developed self-management module demonstrates strong content validity and provides a structured educational tool to support fluid restriction behavior in patients undergoing hemodialysis. Further testing is recommended to evaluate its impact on patient outcomes in clinical practice.

**Keywords:** *Hemodialysis, Self-Management, Excess Fluid Volume, Educational Module, Content Validity,*

### BACKGROUND

Over the past decade, the rates of treated patients with End-Stage Renal Disease (ESRD) have risen and the number of ESRD patients has been escalating globally, ESRD affects an estimated 2 million people worldwide (National Kidney Foundation, 2015). Furthermore, the number of patients diagnosed with the disease is increasing at a rate of 5-7 percent per year (the United States Renal Data System, 2018). ESRD is associated with several complications that have a higher prevalence and intensity at lower levels of kidney function and interact with one another, these complications contribute to high morbidity and mortality as well as poor quality of life and some of these complications are easily defined and quantifiable (i.e., cardiovascular disease, hypertension, anemia, mineral bone disorder, volume overload, electrolytes, and acid-base abnormalities) (Bello et al., 2017). and may necessitate specific treatments such as renal replacement therapy (RRT), as well as a specific management approach for patients to change and maintain an appropriate diet, fluid intake, and medication behaviors to maximize good clinical outcomes (Griva et al., 2011). And hemodialysis is reported to be the most common and effective

treatment method as renal replacement therapy (RRT) for patients with ESRD (Fleming, 2011). Nevertheless, patients who undergoing hemodialysis are required to change behaviors and confront comprehensive management that is complex and difficult, such as self-management in dialysis treatment, medication, fluid, and dietary restriction (Chironda and Bhengu 2016). However, several studies report that many ESRD patients have not completed this management, and fluid overload become the most common problem among patients with ESRD (Ekinci et al., 2018; Zoccali et al., 2017).

In the United States, reported that 10–20% of Hemodialysis patients typically undergo high interdialytic weight gain (IDWG) (Smith et al., 2010). And approximately 14.6% of hemodialysis patients died due to high IDWG (Hecking et al., 2018). Intervention programs that focus on Self-management patients have been known effective to improve adherence to fluid intake among patients with ESRD receiving hemodialysis(Griva et al., 2011). According to Kanfer (1991), Self-management is defined as an individual ability to manage symptoms, treatments, physical and psychological consequences due to the sequels of living with their disease or long-term conditions (Kanfer & Gaelick-Buys, 1991).

Self-management consists of three stages including self-monitoring, self-evaluation, and self-reinforcement. However, the self-management literature regarding fluid overload among patients receiving hemodialysis is very limited. The reported structure of the program varies and the literature in this field offers little consistency. Thus, this paper aimed to develop and validate a self-management module for patients with excess fluid volume. The module is designed for increasing fluid intake management among patients receiving hemodialysis through an education and skill practice program

Excess fluid volume among patients undergoing hemodialysis was associated with several serious complications such as impaired coagulation, delay wound healing and is a risk factor for intra-abdominal hypertension, and can also worsen myocardial and liver function (Prowle, Echeverri, Ligabo, Ronco, & Bellomo, 2010). Moreover, excess fluid volume is associated with increased hospital costs, morbidity, and mortality. (Ogbu, Murphy, & Martin, 2015). Evidence suggests that behavioral intervention strategies such as self-management programs that include self-monitoring training, behavioral contracts, and positive reinforcement can improve adherence to fluid restriction among hemodialysis patients (Howren et al., 2016; Murali et al., 2019). It has been shown that patients who have good self-management in their life are more likely to have good control of fluid intake (Li, Jiang, & Lin, 2014).

However, the self-management literature regarding excess fluid volume among patients receiving hemodialysis is very limited. The reported structure of the program varies and the literature in this field offers little consistency regarding the effectiveness of self-management. To promote effective self-management for hemodialysis patients, nurses should develop the self-management module to improve the patients understanding regarding their treatment. The module is designed to increase fluid intake management among patients receiving hemodialysis through education and skill practice.

## **METHODE**

This study applied a Design-Based Research (DBR) approach, which is characterized by iterative cycles of design, development, and refinement of educational interventions grounded in both theory and real-world practice. The research aimed to develop and validate a self-management module for patients with excess fluid volume undergoing hemodialysis. The DBR process in this study followed three main stages: Analysis of Practical Problems (by reviewing literature and user needs), Development of Solutions (based on theoretical principles and expert input), Validation of the Design (through expert-based content validation).

### **Stage 1: Analysis of Practical Problems**

A comprehensive literature review was conducted to explore the core issues faced by patients undergoing hemodialysis with excess fluid volume, as well as the essential components of effective self-management interventions. Searches were conducted in PubMed, CINAHL, ScienceDirect, and Google Scholar using keywords such as hemodialysis, self-management, educational intervention, and excess fluid volume. Studies were included if they met the following criteria: Experimental or quasi-experimental design, based on a self-management theory or model, addressed outcomes related to knowledge, behavior, or attitudes, involved adult patients receiving hemodialysis, Published in peer-reviewed English journals from 2010 to 2020.

Studies were excluded if the self-management intervention was only a small component of a multimodal program. Findings from this review helped define the conceptual framework and key domains for the module, including Understanding self-management principles, Hemodialysis treatment basics, Fluid restriction education, Behavioral strategies: self-monitoring, self-evaluation, and self-reinforcement,

### **Stage 2: Development of the Intervention**

Based on the defined domains, a draft of the self-management module was developed. The content was organized into thematic units covering both theoretical knowledge and practical skill-building activities. A complementary patient handbook was also created, containing: Educational content consistent with the module, Practical exercises to reinforce behavioral change, such as: Daily fluid tracking sheets, Self-reflection logs, Reinforcement checklists, The design of the module integrated principles from health education and behavior change theories to support improved self-management behavior among patients with fluid volume issues during hemodialysis.

### **Stage 3: Content Validation**

The module's content was validated by a panel of five subject matter experts with clinical and academic backgrounds in nephrology, hemodialysis care, and patient education. Experts were from Indonesia and Thailand, each with over three years of experience in the field. Each module item was rated for relevance using a 4-point Likert scale: 1 = Not relevant, 2 = Somewhat relevant, 3 = Quite relevant, 4 = Highly relevant. Item-level Content Validity Index (I-CVI) was calculated by dividing the number of experts who rated the item as 3 or 4 by the total number of

experts. Items with I-CVI  $\geq 0.80$  were retained. Experts also provided qualitative feedback to improve language clarity, appropriateness of content, and instructional flow. The validation process followed the procedures recommended by Polit & Beck (2010).

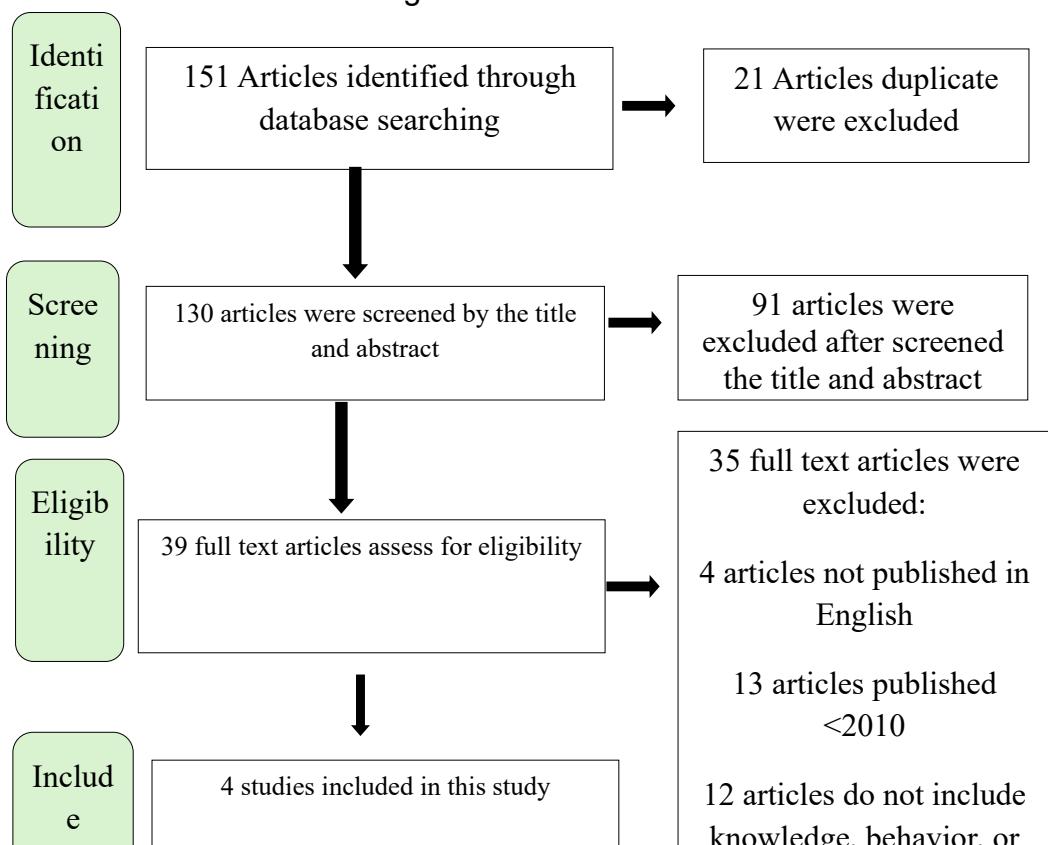
### Instrument Used for Future Evaluation

Although this study did not include empirical feasibility testing, the Fluid Control Hemodialysis Patient Scale (FCHPS) was identified as the planned instrument for future evaluation of the module's effectiveness. The scale measures knowledge, behavior, and attitudes related to fluid restriction in hemodialysis patients. It has demonstrated good internal consistency ( $\alpha = 0.79$  in this study) and strong construct validity in previous studies.

## RESULT and Discussion

### Step 1: Module construct, Domain specification, and Item generation

Electronic database searches retrieved 151 articles, 21 articles duplicate were excluded, 130 articles were screened by the title and abstract and 91 articles were excluded after screening the title and the abstract, and a total of 39 articles were assessed for the full text for a full review. 35 articles were excluded following review: 4 articles not published in English, 13 articles published less than 2010, 12 articles do not include excess fluid volume, knowledge, behavior, and/or attitude as the outcome, 6 articles not applying theory, and Because the number of studies on self-management is very limited in the hemodialysis population, additional subjects have been reported from other populations, such as patients with diabetes mellitus being included as a population similar to the hemodialysis community since nearly all hemodialysis patients are also diagnosed with DM. A total of four publications met the eligibility requirements and were included in the study; the Characteristics of the studies are summarized in figure 1:



**Figure 1:**  
Diagram of studies selection

The HD Self-management module contents were generated based on the four articles that were found and described below:

Table 1 Summary of the literature review of self-management contents for the patient with excess fluid volume undergoing hemodialysis.

Author	Design	Sample	Intervention and Contents	LOE
Bryant et al (2015)	RCT	119 hemodialysis patients (intervention group: 61 patients Control group: 58 patients)	Education and support group: Introduction and rationale of the self-management approach An overview of the relation between self-management processes and fluid management Homework of Self-monitoring: Instruction in self-monitoring skills of fluid intake behavior Goal-setting discussion and patient goal setting for fluid-intake between treatments. Establishing self-administered reinforcement strategies Teaching behavioral stimulus-control Review/evaluation of group experience. Discussion of relapse prevention strategies.	c
Kauric -klein et al (2017)	Randomized control trial	130 hemodialysis patients (Intervention group: 66 patients Control group: 64 patients)	Education sessions: individual counseling on self-management of blood pressure, fluid, and salt intake based on NKF (KDOQI) guidelines. self-management skills practice: through monitoring their BP, sodium and fluid intake, and attainment of BP self-care goals.	c

Kurnia wan et al (2011)	A quasi-experimental study (pre-post intervention)	35 diabetic patients	SM support program: individual education, goal setting, and action planning self-monitoring: comparing their actual behavior with the ideal behavior, and identifying the behavior components which needed to be improved self-evaluation: evaluating and consulting the patients concerning any actions that they had found difficult to complete. self-reinforcement: discussion in respect of goals implemented that week that had been either completely or incompletely achieved. and encouraged to develop improvement goals and action plans for the forthcoming week.	Id
Pann ukgas et al (2015)	A quasi-experimental study (pre-post intervention with the control group)	70 diabetic patients (intervention group:35 and control group:35)	Self-management support program patients were assisted in self-monitoring by reflecting and monitoring their behaviors. individual education and counseling session by using lecture and discussion method Patients were assisted to perform self-evaluation by comparing the current behavior with the desired behaviors Creating goals and the action plan strategies self-reinforcement and follow-up strategies, including weekly telephone follow-up, brief counseling, and face-to-face follow-ups.	Id

## Step 2: Validity Results

HD self-management module showed high content validity for all I-CVI items ranging from 0.80 to 1 and obtained a CVI of 0.96, indicating a very good level of agreement between experts (Table 2). Module content is considered valid. In addition, at the end of the validation process, the experts were also asked to provide a general opinion about the module to be later revised based on their recommendations.

Table 2. Content validity index for HD Self-management module by expert panel members (n = 5).

Item Description	Relevant	Not relevant	CVIa

Introduction of the importance of self-management on fluid:	3	2	0,60
how and why self-management on the fluid is important			
the self-management process (i.e., self-monitoring, self-evaluation, and self-reinforcement)			
Overview of Hemodialysis treatment:	5	0	1
How Hemodialysis works			
Problems Related to Hemodialysis and Kidney Disease			
Nutrition and Fluids for hemodialysis patient			
Fluid management:	5	0	1
What is fluid restriction management			
Effect of overload.			
What is considered a fluid			
Common Fluid Portions			
Tips: Tracking Fluid Intake and Weight			
Tips: Controlling Thirst			
Self-management skill practice:	5	0	1
Goal setting worksheet			
Self-monitoring worksheet			
Self-evaluation worksheet			
Self-reinforcement worksheet			
Average CVI			0,96

\* a CVI is the number of expert panel members who rated the item as relevant rating 3 or 4 divided by the total number of expert panel members (n = 5).

## Discussion

This study succeeded in developing, and validating, of the hemodialysis self-management module. We identified 4 experimental study with a wide variety of interventions with many contents that aim to improve the knowledge, behavior, and attitude of hemodialysis patients regarding fluid intake management. The self-management module was developed based on a systematic process which included the module development from the literature review and validation of the contents by the experts.

A few studies have shown the effectiveness of self-management on fluid excess volume among patients with hemodialysis (Howren et al., 2016; Kauric-Klein, Peters, & Yarandi, 2017; Kurniwawan, Sae-Sia, Rn, & Petpitchetian, 2011; Pamungkas, Chinnawong, & Kritpracha, 2015). Therefore, self-management on hemodialysis must be used as a guideline that would help the patients to focus on fluid management intake (Smith et al., 2010). In chronic hemodialysis, the fluid

status of the patient is reflected in their interdialytic weight gain (IDWG), and IDWG is used as the most reliable test for assessing the fluid status of the hemodialysis patient (Ipema et al., 2016).

Nonadherence to fluid intake is the most common problem among patients receiving hemodialysis (Ekinci et al., 2018; Zoccali et al., 2017). Many factors have a significant influence on the self-management of the patient receiving HD regarding fluid restriction (Efe & Kocaöz, 2015). However, patients themselves related factors are a significant factor of non-adherence to fluid management, the main reasons are lack of knowledge and lack of self-efficacy, and this is the first factor that must be a concern (Pebriantari & Astuti Dewi, 2018). A study from Smith et al., (2010) reported that the facilitator most cited as influencing compliance with fluid restrictions is Knowledge. Moreover, the ability to perform an accurate self-assessment of overall fluid status as well as sodium intake is the second most common facilitator of fluid restriction adherence(Clark-Cutaia, Ren, Hoffman, Burke, & Sevick, 2014).

The knowledge has clear implications for their ability to accurately monitor fluid intake. Interventions to enhance self-management programs that combine patient education and self-practice in fluid management have yielded promising results(Sun & Guyatt, 2013). Based on that result the HD self-management model was developed consisting of two parts, the educational part, and the skill practice part. For the educational module, the contents are expected to educate the patients to gain better knowledge and understanding of the disease and management of the disease, and the skill practice module was developed to assist the patient in self-manage regarding their problem or specific behaviors.

A few studies have been shown that self-management strategies for patients with ESRD undergoing hemodialysis are an effective way to reduce the incidence of mortality and complications and improve the quality of life of patients, some of the facilitators most frequently discussed as factors that can influence adherence to fluid management are patient knowledge as well as independent assessment of disease management (Gela & Mengistu, 2018). Patient knowledge becomes an integral part of the most basic interventions of education programs. Thus, the self-management module was developed and validated before implementation. The self-management module was validated judgmentally by experts in the field. In the process of analyzing the content and the appearance of the self-management module, contributions included judges who were experts in hemodialysis care. The judges provided information relevant to the modification of information provided in the self-management module.

This module was found to have a CVI of 0.90 and it revealed that the HD Self-management module would be acceptable. It is providing a wide range of interventions to improve fluid intake management of patients with excess fluid volume through patient education, counseling, and support on self-management. Based on the results, the hemodialysis self-management module might help the patient to successfully manage their fluid status by increasing the patient's knowledge, behavior and attitude. Knowledge is one of the factors that have a significant influence on the self-management of the patient undergoing HD regarding fluid restriction (Pebriantari & Astuti Dewi, 2018). The educational

strategy in this study allowed the participants to gain knowledge and allowed the participants to intensively discuss any additional information they needed. In addition, the information given to the participants highlighted important information such as how salt can increase the fluid intake, how the fluid can increase the blood pressure, how to control and monitor fluid intake, which helped participants, therefore, they have better knowledge than before.

Numerous studies have also found that educating ESRD patients about fluid restriction adherence can have a positive impact. The use of an educational intervention in a chronic hemodialysis setting is an effective strategy for increasing patient knowledge about hemodialysis treatment and fluid restriction (Cristovao, 2015). For hemodialysis patients, education is the most effective tool for preparing them to adapt to the change of life with the need for dialysis. Moreover, the self-management module in this study consisted of an educational part as well as the skill practice part including the self-monitoring, self-evaluation, and self-reinforcement played an important role in encouraging the adherence of patients with ESRD undergoing HD regarding fluid restriction management.

The combination of educational modules and skill practice module in this study were played an important role in increasing attitudes toward fluid restriction management among patients with ESRD undergoing hemodialysis. First, the educational module allowed the patient to gain and increase their knowledge related to fluid restriction management which increasing knowledge is associated with the greater influence of attitudes on behavior. Moreover, attitudes based on a high level of knowledge were more predictive of environment-related behavior. Other studies have also found that there was a significant correlation between variables of knowledge and attitude of participants on patients undergoing hemodialysis (Rahimi, Oskouie, Naser, Sanandji, & Gharib, 2017). A study by Jafari et., al. (2014) also found that educating patients with a special emphasis on the diet (including fluid restriction) can have a positive effect on their attitude (Jafari, Mobasher, & Mirzaeian, 2014). Moreover, the education of the patient may improve attitudes and practices(Spies, van den Berg, & Nel, 2020).

Second, the self-management module in this study allows the patients to continuously improve their behavior, the attitudes and behavior have a strong relationship where both have a two-way relationship, which behavior can inform and shape our attitudes and attitudes can also inform and shape our behavior some attitudes are more likely to be based on beliefs (Banaji & Heipezt, 2010). From the previous studies, they showed that patients who have good self-management in their life are more likely to have good control in the fluid intake, therefore, disease management programs for patients with CKD need to focus on active participants in the program and positive change of their attitudes (Choi & Lee, 2012). Furthermore, most of the participants in this program were active to discuss and ask questions with interest as one subject mentioned that “the self-management book (module) was good, it help me to understand more about the fluid management and assists me clearly to monitoring and control my fluid intake per day so I can remember how much my fluid consumption per day”. This result was confirmed by Griva, et al., 2018; Howren, et al., 2016; Kauric-Klein, Peters M.,

& Yarandi N., 2017 which reported the progression of self-management behavior after receiving the self-management program

## CONCLUSION

The hemodialysis self-management module was developed, validated, and assessed of the feasibility for the contents and the relevance specifically for use in a patient with excess fluid volume receiving hemodialysis. The module was content validated and can be used to enhance knowledge, attitude, and behavior regarding fluid management. The quantitative approach was used to design and select items necessary for this program. The HD Sem-Mod showed high content validity of individual items (I-CVI range: 0.96). HD Sem-Mod content has the potential to be used as an intervention strategy in educational programs and skills practice for patients with excess fluid volume. Future hemodialysis self-management modules could help to improve the fluid management behavior of patients receiving hemodialysis to improve patient management in fluid intake restriction.

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