

Southern California CSU DNP Consortium

California State University, Fullerton
California State University, Long Beach
California State University, Los Angeles

IMPLEMENTING A SUPPORT PERSON AS AN INTERVENTION FOR
HEMODIALYSIS PATIENTS TO IMPROVE FLUID REGIMEN ADHERENCE

A DOCTORAL PROJECT

Submitted in Partial Fulfillment of the Requirements

For the degree of

DOCTOR OF NURSING PRACTICE

By

Ann Sherly Varghese

Doctoral Project Committee Approval:

Beth Keely, PhD, RN, Team Leader
Margaret Brady, PhD, RN, Team Member

May 2019

Copyright Ann Sherly Varghese 2019 ©

ABSTRACT

The purpose of this quality improvement (QI) project was to implement and evaluate the effect of social support among End Stage Renal Disease (ESRD) patients receiving hemodialysis (HD) to determine if there was an improvement in their adherence to fluid restriction regimens. The objective of this QI project was to improve the patient's adherence levels by monitoring their daily fluid intake and their Intradialytic Weight Gain (IDWG) levels.

The project used a non-experimental pre-post design, to assess the influence of social support on IDWG among HD patients. A purposive sampling method was selected due to the characteristics of the HD population.

The effect of social support was tested by comparing the following variables: (1) mean IDWG of HD treatments, pre and post intervention (without and with social support) to measure the effect on fluid adherence regimens for four weeks; (2) mean number of days the participants did not follow fluid adherence regimens; (3) mean scores obtained on a five-point Likert scale (0-4) on the Dialysis and Diet Fluid Adherence Questionnaire (DDFQ). The mean IDWG of the post-intervention phase was 0.18 kg higher than the value of the pre-intervention phase for all participants with social support. This difference was not statistically significant ($t(9) = -.642, p = .537$); there was no significant change in the IDWG levels post-intervention.

The project findings did not support the published research, which indicated that having a support person helped to improve fluid adherence and lower the mean IDWG levels among HD participants. The DDFQ scores were significant with regard to the frequency and degree of non-adherence with diets and fluids when compared to pre- and post- assessments. The IDWG scores did not decrease over the course of four weeks of HD treatments. The finding suggested that unless there is constant reinforcement from a support person, patients may tend to change their behavior depending on the situation and their lifestyle. The outcome of this QI project may suggest that more behavioral reinforcement regarding fluid and dietary regimens is required for HD patients to adhere to fluid restrictions. Additional intervention studies can be conducted to improve clinical outcomes related to compliance behaviors.

TABLE OF CONTENTS

ABSTRACT.....	iii
LIST OF TABLES.....	vii
LIST OF FIGURES	viii
ACKNOWLEDGMENTS	ix
INTRODUCTION	1
Significance of the Problem.....	2
Purpose Statement.....	3
Supporting Framework	3
REVIEW OF LITERATURE	10
Overview.....	10
Patient Perceptions.....	11
Interventions for Increasing Adherence to Fluid Limitations.....	13
Behavioral Approaches.....	13
Educational Approaches	15
Family/Peer/Significant others support	15
Self-Management and Intention.....	17
METHODS	18
Design	18
Setting.....	18
Usual In-center Dialysis Process	18
Participants.....	19
Inclusion Criteria	19
Exclusion Criteria	19
Ethical Considerations	19
Measures	20
Procedures.....	21
Data Collection and Management.....	23
Plans for Data Analysis.....	23
Evaluation Plan	24

RESULTS	25
Data Analysis	25
Descriptive Statistics.....	25
Pre- and Post- Intervention Comparison.....	27
Intradialytic Weight Gains (IDWG) Results	28
Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ) Results.....	29
Summary.....	30
DISCUSSION	31
Limitations	33
Implications for Practice.....	34
CONCLUSION.....	35
REFERENCES	36
APPENDIX A: IRB APPROVAL LETTER	47
APPENDIX B: FACULTY ADVISOR STATEMENT	48
APPENDIX C: LETTER OF SUPPORT	49
APPENDIX D: NOTICE OF INFORMED CONSENT FOR SUPPORTING PERSON	49
APPENDIX E: NOTICE OF INFORMED CONSENT FOR PATIENT.....	51
APPENDIX F: SURVEY QUESTIONS	53
APPENDIX G: DEMOGRAPHIC QUESTIONNAIRES	54
APPENDIX H: EDUCATIONAL COMPONENT FOR EACH PATIENTS AND THEIR FAMILY MEMBER	56
APPENDIX I: DAILY FLUID INTAKE LOG SAMPLE	59
APPENDIX J: ORAL SCRIPT DURING TELEPHONE CALLS WITH EACH FAMILY MEMBER.....	63
APPENDIX K: TABLE OF EVIDENCE.....	65

LIST OF TABLES

<u>Table</u>	<u>Page</u>
1. Demographic Characteristics of the Participants and their Support Person	26
2. Mean Pre and Post-intervention IDWGs and DDFQ Results.....	28

LIST OF FIGURES

<u>Figure</u>	<u>Page</u>
1. The Theory of Planned Behavior adapted from Behavior Change Models.....	5
2. Mean IDWG pre- and post-intervention histogram.....	29
3. Mean DDFQ values: number of days without violation and self-assessed degree of violation by stage (pre-, post-intervention)	30

ACKNOWLEDGMENTS

Special gratitude goes out to the DaVita research committee members and my facility team members who provided me an opportunity to conduct this project. Many thanks to Dr. Theresa-Director of Advance Practice Team, Dr. Agarwal-CEO of our medical group and all my fantastic nurse practitioner colleagues who gave me continuous support and feedback to find the best ways to promote evidence-based health care among our patients. Having said that I would also thank my committee chairs, Dr. Keely and my team member Dr. Brady and Dr. Weismuller for the insightful comments, immense knowledge and valuable feedback on the project. A special thanks to Dr. Berg, who helped me focus during the challenging times in my life. I would also like to thank Dr. Armendariz, an amazing person for all her time spent on editing the project with me.

Huge thanks to my beloved husband, Jo, for his unconditional love, encouragement, and understanding. A heartfelt thanks to my parents and Abey, my brother who believed in me and always supported me to reach the final goals. To my beautiful friends, Manpreet, Christine and Kate who had profoundly impacted my life by supporting and encouraging me when the journey became difficult. Finally, I thank God, the Almighty for providing me the wisdom and physical ability to do this project.

INTRODUCTION

Patients with end-stage renal disease (ESRD) have an intensive regimen to follow for optimal health. Fluid and dietary restrictions, medication guidelines, and adherence to prescribed hemodialysis (HD) sessions are essential for adequate management of ESRD. Patient adherence to fluid intake restrictions is necessary to balance hypovolemia during HD and decrease the potential for fluid overload between HD treatments.

Non-adherence to fluids and dietary regimens has increased hospital admissions and decreased the quality of life among ESRD patients (Chironda & Bhengu, 2016). Data have shown that an average of two hospitalizations occur yearly among each HD patient due to several co-morbid conditions, such as cardiomyopathy, pneumonia, pleural effusions, and related gastrointestinal disorders (Nissenson, 2014). According to the United States (U.S.) Renal Data System (USRDS), 11.2% of ESRD patients were hospitalized due to fluid-related issues alone in 2012 (Brunelli, Gray, & Cohen, 2016). Fluid-related hospital admissions are a compelling cause for higher cardiovascular hospitalization rate in HD patients, and therefore annual costs may exceed \$250 million (Assimon, Nguyen, Katsanos, Brunelli, & Flythe, 2016). According to the Annual Data Report of 2017 from USRDS, cardiovascular hospitalization rates increased from 1% to 2% for this patient population between 2014-2015 (Weinhandl & Collins, 2018). Frequent fluid-related hospitalizations increase the risk for morbidity and mortality among ESRD patients and decrease patient's quality of life and increase financial burden.

The Significance of the Problem

Evidence has shown that 50% of HD patients are non-adherent with their fluid intake regimen (Chironda & Bhengu, 2016). A lack of attention to fluid restriction leads to fluid overload which increases the patient's risk for adverse outcomes such as pulmonary edema, hypertension, exacerbation of heart failure, swelling, and risk of premature death (Zoccali et al., 2017). A cross-sectional study conducted in Austria with HD patients concluded that fluid overload was directly associated with high cardiovascular morbidity rates (Antlanger et al., 2013). There are several interventions to optimize the fluid adherence in ESRD patients, such as cognitive behavioral therapy, self-efficacy training, coaching, and motivational interviewing (Wong, Craig, Levin, & Strippoli, 2014). These interventions have proven successful in enhancing the dietary and fluid restrictions in dialysis patients; however, such strategies are still a challenge in the dialysis centers because there is inconsistency in patient behavior, which leads to non-compliance with fluid adherence.

During HD sessions, a patient's fluid status is determined by their interdialytic weight gain (IDWG), which indicates weight gain on non-dialysis days. About 10-20% of ESRD patients on HD in the U.S. have a high IDWG (Chan, Zalilah, & Hii, 2012). The Centers for Medicare and Medicaid Services (CMS) monitors U.S. dialysis centers ensuring that the centers meet standards and report their clinical performance to the ESRD quality incentive program (ESRD-QIP), which rewards the dialysis centers for the quality of their performance. Significant reductions in reimbursement to the dialysis centers occur if the center does not meet requirements. One such requirement relates to patient hospitalization (United States Securities and Exchange Commission, 2002).

FluidWise Clinical Pathway-Focus Report, a clinical performance program that assesses the dialysis centers' clinical performances related to fluid management among HD patients, noted a 5% excessive patient IDWG and a 10% hospitalization rate for patients treated in a local dialysis center in San Bernardino, California in the final six months of the year 2016 (Davita Inc., 2017).

Studies demonstrated that individualized fluid consumption goals, self-management of fluids, and motivated compliance did lead to behavioral changes that limited daily fluid intake (Chironda & Bhengu, 2016; Smith et al., 2010; Welch et al., 2013; Wong, Ghebleh, & Phillips, 2017). Therefore, a family support intervention approach seemingly has the potential to improve the fluid adherence among ESRD patients by helping them to comply with their daily fluid intakes. This could prevent fluid-related hospitalizations and fluid overload.

Purpose Statement

The purpose of this quality improvement (QI) project was to implement and evaluate the effect of social support for ESRD patients on HD to improve fluid restriction adherence in a local dialysis center in Southern California. The objective of this QI project was to improve patients' adherence levels by monitoring their daily fluid intake logs and IDWG levels.

Supporting Framework

A supporting framework helps to explain the importance and significance of the research problem (Lederman & Lederman, 2015). Fluid adherence remains a problem among HD patients as evidenced by their rates of admission to the hospital due to fluid overload and their reduced quality of life (Zoccali et al., 2017). Interventions for fluid

adherence are associated with patient's behavioral change. Poor adherence to prescribed behavior change could increase if the patient lacks knowledge of the consequences of fluid overload or if they perceive limitation of fluid as a burden (Smith et al., 2010). Patients demonstrate a positive behavior when they are compliant with a specific therapy and observe self-benefit and good outcomes (Panesar, 2012).

The Theory of Planned Behavior (TPB) was proposed in 1985 by Icek Ajzen. The theory focuses on behavioral control and predicts an individual's behavior is the result of a deliberative action (Ajzen, 1985). The main component of the TPB model is intention as it relates to behavior which is influenced by an individual's attitude towards behavior, subjective norms, and perceived control. According to Ajzen (1985), human action is influenced by three determinants of TPB theory:

- Behavioral beliefs – an individual's beliefs about consequences of the behavior (Ajzen, 1985)
- Normative beliefs – an individual's beliefs about the expectation of others (Ajzen, 1985).
- Control beliefs – an individual's beliefs about the presence of factors that may have a positive or negative influence on the behavior (Ajzen, 1985).

The TPB theory has been applied in various disciplines to address adherence behaviors in chronic conditions (Rich, Brandes, Mullan, & Hagger, 2015). The TPB proposes that a relationship exists between an individual's intention to behave and their production of the behavior (Ajzen, 1985). An individual's ability and motivation could lead to specific behaviors such as smoking cessation, daily medication adherence, and alcohol and drug use. The TPB theory has been applied to several other behavioral

change interventions such as hand hygiene and reporting medication errors (Jeong & Kim, 2016; Natan, Sharon, Mahajna, & Mahajna, 2017). A meta-analysis showed increased efficacy of the theory by predicting adherence to the treatment regimens for chronic conditions (Rich et al., 2015).

For this project, the TPB framework, with an emphasis on subjective norms, was used to implement a family or significant other support intervention for HD patients to evaluate the patient's intention to adhere to fluid restrictions.

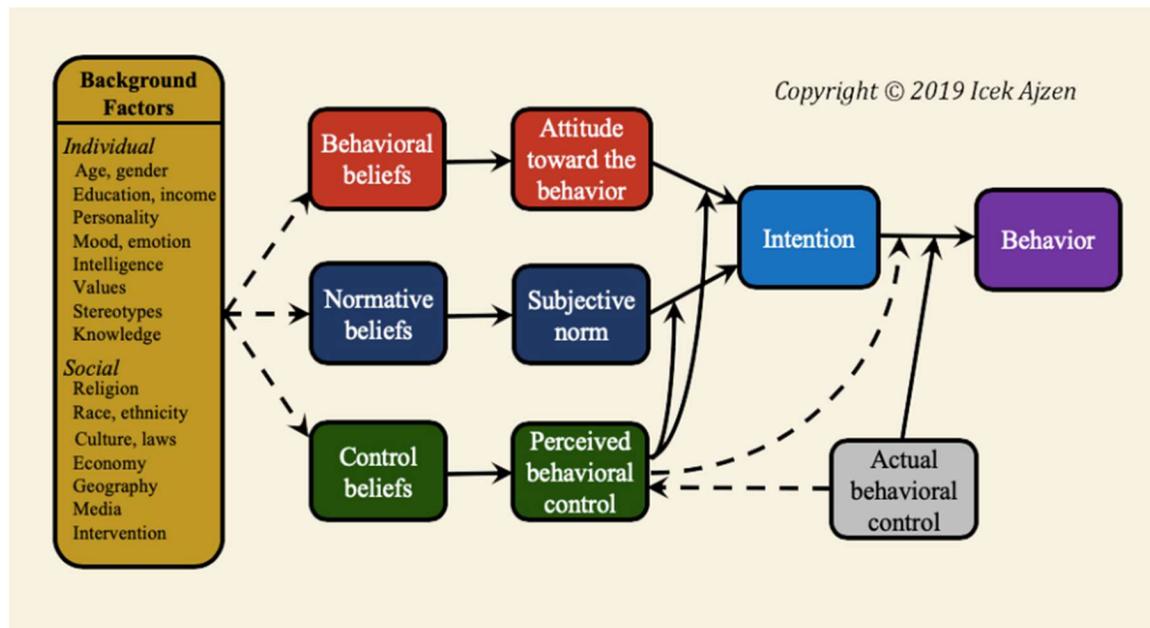


Figure 1. The Theory of Planned Behavior adapted from Behavior Change Models by Ajzen, 1991.

Behavioral Beliefs

The first determinant in the TPB model is the behavioral belief. Behavioral beliefs are beliefs that lead an individual to think that a behavior might produce a certain outcome (Ajzen, 1985). Behavioral beliefs may produce a favorable or unfavorable

attitude toward a certain behavior change, such as daily exercise will reduce weight gains. The more favorable the attitude, the stronger the intention to act (Ajzen, 1985).

Among the renal failure population, HD patients hold beliefs about their fluid intake behavior. They may believe that limiting daily fluid intake to one liter will reduce symptoms such as shortness of breath (SOB), swelling, and will prevent them from going to the hospital due to fluid overload. Patients who are aware of the fluid restrictions and the potential consequences might have a positive attitude toward the behavior of limiting their daily fluids. Another patient may hold beliefs such as “Oh if I drink more water, the dialysis machine will take out the extra fluids from me”, or “It won’t matter if I overdo my fluids on weekends, because I will be better by the end of week.” Such beliefs might generate a negative attitude towards adopting the behavior of fluid restrictions. Attitude toward fluid limits are assumed to be controlled by specific beliefs about the effects of fluid overload. Each belief is evaluated by a subjective value of the outcome in the questionnaire developed for this project that assess the strength of the behavioral beliefs (Fishbein & Ajzen, 2010).

Normative Beliefs

Normative beliefs refer to the beliefs or expectations of significant others such as family, co-workers, friends, relatives, or HD friends who agree or disagree with the behavior to be adopted (Ajzen, 1985). Normative beliefs also include long-continued practices or cultural behaviors within a group of people (Ajzen, 1985). That is, if individuals believe that significant others could influence their behavior, they might engage in positive or negative behaviors.

A study conducted in Iran concluded that renal failure patients on HD who had social support and engagement from significant others showed a greater adherence to dietary and fluid restrictions (Ahrari, Moshki, & Bahrami, 2014). A patient might consider what others would expect from him. The patient might believe that he would be ridiculed or might anticipate receiving adequate support from significant others for his behavior. Normative beliefs can be assessed through subjective reflection from HD patients to discern whether they perceive social pressures as positive or negative. For example, a patient who is accompanied by a spouse to the educational session might intend to adhere to his daily dietary intake limitations due to reinforcement from the spouse (Alikari, Matziou, Tsironi, Theofilou, & Zyga, 2015).

Control Beliefs

Control beliefs refers to an individual's beliefs about the presence of factors that may have an impact on the individual's ability to perform the behavior. According to Ajzen (1985), a combination of behavioral beliefs and perceived social pressure could help a person to change his behavior. Control beliefs also refers to how an individual perceives behavior complexity. Perceived control beliefs are directly associated with perceived factors that will either augment or inhibit the behavioral performance. For example, an HD patient should be evaluated to see if he has the knowledge to perform a behavior or if he is confident to perform a behavior. The more complex the intervention, the more difficult the patient believes it is to perform a behavior. Perceived control beliefs vary by situation which could alter an individual's perception of the behavior. The availability of more resources could increase the perceived ability of a person to perform a behavior and decrease the barriers (Phillips, 2013).

The patient can be further evaluated to determine if he has resources or tools available. In this study, resources to adhere to fluid intake would be included in the teaching session. These educational programs are focused and individualized for HD patients to increase their perceived control beliefs and to decrease the presence of barriers. In conclusion, an individual's intention to perform the behavior depends on favorable attitude, (behavioral beliefs), good subjective norms (normative beliefs), and strong perceived behavioral control (control beliefs).

Application of TPB Framework

The TPB theory highlights how behavioral changes can improve a patient's quality of life (Phillips, 2013). Beliefs and intentions should be considered when providing interventions for behavioral changes. Using the TPB framework, this project focuses on one of the constructs of the framework, normative beliefs. This construct will help to explain how the use of a family support intervention for HD patients may improve fluid intake adherence. The intervention will also identify how normative beliefs could significantly influence HD patients' attitudes towards fluid restrictions as well as their adherence to the regimen. Normative beliefs help to explain why certain people in the patient's life may help to influence behavior changes and expectations. Thus, it is determined that normative beliefs could play a significant role in a HD patient's decision whether he should restrict his fluid intake or not. He knows that hospitalization related to fluid overload is something that his family or significant others dislike and may perceive as an inconvenience. As a result, the HD patient's response will likely be contingent upon this subjective norm. He may become more vigilant of his fluid intake and restrict himself if he believes that his family is critical of his lack of adherence. Thus, the role of

subjective norms proposes that the individual's behavior is influenced by their intention to engage in the behavior and is also influenced by their family or significant others.

REVIEW OF LITERATURE

A literature review was conducted utilizing the following electronic databases: PubMed, CINAHL, EBSCO, and Google Scholar. Included search terms were “*fluid compliance, fluid restrictions, fluid adherence, social support, family support, significant others, ESRD, and hemodialysis.*” Limits on the search include journals published between 2012 and 2018 and English language only. However, a few journal articles outside of this timeframe were used due to their relevance and because no newer relevant literature was found. Research articles that address hemodialysis treatment regimens using mobile technology, treatment compliance among children or pregnant women were excluded. There were no articles retrieved in the unpublished form within the time frame. This literature review focused on the following topic areas: (a) patient perceptions on fluid restrictions; (b) interventions for increasing adherence to fluid limitations; (c) family/peer/significant others support; and (d) self-management and intention.

Overview

Adherence is a significant concern for ESRD patients on HD. Adherence is the extent to which an individual follows instruction for a prescribed treatment (Hugtenburg, Timmers, Elders, Vervloet, & Dijk, 2013). The treatment regimen for patients with ESRD is complex, requiring alterations in diet and fluid consumption, medication adherence, and thrice-weekly visits to the dialysis center for hemodialysis. According to Howren et al. (2016), the most challenging behavior in the ESRD regimen is fluid restriction. Patients are usually limited to one liter of fluid per day. Sometimes weight gains from increased fluid intake among HD patients could be affected by the disruption of their normal body functioning, such as thirst or by a desire to drink more water

(Bossola, Pepe, & Vulpio, 2018). Patients with ESRD have, by nature of their illness, fluid retention. Non-adherence to fluid restrictions results in greater fluid retention, which in turn may lead to frequent hospitalizations and a greater risk for earlier mortality (Estridge, Morris, Kolcaba, & Winkelman, 2018; Pasyar, Rambod, Sharif, Rafii, & Pourali-Mohammadi, 2015; Sontakke, Budania, Bajait, Jaiswal, & Pimpalkhute, 2015). Evidence has shown that fluid compliance rates among individuals receiving HD are poor worldwide (Griva et al., 2018; Howren et al., 2016; Jia, Huang, Chu, Lu, & McArthur, 2016; Khalil & Darawad, 2013). A variety of interventions using behavioral, educational and psychological components have been employed to increase adherence rates. These studies are discussed in the section entitled “Interventions for Increasing Adherence to Fluid Limitations.”

Patient’s Perceptions

Qualitative research studies have explored the perceptions of patients with ESRD about their regimen, including two meta-analyses (Nielsen, Juhl, Feldt-Rasmussen, & Thomsen, 2017; Palmer et al., 2015; Reid, Seymour, & Jones, 2016). Although one of the meta-analyses relates to dietary and fluid restriction (Palmer et al., 2015), and the other is a more general report on the experiences of patients receiving hemodialysis (Reid et al., 2016), some of the identified themes overlap. One of the themes identified is that dialysis patients often have difficulty fulfilling role responsibilities once dependent on dialysis. Many of these patients experience a loss of identity and a new understanding that they are no longer self-reliant. There is also the acknowledgment of restriction; the restriction related to fluid, to diet, to home, and those imposed by the dialysis centers. Patients felt deprived by these restrictions (Palmer et al., 2015). Similarly, Reid

et al., (2016) and Karamanidou, Weinman, & Horne (2014) identified that patients felt interference with their previous roles and because of their illness were required to give up some responsibilities. These patients were worried about being a burden to the family. Many chose to live the life at present (Reid et al., 2016). Other patients struggled to balance between the treatments imposed by their illness and their daily responsibilities (Karamanidou et al., 2014).

In other qualitative studies, comments reflected that fluid restriction adherence required an alteration in the patients' daily social life, physical activity, and sense of being a 'normal person' (Griva et al., 2013; Hong, Yuae, & Chen, 2017; Karamanidou et al., 2014). Hong et al. (2017) conducted a qualitative study to examine patients' perceptions of the challenges of maintaining a fluid restriction regimen. The researchers identified that the participants acknowledged the necessity of fluid restrictions, but they were often not able to keep track of their fluid intake. The participants tried to curtail their fluid intake by drinking less right before their next dialysis date. Similar decision-making thoughts were identified in the study by Karamanidou et al. (2014). The patients were aware of negative consequences of their behavior, but still did not adhere to the treatment regimen.

Griva et al. (2013) identified perceived facilitators and barriers to adherence. The participants identified family support as a facilitator to help them manage their treatment regimens, but only when the family was encouraging them. The participants reported that they owed a debt to their families and peers to stay healthy and not become a burden and thus they were more motivated to adhere (Griva et al., 2013). Studies also found that the support from health professionals was valuable, as was the support given by peers in

support groups (Griva et al., 2013; Hong et al., 2017; Palmer et al., 2015). Other facilitators were being aware of the consequences of non-adherence, knowledge of the regimen and its incorporation into a daily routine (Griva et al., 2013). Reid et al. (2016) noted that over time, as patients became adjusted to life with ESRD and being on dialysis, this made the restrictions a bit easier.

Barriers related to low self-efficacy or a lack of confidence that the patient would be able to self-manage. Griva et al. (2013) found that the participants who had limited understanding and felt a lack of control over diet and fluid regimens expressed concerns about remembering all of the details in the treatment regimen. They admitted they had the most difficulty with medications, diets, and fluid limitations. Similarly, another study found there was a lack of self-efficacy for items such as *knowledge, attitude, and feedback* (Meuleman, Hoekstra, Dekker, Boog, & Dijk, 2018).

In summary, the studies described above show that patients perceive diet and fluid restrictions as the most challenging aspects of self-management (Karamanidou et al., 2014; Meuleman et al., 2018; Reid et al., 2016). The recommendations are that support mechanisms such as family, health professional, and peer support can help patients to adhere to the restrictive regimen (Griva et al., 2013; Hong et al., 2017; Palmer et al., 2015). Also, there is a need to repeatedly educate and help patients to feel as if they can manage the regimen (Griva et al., 2013).

Interventions for Increasing Adherence to Fluid Limitations

Behavioral Approaches

Behavioral interventions for increasing adherence to fluid restriction have shown mixed results (Griva et al., 2018; Howren et al., 2016; Wileman et al., 2016). Griva et

al., (2018) evaluated the effectiveness of the Hemodialysis Self-Management Randomized Trial (HED-SMART) intervention on patients' adherence to diet and fluids. The HED-SMART intervention was based on Bandura's social cognitive theory and was designed to increase the hemodialysis patient's ability to self-manage. A variety of outcomes were assessed immediately after the program, three months post-intervention and nine months later. Participants showed significant improvements after the program, but these improvements did not sustain at nine months. In another behavioral intervention study, Howren et al. (2016) used self-regulation as a guiding framework. The authors used interventions such as self-monitoring skills, setting patient goals, understanding behavioral stimulus-cues, and weekly evaluation of behavior performance. The results showed no significant differences between usual care and intervention participants for IDWG.

Wileman et al. (2016) used an intervention based on self-affirmation theory and found that although there was an effect on IDWG post-intervention, there was some doubt about the link to self-affirmation. The other outcome measures based on self-affirmation interventions did not show any changes. A pilot study used motivational interviewing (MI) coaching techniques and Prochaska's Change Model to identify the patient's readiness to change (Crown, Vogel, & Hurlock-Chorostecki, 2017). The results showed patient satisfaction with MI and concluded that the patients require a set of interventions to self-manage their fluid intake. MI techniques were used in previous studies that resulted in a change in health behavior and patient's intention to change (Hettinga & Hendricks, 2010; Russell et al., 2017).

In summary, behavioral interventions to improve adherence among HD patients demonstrated a positive impact on patient's behavior, but these behavioral changes were not always sustained. Further research in the area is warranted.

Educational Approaches

Research indicates that health education plays an essential role in reducing the risk of complications and increasing adherence to treatments regimens among hemodialysis patients (Alikari et al., 2015; Parvan, Hasankhani, Seyyedrasooli, Riahi, & Ghorbani, 2015). Parvan et al. (2015) compared the effect of two educational methods: face-to-face training and providing a pamphlet to patients. The results showed a greater increase in knowledge and adherence to treatments for the group who received face-to-face training compared to the group receiving the pamphlet. Similarly, Alikari et al. (2015) concluded that an educational program about hemodialysis increased patients' level of adherence, knowledge, and quality of life. However, a systematic review showed that providing an educational component alone did not result in increased treatment adherence (Natashia & Irawati, 2016). It has been suggested that an educational component should be combined with other interventions to engage patients in promoting adherence (Natashia & Irawati, 2016; Kearney et al., 2014). In summary, even though, there is a need to provide education for patients with ESRD and about HD regimen, it is also recommended to consider multi-focus strategies to improve health outcomes.

Support from Family, Peer, and Significant Others

Studies have shown that social support is one of the factors that improve patients' adherence levels (Chironda & Bhengu, 2016; Griva et al., 2013; Jia et al., 2016). Jia et al. (2016) identified the importance of caregiver involvement in helping patients manage

fluid intake restriction. The caregivers expressed a willingness to accompany patients to HD and receive education from the nurses regarding the treatment regimens. The findings of the study concluded that the HD patients with supportive others accompanying them to their HD treatments were adherent to the fluid-intake restrictions.

Similarly, Alexopoulou et al. (2016) and Theodoritsi et al. (2016) identified that patients who had good support systems, especially from family and significant others, were more likely to adhere to their treatment regimens. Alexopoulou et al. (2016) found that the higher the support from significant others and family, the higher the patient's quality of life based on a measurement tool – Missoula-VITAS Quality of Life Index (MVQOLI-15). Similar results were found in previous studies which showed that HD patients who perceived social support systems as positive were more likely to show an improved quality of life and adherence (Ahrari et al., 2014; Cicolini, Palma, Simonetta, and Nicola, 2012; Rambod & Rafii, 2010; Tel & Tel, 2011).

Research indicates that patients can also benefit from peer support by interacting and sharing their feelings (Chironda & Bhengu, 2016; Griva et al., 2013; Russell et al., 2017). Chironda and Bhengu (2016) reported that peer interaction increased patients' ability to self-manage the HD regimen. A pilot quality improvement project identified that help from their peers had a positive impact on HD patients' self-management behaviors (Russell et al., 2017). It is evident that the role of peer support has been a promising interventional approach to help patients to improve their quality of life and increase adherence to the treatment regimens.

Self-Management and Intention

Many studies have used the Theory of Planned Behavior as a theoretical model to improve treatment adherence among patients who are chronically ill. It has been effective in explaining a range of behaviors such as dietary adherence, exercise, medication compliance, fluid adherence, and health screening behaviors (Ferreira & Pereira, 2017; Kopelowicz et al., 2015; Rich et al., 2015; Wu, Lennie, Dunbar, Pressler, & Moser, 2017). Successful intention-change interventions have facilitated patients' self-management such as adherence to the diet, exercise, and medications (Deek et al., 2015; Howren et al., 2016; Wileman et al., 2016).

In summary, using a patient-centered approach that fosters collaboration, empowers the patient to be more involved in his care. Collaboration that involves the family or significant others could help the HD patients take responsibility for his choices. This, in turn, can lead to self-management of behavioral attitudes towards fluid intake restrictions.

METHODS

Design

This DNP project was designed to evaluate the effect of social support for ESRD patients on HD related to fluid restriction adherence. This QI project used a non-experimental pre-post measure design to collect data on patients' IDWG and the frequency and degree of non-adherence with fluids pre-and post- intervention.

Setting

The project was implemented in an outpatient HD facility in Southern California. Patients are scheduled for HD treatments three days a week, either Monday, Wednesday, and Friday or Tuesday, Thursday, and Saturday. The outpatient hemodialysis facility accommodates 22 patients in each of three daily shifts.

Usual In-center Dialysis Process

Patients at the HD facility have been diagnosed with ESRD and require dialysis treatment three times weekly for three to four hours each treatment. The facilities are open Monday through Saturday. Nephrologists and Nurse Practitioners (NPs) visit patients during their HD treatment session three to four times per month (approximately once a week). The role of nephrology NPs in the HD settings is to assess, evaluate, educate, and provide necessary changes in treatment for the patients. At each HD session, the patient's fluid compliance is monitored by their intradialytic weight gains (IDWG) before starting the treatment. The IDWG are defined as weight gain that occurs between dialysis days. The IDWG are measured using the facility's scale at each visit. Patients who routinely gain more than 3 kg between each HD sessions are labeled as "*non-adherent and high IDWG*" patients. According to the National Kidney

Foundation (What is Dry Weight, n.d.), HD patients are instructed to limit their IDWG to no more than one kilogram between each treatment. In the study setting, all patients receive education from nurses and health care providers on diet restrictions, fluid limitations, medication adherence, modality options such as home dialysis or nocturnal dialysis, as well as general information on other topics, such as social issues, each time they come to the facility. Currently, the educational sessions do not involve the presence of family members or significant others.

Participants

This QI project used purposive sampling to select participants based on the characteristics of the HD population. Inclusion in the study was limited to HD patients who were found to be non-compliant with fluid limitations and with an IDWG of more than 3 kg as indicated on the facility fluid management reports.

Inclusion Criteria

Inclusion criteria for this project included all eligible participants at the setting's HD center who were over 18 years of age, had an IDWG of more than 3 kg, and agreed to participate and had a support person who also agreed to participate in the project.

Exclusion Criteria

Exclusion criteria included patients who were non-English speaking, were without a support person or living alone, were on diuretics such as Lasix, had residual urine function, and had an IDWG less than 3 kg.

Ethical Considerations

Institutional Review Board (IRB) approval was obtained from California State University, Long Beach (See Appendix A) and a faculty support letter submitted

(Appendix B). A permission letter for conducting the project was acquired from the dialysis facility administrator as well as the Chief Executive Officer (CEO) of Nephrology Associates of Medical Group (NAMG), Riverside (See Appendix C). After IRB approval, the author approached eligible HD patients and talked to them directly about the study, their eligibility and whether they were willing to participate. Support persons and the patients who agreed to participate were asked to sign an informed consent (See Appendices D and E).

Consent was also obtained from the designated support person who agreed to participate in the project. A copy of the consent was given to the patient and the support person for their records. Both the HD patient and the support person were informed of the risks and benefits of participation, and that they could withdraw from the project at any time. All data obtained, including questionnaire and patient results, were scanned and stored on a password-protected laptop. The original documents were placed in a locked file cabinet to which only the project leader has access. The daily weights were obtained by the nurses at the facility from a password protected facility computer, which was accessed by the project leader for data collection purposes. The patients were given an ID number, and no identifiers were on any documents.

Measures

A self-administered questionnaire packet was given to the participants and contained a modified version of the Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ), which is a four-item questionnaire that captures the frequency and degree of non-adherence with diets and fluids (Vlaminck, Maes, Jacobs, Reyntjens,

& Evers, 2001). For this project, this instrument was modified to two -items related to adherence with seven-day fluid restrictions (See Appendix F).

The survey questionnaire had two-items that were queried: 1) the frequency of non-adherence measured by the number of days of non-adherence reported in patient's report of fluid intake for the last seven days, and 2) the degree of non-adherence scored on a five-point Likert scale (0-4). The higher the score for the frequency of adherence, the higher the patient's adherence to fluid limitations. Conversely, the higher the score for the degree of non-adherence, the farther the patient deviated from the fluid guidelines. A demographic questionnaire was used to collect information related to patient name, gender, age, time on HD in months, support person's demographics such as relationship to the patient, gender, and age (See Appendix G)

Procedures

The project steps are described below:

- 1) The patient and the support person were asked to sign consents (See Appendices D and E).

The standardized consent for the patient consisted of the following behavioral recommendations:

- a) Complete a brief questionnaire;
- b) Maintenance of a record of the patient's daily fluid intake logs;
- c) Agreement to follow the fluid adherence regimens for four weeks.

The standardized consent for the support person consisted of the following behavioral recommendations:

- a) Agreement to communicate with the project leader over the phone weekly for 10-15mins to clarify any concerns with the patient's treatment regimens;
 - b) Maintenance of a record of the patient's daily fluid intake logs;
 - c) Agreement to follow the fluid adherence regimens for four weeks.
- 2) Demographic questionnaires and the DDFQ questionnaire were collected from the patients and the designated support person before beginning the educational intervention.
 - 3) Because the data (pre-post) on IDWG were already available at the facility, the data were accessed through a password -protected facility computer.
 - 4) An educational summary on fluid restrictions (See Appendix H) was provided to reinforce educational components already provided by the facility. The reinforcement included the following: fluid limitations; how to monitor and keep a log of daily fluid intake; and fluid-related dietary information (See Appendix I).
 - 5) The support person received the same educational component which was presented along with the patient at the start date of the project.
 - 6) During the educational session, the patient was given measuring cups to aid the individual in monitoring fluid intake.
 - 7) If more than one support person was present during the educational session, the patient was asked whom he/she preferred to be the primary support person for the project.

Data Collection and Management

Data collection and management involved the following steps:

- The patients were instructed to turn in their daily fluid intake logs each time they return for their treatment sessions or at the end of every third HD treatment.
- The dieticians or nurses collected the records and kept them in a locked file cabinet.
- The patients were seen weekly by the NP at the facility to gather information regarding problems they might have in following their treatment instructions and to reinforce the behavioral adherence.
- The support person was called by phone weekly to clarify any concerns with the patient's treatment regimens. Each call lasted for 10-15 minutes using a script in order to standardize the conversation and ensure that the project purpose is addressed (see Appendix J).
- The patient's weight was monitored and evaluated before and after each dialysis session. The data were entered into the password protected facility computer by the nurses at the facility, which was accessible for the project leader.

Plans for Data Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) 23 for Windows (SPSS Inc, Chicago, Illinois). The initial demographic questionnaire captured the demographic data, and the descriptive statistics were used to summarize the characteristics of participants. Descriptive statistics were used along with results from the DDFQ. The patient's pre-weight for HD sessions determined how much weight gain (IDWG) was noted between HD treatments and to note if the patient had an IDWG of

more than 3 kg. Interval data measuring the differences in the weight gains during HD treatments were summarized using t-tests and displayed using histograms.

Evaluation

By the end of four weeks, as stated in the consent, the patient's mean weight gain between treatments was used as a measure of fluid compliance. This determined if the patient was successful in maintaining IDWG less than 3 kg between HD sessions.

RESULTS

Pre- and post- intervention data were compared in order to explore the effect of social support on ESRD patients on HD fluid restriction adherence. Paired samples t-tests were conducted for the IDWG to determine whether the difference between the mean IDWG values based on pre-intervention measures (without social support) and post-intervention measures (with social support) were significantly different. The two DDFQ questions were measured using paired samples t-tests for the mean scores of the five-point Likert scale which was used to self-assess the deviation from fluid restrictions (0 – no deviation to 4 – severe deviation) and the mean number of days when fluid restrictions were not followed. Taking into account that the paired samples t-tests are robust to normality violations (the data are normally distributed) and used for small sample sizes (Kang & Haring & Li, 2015), this was the most appropriate test for this project's small sample size. The corresponding p-values of the test statistics were compared to conventional significance level ($\alpha = .05$).

Data Analysis

Descriptive statistics

There were ten patients who qualified for this QI project who were found to be non-compliant with fluid limitations and who had an IDWG of more than 3 kg as indicated in their facility fluid management records. Table 1 summarizes the socio-demographics findings of the participants.

Table 1

Demographic Characteristics of the Participants and their Support Person

Categorical variables		Count	Percent
Sex	Male	7	70.0%
	Female	3	30.0%
Age	35-44 years old	1	10.0%
	45-54 years old	3	30.0%
	55-64 years old	2	20.0%
	65-74 years old	2	20.0%
	75 years or older	2	20.0%
Time on HD	1-3 years	2	20.0%
	3-5 years	5	50.0%
	5-10 years	3	30.0%
Relationship to support person	Spouse	5	50.0%
	Friend	1	10.0%
	Family member (daughter/son/grandchildren)	4	40.0%
Sex of Support person	Male	2	20.0%
	Female	8	80.0%
Age of Support person	35-44 years old	4	40.0%
	45-54 years old	3	30.0%
	55-64 years old	1	10.0%
	65-74 years old	2	20.0%

The project sample consisted of 7 males (70%) and 3 females (30%) with an age range of 35 to 75 years or older. The distribution of the age groups was as followed: one participant in the 35-44 year old group, two in each of the following age group, 55-64, 65-74 and 75+; and three participants in the 45-54 year old age group. Half of the patients

(n = 5, 50%) had 3 to 5 years of HD, followed by three patients with 5-10 years of HD and 2 with 1-3 years of HD.

The person most identified as a support person was a family member: for half of the participants the support person was a spouse (n = 5, 50%) and four participants identified a family member (daughter, son, grandchildren) (40%) as their support person. Only one of the participants had identified a friend as their support person.

The majority of support persons were female (n = 8, 80%) with only two (20%) males. The majority of the support persons were spouses or children of the patients, with the support person being younger than the patient every time. There were 40% (n = 4) of support persons between the age of 35 and 44, three (30%) were in the 45-54 age group, one support person was 55-64 years old and another two (20%) belonged to the 65-74 age group.

Pre- and Post-Intervention Comparison

The effect of social support was tested by comparing the following variables:

- Mean IDWG of HD treatments, pre and post intervention to measure the effect on fluid adherence regimens for four weeks;
- Mean number of days the participants did not follow fluid adherence regimens;
- Mean scores obtained on a five-point Likert scale (0-4) in the DDFQ.

A mean value was obtained from the IDWG for the HD treatments in four weeks. It should be noted that the actual number of valid IDWG values differed between patients and ranged from a minimum of 13 to a maximum of 16 measures (HD treatments) at the pre-phase and from 12 to 16 (HD treatments) at the post-phase. Some patients required

extra treatments in a month due to fluid overload, therefore the data points (IDWG values) are varied in different participants. Table 2 presents the results of these measures for the pre and post intervention.

Table 2

Mean pre- and Post-intervention IDWGs and DDFQ Results

	Pre-intervention		Post-intervention		t-test	p-value
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Mean IDWG	2.71	0.93	2.89	1.45	-.642	.537
Maximum IDWG	5.58	1.94	4.78	1.71	2.230	.053 [†]
Days not following fluid guidelines	3.20	1.23	1.60	1.71	2.667	.026*
Degree of deviation (0-4 Likert scale)	2.00	0.67	1.30	0.82	3.280	.010*

Note: * marks a significant difference at 95% confidence interval, [†] marks a significant difference at 90% confidence interval.

Intradialytic Weight Gains (IDWG) Results

The mean IDWG of the post-intervention was 0.18 kg higher than the value of the pre-intervention phase. However, this difference was not statistically significant ($t(9) = -.642, p = .537$), meaning that there was no significant change in participants' IDWG after the intervention. The distribution of the means of the IDWG at before and after the intervention is shown in Figure 2. It shows that the presence of a support person resulted in lower values of mean IDWG for most of the participants. However, some outliers showed high IDWG. Thus, the post-intervention phase resulted in the overall mean value being higher than pre-intervention.

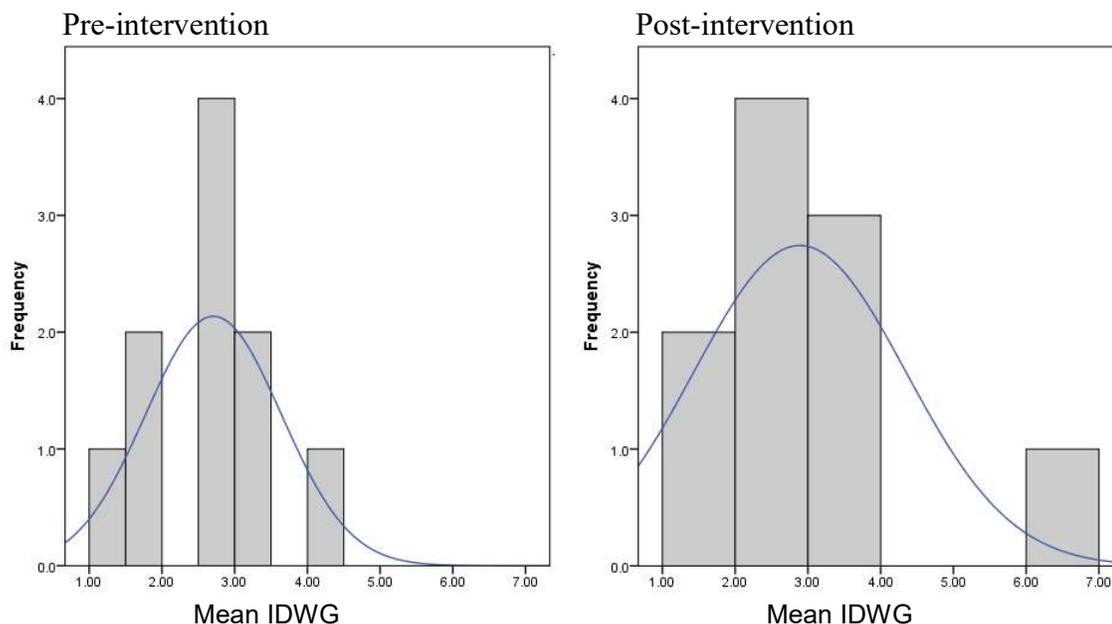


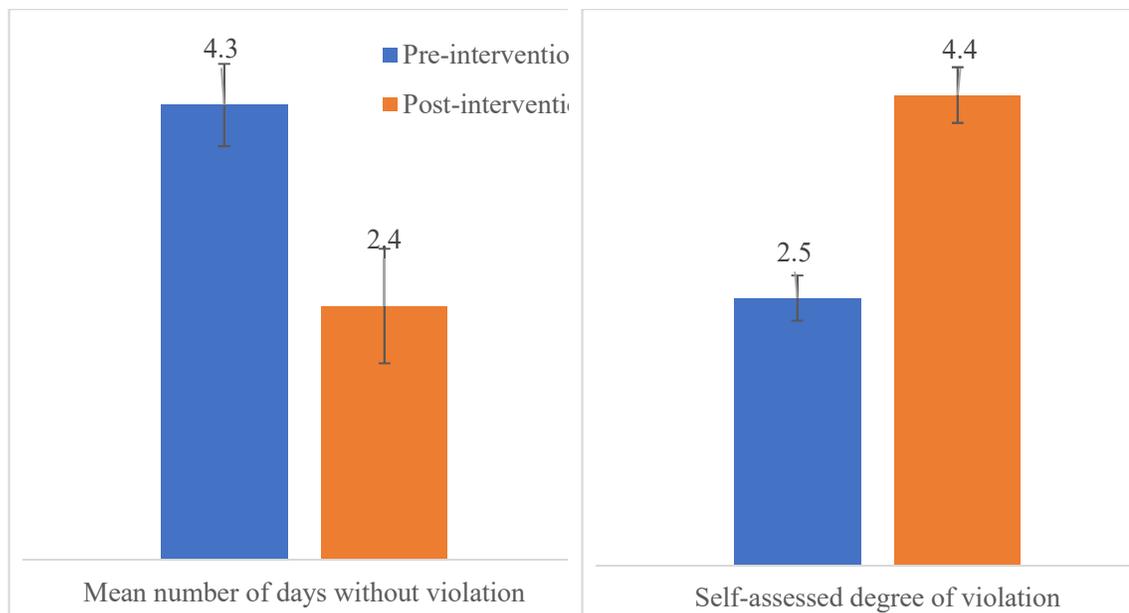
Figure 2. Mean IDWG pre- and post-intervention histogram

To further explore the IDWG change, the maximum IDWG values were also compared before and after the intervention. These results showed a decrease in the maximum IDWG from 5.58 (SD = 1.94) to 4.78 (SD = 1.71), but this was also not statistically significant ($t(9) = 2.230, p = .053$). The results showed that after having a support person help follow the instructions of the fluid diet, two of the ten participants did not show any IDWG greater than 3 kg, while the remaining participants had at least one incident of more than 3 kg gain at the post-intervention stage.

Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ) Results

The self-assessed DDFQ questions (Figure 3) regarding adherence to fluid regimens showed a statistically significant ($t(9) = 2.667, p = .026$) change in the mean number of days when the patient did not follow the fluid guidelines: from 3.2 (SD = 1.2) to 1.6 (SD = 1.7). Similarly, self-assessment of the deviation based on the five-point

Likert scale showed a reductions from 2.0 (SD = 0.67) to 1.3 (SD = 0.82), which was also statistically significant ($t(9) = 3.280, p = .010$).



*Whiskers show SE for each mean value

Figure 3. Mean DDFQ values: number of days without violation and self-assessed degree of violation by stage (pre-, post-intervention)

Summary

The results of the pre- and post-intervention comparisons showed that having a support person to help follow the dialysis fluid regimen leads to a lower mean number of days when the patient violates the regimen and the smaller degree of their violation, based on self-assessment. However, this improvement did not lead to a statistically significant change in mean IDWG.

DISCUSSION

The purpose of this QI project was to implement and evaluate how social support affects fluid restriction adherence for ESRD patients on HD. The project findings did not support previous research, which showed that having a support person helps to improve fluid-restriction adherence and lower the mean IDWG. However, the sample size was small (N=10) and there were outliers who were likely to have screwed the results. The DDFQ scores were significant with regard to the frequency and degree of non-adherence with fluid restriction post-intervention when compared to pre-intervention. The IDWG scores did not decrease during HD treatments. The outcome of this QI project may suggest that there was a limited effect on HD patients' fluid adherence after having a support person.

In this QI project, IDWG was measured to assess compliance with fluid restrictions. A weight gain of more than 3 kg was used as evidence for non-compliance based on the patient's base (target) weight. The HD patient identified a support person who helped them to comply with their fluid intake. In this project, all designated support persons expressed interest in helping the HD patients to manage fluid regimens by measuring their fluid intake and participating in weekly telephone calls with the project leader. The literature has identified the importance of having a caregiver or a support person involved in the care of the HD patient in their fluid and diet management (Chironda & Bhengu, 2016; Griva et al., 2013; Jia et al., 2016). In this study, all patients participated along with their designated support person to achieve behavioral compliance in maintaining weekly fluid logs. Other studies have identified the support person's positive impact on patient's self-management behaviors (Russell et al., 2017). In this

project, even though the presence of a support person reflected positive results in decreasing IDWG among some participants, the overall results were not statistically significant.

The research by Howren et al. (2016) showed non-significant results with various behavioral intervention approaches such as self-monitoring skills and setting patient goals, making it hard to conclude if specific behavioral interventions are more effective than others. The findings of this QI project showed that although having a support person lead to positive outcomes, follow up is needed to determine if the outcomes are temporary or last for an extended period of time. Other studies (Griva et al., 2018; Howren et al., 2016; Wileman et al., 2016) have found that patient's adherence to diet and fluid restrictions are unsustainable; therefore, it may be inconclusive to measure the influence of a support person over a short period of time.

There were outliers in the IDWG levels among HD patients in this project, which may have contributed to the non-significant results. These outliers had higher IDWG levels during the post-intervention phase. Their IDWG could have been affected by the disruption of the patient's normal body functioning such as increased thirst or a desire not to comply with the fluid limitations (Bossola et al., 2018). In this project, some patients had more than the regular 12 HD treatments in a month, which means that they needed additional HD treatments during that month because they had fluid overload.

The results of the DDFQ questionnaire showed that HD patients were adherent on more days and followed the fluid intake regimen which was measured by the Likert scale during the post intervention phase. Some patients reported higher adherence to fluid guidelines after the implementation of a social support person when compared to the pre-

intervention phase period of the project. Some patients reported that they had fewer days of non-adherence to fluid guidelines in each week for the four weeks after the intervention when compared to the pre-intervention period. The findings reflect that the patients were better able to follow their fluid intake regimens. Studies have showed that there were significant correlations between DDFQ that captures the subjective perception of patients' non-adherence and IDWG levels, an objective marker for fluid adherence (Ahrari et al., 2014; Khalil & Darawad, 2013). However, in the QI project, this finding did not demonstrate improvement in the IDWG levels.

Strategies of behavioral interventions based on the TBP framework were implemented in this QI project such as involving a social support person, brief educational interventions, and constant reinforcements. The TBP was a valuable framework that allowed the project author to describe the influence of a designated support person for patients in this project. When the patients have a designated support person to help with their adherence to fluid intake regimens, it is reasoned that the patients will have more success in adherence. The patients were able to show interest in self-managing their fluid limitations with the help of a support person and participated in maintaining weekly fluid logs. Similar interventions using support persons were described in previous studies, supported by the TPB framework have been successful (Ferreira & Pereira, 2017; Kopelowicz et al., 2015; Rich et al., 2015; Wu et al., 2017).

Limitations

A limitation of this QI project is the small sample size. Because of the small sample size, generalization of the findings is limited, and an outlier effect was also noted. The project was conducted during the holiday season, which could have resulted in

variability in patient's IDWG levels. This variability in IDWG levels could be the result of holiday celebrations, which typically involve drinking beverages and eating holiday foods, much of which is not included in a HD diet and fluid regimens. The intervention was carried out for only four weeks. Significant outcomes might have resulted if the project had been sustained for an extended period.

Implications for Practice

The project showed that monthly discussions with the HD patient and support person about the patient's self-reported fluid gains during the prior month may have a positive benefit in lowering IDWG levels. This type of discussion may help patients understand how their behaviors affect their health. The findings of this QI project suggested that an emphasis be placed on conducting a weekly follow-up with patients about their IDWG levels that also involves all healthcare providers along with the support person. Possible solutions to nonadherence should be addressed during these follow-up sessions. These interventions include early intervention when high fluid gains are found through daily monitoring, education, and reinforcement, which will help to lower IDWG levels. Adherence is an ongoing behavioral process that requires monitoring of IDWG levels and the patient's fluid intake. The findings showed that the use of a support person provided an alternative to help the patients control their adherence to related regimens. However, other multi-focus strategies such as educational approaches, behavioral management approaches, coaching techniques could also benefit along with the use of support person. More intervention studies can be conducted to improve the clinical outcome of compliance related behaviors.

CONCLUSION

In conclusion, the results of this project showed that there was a limited effect on the HD patients to manage fluid adherence by having a social support person. Though the involvement of a support person has been introduced in the literature as a successful intervention to manage fluid adherence for HD patients, efforts should be made to provide more effective supports and continuous reinforcements. The non-significant relationship between the objective measurement (IDWG levels) and self-reported subjective measurement (DDFQ) provides an assumption that the patients were not adherent to the fluid regimens, even with the help of a support person. There is always the possibility that a type one error occurred.

Future research efforts should be directed at investigating the effect of early involvement of a social support person to help the patient monitor his/her fluid management when HD treatment is first initiated. In this project adherence levels varied from individual to individual. Therefore, interventions tailored to the needs of individual HD patients might improve adherence to HD prescribed regimens, such as fluid, diet, medications, and dialysis. Using tailored individualized interventions may bring a positive outcome clinically, emotionally and physically. Lastly, prompt intervention when IDWG and DDFQ findings first point to nonadherence in fluid management is needed to establish a quick response plan. Determining criteria that mark an individual at risk for nonadherence is an important area of study.

REFERENCES

- Ahrari, S., Moshki, M., & Bahrami, M. (2014). The relationship between social support and adherence of dietary and fluid restrictions among hemodialysis patients in Iran. *Journal of Caring Sciences*, 3(1), 11-19. doi:10.5681/jcs.2014.002
- Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. In J. Kuhl, & J. Beckmann, *Action-Control: From Cognition to Behavior* (pp. 11-39). New York: Springer-Verlag
- Ajzen, I. (1991). The theory of planned behavior: Organization behavior and human decision process. *50*, 179-211. Retrieved from <http://people.umass.edu/ajzen/tpb.background.html>
- Alexopoulou, M., Giannakopoulou, N., Komna, E., Alikari, V., Toulia, G., & Polikandrioti, M. (2016). The effect of perceived social support on hemodialysis patients' quality of life. *Journal of the Academy of Medical Sciences*, 28(5), 338-342. doi: 10.5455/msm.2016.28.338-342
- Alikari, V., Matziou, V., Tsironi, M., Theofilou, P., & Zyga, S. (2015). The effect of nursing counseling on improving knowledge, adherence to treatment and quality of life of patients undergoing hemodialysis. *International Journal Of Caring Sciences*, 8(2), 514-518.
- Antlanger, M., Hecking, M., Haidinger, M., Werzowa, J., Kovarik, J. J., Paul, G., . . . Säemann, M. D. (2013). Fluid overload in hemodialysis patients: A cross-sectional study to determine its association with cardiac biomarkers and nutritional status. *BioMed Central Nephrology*, 14(266). doi:10.1186/1471-2369-14-266

- Assimon, M. M., Nguyen, T., Katsanos, S. L., Brunelli, S. M., & Flythe, J. E. (2016). Identification of volume overload hospitalizations among hemodialysis patients using administrative claims: A validation study. *BioMed Central Nephrology*, *17*, 173. doi: 10.1186/s12882-016-0384-6
- Bossola, M., Pepe, G., & Vulpio, C. (2018). The frustrating attempt to limit the interdialytic weight gain in patients on chronic hemodialysis: New insights into an old problem. *Journal of Renal Nutrition*, *28*(5), 293-301. doi:10.1053/j.jrn.2018.01.015
- Brunelli, S. M., Gray, K. S., & Cohen, D. E. (2016, November). In-Center hemodialysis absenteeism: Prevalence and association with outcomes. Minneapolis, MN: Poster session presented at the Dialysis Clinical Research.
- Chan, Y. M., Zalilah, M. S., & Hii, S. Z. (2012). Determinants of compliance behaviors among patients undergoing hemodialysis in Malaysia. *PLoS ONE* *7*(8). doi: 10.1371/journal.pone.0041362
- Chironda, G., & Bhengu, B. (2016). Contributing factors to non-adherence among chronic kidney disease (CKD) patients: A systematic review of literature. *Medical and Clinical Reviews*, *2*, 229. doi:10.21767/2471-299X.1000038
- Cicolini, G., Palma, E., Simonetta, C., & Nicola, M. D. (2012). Influence of family carers on haemodialyzed patients' adherence to dietary and fluid restrictions: An observational study. *Journal of Advanced Nursing*, *68*(11), 2410-2417. doi:10.1111/j.1365-2648.2011.05935.x

- Crown, S., Vogel, J. A., & Hurlock-Chorostecki, C. (2017). Enhancing self-care management of interdialytic fluid weight gain in patients on hemodialysis: A pilot study using motivational interviewing. *Nephrology Nursing Journal*, *44*(1), 49-55. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/29237109>
- Davita Inc. (2017). Retrieved from <https://www.davita.com/>
- Deek, H. D., Noureddine, S., Newton, P. J., Inglis, S. C., MacDonald, P. S., & Davidson, P. M. (2015). A family-focused intervention for heart failure self-care: Conceptual underpinnings of a culturally appropriate intervention. *Journal of Advanced Nursing*, *72*(2). doi:10.1111/jan.12768
- Estridge, K. M., Morris, D. L., Kolcaba, K., & Winkelman, C. (2018). Comfort and fluid retention in adult patients receiving hemodialysis. *Nephrology Nursing Journal*, *45*(1), 25-33.
- Ferreira, G., & Pereira, M. (2017). Physical activity: The importance of the extended theory of planned behavior, in type 2 diabetes patients. *Journal of Health Psychology*, *22*(10), 1312-1321. doi:10.1177/1359105315626787
- Fishbein, M., & Ajzen, I. (2010). Predicting and changing behavior: The reasoned action approach. New York: Psychology Press.
- Griva, K., Nandakumar, M., Ng, J. H., Lam, K. F., McBain, H., & Newman, S. P. (2018). Hemodialysis self-management intervention randomized trial (HED-SMART): A practical low-intensity intervention to improve adherence and clinical markers in patients receiving hemodialysis. *American Journal of Kidney Diseases*, *71*(3), 371-361. doi:10. 1053/j.ajkd.2017.09.014

- Griva, K., Ng, H., Loei, J., Mooppil, N., McBain, H., & Newman, S. (2013). Managing treatment for end-stage renal disease – A qualitative study exploring cultural perspectives on facilitators and barriers to treatment adherence. *Psychology & Health*, (28), 13-29. doi:10.1080/08870446.2012.703670
- Hettema, J., & Hendricks, P. (2010). Motivational interviewing for smoking cessation: A meta-analytic review. *Journal of Clinical Psychology*, 78(6), 868-884. doi:10.1037/a0021498
- Hong, L., Yuce, E., & Chen, H.C. (2017). Dietary and fluid restriction perceptions of patients undergoing haemodialysis: An exploratory study. *Journal of Clinical Nursing*, 26(21-22), 3664-3676. doi:10.1111/jocn.13739
- Howren, M. B., Kellerman, Q. D., Hillis, S. L., Cvengros, J., Lawton, W., & Christensen, A. J. (2016). Effect of a behavioral self-regulation intervention on patient adherence to fluid-Intake restrictions in hemodialysis: A randomized controlled trial. *Annals of Behavioral Medicine*, 50(2), 167-176. doi:10.1007/s12160-015-9741-0
- Hugtenburg, J. G., Timmers, L., Elders, P. J., Vervloet, M., & Dijk, L. v. (2013). Definitions, variants, and causes of nonadherence with medication: A challenge for tailored interventions. *Patient Preference And Adherence*, 7, 675-682. doi:10.2147/PPA.S29549
- Jeong, S. Y., & Kim., K. M. (2016). Influencing factors on hand hygiene behavior of nursing students based on theory of planned behavior: A descriptive survey study. *Nursing Education Today*, 36, 159-164. doi:10.1016/j.nedt.2015.09.014.

- Jia, S., Huang, B., Chu, Y., Lu, Y., & McArthur, A. (2016). Management of non-adherence to fluid intake restrictions in hemodialysis patients in a tertiary hospital: A best practice implementation project. *JBI Database System Reviews and Implementation Reports*, *14*(8), 309-322. doi:10.11124/JBISRIR-2016-003046.
- Karamanidou, C., Weinman, J., & Horne, R. (2014). A qualitative study of treatment burden among hemodialysis recipients. *Journal of Health Psychology*, *19*(4), 556-569. doi:10.1177/1359105313475898
- Kang, Y., Harring, J. R., Li, M. (2015). Reexamining the impact of nonnormality in two-group comparison procedures. *Journal of Experimental Education*, *83*(2), 147-174. doi: 10.1080/00220973.2013.876605
- Kearney, O., Lenderyou, R., Pascoe, S., Wade, B., Collinson, A., & Sadler, H. (2014). A clinical audit and service evaluation exploring fluid management and factors associated with non-adherence in hemodialysis patients. *European Journal of Nutrition and Food Safety*, *4*(3), 287-289. Retrieved from http://www.journalrepository.org/media/journals/EJNFS_30/2014/Feb/Kearney432013EJNFS8307.pdf
- Khalil, A. A., & Darawad, M. W. (2013). Objectively measured and self-reported nonadherence among Jordanian patients receiving hemodialysis. *Hemodialysis International*, *18*(1), 95-103. doi:10.1111/hdi.12093

- Kopelowicz, A., Zarate, R., Wallace, C., Liberman, R., Lopez, S., Mintz, J., & Nezu, Arthur M. (2015). Using the theory of planned behavior to improve treatment adherence in Mexican Americans with schizophrenia. *Journal of Consulting and Clinical Psychology, 83*(5), 985-993. doi: 10.1037/a0039346
- LaMorte, W. (2018). Behavior change models. Retrieved from <http://sphweb.bumc.bu.edu/otlt/MPH-modules/SB/BehavioralChangeTheories/BehavioralChangeTheories3.html>
- Lederman, N. G., & Lederman, J. S. (2015). What is a theoretical framework? A practical answer. *Journal of Science Teacher Education, 26*(7), 593-597. doi:10.1007/s10972-015-9443-2
- McMaster, F., & Resnicow, K. (2015). Validation of the one pass measure for motivational interviewing competence. *Patient Education and Counseling, 98*, 499-505. doi:10.1016/j.pec.2014.12. 014
- Meuleman, Y., Hoekstra, T., Dekker, F. W., Boog, P. J., & Dijk, S. V. (2018). Perceived sodium reduction barriers among patients with chronic kidney disease: Which barriers are important and which patients experience barriers? *Internal Journal of Behavioral Medicine, 25*, 93-102. doi:10.1007/s12529-017-9668-x
- Natan, B., Sharon, I., Mahajna, M., & Mahajna, S. (2017). Factors affecting nursing students' intention to report medication errors: An application of the theory of planned behavior. *Nursing Education Today, 58*, 38-42. doi:10.1016/j.nedt.2017.07.017

- Natashia, D., & Irawati, D. (2016). Interventions to improve fluid adherence among patients undergoing hemodialysis: A systematic review. *Proceedings: The 2nd International Multidisciplinary Conference*, 555-559.
- Nielsen, T. M., Juhl, M. F., Feldt-Rasmussen, B., & Thomsen, T. (2017). Adherence to medication in patients with chronic kidney disease: A systematic review of qualitative research. *Clinical Kidney Journal*, 1-15. doi:10.1093/ckj/sfx140
- Nissenson, A. R. (2014). Improving outcomes for ESRD patients: Shifting the quality paradigm. *Clinical Journal of the American Society of Nephrology*, 9(2), 430-434. doi:10.2215/CJN.05980613
- Palmer, S. C., Hanson, C. S., Craig, J. C., Strippoli, G., Rusopo, M., Campbell, K., . . . Tong, A. (2015). Dietary and fluid restrictions in CKD: A thematic synthesis of patient views from qualitative studies. *American Journal of Kidney Diseases*, 65(4), 559-573. doi:10.1053/j.ajkd.2014.09.012
- Panesar, K. (2012). Patient compliance and health behavior models. *Medication management*, 37(4), 12-14. Retrieved from <https://www.uspharmacist.com/article/patient-compliance-and-health-behavior-models>
- Parvan, K., Hasankhani, H., Seyyedrasooli, A., Riahi, S. M., & Ghorbani, M. (2015). The effect of two educational methods on knowledge and adherence to treatment in hemodialysis patients: Clinical trial. *Journal of Caring Sciences*, 4(1), 83-93. doi:10.5681/jcs.2015.009

- Pasyar, N., Rambod, M., Sharif, F., Rafii, F., & Pourali-Mohammadi, N. (2015). Improving adherence and biomedical markers in hemodialysis patients: The effects of relaxation therapy. *Complementary Therapies in Medicine, 23*(1), 38-45. doi:10.1016/j.ctim.2014.10.011
- Phillips, R. L. (2013). Nonadherence in individuals on hemodialysis: A discussion of three theories to improve adherence. *National Kidney Foundation Journal of Nephrology Social Work, 38*(1), 26-30. Retrieved from https://www.kidney.org/sites/default/files/v38a_a3.pdf
- Rambod, M., & Rafii, F. (2010). Perceived social support and quality of life in Iranian hemodialysis patients. *Journal of Nursing Scholarship, 42*(3), 242-9. doi:10.1111/j.1547-5069.2010.01353.x.
- Reid, C., Seymour, J., & Jones, C. (2016). A thematic synthesis of the experiences of adults living with hemodialysis. *Clinical Journal of American Society of Nephrology, 11*, 1206-1218. doi:10.2215/CJN.10561015
- Rich, A., Brandes, K., Mullan, B., & Hagger, M. S. (2015). Theory of planned behavior and adherence in chronic illness: a meta-analysis. *Journals of Behavioral Medicine, 38*(4), 673-688. doi:10.1007/s10865-015-9644-3
- Russell, J. S., Southerland, S., Huff, E. D., Thomson, M., Meyer, K. B., & Lynch, J. R. (2017). A peer-to-peer monitoring program for In-Center hemodialysis: A patient-centered quality improvement program. *Nephrology Nursing Journal, 44*(6), 481-489, 496.

- Smith, K., Coston, M., Glock, K., Elasy, T. A., Wallston, K. A., Ikizler, T. A., & Cavanaugh, K. L. (2010). Patient perspectives on fluid management in chronic hemodialysis. *Journal of Renal Nutrition, 20*(5), 334-341. doi: 10.1053/j.jrn.2009.09.001
- Sontakke, S., Budania, R., Bajait, C., Jaiswal, K., & Pimpalkhute, S. (2015). Evaluation of adherence to therapy in patients of chronic kidney disease. *Indian Journal of Pharmacology, 47*(6), 668-671. doi: 10.4103/0253-7613.169597
- Tel, H. & Tel, H. (2011). Quality of life and social support in hemodialysis patients. *Pakistan Journal of Medical Sciences. 27*(1), 64-7. Retrieved from <http://pjms.com.pk/index.php/pjms/article/view/815/23>
- Theodoritsi, A., Aravantinou, M.-E., Gravani, V., Bourtsi, E., Vasilopoulou, C., Theofilou, P., & Polikandrioti, M. (2016). Factors associated with the social support of hemodialysis patients. *Iranian Journal of Public Health, 45*(10), 1261-1269. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5149489/>
- Tovazzi, M. E., & Mazzoni, V. (2012). Personal paths of fluid restriction in patients on hemodialysis. *Nephrology Nursing Journal, 39*(3), 207-215. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/22866360>
- United States Securities and Exchange Commission. (2002). *Annual report pursuant to section 13 or 15(d) of the securities exchange act of 1934*. Washington, D.C.: Davita INC.

- Vlaminck, H., Maes, B., Jacobs, A., Reyntjens, S., & Evers, G. (2001). The dialysis diet and fluid non-adherence questionnaire: Validity testing of a self-report instrument for clinical practice. *Journal of Clinical Nursing, 10*(5). doi:10.1046/j.1365-2702.2001.00537.x
- Weinhandl, E., & Collins, A. (2018, January 8). Troubling health trends in the new USRDS annual data report. *Nephrology News & Issues*. Retrieved from: <https://www.nephrologynews.com/troubling-health-trends-new-usrds-annual-data-report/>
- What is Dry Weight. (n.d.). Retrieved from <https://www.kidney.org/atoz/content/dry-weight>
- Wileman, V., Chilcot, J., Armitage, C. J., Farrington, K., Wellsted, D. M., Norton, S., . . . Almond, M. (2016). Evidence of improved fluid management in patients receiving hemodialysis following a self-affirmation theory-based intervention: A randomised-controlled trial. *Psychology and Health, 31*(1), 100-114. doi:10.1080/08870446.2015.1073729
- Wong, M. M., Craig, J. C., Levin, A., & Strippoli, G. F. (2014). Interventions for promoting adherence to fluid intake and dietary salt restriction in people with end-stage kidney disease. *Cochrane Database of Systematic Reviews*(11). doi:10.1002/14651858.CD011410.
- Wu, D., Lennie, J., Dunbar, T., Pressler, S., & Moser, S. (2017). Does the theory of planned behavior predict dietary sodium intake in patients with heart failure? *Western Journal of Nursing Research, 39*(4), 568-581. doi: 10.1177/0193945916672661

Zoccali, C., Moissl, U., Chazot, C., Mallamaci, F., Tripep, G., Arkossy, O., . . . Stuard, S.
(2017, May 5). Chronic fluid overload raises mortality risk in dialysis patients.
Nephrology News & Issues, 28(8), 2491-2497. doi: 10.1681/ASN.2016121341

APPENDIX A

IRB APPROVAL LETTER



CALIFORNIA STATE UNIVERSITY, LONG BEACH
OFFICE OF RESEARCH & SPONSORED PROGRAMS

DATE: October 30, 2018
 TO: ANN SHERLY VARGHESE, MSN
 FROM: CSULB IRB
 PROJECT TITLE: [1315803-3] A Quality Improvement Project: Implementing a Support Person as an Intervention for Hemodialysis patients to Improve the Fluid Regimen Adherence
 REFERENCE #: 19-077
 SUBMISSION TYPE: New Project
 REVIEW TYPE: Administrative Review
 ACTION: APPROVED
 APPROVAL DATE: October 30, 2018

This is to advise you that the Institutional Review Board for the Protection of Human Subjects (IRB) of California State University, Long Beach, has reviewed your protocol application.

Your application is approved by Administrative Review according to the U.S. Department of Health & Human Services regulation at 45 CFR 46.101 (b)(1)(2).

Approval is effective beginning October 30, 2018 and conditional upon your willingness to carry out your continuing responsibilities under University policy.

1. You must clearly indicate in the header or footer of each page of your approved Informed Consent Form and recruitment material as follows: **"Approved October 30, 2018 by the CSULB IRB"**
2. If you need to make changes/revisions to this approved project, you must submit a Request for Amendment to an Approved Protocol form in addition to any documents affected by the requested change. Submit these documents as a subsequent package to your approved project in IRBNet. You are not allowed to implement any changes to your research activities prior to obtaining final approval of your Amendment from the CSULB IRB.
3. You are required to inform the Director of Research Integrity and Compliance, Office of Research & Sponsored Programs, via email at ORSPCompliance within twenty-four hours of any adverse event in the conduct of research involving human subjects. The report shall include the nature of the adverse event, the names of the persons affected, the extent of the injury or breach of confidentiality or data security, if any, and any other information material to the situation.
4. Maintain your research records as detailed in the protocol.
5. Respond to the Annual Check-in notice via IRBNet if you intend to continue the project after October 29, 2019.

Should you have any questions about the conduct of your research under this protocol, particularly about providing informed consent and unexpected contingencies, please do not hesitate to call the Office of Research & Sponsored Programs at (562) 985-8147. We wish you the best of success in your research.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within California State University, Long Beach Institutional Review Board's records.

1250 Bellflower Blvd., Long Beach, CA 90840
 Ph. (562) 985-8147 Fax. (562) 985-8665

APPENDIX B

FACULTY ADVISOR STATEMENT



CALIFORNIA STATE UNIVERSITY, LONG BEACH
SCHOOL OF NURSING

Faculty Advisor Statement

TO: CSULB Institutional Review Board

FROM: Beth Keely, Ph.D., R.N.

NAME OF STUDENT: Ann Sherry Varghese

TITLE OF PROJECT: A Quality Improvement Project: Implementing a Support Person as an Intervention for Hemodialysis patients to Improve the Fluid Regimen Adherence

STATEMENT OF THE ADVISOR:

I, Dr. Beth Keely, certify that I have reviewed and confirmed the following regarding the aforementioned project.

The student and I have discussed and reviewed the submission for appropriateness and completeness with regard to the collection and protection of subject data.

The research methodologies align with acceptable methodologies of this discipline.

The risk/benefit ratio is appropriate for the project activities.

The potential risks include: 1) Discomfort answering demographic questionnaires, 2) Discomfort in participating in the project for 4 weeks due to their limitations in fluid restrictions to one liter a day, the recommended intervention for hemodialysis patients.

The appropriate safeguards in place to minimize the risks include: 1) The patients will be given an ID number, and no identifiers will be on any documents 2) Both the patient and the support person will be informed of the risks and benefits of participation, and that they can withdraw from the project at any time.

I will continue supervision of this project and ensure the student remains compliant with CSULB research policies by meeting with the student on a regular basis and maintaining contact with the supervising physician as necessary.

1250 BELFLOWER BOULEVARD-MS 0301 · LONG BEACH, CALIFORNIA 90840-0301 · 562/985-4463 · FAX 562/985-2382

My signature below certifies that I as the Faculty Advisor of this research have read and approved the attached IRB Application.

X *Beth Keely*

Faculty Advisor/Thesis Chair

[Nursing Department]
[562-985-4478]
[beth.keely@csulb.edu]

APPENDIX C

LETTER OF SUPPORT



Minneapolis Office
825 South Eighth Street
Suite 300
Minneapolis, MN. 55404
(612) 852-7000 phone
(612) 852-3241 fax

California State University, Long Beach (CSULB)
Office of Research and Sponsored Programs
CSULB: 1250 Bellflower Blvd., Long Beach, CA-90840
ORSPCompliance@csulb.edu
(562) 985-6147

September 19, 2018

Re: Letter of Support – "A Quality Improvement project: Implementing a support person as an intervention for hemodialysis patients to improve the fluid regimen adherence"

Dear Members of the IRB Committee:

On behalf of DaVita Clinical Research (DCR) I am writing to formally indicate our awareness of the Quality Improvement (QI) Doctoral Project by Ann Sheryl Varghese, a doctoral student at California State University of Doctoral Cohort Program at Fullerton. We are aware that Ann Sheryl Varghese intends to conduct her QI project titled "A Quality Improvement project: Implementing a support person as an intervention for hemodialysis patients to improve the fluid regimen adherence" at our facility.

Ms. Sheryl (Principal Investigator) will be distributing a self-administered questionnaire packet to the eligible participants to assess the patient's perception of fluid adherence regimens. All data obtained, including the questionnaire, survey, logs from the patient and the family members will be placed in a locked file cabinet. The daily weights will be documented in a password protected facility computer by the nurses at the facility, which will be accessed by the principal investigator for data collection purposes. All eligible participants' information will be de-identified for the QI project.

The risk/benefit ratio is appropriate for the project activities:

The potential risks include 1) Discomfort answering demographic questionnaires, 2) Discomfort in participating in the project for four weeks due to their limitations in fluid restrictions to one liter a day, the recommended intervention for hemodialysis patients.

The appropriate safeguards in place to minimize the risks include: 1) The patients will be given an ID number, and no identifiers will be on any documents 2) Both the patient and the support person will be informed of the risks and benefits of participation, and that they can withdraw from the project at any time.

Please note this letter does not serve as official study approval from DaVita Clinical Research. Only at the time when you receive official study approval terms are you allowed to begin executing your proposed research project within the DaVita network.



I permit Ms. Sheryl to conduct her QI project at our facility. I support this effort and will provide any assistance necessary for the successful implementation of this study. If you have any questions, please do not hesitate to contact me.

Sincerely,

Amy Young

Vice President & General Manager
DaVita Clinical Research
825 S. 8th Street, Suite 300 | Minneapolis, MN 55404

Please note this letter does not serve as official study approval from DaVita Clinical Research. Only at the time when you receive official study approval terms are you allowed to begin executing your proposed research project within the DaVita network.

APPENDIX D**NOTICE OF INFORMED CONSENT FOR SUPPORTING PERSON**

Project Title: A Quality Improvement Project: Implementing a Support Person as Intervention for Hemodialysis Patients to Improve the Fluid Regimen Adherence

Investigator(s): Ann Sherly Varghese, Dr. Beth Keely, Dr. Anita Fitzgerald

Project Contact: asvarghese@csu.fullerton.edu, 909-215-0803

California State University, Long Beach (CSULB)

Office of Research and Sponsored Programs, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840

You are being asked to participate in a quality improvement study.

The purpose of this study is to implement and evaluate the effect of social support for End Stage Renal Disease (ESRD) patients on hemodialysis (HD) to improve fluid restriction adherence in a local dialysis center in Southern California. If you decide to participate you will be asked to: a) Maintain a record of the patient's daily fluid intake logs; b) agree to communicate with the PI over the phone weekly for 10-15 mins to clarify any concerns with the patient's treatment regimens; and c) Agree to follow the fluid adherence regimens which will be identified during the initial project visit which is scheduled for approximately for 20-30 minutes.

The total time of your participation required to maintain the patient's daily log is expected to last for four weeks.

The risks to participating in this study include 1) Discomfort answering demographic questionnaires; 2) discomfort and unavailability for phone conversations weekly; and 3) discomfort in participating in the project for 4 weeks due to the limitations in fluid restrictions to one liter a day for the patient, the recommended intervention for hemodialysis patients.

Approved October 30, 2018 by the CSULB IRB

The investigator will make every attempt to reduce these risks by 1) providing you with the patient's ID number, and no identifiers will be on any documents; 2) an oral script will be used in order to standardize the phone conversation and ensure that the project purpose is addressed and the call will be limited to 10-15 mins; and 3) informing you of the risks and benefits of participation, and that you can withdraw from the project at any time.

You may not directly benefit from participating in this study. However, the results of this study may benefit the patient's adherence levels by monitoring their daily fluid intake logs and IDWG levels. Any information collected from you in this study will be stored in a secure location and will not be shared with anyone who does not have appropriate provisions to access the information.

You may contact the Office of Research and Sponsored Programs at ORSPCompliance@csulb.edu, or calling (562) 985-8147, if you have questions about your rights as a research participant.

Signing this document means that all information about the study has been explained to you orally, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

Name of Supporting person (Printed)

Supporting Person Signature

Date

Approved October 30, 2018 by the CSULB IRB

APPENDIX E**NOTICE OF INFORMED CONSENT FOR PATIENT**

Project Title: A Quality Improvement Project: Implementing a Support Person as Intervention for Hemodialysis Patients to Improve the Fluid Regimen Adherence

Investigator(s): Ann Sherly Varghese, Dr. Beth Keely, Dr. Anita Fitzgerald

Project Contact: asvarghese@csu.fullerton.edu, 909-215-0803

California State University, Long Beach (CSULB)

Office of Research and Sponsored Programs, CSULB: 1250 Bellflower Blvd., Long Beach, CA 90840

You are being asked to participate in a quality improvement study.

The purpose of this study is to implement and evaluate the effect of social support for End Stage Renal Disease (ESRD) patients on hemodialysis (HD) to improve fluid restriction adherence in a local dialysis center in Southern California. If you decide to participate you will be asked to: a) complete a brief questionnaire; b) Maintain a record/log of your daily fluid intake; and c) Follow the fluid adherence regimens which will be identified during the initial project visit which is scheduled for approximately 20 – 30 minutes.

The total time of your participation required to maintain the daily log is expected to last for four weeks.

The risks to participating in this study include 1) Discomfort answering a demographic questionnaire; and 2) discomfort in participating in the project for 4 weeks due to the limitations in fluid restrictions to one liter a day, the recommended intervention for hemodialysis patients.

The investigator will make every attempt to reduce these risks by 1) providing you with an ID number, and no identifiers will be on any documents; and 2) informing you of

the risks and benefits of participation, and that you can withdraw from the project at any time.

You may directly benefit from participating in this study by improving the daily fluid requirement levels and by monitoring the weight gains on non-dialysis days. Any information collected from you in this study will be stored in a secure location and will not be shared with anyone who does not have appropriate provisions to access the information.

You may contact the Office of Research and Sponsored Programs at ORSPCompliance@csulb.edu, or calling (562) 985-8147, if you have questions about your rights as a study participant.

Signing this document means that all information about the study has been explained to you orally, the investigator has answered any questions you have about the study and that you voluntarily agree to participate.

Name of Patient (Printed)

Patient's Signature

Date

APPENDIX F
SURVEY QUESTIONS

Dialysis Diet and Fluid Non-Adherence Questionnaire

1. “How many days during the last seven days did you not follow your fluid guidelines?”

2. “To what degree did you deviate from your fluid guidelines?”

No deviation Mild Moderate Severe very severe deviation
_____ 0 _____ : _____ 1 _____ : _____ 2 _____ : _____ 3 _____ : _____ 4 _____

APPENDIX G
DEMOGRAPHIC QUESTIONNAIRES

1. Please tell me your name

2. What is your age?

- 18-24 years old
- 25-34 years old
- 35-44 years old
- 45-54 years old
- 55-64 years old
- 65-74 years old
- 75 years or older

3. What is your sex?

- Male
- Female

4. Time in Hemodialysis

- 0 - 6 months
- 6 months - 1 year
- 1 – 3 years
- 3 - 5 years
- 5 – 10 years
- 10 – 15 years
- > 15 years

5. Relationship with your support person.

- Spouse
- Friend
- Family member (daughter/son/grandchildren)
- Relative
- Caregiver

6. Age of the support person

- 18-24 years old
- 25-34 years old
- 35-44 years old
- 45-54 years old
- 55-64 years old
- 65-74 years old
- 75 years or older

7. What is your support person's sex?

- Male
- Female

APPENDIX H
EDUCATIONAL COMPONENT FOR EACH PATIENTS
AND THEIR FAMILY MEMBER

Diet

What Is Sodium? Sodium is a part of salt. Sodium is present in canned, packaged, and “fast” foods. It is also found in other things such as condiments, seasonings, and meats. It is necessary to consume less than 2,300 milligrams of sodium each day.

Foods that are low in sodium.

- Fresh or frozen fruits and vegetables
- Cooked cereal without added salt
- Fresh meat, poultry, seafood
- Low-fat, low-sodium cheese
- Unsalted nuts
- Low- and reduced-sodium frozen dinners, salad dressings
- Air-popped popcorn

Foods that are high in sodium.

- Bacon, corned beef, ham, hot dogs, luncheon meat, sausage
- Bouillon, canned, noodles, and instant soups
- Boxed mixes, like hamburger meals and pancake mix
- Canned beans, chicken, fish and meat
- Canned tomato products, including juice
- Canned and pickled vegetables, vegetable juice
- Cottage cheese

- Frozen meals
- Frozen vegetables with sauce
- Olives, pickles, relish
- Pretzels, chips, crackers, salted nuts
- Salt and salt seasonings, like garlic salt
- Seasoning mix and sauce packets, Soy sauce
- Salad dressings, bottled sauces, marinades
- Some ready-to-eat cereals, baked goods, bread
- Ready-to-eat boxed meals and side dishes

Fluids

- Limit fluids to 1-1.2 L /day
- Dry Mouth – suck on hard candy or a wedge of lime or lemon
- Diabetes patients – maintain blood glucose levels
- Take medicines with meals. Swallow pills with applesauce if possible
- Use small cups or glasses

Common Fluid Portions

1 small juice glass	1 cup	1 large mug	1 can	1 Big Gulp
				
6 fluid ounces	8 fluid ounces	10-12 fluid ounces	12 fluid ounces	32 fluid ounces

Anything that is liquid at room temperature, such as

- Water, juice, milk, yogurt
- Coffee, tea
- Soups, Broths

- Gelatin desserts, puddings
- Ice cubes, ice cream, popsicles, watermelon

Overall points to remember

- Consume fresh foods
- Cook foods if possible, consume less fast, canned foods, etc
- Use spices/herbs instead of salt
- Thoroughly rinse canned veggies/beans
- When shopping, look for low sodium labels – sodium word - salt-free, unsalted, lightly salted, reduced sodium, etc
- Limit fluids 1-1.2 L/day

APPENDIX I
DAILY FLUID INTAKE LOG SAMPLE

Days	Fluid Consumption		In ozs/in mls/in L	Total	Pre-weight HD	Post weight HD
Day 1	Watermelon	Sprite soda	16oz	24oz		
			8 oz			
		Glass of	8 oz			
		water (2)				
Day 2						

Days	Fluid Consumption		In ozs/in mls/in L	Total	Pre-weight HD	Post weight HD
Day 3						

Days	Fluid Consumption		In ozs/in mls/in L	Total	Pre-weight HD	Post weight HD
Day 4						

Days	Fluid Consumption		In ozs/in mls/in L	Total	Pre-weight HD	Post weight HD
Day 5						
Day 6						
Day 7						

APPENDIX J

ORAL SCRIPT DURING TELEPHONE CALLS WITH EACH FAMILY MEMBER

Hello, my name is Sherly Varghese, Nurse Practitioner from Nephrology Associates Medical Group. I am calling regarding the educational session we had last time with the patient in the dialysis facility about fluid restrictions. I would like to ask you a series of questions about any concerns or questions regarding the daily intake of fluid logs or fluid related dietary information.

I would also like to know if the patient is compliant with his fluid limitations. Your participation is entirely voluntary and may skip any questions that you don't want to answer.

Would it be okay, to begin with, my questions?

1. On a scale of 1 to 5, 5 is excellent, 4 is very good, 3 is good, 2 is poor, and 1 is very poor, how is the patient doing with the daily fluid intake?
2. For the past one week, did the patient drink more than 1.5 L on any days, yes/no?
3. Does the patient monitor his pre-dialysis and post-dialysis weight to keep track of his weight gains, yes/no?
4. On a scale of 1 to 5, 5 is excellent, 4 is very good, 3 is good, 2 is poor, and 1 is very poor, how do you feel your support is helping the patient manage his fluid intakes?

Thanks for your time and I am expecting the completed fluid logs for last week when I see the patient next week at the unit. I will follow-up with you over the weekend if you do not have any objections. You have a good day.

APPENDIX K
TABLE OF EVIDENCE

Table 1

The Management of Fluid Restriction among ESRD Patients Receiving Hemodialysis Treatment

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
The effectiveness of HED-SMART intervention on adherence to treatment regimens (Griva et al., 2018)	Quantitative, Experimental- RCT	Sample: Convenience sample n = 235 . (HED-SMART n = 101; Usual group = 134)	HED-SMART interventions = skills & strategies for behavior change a) Group format b) 3 core sessions and 1 booster session c) Each session – self-management behaviors with goals	Achieved clinical targets for IDWG & serum phos, K levels Statistical significant results at 1 week and 3 months post intervention	Absolute changes were small, however HED-SMART achieved clinical targets for IDWG, phos, K levels. Good Improvements at 3 months, after continuous contacts with telephone call
	IV: HED-SMART DV: IDWGs, self-reported adherence, self-management skills, serum K and serum Phos levels	Duration: 9 months Setting: Singapore HD centers EC: Current psychiatric disorders, dementia, learning disability, current medical hx, hearing issues, not fluent in English, Mandarin, or Malay	Intervention was measured by audits. a) Goal setting sheets b) Intervention logs c) Checklists Self-reported adherence to fluid and diets measured by RABQ	↑ improvements with IDWG, serum K & Serum phos levels from baseline.	Self-management skills, self-efficacy, and self-reported adherence – shows behavior change -leads good clinical outcomes.

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
			Self-reported adherence to medication measured by MARS	No improvements after 9 months of post intervention	Future research is needed to assess the cost-effectiveness of the program.
			Self-management skills measured by HEIQ	↓adherence, self-efficacy, self-management skills after 9 months.	Limitations: It was convenience sample, instead of probability sample, limits generalizability to other populations
			Self-efficacy was measured by MCDQ		
			IDWGs measured by weight gains in HD centers and blood serum labs values for Serum K's & serum phos		Notes: An extensive research of HED-SMART interventions need to apply among patients for successful outcomes.
Exploring the impact of fluid self-management using MI techniques in ESRD patients on hemodialysis (Crown, Vogel, Hurlock-Chorostecki, 2017) (Focuses on the fluid self-management through patient-centered and	Quantitative, Quasi-experimental, pilot study IV: MI coaching DV: Readiness to change, IDWG	Sample: Convenience sample n = 18 . {♂-15, ♀- 3), \bar{x} age – 55, \bar{x} HD years – 3.2, Anuric -8, \bar{x} IDWG = pre – 1.46 kg, & post – 1.40 kg} Duration: 8 Wks Setting: 9 chair satellite HD unit located at a	MI coaching interventions (conversations + coaching) for 3-4 times over 4 wk period. MI coaching interventions validated by OnePass measure tool adapted from McMaster & Resnicow, (2015). Measured by patient satisfaction survey with 4 questions and participant comments on the interviewing. Readiness to change measured by readiness ruler tool &	94% attended HD, except one got hospitalized Half of the participants (n = 8) showed ↓ in IDWG & no change in IDWG (n = 3) Wide confidence interval (-0.21-0.33) – insufficient	IDWG differences between pre & post was 0.06 kg – suggested MI alone is insufficient Complexity is high to change the behaviors associated with FA based on participant's comments Positive satisfaction survey on MI however

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
conversational MI approach)		community hospital in Ontario, Canada.	summary log of weekly fluid intake	sample & a small study.	decreased feasibility in large scale study
		EC: HD -2 days or more / week, speak and understand English	Pre IDWG (before MI) and Post IDWG (during MI) measured by HD unit weigh scale	No statistically significant results between pre-IDWG & Post IDWG	Robust approach and large-scale study can be beneficial Limitations: small sample size, pilot study, participation bias, shorter time frame (total = 12 days in 4 wks) ↓ a change in behavior
		Exclusions: Weight loss program, unable to use HD unit weight scale		Participant's comments on motivation, mastery and opening up include 'need time to learn fluid intake, dislike weigh scale, post HD fatigue, etc.	
				MI helped among 93% participants, learned the importance of IDWG & FR, self-management of fluids and diets	Notes: Nurses in HD can utilize MI tool to influence behavior change. However, it is difficult to use such tools if the pts are not self-managing appropriately
Explore the effectiveness of social support on the quality of life among HD patients (Alexopoulou et al., 2016)	Quantitative, descriptive study IV – social support (family, friends, or significant others) DV – quality of life	Sample: Convenience sample n = 258. {♂-139, ♀- 119), age > 70 –88 & age 61-70 - 80, HD < 6years – 118 & HD > 10years - 57}	Social support measured by MSPSS questionnaire – assess three dimensions a) family, b) significant others support, c) friends support Each dimension – 7 questions rated at 7-point Likert Scale.	Highly supported from significant others & family ↑score in interpersonal relationships	↑social support = ↑ quality of life ↓social support = ↓adherence to treatment regimens, ↑ mortality risk, ↓quality of life
		Duration: 4months			

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
		Setting: HD centers in Greece EC: ESRD diagnosis, current on HD, native language (Greek), volunteer participation	Quality of life measured by MVQOLI. Assessed five dimensions a) symptoms, b) functionality, c) interpersonal relationships, d) well-being, e) transcendent.	Moderate scores in symptoms, functionality, and transcendent ↓score in well being Pts felt moderate quality of life overall ↑social support from significant others & family ↑quality of life.	Supportive social network could ↓hospital admissions Encouraging environment ↑ positive attitudes towards disease Limitations: paucity of research - the association of social support and quality of life Notes: Social support could influence the patient's positive attitude towards adherence regimens.
Effectiveness of behavioral intervention based on SA theory for ESRD patients on HD treatments (Wileman et al., 2016) (Really focusing on fluid restriction adherence)	Quantitative, Experimental – RCT IV: SA behavioral intervention, HI DV: IDWG levels, perceptions of HI, intention and SE about fluid restriction, self-reported FA and	Sample: Convenience sample n = 89 . {CNTRL group – 40(♂-30, ♀- 10), \bar{x} age – 58.2, \bar{x} HD years – 2.9, \bar{x} IDWG – 2.45 kg} {INT group – 49(♂-35, ♀- 14), \bar{x} age – 62.8, \bar{x} HD years – 2.6, \bar{x} IDWG – 2.40 kg}	SA manipulation initiated by questionnaires INT group: 10 SA questions - yes or no + brief answer CNTRL group: 10 matched control questions with no self-affirming questions	Mean IDWG at baseline – 2.4 kg indicates inadequate FC. No differences between groups on any demographic factors, baseline IDWG, comorbidity status.	Inadequate FC measured by IDWG is associated with poor outcomes in HD pts Behavioral intervention based on SA theory among ESRD self-affirmed patients ↓ IDWG levels, altered patient's

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
	associated factors, such as thirst, depression	Duration: 12 months	Post HI responses measured by questionnaires	Evaluation of HI – no differences between the two groups.	perceptions of HI, ↑ self-reported FA
	INT group – received HI and SA activity	Setting: 6 HD units in the UK	Both groups: 11 items-questions were measured on 7-point (1-7) scales		Limitations: control not achieved, small sample size, 33% attrition rate, loss of RRF within 12 months could ↑ IDWG
	CNTRL group – received HI with no SA activity	EC: 3-month average IDWG >2 kg, were ≥ 3 months from the initiation of HD, fluent in reading English, no previous hospitalization in 3 months, no co-morbidities that compromise short-term survival	IDWG levels were measured from HD units databases (pt's DW + kt/v) for both groups	↓ in IDWG with 0.34 kg for INT group & no ↓ in CNTRL group from baseline to 6 months.	Notes: SA activity and education on HI will ↑ knowledge in pts and improve FA – might help the strategy if used along with self-management activities
			Intention and SE – 3 items were measured on 7-point (1-7) scales for both groups	After initial 6 months, ↑ in mean IDWG levels for both groups	
			Self-reported FA measured by one question on 5-point scale for both groups		
			Depressive symptoms associated with self-reported FA measured by– Patient Health Questionnaire	Self-reported FA scores were ↑ after 1 month in INT group	
			Thirst associated with self-reported FA measured by Dialysis Thirst Inventory		

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
Determining if a relationship between social support and adherence to fluids and diet among HD pts (Ahrari, Moshki, & Bahrami, 2014)	Quantitative, Descriptive Correlational IV: Social support (family, friends, significant others) DV: Diet and fluid adherence, IDWG	Sample: Convenience sample n = 273 { \bar{x} age- 46.1 years, (σ - 157 > σ - 116 Married- 243 > Single- 30} HD duration – 3 months Setting: 2 HD units in eastern region of Iran Exclusion: physical disabilities, mental disorders	Survey – 3 questionnaires with 20 min interview 1 st section – personal data questionnaire – age, gender, marital status, hx of pt, pre wt & post wt HD, lab reports 2 nd Section – DDFQ adapted by Vlaminc et al., (2001) – 4 subscales with 2 questions on a 5-point Likert scale measured behavior related to adherence to diet and fluid limitations in HD pts 3 rd section – MSPSS -12 questions on a 7-point Likert scale assessing perceived social support of individuals – family, friends, significant others	Wt gain \uparrow average – 1.5 kg \uparrow in age \downarrow level of non-adherence Significant positive correlational between non-adherence and IDWG	Best support – family; least support – friends Older pts – more conservative & more compliance Biochemical values such as lab values – measurement of non-adherence Pts with \uparrow level of social support showed \uparrow level of non-adherence to dietary & fluid restrictions Family members play a great role in self-care behaviors Notes: The differences in the culture could influence the pt from social support. However, educating families could be a useful approach to self-manage fluid/dietary restrictions.

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
Exploring the patients' perception of the experience with FA during hemodialysis treatments (Tovazzi & Mazzoni, 2012)	Qualitative, Phenomenological approach	<p>Sample: Purposive sample n = 12</p> <p>{\bar{x} age- 58years, ♂-8, ♀- 14, \bar{x} HD years – 7 months- 32 years, \bar{x} IDWG – 2.4 kg, FA – 5 (3.5% under IDWG), Non-FA – 7 (35% above IDWG)}</p> <p>Setting: a limited assistance HD clinic, Italy</p> <p>EC: > 18 years, in HD treatment for min 6 months, able to consent, able to describe research experience</p> <p>Exclusion: Cognitive deficits, non-Italian speaking language</p>	<p>Face to face interviews on HD days before HD session for 30-60mins.</p> <p>Phenomenological model and approaches were used for interview analysis</p> <p>Direct quotes -patient's perceptions</p>	<p>Pt's perception on fluid restriction is like an "addiction" and requires individual strategies to improve FA</p> <p>Awareness to FA is ↓ in practical life</p> <p>Addiction to fluids described as "mirages" often</p> <p>Loss of understanding about diet, FA, mechanism of HD, requesting for more info on treatment and their condition.</p> <p>Non-adherence to fluids is caused by lack of understanding about the importance of FR. Pt's consider them as "dialysis rules."</p>	<p>FA contains elements such as IM, mental control, own experience, time, good support.</p> <p>Decreased adjustment to fluids at the initiation of HD, pt's do not comprehend all educational messages</p> <p>Patients trust their common sense when they feel a disconnection from their needs and info from HP. Therefore, HP should reinforce, educate, and explore the pt's difficulties.</p> <p>Good outcomes and reduced costs are attained when pt's co-involve in the treatment process</p> <p>Limitations: limited generalization among HD population, require additional info about</p>

Purpose, Study, Questions (Author (s), Year)	Study Design & Key Variables	Sample & Setting	Measures	Results	Author Conclusions, Limitations, & Notes
					FR experience, assessment of non-adherence to FR Notes: Patients have difficulty in adhering FR always. An individualized and holistic approach could benefit pt to restrict fluids.

Note: HED-SMART = Hemodialysis Self-management Intervention Randomized Trial, SA = Self-affirmation, ESRD = End-Stage Renal Disease, RABQ = Renal Adherence Behavior Questionnaire, MARS = Medication Adherence Reported Scale, HEIQ = Health Education Impact Questionnaire, MCDQ = Managing Chronic Disease Questionnaire, HD = Hemodialysis, HI = Health-risk Information, IDWG = Interdialytic Weight Gain, EC = Eligibility Criteria, HBM = Health Belief Model, INT = Intervention, CNTRL – Control, DW = dry weight, kt/v – Dialysis adequacy, K = Potassium, Phos = Phosphate, SF-36 = Short form Survey, BD = Burden of diet therapy, DQ OL = Diet-related quality of life, IM = Individual motivation, DSE = Dialysis staff encouragement, pt = Patient, HP = Health care Professionals, HE = Health Education, MH = Mental Health, Info = Information, MI = Motivational Interviewing, FR = Fluid Restriction, IHLOC = Internal health locus of control, DMSES = Dietary management self-efficacy scale, MSPSS = Multidimensional Scale of Perceived Social Support questionnaire, MQOLI = Missoula-VITAS Quality of Life Index, SE = Self-efficacy, FA = Fluid adherence, FC = Fluid control, RRF = Residual Renal Function