

November 06, 2017

**Effect of Motivational Interviewing and Education Based on Watson's Theory of
Human Caring in Individuals Receiving Hemodialysis: Randomized Controlled Trial**

NCT Number: **NCT04174638**

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1. INTRODUCTION

Hemodialysis is the most common treatment in the end stage renal disease. In the 2018 report of the World Health Organization, it was stated that 2.62 million people received dialysis treatment in 2010 and 1.2 million people died from kidney disease in 2015 (Luyckx, Tonelli, & Stanifer, 2018). Hemodialysis consists of a complex process and adherence to treatment is very important for individuals receiving hemodialysis treatment. Adherence to fluid intake, diet and drug management is indicators of adherence to treatment (Naalweh et al., 2017; Tohme et al., 2017). Non-adherence to treatment leads to increased complications, decreased quality of life (QOL) and increased morbidity and mortality (Naseri-Salahshour, Sajadi, Nikbakht-Nasrabadi, Davodabady, & Fournier, 2020). Therefore improving adherence to treatment is important in hemodialysis.

Motivational interviewing and education are frequently used to improve adherence to treatment and to develop healthy behavior in individuals receiving hemodialysis treatment (Crown, Vogel, & Hurlock-Chorostecki, 2017; Tao, Tao, Wang, & Bi, 2020). Since creating behavioral change is a complex process, it is recommended that the intervention be implemented systematically. Models or theories are important in guiding the interventions and their systematic application (Fawcett, 2005). One of these theories, Jean Watson's Theory of Human Caring dwell on nursing care to be humanistic, conscious, purposeful and careful (Watson, 2018). It is thought that performing of motivational interviewing and education based on Watson's Theory of Human Caring to individuals receiving hemodialysis treatment will contribute to improving adherence to treatment, patient satisfaction and QOL.

This statistical analysis plan (SAP) will give more detailed descriptions of the endpoints in the study and the corresponding analyses.

2. STUDY DESIGN

2.1 Objective and Hypothesis

The aims of the study were to evaluate the effectiveness of Motivational interviewing and education based on Watson's Theory Of Human Caring on adherence to treatment, satisfaction and QOL in individuals receiving hemodialysis treatment. We hypothesized that intervention group who received Motivational interviewing and education based on Watson's Theory of Human Caring would increase (a) adherence to fluid intake, (b) adherence to diet, (c) adherence to drug management, (d) QOL compared to the control group and (e)

intervention group who receiving motivational interviewing and education based on Watson's Theory of Human Caring would satisfied with introduced intervention.

2.2. Design / Methodology

A randomized controlled trial.

2.3. Sample Size Calculation

In this study, the sample size was calculated based on the "The Scale for Dietary Behaviors in Hemodialysis Patients" used in a similar study (Düzalan & Pakyüz, 2018). A total of 70 individuals receiving hemodialysis treatment, 35 patients in each group, were included in the study based on a common type-I error rate of 0.05, the effect size rate of 0.80 and estimated loss to follow-up of 10%.

2.4. Inclusion and Exclusion Criteria

Inclusion criteria of the study were as follows:

- participants were individuals aged ≥ 18 years,
- received hemodialysis for at least 3 months,
- had 1 and over from Diet and Fluid Non-Adherence Questionnaire (DDFQ) total score,
- had 0 or 1 score from 1., 2. and 6. questions or 3., 4. and 5. questions in the Modified Morisky Scale (MMS),
- willing to participate,
- participants without language or communication barriers.

The exclusion criteria of the study were as follows:

- The participants diagnosed with psychiatric illness or malignancy were excluded from the study.

2.5. Randomization and blinding

The simple randomization method will used. Individuals receiving hemodialysis who met the inclusion criteria, agreed to participate in the study and signed the informed consent form were divided into either a intervention group or control group by coded randomization by researcher. An independent, blind statistician who will not involved in the research process

prepared the random number table with SAS package 9.4. It will not possible allocation concealment as the intervention was performed by the researcher who received motivational interviewing and education. The researcher will not participate in the data analysis, the analyzes will made by an expert statistician.

2.6 The Intervention

The intervention group will received 15 minute motivational interviewing in four session once a month and one session face-to-face education with booklet at the first motivational interviewing based on Watson's Theory of Human Caring before the hemodialysis session in a separate room in the hemodialysis unit.

Motivational Interviewing: The semi-structured interview based on Watson's Theory of Human Caring according to the principles of motivational interviewing such as open-ended questions, affirmation, reflection, summaries and speaking change will perform. In the motivational interviewing sessions, the agenda will set for the individuals to talk about their current concerns about fluid intake, diet and drug management, and physical, psychological and social support problems. It will aimed to reveal the individuals' personel goals to improve their adherence to treatment and the obstacles they perceived to achieve these goals. By working with the ambivalence of the individuals, supporting their optimism and self-efficacy and positive changes, individuals will enable to determine their own solutions. In addition, individuals will support for the maintaining of behavior change.

Education: The education will apply face-to-face in one session for 30 minutes in the first motivational interviewing and an education booklet will give to the participants. The education booklet has been prepared by the researcher, according to evidence-based guidelines, literature search and result of study (<https://rb.gy/nxkgf4>, Accessed date: 24.11.2017; <https://rb.gy/totnpp>, Accessed date: 27.11.2017). The education booklet was evaluated by 10 experts in the field of nephrology and hemodialysis according to Discern guide. The educational booklet includes sections on kidneys, kidney functions, causes, symptoms, stages and treatment of chronic kidney disease (CKD), nutrition in hemodialysis, fluid intake, drugs, hemodialysis related problems, laboratory parameters.

Conceptual-theoretical-empirical (C-T-E) system-based nursing practice was used in the study. The C-T-E structure provide a purposeful and systematic process for nursing practice (Fawcett, 2005).

2.7 Control Group

The control group will receive routine hemodialysis treatment and nursing care in the hemodialysis unit. Routine nursing care consisted of dietary recommendations for high laboratory parameters and recommendations for patients' needs. The control group will receive face-to-face education for 30 minutes and education booklet at the 12th week.

2.6. Outcomes

This section will present the outcomes investigated to answer the study aims and objectives. The analyses are described in section 3 Analyses.

- Adherence to fluid intake: it will be measured at baseline and 12th week using Fluid Control in Hemodialysis Patients Scale.
- Adherence to diet: it will be measured at baseline and 12th week using The Scale for Dietary Behaviors in Hemodialysis Patients.
- Adherence to drug management: it will be measured at baseline and 12th week using Modified Morisky Scale.
- Patient satisfaction: it will be measured at 12th week in the intervention group using Watson Caritas Patient Score and Motivational Interviewing Evaluation Form.
- Quality of life: it will be measured at baseline and 12th week using Kidney Disease Quality of Life-36 Scale.
- Physical parameter: it will be measured at baseline and 12th week.

Physical Parameters

- Blood Pressure
- BMI
- Glucose mg/dL
- BUN mg/dL
- Creatinine mg/dL
- Albumin g/dL
- Potassium mEq/L

- Phosphorus mEq/L
- Hematocrit %
- Hemoglobin g/dL
- Total Protein mg/dL
- Sodium mEq/L
- Calcium mEq/L

3. ANALYSIS

The data were analysed with the IBM Statistical Package for Social Science (SPSS) for Windows version 25 (IBM, 2017). The normality test was performed with the graphical assessment, skewness and kurtosis test. Descriptive statistics for normally distributed numerical variables were presented as mean, standard deviations, n (%) or minimum-maximum. While evaluating statistical significance, it was considered according to the p value of <0.05.

Adherence to fluid intake, diet and drug management, physical parameters and quality of life will compare intervention groups (motivational interviewing and education based Watson's Theory of Human Caring vs control treatment) on their mean change between baseline and 12 weeks using independent sample t-test. In addition, effect size will evaluated by calculator for student's t-test using G-Power programme. To identify the relationship of the change adherence to fluid intake, diet and drug management, physical parameters and quality of life with other variables such as group and demographic variables will use multivariate linear regression.

Patients satisfaction will analyzed using descriptive analysis such as n (%) or minimum-maximum.

References

- Crown, S., Vogel, J. A., & Hurlock-Chorostecki, C. (2017). Enhancing Self-Care Management of Interdialytic Fluid Weintervention groupht Gain in Patients on Hemodialysis: A Pilot Study Using Motivational Interviewing. *Nephrology Nursing Journal*, 44(1), 49-55.
- Düzalan, Ö. B., & Pakyüz, S. Ç. (2018). Educational interventions for improved diet and fluid management in haemodialysis patients: An interventional study. *Journal of Pakistan Medical Association*, 68(4), 532-537.
- Fawcett, J. (2005). Watson's Theory of Human Care. In J. Fawcett (Ed.), *Contemporary Nursing Knowledge an Analysis and Evaluation of Nursing Models and Theories* (pp. 553-599). Philadelphia: F.A. Davis Company.
- IBM. (2017). SPSS version 25.0. New York: IBM Corporation.
- Luyckx, V. A., Tonelli, M., & Stanifer, J. W. (2018). The global burden of kidney disease and the sustainable development goals. *Bulletin of the World Health Organization*, 96(6), 414-422. doi:10.2471%2FBLT.17.206441
- Naalweh, K. S., Barakat, M. A., Sweileh, M. W., Al-Jabi, S. W., Sweileh, W. M., & Sa'ed, H. Z. (2017). Treatment adherence and perception in patients on maintenance hemodialysis: A cross-sectional study from Palestine. *BMC Nephrology*, 18(1), 178-186. doi:10.1186/s12882-017-0598-2
- Naseri-Salahshour, V., Sajadi, M., Nikbakht-Nasrabadi, A., Davodabady, F., & Fournier, A. (2020). The effect of nutritional education program on quality of life and serum electrolytes levels in hemodialysis patients: A single-blind randomized controlled trial. *Patient Education and Counseling*, In press. doi:10.1016/j.pec.2020.03.021
- Tao, W. W., Tao, X. M., Wang, Y., & Bi, S. H. (2020). Psycho-social and educational interventions for enhancing adherence to dialysis in adults with end-stage renal disease: A meta-analysis. *Journal of Clinical Nursing*, 29(15-16), 2834-2848. doi:10.1111/jocn.15301
- Tohme, F., Mor, M. K., Pena-Polanco, J., Green, J. A., Fine, M. J., Palevsky, P. M., & Weisbord, S. D. (2017). Predictors and outcomes of non-adherence in patients receiving maintenance hemodialysis. *International Urology and Nephrology*, 49(8), 1471-1479. doi:10.1007/s11255-017-1600-4
- Watson, J. (2018). *Unitary Caring Science: Philosophy and Praxis of Nursing*. Colorado: University Press of Colorado.