Protocol

# The Effect of Nursing Counseling on Improving Knowledge, Adherence to Treatment and Quality of Life of Patients Undergoing Hemodialysis

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**Abstract**

**Background** The success of hemodialysis (HD) treatment depends largely on patient adherence to strictly recommended treatment regimen. Non adherence to therapeutic recommendations may have unpleasant results on quality of life (QoL), increased morbidity, mortality and health cost.
**Aim** The aim of this study protocol is to investigate i) the effect of an educational program on the patient knowledge level, patient adherence level with treatment regimen and QoL ii) to correlate the knowledge, received by the patient through the educational program, with adherence to treatment regimen and iii) to correlate the adherence with QoL.
**Method** The sample will be around 180-200 patients undergoing HD treatment and will be divided into two groups: the experimental group and control group. Each subject's level of knowledge, adherence and quality of life will be measured using the following instruments: i) The Kidney Disease Questionnaire ii) Greek Simplified Medication Adherence Questionnaire and iii) Missoula - VITAS Quality of Life Index- 15. Counseling intervention, handouts and videos will follow for experimental group. Control group will receive handouts and videos but not counseling intervention. Two weeks later questionnaires the first two questionnaires will be given to both groups. Missoula - VITAS Quality of Life Index-15 will be given 3 months after the counseling intervention.
**Results** Patient knowledge, adherence and quality of life are expected to be related to the educational intervention.

**Key-words:** Hemodialysis patient, adherence, quality of life, patient knowledge, educational intervention, counseling

## Background

Hemodialysis (HD) is the most common type of renal replacement for patients with End Stage Renal Disease (E.S.R.D.).(Kim et al 2010) Patients undergoing HD have multiple problems, such as sodium and water retention, hypertension, anemia, and heart disease. To address all these problems, adherence (also termed compliance) with treatment regimen is required (Alikari et al 2015, and Zyga & Kolovos 2013).

Adherence is defined as: "… the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health-care provider" (WHO, 2003). Several studies have shown the factors affecting adherence and quality of life (QoL). These factors are related to the patient training about ESRD and HD treatment, pill burden, social support or self-efficacy. Especially, it has been shown that educational intervention can affect the

levels of patient knowledge, adherence and QoL (Devins et al 1990, and Lee & Molassiotis 2002, and Casey et al 2002, and Tsay 2003, and Curtin et al 2004, and Barnett et al 2008).

Patient knowledge about End Stage Renal Disease and hemodialysis has been shown to affect positively patient outcomes. Self-efficacy and participation in clinical decision making are positively related to high levels of disease related knowledge. Moreover, a well-informed patient takes the role of the collaborator in kidney disease management (Devins et al 2000, and Devins et al 2005, and Alikari & Zyga 2014).In a study related to adherence to diet and fluid restrictions in Chinese patients undergoing HD researchers found that adherence depends on knowledge regarding diet (Lee & Molassiotis 2002).

Similarly, in a cross sectional study conducted in Egypt, researchers compared serum phosphorus levels and the knowledge about diet parameters. Patients who had higher levels of knowledge on diet parameters had less hyperphosphatemia than those with lower levels of knowledge (Afifi et al 2005). To be able to increase knowledge, adherence and quality of life, patients need to be educated through nurse-led individualized educational programs (Galloway et al 1997, and Curtin et al 2004, and Timmins 2006, and Barnett et al 2008).

In a study conducted in 2002 by Casey et al compliance levels improved in 48% of participants after an educational intervention (Casey et al 2002). In a similar study the average of interdialytic weight gain (IWG) decreased, while levels of adherence to fluid restrictions increased after educational intervention (Barnett et al 2008). Devins et al in the study of the development of the Kidney Disease Questionnaire scale found that, after an educational intervention, patients had increased their knowledge level about their disease (Devins et al 1990).

Other researchers found positive correlation between adherence to antihypertensive medications and quality of life (García-Llana et al 2013). In another study among pre-dialysis patients, researchers found that patients, who participated in an education program, showed higher levels of well-being, less sense of loneliness, lower levels of anxiety and better mood than the control group (Klang et al 1998). Controversially, low levels of knowledge about illness and treatment is associated with poor health outcomes (Affi et al 2005).

The aim of the present study is to investigate if an educational intervention can increase hemodialysis knowledge, patient adherence level to treatment regimen and quality of life among hemodialysis patients. Furthermore, this study will investigate the relationship between

i) hemodialysis knowledge and adherence to treatment regimen

ii) adherence and QoL .

## Methods

A cohort of around 180-200 patients undergoing HD treatment will be selected from HD Units located in Athens. A two group quasi-experimental design will be used with probability random sample. The inclusion criteria are: i) >18 years old ii) ability to speak and read Greek iii) HD treatment for at least 6 months iv) orientation as to time and space. The exclusion criteria are: i) patients without psychological or cognitive disorders, ii) patients without functional disabilities, visual or hearing disorders.

Written approval to conduct the study will be taken from the Scientific Council of the hospitals. According to the ethical standards of the Helsinki Declaration all patients will be informed about their rights to refuse or stop the participation in the study. Subjects will sign a consent form for participation.

Pilot study will take place for the measuring of the repeatability of the questionnaires.

The psychometric tools included in the study are presented below.

## Instruments

Devin's et al created The Kidney Disease Questionnaire (KDQ) (Devins et al 1990). The KDQ is an instrument that assesses the level of knowledge of HD patient. It consists of two forms of 13 multiple choice items for each. The total score is calculated by adding of scores responses of patients. The higher the score the highest is the level of knowledge. Cronbach's alpha for Form A was 0.75 and for Form B 0.85. Because of the fact that KDQ have never been used in Greek patients, translation and cultural adaptation will be occurred. Translation will be carried out according to World Health Organization (WHO) guidelines (http://www.who.int/ substance_abuse/research_tools/translation/en/).

The procedure will include the independent translation of the original English questionnaire (forward translation) in the Greek language by two different health care professionals. After that a comparison of the two translations will be carried out by a third health care professional and a reconciled version will be created. A backward translation of this version of

the questionnaire will be made by a bilingual person whose maternal language is English who is also a professional translator and will not aware of the original version of the questionnaire. The backward translation will sent to the creators of the questionnaire for comments. Their comments will be incorporated giving a second Greek version of the questionnaire (2nd reconciliation version). This version will be used for the pilot testing of the questionnaire. Cultural adaptation of the scale will be carried out among 20 HD patients. Patients will be asked to refer any obscure points. These points will be discussed by the members of the health care team. This will help researchers to ensure that HD patients can easily understand the Greek version of the KDQ. The psychometric properties will be investigated as well.

Greek Simplified Medication Adherence Questionnaire (GR-SMAQ) (Theofilou 2012) is a self-administered questionnaire which was used by Theofilou in order to measure the level of patient adherence in a sample of 10 Greek patients with lung cancer. The original form (Knobel et al 2002) of the questionnaire was used to measure the level of patient adherence under antiretroviral therapy. To use this scale in Greek patients, translation and cultural adaptation was occurred. It consists of 6 questions which evaluate different aspects of patient adherence: forgetfulness, routine, side effects, and quantification of omissions. As far as the field of Nephrology is concerned, the scale has been used in order to measure the level of patient adherence in phosphate-binding drugs but its validity have not been tested (Arenas et al 2010a, Arenas et al 2010b).

In the present study we will add questions related to patient adherence to fluid restriction, potassium foods and the presence of the dialysis session. These questions will be chosen by a health care team after a systematic literature review in data bases. We aim to investigate the psychometric properties of the scale that will result.

Missoula - VITAS Quality of Life Index- 15 (MVQOLI-15) is an instrument created in order to measure patient-reported information about QoL during the last stage of illness (Schwartz et al 2005).The MVQOLI-15 investigates 5 dimensions of QoL: symptoms, function, interpersonal, well-being and transcendence. The questions use a five-point Likert scale. The lower the score the less desirable situation and inversely. The internal validity of the questionnaire was satisfactory (Cronbach's alpha 0.74). Translation, cultural adaptation in Greek and validation has been occurred (Theofilou et al 2012, and Theofilou et al 2013). The basic socio-demographic and clinical characteristics of the patients will be collected.

**Data collection procedure**

The study population will be divided into two groups: the experimental group and control group. Experimental group will be chosen randomly while the two groups be equated regarding the demographic and clinical characteristics.

**Stages of the study**

In the first stage questionnaires will be given both to the experimental and control group. Immediately after the first stage, the second stage will follow. This phase concludes individual educational intervention of 30 minutes for the experimental group but not for the control group. The educational intervention will be written exclusively by the researchers and will include the following topics: i) Renal Function ii ) basic topics about End Stage Renal Disease, iii) Diet and Fluid restrictions, iv) Medication, v) Laboratory tests and vi) Pathological conditions associated with E.S.R.D. In addition, handouts in Greek language will be given to experimental group and educational videos will be shown. Control group will receive only handouts. The third stage will take place two weeks after the first phase. In both groups of patients the questionnaires KDQ and SMAQ will be given. In order to measure the QoL after the educational intervention, MVQOLI will be given to both of the groups 3 months after the education intervention.

**Data analysis**

Statistical analysis will be done with Statistical Package for Social Sciences (SPSS 20.0 for Windows). The reliability of the tools will be tested using the following measures: internal consistency, repeatability, test-retest reliability and convergent validity. Internal consistency will be rested using Cronbach's Alpha. Construct validity will be tested using factor analysis. A P value of 0.05 or less is considered to indicate statistical significance. Pearson Product-Moment Correlation Coefficient (r) will be used to determine relationships between HD knowledge and adherence. T-tests will be used to determine differences between HD knowledge scores and adherence scores. Kolmogorov-Smirnov tests will be performed in order to check whether the values of the sample fall within a normal distribution.

**Discussion**

This study will find the correlation between educational intervention - knowledge, adherence and QoL. We will, also, try to find out the correlation between

knowledge–adherence and adherence–QoL. The findings of this study can be used in order to promote the active role of the patient and patient involvement in clinical decision making

## Limitations

During the conduction of the study limitations may occur: i) interference of external factors (noise, fatigue of the patients, interruptions by the personnel as the study will take place in the hemodialysis unit ii) low health literacy of the patients. The researcher will read the medical terms of the questionnaires and handouts and explain iii) it is not clear if the participants of the control group will be able to read the handouts. To overcome this limitation, patients without sight problems will be chosen.

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