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A protocol for a pilot randomized controlled trial to assess the feasibility and effect of a cognitive behavioral intervention on quality of life for patients on hemodialysis

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ABSTRACT

Introduction: Poor health-related quality of life (HrQOL) is highly prevalent in patients on hemodialysis (HD), and is associated with increased hospitalizations and mortality. Cognitive behavioral (CB) techniques have improved HrQOL in HD patients but have not been routinely translated into clinical practice. The investigators present the rationale, study design and protocol of a randomized controlled trial to pilot the feasibility and effect of a translatable, behavioral-education intervention using CB techniques to improve poor HrQOL and self-management in hemodialysis patients.

Methods: Forty-eight HD patients will be randomly assigned to either the study intervention which includes 8–12 behavioral-education sessions with incorporated CB techniques delivered over 12 weeks or a control group of dialysis education without incorporated CB techniques. Subjects will be followed for 16 weeks and the primary outcome, change in kidney disease quality of life (KDQOL)-36 scores, will be measured at 0, 8, and 16 weeks. The study will have 85% power to detect an 8-point change in KDQOL-36 scores. At the end of the study, qualitative data will be gathered through end-of-study focus groups, and semi-structured interviews. These data will be used to refine the intervention and help translate it into clinical practice.

Discussion: There is promising evidence in support of CB-based interventions to improve HrQOL for patients on HD. Despite this, these interventions have not been routinely incorporated into clinical practice. The proposed intervention has the potential to improve both HrQOL and self-management, while also being easily translatable to other HD units.

1. Introduction

Currently > 400,000 adults receive hemodialysis (HD) treatment in the United States and > 100,000 start treatment yearly [1]. Compared to the general population, health related quality of life (HrQOL) scores are lower in HD patients and are among the worst of any other chronic illness [2,3]. In a study of 7378 European, Japanese and US HD patients both physical component quality of life scores (PCS) and mental component quality of life scores (MCS), using the kidney disease quality of life (KDQOL)-36 survey, were significantly lower than norms for the general population [4].

Low HrQOL scores in patients on HD are associated with worse medical outcomes including a higher risk of hospitalizations and death. In a study of 10,030 HD patients from the Dialysis Outcomes and Practice Patterns Survey database, the adjusted risk of death was 93% higher and the risk of hospitalization 56% higher in the group with the lowest quintile of PCS sores compared to the highest quintile group [5]. In this study, the relative risk of mortality was 1.13 times higher for MCS, and 1.25 times higher for PCS per 10-point lower score [5]. Furthermore, each 1-point increase in PCS or MCS has been associated with a 2% drop in the relative risk of death, and each 1-point increase in PCS or MCS has been associated with a 1–2% drop in hospitalization [6]. This association between adverse medical outcomes and low HrQOL scores in HD patients is likely, in part, mediated by poor self-

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management. HrQOL has been consistently associated with higher phosphorus and potassium levels, and higher interdialytic weight gains [7]. Inactivity has been associated with lower HrQOL scores [8]. Additionally, depressive symptoms, a major component of HrQOL, are associated with non-adherence to medications, diet and fluid restrictions, and dialysis sessions [9]. Clearly, interventions are needed to improve self-management and HrQOL for adults with end stage renal disease (ESRD) requiring chronic HD.

Improving self-management behaviors is critically important to optimizing clinical outcomes for patients on hemodialysis [10]. These self-management behaviors include adherence to medications and dialysis treatment, adherence to salt, liquid and phosphorus restricted diets, and physical activity [10]. Major barriers to self-management are maladaptive health behaviors that have developed over time, and, in many cases, have contributed to the development of ESRD, and negative emotions and dysfunctional cognitions surrounding ESRD and dialysis. Interventions that target these behaviors, emotions and cognitions may improve quality of life and self-management at a critical point for these patients that have developed a serious complication (ESRD). Improving clinical outcomes is still possible; moreover, patients may be motivated to improve their self-management with the realization that they have developed ESRD.

Cognitive behavioral therapy (CBT) is a structured psychotherapy intervention designed to address and treat dysfunctional cognitions, negative emotions and maladaptive behaviors. In patients with ESRD, cognitive behavioral (CB) techniques integrated into educational programs have successfully improved HrQOL, self-management, and depressive symptoms [11,12]. These techniques are designed to reframe negative emotions and dysfunctional cognitions related to self-management and to replace maladaptive behaviors with health-promoting behaviors. For example, patients are taught to reframe nihilistic thoughts about hemodialysis to more positive thoughts about the benefits of healthy behaviors. Additionally, behavioral shaping strategies such as goal setting, and problem-solving techniques are taught. Unfortunately, prior CB-based interventions have been limited by poor patient and physician adoption [11,12]. There are several possible explanations for this including: 1) patients feeling stigmatized by interventions addressing mental health [13,14]; 2) providers feeling uncomfortable treating poor HrQOL [15]; and 3) poor methodological quality of trials [16–19]. To date, these barriers have limited the widespread adoption of CB-based interventions to improve HrQOL in the HD population [20,21].

In order to increase the likelihood of widespread adoption, CB-based, HrQOL interventions for HD patients must be easily integrated into routine HD care and applicable to the majority of HD patients. The intervention described in this protocol uses previously successful CB techniques such as cognitive restructuring and goal setting to improve HrQOL and self-management in HD but also delivers this behavioral training in the context of an educational program that is applicable to the majority of hemodialysis patients and is highly translatable to other US HD units.

2. Materials and methods

2.1. Study aims and study design summary (Fig. 1)

The primary aim of the Improving Quality of Life in Hemodialysis Trial is to pilot test the effectiveness of a translatable 3-step intervention to improve poor HrQOL in HD patients. In the first phase of the study, a two-arm, 16-week randomized controlled trial in 48 subjects on HD with below average HrQOL will be conducted. This trial will test the impact of the intervention on HrQOL and self-management. Study outcomes will be assessed at weeks 0, 8, and 16.

The secondary aims of this trial are to test the feasibility of this intervention and assess its translatability to other US hemodialysis units. In the second phase of the study, qualitative data, obtained through focus groups and semi-structured interviews, will be collected so that the intervention can be readily adapted to other US HD units and so that a toolbox of exportable materials can be created for these units.

2.2. Design and development of the intervention

2.2.1. Summary of the intervention

The intervention has 3 steps. The first step is a one-page dashboard that presents actionable HrQOL information to key stakeholders (social workers, nutritionists, primary nurses, nurse-practitioners, physicians,

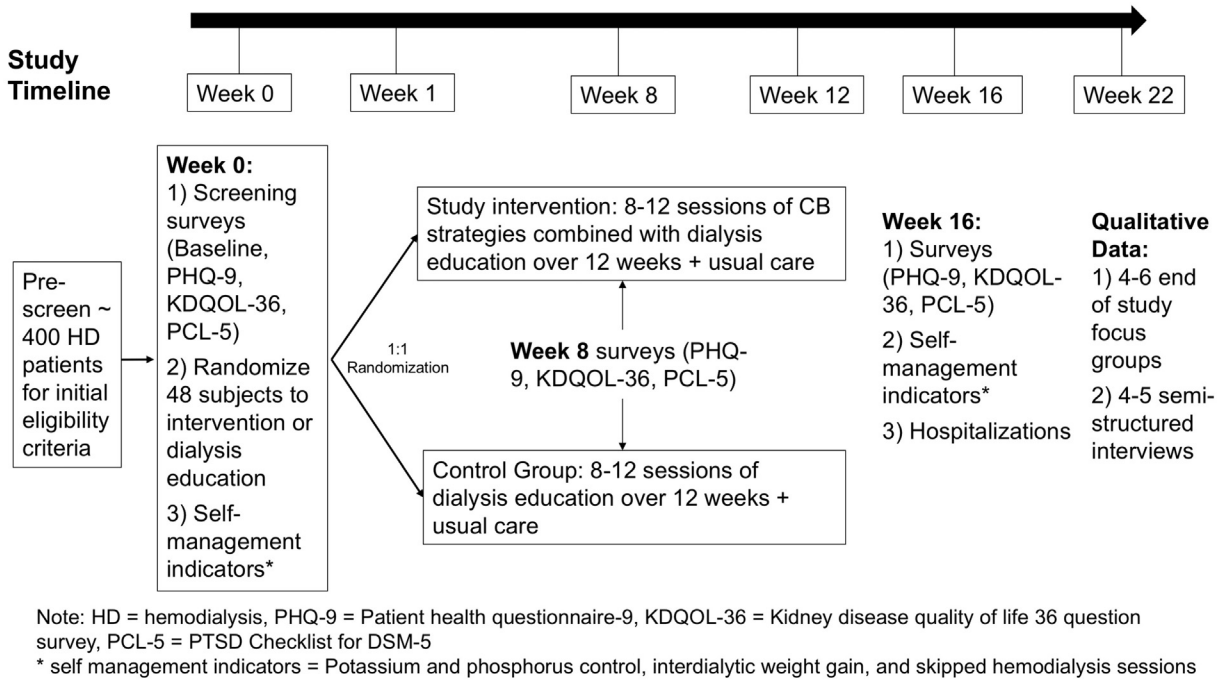

Fig. 1. Study Timeline.

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