

The effectiveness of nurse-led self-management support program for people with chronic kidney disease stage 3-4 CKD-NLSM: study protocol for a randomized controlled trial

ABSTRACT

The complexity of chronic kidney disease (CKD) and its treatments have made self-management behaviors inevitably challenging. However, supplementing education with self-management skills may improve numerous health outcomes in people with nondialysis CKD. This study protocol describes a randomized controlled trial (RCT) aimed to evaluate the effects of a nurse-led self-management support program as an intervention for kidney disease knowledge and CKD self-management behaviors among people with pre-dialysis CKD. In Phase 1, people with CKD stage 3–4 and their family members are involved in co-designing, development and pilot testing of a theory-based self-management intervention. In Phase 2, we perform a cross-cultural adaptation of the Kidney Disease Knowledge Survey, CKD Self-Management and Self-efficacy for Managing Chronic Disease questionnaires. In Phase 3, a parallel RCT will be conducted to evaluate the intervention where 154 participants with CKD stage 3–4 will be randomly assigned to either the intervention (n = 77) or control group (n = 77). The intervention group will receive 6-week self-management program from a nurse-coach in addition to standard usual care, while the control group will receive only standard usual care. Outcome measures include kidney disease knowledge, CKD self-management behavior, self-efficacy, quality of life, blood pressure control and adherence to CKD diet as indicated by 24-h urine urea nitrogen, 24-h urine sodium and net endogenous acid production. Data will be collected at baseline and 12-week post-baseline. The between- and within-group intervention effects will be estimated using the Generalized Estimating Equations. The self-management intervention offers strategies to delay CKD progression and to encourage motivation to better self-manage at home. This study integrates self-management education and psychosocial support with culturally relevant scenarios and evaluates important self-reported and objective outcomes. Clinical Trials Registration: www.ClinicalTrials.gov, identifier: NCT03974646.

Keyword: Chronic kidney disease; Self-management program; Kidney disease quality of life; Nurse-led group-based education; Clinical trial