

HP-00058634

NCT03038126

Care Coordination/Home Telehealth to Safeguard Care in CKD

10.8.2019

Analysis Plan: In this pilot trial, the analysis will adhere to the principle of intention-to-treat with anticipated causes of drop-out including ESRD, death, and loss to follow-up. ESRD and death will be treated as end-points and for these, as well as, in the event of loss to follow-up, exposure time will include only the time accrued until last contact (last study visit).

Aim 1: Several (and heterogeneous) adverse safety events will be recorded both individually (e.g. hypoglycemia, hypotension, etc.) and collectively (count of all events in a given group) with a summation of all events as reported at each study visit. Each participant will likely experience multiple events and since follow-up time may vary from individual to individual (if subjects are lost to follow-up prior to the final six-months) we will use person-months derived from study visits to calculate an event rate and will contrast pooled crude event rates in the two groups (intervention/CCHT vs usual care).

Aim 2: Difference in kidney function will be determined by subtracting final kidney function assessment at end of study (6 months), or last available measure (3 months), from initial (baseline) measurement. Kidney function will be calculated from measured serum creatinine at study visit and using the CKD-Epi equation to estimate GFR. Rate of change in renal function will be calculated as quotient of difference in kidney function last to first visit over the time in months between two index visits resulting in ml/min/1.73m² per month change in GFR. Negative values representing loss in kidney function. We will contrast median change in kidney function in the two groups (intervention/CCHT vs usual care).

Aim 3: Hospitalization events will be recorded and captured at each study visit with summarization of reported events using the same approach outlined in Specific Aim 1. Pooled event rates will be reported and contrasted for the two study groups.