

## **Trial Description Document**

**Trial Leader:** Ann Young

**Trial Mentor:** Amit Garg

**Mentor's Email:** [amit.garg@lhsc.on.ca](mailto:amit.garg@lhsc.on.ca)

### **Content Area:**

Transformative research program focused on strengthening health services delivery for patients with chronic kidney disease (CKD). Specifically, my interest is in innovative approaches to leveraging Ontario's health administrative data at ICES to enable population-level case-finding of patients at high risk for kidney failure, who are not known to a nephrologist, to directly contact and connect them with needed kidney care.

### **Trainee Goal:**

Participation in this program will put me in the best position to succeed in launching and completing it. I will benefit from the learning management system and mentorship to help me refine the pilot (Vanguard phase) of my trial protocol, specifically elements of the pragmatic randomized trial design to maximize the validity of this trial. I am particularly looking forward to new training in implementation science. I will continue to enhance my knowledge of culturally safe health research practices which I will be able to apply to future related trials (e.g., a pilot trial of KidneyCare Outreach appropriate for Indigenous peoples with kidney disease).

### **Trial goal/background:**

Despite efforts to improve the recognition of chronic kidney disease, late referrals for specialized kidney care continue to be a problem. Many at-risk individuals in the population are not receiving evidence-based therapies that could significantly slow their disease progression. To help address this, we designed a new KidneyCare Outreach program that will connect individuals at high risk of kidney failure with specialist care.

### **Research Objectives:**

To assess the feasibility of our KidneyCare Outreach program features and to compare process-of-care outcomes between individuals randomly allocated to the intervention vs. usual care.

### **Intervention:**

A concealed allocation scheme will be generated at ICES and eligible individuals will be randomly assigned 1:1 to the intervention group or usual care (control group). Those in the intervention group will be contacted and invited to participate in the KidneyCare Outreach program. Those who agree to participate will complete lab tests, be assessed

by a trial nephrologist via telemedicine, and be referred to a local nephrologist for ongoing management.

**Methodology:**

The pilot will serve as the Vanguard phase for a larger trial designed to prove that our KidneyCare Outreach program versus usual care reduces the incidence of kidney failure.

**Setting:**

Primary care Practices in Ontario.

**Participants/population:**

Adults in Ontario with a 2-year predicted risk of kidney failure  $\geq 25\%$  or an estimated glomerular filtration rate (eGFR)  $\leq 15$  mL/min per  $1.73 \text{ m}^2$  who are not receiving nephrologist care. We will use a case-finding algorithm applied to administrative healthcare data at ICES to identify all eligible adults in Ontario. The sample size for the pilot trial will be 200 eligible individuals with complete contact information.

**Outcomes:**

Key program features (assessed in the intervention group only) will include the contact-to-enrollment ratio, intervention uptake, and the positive predictive value of the case-finding algorithm.

**Data:**

Process-of-care measures (assessed in both the intervention and usual-care groups using ICES data) will include outpatient nephrology assessment and new use of kidney-protective medications.