Controlling Hypertension through Education and Coaching in Kidney Disease (CHECK-D): protocol of a cluster randomised controlled trial

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ABSTRACT

Introduction Chronic kidney disease (CKD) affects 30 million Americans. Early management focused on blood pressure (BP) control decreases cardiovascular morbidity and mortality. Less than 40% of patients with CKD achieve recommended BP targets due to many barriers. These barriers include a lack of understanding of the implications of their diagnosis and how to optimise their health. This cluster randomised control trial hypothesises that the combination of early primary care CKD education, and motivational interviewing (MI)-based health coach support, will improve patient behaviours aligned with BP control by increasing patient knowledge, self-efficacy and motivation. The results will aid in sustainable interventions for future patient-centric education and coaching support to improve quality and outcomes in patients with CKD stages 3–5. Outcomes in patients with CKD stages 3–5 receiving the intervention will be compared with similar patients within a control group. Continuous quality improvement (CQI) and systems methodologies will be used to optimise resource neutrality and leverage existing technology to support implementation and future dissemination. The innovative approach of this research focuses on the importance of a multidisciplinary team, including off-site patient coaching, that can intervene early in the CKD care continuum by supporting patients with education and coaching.

Methods and analysis We will test impact of BP control when clinician-delivered education is followed by 12 months of MI-based health coaching. We will compare outcomes in 350 patients with CKD stages 3–5 between intervention and control groups in primary care. CQI and systems methodologies will optimise education and coaching for future implementation and dissemination.

Ethics and dissemination This study was approved by the University of Michigan Institutional Review Boards (IRBMED) HUM00136011, HUM00150672 and SITE00000092 and the results of the study will be published on ClinicalTrials.gov, in peer-reviewed journals, as well as conference abstracts, posters and presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a randomised control trial of an education/coaching intervention in Chronic kidney disease, where reviews have shown many prior educational studies have not been randomised or with control populations.
⇒ The methods employ evidenced-based, patient-focused education and support tools that were developed from rigorous prior work and evidence-based research.
⇒ Methods leverage use of an existing electronic medical record-based tool, and a rigorous patient coaching programme with an online coach console to support participant communications as well as rigour in study data collection, logging and tracking.
⇒ It is not possible to conceal clinician, patients or study team members to the study arms.
⇒ Patients who agree to participate are likely to be more involved in their care compared with those who decline.

Trial registration number NCT04087798.
well controlled, patients experience lower risk of CKD progression and less cardiovascular events.\textsuperscript{3-6,11} However, as few as 40% of patients with advanced CKD achieve recommended values.\textsuperscript{4,12} At least two patient-centric barriers impede BP control: patient lack of knowledge about their diagnosis and, at times, lack of coordinated patient support across the continuum of CKD care.\textsuperscript{15,14} Promoting patient behaviours requires coordinated education programmes with ongoing clinical support; yet the best model for this is still undefined.\textsuperscript{15,16}

Several systematic reviews show evidence based, patient education programmes are implemented too late, often when patients have progressed to end-stage kidney disease.\textsuperscript{17-22} Despite growing interest, (eg, patient registries,\textsuperscript{23} clinician prompting,\textsuperscript{24} patient-centred technologies\textsuperscript{25}), more evidence is needed to guide kidney disease.\textsuperscript{17-22} Despite growing interest, more evidence is needed to guide patient education intervention for improved health outcomes.\textsuperscript{26}

Some evidence, described by Sanders et al, suggests that motivational enhancement to strengthen patient’s commitment to health behaviour modifications is needed to slow disease progression.\textsuperscript{27} Motivational interviewing (MI), an evidenced-based health behaviour change model, with core tenets of self-determination theory, offers a way to uphold patients’ values while increasing commitment to change health behaviours and improve outcomes, for example, BP control.

This research study will deliver evidence-based, patient-focused, education and health coaching support to patients with CKD who are not on dialysis, compared with patients in the control group. Building on prior research, this multilevel intervention could improve patient knowledge, motivation and self-efficacy as well as clinical outcomes.\textsuperscript{28} This study includes clinician education to optimise CKD education and communication for patients, and follows with coaching on behavioural modifications to improve patient knowledge, motivation and self-efficacy, as well as BP control and other clinical outcomes.\textsuperscript{29,30}

METHODS AND ANALYSIS

Overarching objective and aims
This study is designed as a cluster randomised controlled clinical trial to test the impact of BP control when clinician-delivered patient education is followed by 12 months of MI-based patient health coaching. The researchers will compare outcomes in 350 patients with CKD stages 3–5 between intervention and control groups in primary care. Continuous quality improvement and systems methodologies will optimise the education and coaching for seamless future implementation and dissemination.

Trial design and setting
There are 10 academic-affiliated, primary care clinics, 8 at the University of Michigan (UM) Michigan Medicine and 2 at Wayne State University/Wayne Health System (WSU), which serve as units of randomisation. Five of the clinics (four UM and one WSU) were randomised to the intervention group, and the complement were randomised to the control group (figure 1, clinical randomisation). Within intervention clinics, patients are given a clinician-led educational intervention (EDI) describing their CKD diagnosis, current level of kidney function and latest BP values to ensure patients have a baseline understanding of their CKD diagnosis and BP goals. Health coaches provide intervention participants –4 to 6 calls on topics related to optimising BP control. Systolic BP along with various other outcomes (table 1) is measured and compared over 12 months from enrolment with the primary outcome being systolic BP as a continuous measure—comparing time to enrolment to time of study completion, 12 months later.

The conceptual model for this project is adapted from the health belief model\textsuperscript{31-34} and includes aspects of the theory of planned behaviour—showing that motivation partly determines behavioural performance.\textsuperscript{31} This adapted model demonstrates the link between patient knowledge, self-efficacy and motivation, highlighting potential behaviour modifying factors to improve outcomes (figure 2, shading shows areas impacted by education and coaching).

Patient and public involvement
One of the study coauthors is a patient and significantly contributed to the patient education materials and review of the coaching programme. Vetted CKD patient education materials are used to support patient education during the study and the EDI was based on prior work/research of an original patient education worksheet developed by the National Kidney Disease Education Programme, National Institutes of Health (NIH) with patient and community input as well.

Aims and hypotheses
Aim 1: to identify the impact of a provider-led, coach-supported patient education intervention on patient clinical and self-reported outcomes over 1 year based on a cluster randomised controlled clinical trial
The primary outcome is change in BP from enrolment to 12 months after enrolment, and the secondary outcomes are estimated glomerular filtration rate (eGFR),\textsuperscript{35} urine protein, patient knowledge, self-efficacy, motivation, medication adherence and satisfaction. We hypothesise that, compared with patients in the control group, that patients in the intervention group will: (A) have lower BP, (B) experience higher eGFR, greater reductions in urine protein and higher medication adherence and (C) have greater knowledge about CKD, and higher knowledge, self-efficacy and motivation, with/in CKD care.
Aim 2: to identify whether and to what extent implementation outcomes (clinician adoption, fidelity, perceived usefulness) are associated with clinical and patient-reported outcomes

We hypothesise that: (A) clinician adoption, perceived usefulness of and fidelity to the clinician-delivered education tool will be high and positively associated with clinical and patient-reported outcomes in both groups and (B) clinicians will perceive the intervention of the EDI and health coaching as beneficial and feasible for future translation into community settings.

Each of these specific aims is associated with measuring many outcomes as discussed further in the methods.

Provider-led review of patient education intervention

The patient EDI is a worksheet (available in both hard copy and digital formats within the electronic medical record (EMR)) that provides an overview of CKD and the importance of BP control. It is reviewed and given to the patients during routine clinical encounters with their primary care clinician. The EDI is incorporated into the patient’s EMR using just a few keystrokes or can also be used at the point of care in hardcopy/paper format (online supplemental file).

For the control group, the EDI includes generic data applicable to all patients with CKD and a diagnosis of high BP. For the intervention group, the EDI contains similar information but adds select patient individual health information (most recent eGFR, urine protein measurements (typically urine microalbumin), and recent BP), along with a space for the clinician to type in individualised patient goals. Labs are used one time only for the purpose of these study measures. After the primary care encounter where the clinician reviews the EDI, a patient is subsequently approached to enroll in longitudinal surveys and BP measurements for the control group and longitudinal surveys, BP measurements and coaching if they are in the intervention group. Pilot work shows the EDI takes seconds (two keystrokes) to populate into an EMR, and review with patients takes providers ≤2 min by providers. At checkout, the worksheet is automatically printed and given to the patient for in-person visits or sent via the health portal or US mail for telehealth visits.

Figure 1 Study flow chart, activities and when patient measures are taken/collected. BP, blood pressure; PCP, primary care provider.
<table>
<thead>
<tr>
<th>Measures and individual characteristics</th>
<th>Aim applicable to:</th>
<th>Time point measured (s)</th>
<th>Outcome type or patient/provider characteristic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics/patient characteristics (age, sex, gender, race, ethnicity, education, income, general health status)</td>
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<td>Patient characteristic</td>
<td></td>
</tr>
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<td>Patient Characteristic</td>
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<tr>
<td>Health Literacy (REALM-SF)</td>
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<td>Patient Characteristic</td>
<td></td>
</tr>
<tr>
<td>Medications of interest (BP, diuretics and statins)</td>
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<td>Patient Characteristic</td>
<td></td>
</tr>
<tr>
<td>Numeracy (SNS)</td>
<td>t(0)</td>
<td>Patient Characteristic</td>
<td></td>
</tr>
<tr>
<td>BMI (weight in kg/height in metres squared)</td>
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<td>Patient Characteristic</td>
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</tr>
<tr>
<td>Change in systolic BP between baseline and 12 months</td>
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<td>t(0), t(3)</td>
<td>Primary</td>
</tr>
<tr>
<td>Change in diastolic BP between baseline and 12 months</td>
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<td>t(0), t(3)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Slope of systolic BP between baseline and 12 months using all available BP values</td>
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<td>t(0), t(1), t(2), t(3S)</td>
<td>secondary</td>
</tr>
<tr>
<td>Slope of diastolic BP between baseline and 12 months using all available BP values</td>
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<td>Secondary</td>
</tr>
<tr>
<td>Estimated glomerular filtration rate</td>
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<td>t(0), t(3)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Serum creatinine</td>
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<td>Secondary</td>
</tr>
<tr>
<td>Urine protein-creatinine ratio</td>
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<td>t(0), t(3)</td>
<td>Secondary</td>
</tr>
<tr>
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<tr>
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<td>Secondary</td>
</tr>
<tr>
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<tr>
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<td>Secondary</td>
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<tr>
<td>Self-efficacy for disease self-management (PKDSMS)</td>
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<td>t(0), t(1), t(2), t(3)</td>
<td>Secondary</td>
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<tr>
<td>Patient motivation (TSRQ)</td>
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<td>Secondary</td>
</tr>
<tr>
<td>Satisfaction with CKD care</td>
<td>1</td>
<td>t(0), t(1), t(2), t(3)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Satisfaction with CKD care</td>
<td>1</td>
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<td>Secondary</td>
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<tr>
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<td>t(0), t(1), t(2), t(3)</td>
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<td>t(1), t(2), t(3)</td>
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</tr>
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<td>Provider years in practice</td>
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<td>Provider characteristic</td>
<td></td>
</tr>
<tr>
<td>Provider gender</td>
<td>t(0)</td>
<td>Provider characteristic</td>
<td></td>
</tr>
<tr>
<td>Provider race</td>
<td>t(0)</td>
<td>Provider characteristic</td>
<td></td>
</tr>
<tr>
<td>Provider practice size (no of patients yearly)</td>
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<td>Provider characteristic</td>
<td></td>
</tr>
<tr>
<td>Provider affiliated health system</td>
<td>t(0)</td>
<td>Provider characteristic</td>
<td></td>
</tr>
</tbody>
</table>

Continued
Participants enrolled from intervention clinics receive health coaching from a professional health coach. Each participant will receive approximately 4–6, 30–60 min, telephonic counselling calls during the 12-month intervention period. This time frame was chosen to maintain relatively consistent dosing amounts of coaching across the trial (every 2–3 months) while balancing patient

<table>
<thead>
<tr>
<th>Measures and individual characteristics</th>
<th>Aim applicable to:</th>
<th>Time point measured (s)</th>
<th>Outcome type or patient/provider characteristic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic ‘discipline’</td>
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</tr>
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<td>Provider characteristic</td>
<td></td>
</tr>
<tr>
<td>Clinic characteristics</td>
<td>t(0)</td>
<td>Provider characteristic</td>
<td></td>
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<tr>
<td>Provider adoption based on EMR query and patient survey</td>
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<td>t(0)</td>
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<tr>
<td>Perception of usefulness by provider survey</td>
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<td>t(3)</td>
<td>Secondary</td>
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<tr>
<td>Provider fidelity measured by EMR query</td>
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<td>t(0)</td>
<td>Secondary</td>
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<tr>
<td>Visit time with provider</td>
<td>2</td>
<td>t(0)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Total time in clinic</td>
<td>2</td>
<td>t(0)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Coach perceptions of coach intervention</td>
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<td>t(3)</td>
<td>Exploratory</td>
</tr>
<tr>
<td>No. of calls, no. completed on time, length of time, coach content of calls</td>
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<td>Across study duration</td>
<td>N/A</td>
</tr>
<tr>
<td>Coach call survey—online questions coach asks at follow-up calls</td>
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<td>Across study duration</td>
<td>Exploratory</td>
</tr>
<tr>
<td>Coach baseline survey—patients’ values report cared, grades of behaviours</td>
<td>1</td>
<td>t(0)</td>
<td>Exploratory</td>
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<tr>
<td>Goal reminder questions</td>
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<td>Across study duration</td>
<td>Exploratory</td>
</tr>
<tr>
<td>Patient perceptions of health coaching</td>
<td>2</td>
<td>t(3)</td>
<td>Secondary</td>
</tr>
<tr>
<td>Cost and efficiency of coaching related to intervention</td>
<td>2</td>
<td>t(3)</td>
<td>Exploratory</td>
</tr>
</tbody>
</table>

t(0) is time of enrolment, and t(1), t(2), t(3) are at 1 month, 6 months and approximately 12 months following enrolment.

BMI, body mass index; BP, blood pressure; CHF, congestive heart failure; CKD, chronic kidney disease; EDI, educational intervention; EMR, electronic medical record; KiKS, Kidney Knowledge Survey; MMAS-8, 8-item Morisky Medication Adherence Scale; N/A, not applicable; PKDSMS, The Perceived Medical Condition Self-Management Scale; REALM-SF, Rapid Estimate of Adult Literacy in Medicine - Short Form; SNS, Subjective Numeracy Scale; TSRQ, Treatment Self-Regulation Questionnaire.

Figure 2  Conceptual model for how patient education and health coaching influence intermediate and end-clinical outcomes in CKD. CKD, chronic kidney disease.
autonomy. Participants have the flexibility to reschedule coaching calls based on their needs at any time. Typically, rescheduling of calls will be done within a 7-day window, especially for the first call that involves a baseline assessment. However, the health coaches can also accommodate rescheduling requests beyond the 7-day window to provide additional flexibility.

Using the MI skill of shared agenda setting, participants choose one of four goal areas known to affect BP as an area to work on during the coaching sessions. To inform the coaching session, intervention participants complete a baseline assessment about physical activity, weight loss/maintenance, sodium intake and medication adherence (ie, ‘baseline survey’). While the health coaches will make an effort to encourage participants to prioritise the four goal areas during coaching sessions, they also allow participants to discuss other areas related to BP management. The MI coaching is guided by the framework ‘Explore-Guide-Choose’ and is grounded in participant autonomy, allowing for flexibility to include the participant’s values and strengths to increase motivation by reducing emotional and practical barriers to change.36

Educational resources adapted from vetted UM and national kidney education resources are available to intervention participants in the study web-based portal.

All activities related to coaching and coach-patient calls will be documented via the online health coaching portal, created by the UM study team with the Centre for Health Communications Research, as adapted from prior work.37,38 The coaches document all coaching activities in this secure portal. It provides a graphical patient-user and provider-user interface and support resources for coaches including surveys and scripts to use during calls. Further, from the coaching portal, facsimiles are sent to the intervention primary care physicians with participant updates and progress on goals. The portal also sends automated text messaging to participants with supportive reminders for their goals and future coaching calls.39

Coach selection and training
Health coaches (HCs) will have a degree in one or more of the following: health education and health behaviour, dietetics and nutrition, counselling psychology, nursing and social work. In addition, HCs complete 3 days of face-to-face training led by the MI supervisors, coinvestigators, social workers, renal dieticians and study team members with expertise in nephrology, health coaching, behaviour change, CKD and MI. Initial training components include study protocol, background information on behavioural therapy, focused didactics and MI practice.

Further education occurs with real-time interaction by coach supervisors/investigators using ONE-PASS,40 a validated instrument to assess and enhance effectiveness in MI. There is coach feedback with remediation and retraining if needed for additional skill building. Lastly, HC encounters are recorded with a 10% sample review of all calls for continued improvement and to optimise the fidelity of intercoach reliability. HCs must maintain an average ONE-PASS score ≥ 5.0 (out of 7.0) throughout the study and with remediation if they do not achieve this score.

Eligibility, randomisation and recruitment
Clinics and randomisation
Randomised units or clusters are primary care clinics in southeast Michigan from UM and WSU as described above. Clinic inclusion criteria include: (1) primary care clinic caring for adult patients with CKD and hypertension, (2) supporting infrastructure to deliver the EDI either through an EMR or on paper, (3) ability to identify patients who meet eligibility criteria prior to provider visits and (4) space for in-study activities or virtual activities as dictated by COVID policies. The clinics were selected because they (1) met eligibility criteria, (2) have large patient volume for enrolment, (3) offer a mix of academic-community and academic-urban practices and (4) include diverse geographical and sociodemographic variability to increase generalisability.

Clinics will be randomised to the intervention or control group, with an equal number in each arm (five clinics in each). Clinics will be stratified by primary care provider discipline, geographic location and socioeconomic status to promote treatment balance on those factors. Prior to recruitment, a random number generator using the PROC PLAN procedure of SAS version 9.4 software (SAS Institute) will determine the randomised order of the clinics.

Participant eligibility, recruitment and retention
All patients scheduled for appointments with participating primary clinicians will be screened for eligibility. Patients will only be recruited at routine primary care visits and ambulatory clinics and not in nephrology clinics. The goal of the current study is to test how to improve care within the primary care setting, early in CKD care, and during routine primary care provider visits. Thus, the EDI was designed to be used in a primary care setting during this study.

Patients will be eligible if they are adults (21–85 years old), have a diagnosis of hypertension and meet criteria of uncontrolled hypertension, have CKD stages 3–5, are not pregnant, and do not have cognitive, language, or vision impairments that prohibit participation in study activities. CKD diagnosis is defined as a eGFR<60 mL/min/1.73 m² persisting for 3 months or more within the last 18 months as well as documented diagnosis of CKD in the medical records. Uncontrolled BP was defined as a systolic BP≥140 mmHg or a diastolic BP≥90 mmHg at study start. The UM has a registry of all patients within the system’s ambulatory clinics with CKD and hypertension, and we have found that a single, most recent BP correlates very closely with an average of the three most recent BPs taken within ambulatory clinics. The ambulatory clinic BPs are typically taken in one arm after a period of 5 min rest with no talking and patients’ feet flat on the floor.

We have chosen to limit the study to patients with a documented diagnosis of CKD in their medical records.
to ensure that the CKD diagnosis has been made and approved by the patient’s primary care provider and/or care team to avoid the study team from inadvertently or inaccurately giving a CKD diagnosis to patients. When patients are identified with all other parameters for having CKD but it is not on the problem list, we will confirm with providers if they feel this should be added or not, as it is up to the provider to place diagnoses on the record.

The study will exclude patients who meet any of the following criteria: end-stage renal disease, currently undergoing dialysis, history of a kidney transplant, pregnancy, terminal illness, presence of cognitive, language or vision impairments that would hinder participation in educational activities, surveys, or coaching sessions.

A typical distribution of how patients self-identify within ambulatory clinics is as follows: 50% female, 24% African American, 7% Hispanic or Latino, 12% identifying with other or combined races (American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, more than one race). Similar participant proportions are expected at enrolment completion.

Patient recruitment is based on our prior studies. We will use patient incentives as they have been shown to be beneficial to participation. Our recruitment commenced in February 2020 and is scheduled to conclude by the end of 2023. The flow diagram of the study, all activities and measures are shown in figure 1.

Following enrolment, the study team will retrieve and record the following information from the participant’s medical records into the REDCap database: the participant’s most recent BMI, relevant medical history and medications (such as BP medications, diuretics, statins or other cholesterol medication, and SGLT2 inhibitors). During each follow-up visit, the study team will collect the BMI and medication data from the EMR that is closest to the date of the study visit.

Outcomes, variables and measurement
The primary outcome for this trial is systolic BP in mm Hg (continuous measure) as a change from time of enrolment, t (0), versus time end of patient follow-up, that is, at 12 months, t(3), comparing the control and intervention groups. There are four time periods of longitudinal study measures and they are designated as t(0) (meaning time zero, at enrolment), t(1) (time 1 at approximately 1 month after enrolment), t(2) (time 2, 6 months after enrolment) and t(3) (time 3 or approximately 12 months after enrolment). Systolic BP was chosen because it most consistently relates to cardiovascular and other end outcomes in kidney disease. BP will be measured at four time points, t(0), t(1), t(2), t(3), over the 12 months that patients are enrolled. BP is taken in person during study visits when COVID policies allow, or at home using study OMRON-Model 7250 BP cuffs when virtual. All participants get a home study OMRON cuff with training on paper and over the phone by research assistants with standardised education protocols derived from the manufacturer and study team that aligns with how ambulatory clinic BPs are done. Participants will be reminded by study staff about timepoints for BP measurements. BP readings are recorded by research staff and entered into the study REDCap study database which is stored on highly restricted servers at the UM. Furthermore, when BP’s are collected, the time and manner in which it was obtained will also be recorded for every BP.

Secondary outcomes include survey measures (patient–provider reported outcomes) and biological variables (eg, eGFR and urine protein measurements) (table 1). Surveys can be collected in person, entered on a secure online platform into REDCap, or sent on paper through the mail. All data will be entered into REDCap. Serum creatinine will be collected at enrolment and 12 months, t(0) and t(3), and will be used to calculate eGFR. Urine protein (measured by spot urine protein: urine creatinine ratios) will be collected at t(0) and t(3). Medication adherence will be measured at enrolment, 1 month, 6 months and 12 months (t(0), t(1), t(2), t(3)), in two ways: (1) using an eight-item Medication Adherence Scale developed by Morisky et al, and validated in hypertensive patients. It is reliable (α=0.83) and practical to use in clinical settings and (2) with an EMR query, which allows capture of medication refills—an indirect assessment of adherence.

Patient CKD knowledge, self-efficacy, motivation and satisfaction with provider communication and care will be measured using validated surveys. Patient CKD knowledge will be measured using the kidney knowledge survey (KiKS) developed by the principal investigator (PI). KiKS is a 28-item questionnaire measuring objective CKD disease knowledge and includes questions about BP goals, cardiovascular risk and antihypertensive medications. Self-efficacy will be measured in two ways: (1) self-efficacy with medication adherence and (2) self-efficacy in disease self-management. The medication adherence self-efficacy scale-revised is a 13-item scale validated in hypertensive populations to measure patient self-efficacy in taking antihypertensive medications (α=0.90). Self-efficacy with disease self-management will be measured using an adapted version of the perceived medical condition self-management scale, a generalised self-efficacy measure to assess patients’ perceived abilities in managing their chronic medical conditions. This eight-item measurement shows good reliability (α=0.78–0.83). Motivation will be measured using a 15-item scale with 7-point Likert response options, adapted from a survey used in patients with carotid plaques, to assess motivation for health behaviours aligned with reducing cardiovascular risk. Patient satisfaction will be measured in two ways; (1) using makoul et al’s communication assessment tool, a 15-item questionnaire measuring patient satisfaction with provider communication, which has high scale reliability (α=0.96) and (2) the consultation care measure, a 21-item, 4-point Likert scale whereby patients rate their perceptions about the patient-centredness of medical care received from primary care providers (α=0.84–0.96 range, for subscales within the
survey). Data have shown that self-reported patient behaviour is often inaccurate and significantly underestimates when individuals are ‘at-risk’ for unhealthy behaviours. However, for exploratory purposes, we will ask patients a few BP-related questions about behaviours in the past 1 week (e.g. sodium restriction, activity) and 2–3 exploratory questions about patients’ perceptions of health coaching. Surveys will be administered at four time points: t(0) through t(3). Table 1 summarises all variables and measures in this study.

Lastly, an unresolved issue in patient education and support is how to evaluate and conceptualise successful implementation of these programmes. In aim 2, we will examine aspects of implementation by looking at two factors: (1) provider perceptions of the intervention, (2) whether providers adopt portions of the intervention, for example, routine use of the EDI during clinical appointment. Provider perception of the usefulness of the intervention (education worksheet and health coach) will be assessed through a brief survey. Provider adoption will be measured: (1) through a provider survey, (2) integrated into patient surveys (a question asking if providers used the education worksheet with the patient) and (3) EMR query (examining if the education worksheet was populated into the patient’s EMR) or via research staff if the EDI was used as a paper version in clinic. Provider fidelity to the education worksheet will be measured: (1) examining whether the provider entered 1–2 additional messages as suggested (queried through the EMR) or assessing if used on paper during face-to-face encounters, (2) asking patients via surveys whether the worksheet was reviewed. Lastly, although a formalised analysis of coaching cost projections is outside the scope of this study, we will be able to provide important data on the costs of coaching (based on hours of coaches worked) per patient coached.

**Estimated sample size and power calculations**

A conservative difference of systolic BP between intervention and control groups ranges from 3 to 5 mm Hg. It is assumed that each patient will have BP checked at least four times. Additional clinical BPs recorded in the EMR will be recorded as available. Sample size calculations are based on a comparison of intervention and control groups in baseline minus 12-month differences in a cluster randomised controlled trial. A significance level of 0.05, power of 0.90 and an SD of 7 for the between-patient variation in baseline minus 12-month differences were assumed in all calculations. Based on prior studies, the intraclass correlation coefficient (ICC) for clinics is likely to be 0.10 or lower. Table 2 gives the total number of clinics required to detect a difference between groups of 3–5 mm Hg with 90% power for ICCs of 0.05, 0.10 and 0.15, assuming 30, 50 or 100 patients per clinic. Based on these power calculations, balancing rigour and efficiency, 9.4 clinics (rounded to 10) are needed if we recruit 30 patients at each clinic, to detect a difference of 4 mm Hg between the intervention and control group clinics with an ICC of 0.10. However, prior similar studies show there may be patient dropouts along the study of up to 10%–15%. Thus, we will inflate recruitment targets by 15% for a targeted enrolment of 35 patients who complete the study from each clinic for a total enrolment of 350 patients. Table 2 shows effect sizes from which we determined sample size for this study.

**Statistical analysis**

Reporting of this protocol follows SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines. We will follow international guidelines for analysis and reporting of cluster randomised clinical trials. We will first examine the distributions of all study variables to assess missing data, possible coding errors and distributional form, including skewness, variance and extreme values. Next, we will explore bivariate associations between study variables. We will examine baseline data for clinically important differences between treatment groups for demographics and clinical data, including BP and other potential prognostic indicators.

For the primary outcome (the difference between baseline and 12-month systolic BP): an intention-to-treat analysis will be used, by which all participants are included in the statistical analysis and analysed according to the group they were originally assigned, regardless of their level of participation in each aspect of the trial. Treatment (intervention) effects tested in the initial models are described for cluster-randomised trials with preplanned covariates. Systolic BP is a continuous variable and analysis requires accommodating correlation within clinics, so we will use linear mixed models with a random effect for clinic implemented using the MIXED procedure in SAS software. The baseline systolic BP will be included as a covariate. Baseline covariates that significantly differ

<table>
<thead>
<tr>
<th>Difference (mm Hg) between groups</th>
<th>Intraclass correlation</th>
<th>SD</th>
<th>Patients per clinic</th>
<th># Clinics needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>0.05</td>
<td>7</td>
<td>3</td>
<td>10.3</td>
</tr>
<tr>
<td>3</td>
<td>0.05</td>
<td>7</td>
<td>5</td>
<td>8.9</td>
</tr>
<tr>
<td>3</td>
<td>0.05</td>
<td>7</td>
<td>100</td>
<td>7.8</td>
</tr>
<tr>
<td>3</td>
<td>0.1</td>
<td>7</td>
<td>3</td>
<td>15.9</td>
</tr>
<tr>
<td>4</td>
<td>0.1</td>
<td>7</td>
<td>3</td>
<td>9.4</td>
</tr>
<tr>
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<td>7</td>
<td>5</td>
<td>5.6</td>
</tr>
<tr>
<td>4</td>
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<td>7</td>
<td>3</td>
<td>12.5</td>
</tr>
<tr>
<td>5</td>
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<td>7</td>
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<td>8.3</td>
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<td>5</td>
<td>0.15</td>
<td>7</td>
<td>5</td>
<td>7.9</td>
</tr>
</tbody>
</table>

Shaded row shows 10 clinics (5 per group) yield 0.90 power to detect a 4 mm Hg difference in systolic BP between the control and intervention group, with alpha=0.05. BP, blood pressure.
Analyses of secondary outcomes
The majority of the secondary outcomes are continuous variables (eg, time patients spend in clinic visit at t(0), eGFR, urine protein or ordinal (eg, survey measures, including: patient knowledge, self-efficacy, motivation, medication adherence and satisfaction) for which power can be calculated based on effect sizes (multiples of the SD) for any specific outcome. With a total of 350 participants, we have a 90% power to detect an effect size of 0.4 assuming an ICC of 0.10 within cluster. This is a small to moderate effect on Cohen’s scale where approximately 0.25 is a small effect and 0.50 is moderate.

As above, for continuous or ordinal data, analysis requires accommodating correlation within clinics, so we will use linear mixed models with a random effect for clinic implemented using the MIXED procedure in SAS to test the treatment (intervention) impact on outcome. The respective baseline continuous measure will be included as a covariate in each model. For outcomes that are categorical we will test intervention effects using logistic regression for longitudinal data (SAS Genmod or Glimmix procedure).

For surveys, we will use surveys that are previously validated instruments where possible. New surveys or those adapted for this study will be examined for evidence of reliability and validity. We will use principal component factor analysis to characterise clustering of items and potential subscales. We will evaluate for evidence of validity comparing correlation to original scales when surveys are adapted, or to examine for expected associations when no prior scales have been developed. To detect associations between the survey scales and measured characteristics (eg, patient sex, age) \( \chi^2 \) tests, t-tests and Kruskal-Wallis tests will be used depending on the variables compared.

Missing data and drop-outs
If a clinic discontinues participation in the study or is not on track with study timelines to enrol the number of participants required, we will consider asking other clinics at study sites to participate as well—as a ‘helper’ clinic to achieve study enrolment targets collectively. If a clinic drops out after study enrolment commences, they will be analysed as intention to treat.

Quality control of study protocols and procedures
All study data other than coach-specific activities will be captured in a REDCap database. Coach activities are logged and tracked in the secure online coaching portal. Only study approved personnel have access to these databases. Further, the study will be reviewed with providers and staff at each participating clinic at study start and periodically throughout the study for project updates and as an opportunity for the feedback. We will include a review of EDI delivery at these sessions and develop virtual mechanisms for providers to learn about the study.

Study safety and integrity
The study will have an appointed data safety and monitoring board (DSMB) with regular team reports at the study onset and at 25%, 50% and 100% enrolment or yearly, whichever comes first. This board includes clinicians in internal medicine and nephrology, educators, social workers, statistical/epidemiological experts, and meetings are run by the PI, project manager and project statisticians. The study was submitted to the institutional review board (IRB) for all participating sites and informed consent will be obtained for each participant prior to enrolment by the IRB-approved study research team. An example copy of the consent form is provided in the appendices (online supplemental appendix 1). The IRB approved for providers to review the EDI prior to patient enrolment, as our prior work showed that patients often may not be aware that they have CKD.

Ethics and dissemination
This study was approved by the University of Michigan Institutional Review Boards (IRBMED) HUM00136011, HUM00150672 and SITE00000092, with a single site IRB at UM, and the results of the study will be published on ClinicalTrials.gov and placed into NIH recommended repositories, with scholarly work/reporting, in peer-reviewed journals, as well as conference abstracts, posters and presentations. Any changes or modifications to the study will first be approved by the IRB and DSMB prior to implementation and included in any scholarly reporting.

To ensure consistent delivery of the intervention and uniform application of enrolment and data collection protocols, we will host a kick-off meeting in year 1 to be attended by investigators, research staff, coaches and representatives from each site. Goals of the study will be discussed along with design and procedures. Data quality issues will be discussed at weekly meetings between project staff and the PI and sooner if needed. Data integrity and completeness will be checked periodically by research personnel and reported at biweekly team meetings, with routine audits in person at all participating sites at study start and no less than yearly thereafter. Adverse events will be addressed immediately and escalated to the IRB and DSMB as stated in our manual of operations and data safety and monitoring plan.

DISCUSSION
This trial will test a patient education tool and a coaching intervention to determine their impact on improving BP control in patients with CKD. This research represents a new and substantially different approach to addressing an important public health problem by coupling provider-led
EMR EDI in primary care with follow-up health coaching. In addition, there are several important benefits of this work.

Prior CKD educational research focused on end-stages of disease.17 In contrast, this research focuses early in the care continuum, partnering with primary care. Further, systematic reviews point out a lack of rigour in patient-focused education studies18 and suggest there is little research examining provider or system factor influence on success.66 This study is a step towards filling this gap early in care adding education as a launch to patient-centred coaching. The clinician-led education for patients leverages the EMR, which offers efficiency for providers at the point of care and is novel in CKD trials. Another strength of this study is a wide array of outcomes and variables planned to collect which will allow for many additional explorations not previously well studied in CKD education trials, for example, whether and to what extent provider demographics associate with outcomes or changes observed. Lastly, this research benefits from an established, evidence-based coaching programme that does not demand significantly more time from primary care clinicians, supporting patients using other trained staff.

There are limitations to this study, some of which we can minimise in study processes and design. It will not be possible to conceal clinicians or patients to study arms. Thus, clinicians and patients might be prompted to engage more in patients’ healthcare than they might otherwise. Patient autonomy is a core tenet of MI, empowering the patient to improve their health behaviours and involvement in their care.67 We worked to minimise barriers known to reduce the likelihood of participation.68 69 Participants in both arms received BP cuffs and gift cards. Additionally, our study’s primary focus is to assess the impact of the intervention within the 12-month time frame. Investigating the intervention’s effects beyond the final coaching call is currently beyond the scope of this study. However, in future investigations we may consider adding supplements to the study (with IRB approvals) to examine outcomes after a longer time period. Lastly, because protocols in the COVID-19 pandemic required changes for the study to continue, we will have BP measures both in person from ambulatory clinics and from home, using our study omron BP cuffs, making this outcome measurement potentially different between visits or participants in some cases. We believe we have optimised standardisation as much as possible when BP is taken and will consider exploring in analysis if differences observed indeed change by BP measure modality.

A pilot study informed the EDI’s design to ensure that integrating the tool into clinical was feasible and supported by clinicians.28 Engaging site representatives to serve as project champions is being employed to optimise clinician voice and participation for intervention completion rates. A protocol amendment due to the COVID-19 pandemic added flexibility with virtual visits, for study measures and coaching. Our education and coaching intervention has high promise to improve BP values in patients with CKD and optimise outcomes for all patients. Future efforts will seamlessly expand further within primary care and other types of practices statewide.

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